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Toronto Superior Court of Justice / Cour supérieure de justice

PERELL J.

Court File No.: CV-19-00620048-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

DARRYL GEBIEN, STEPHEN PYE, MICHAEL ROELOFSEN, REBECCA STINTON, AMANDA CANELLA, MEGAN BRAYSHAW, AND SIOBHAN MACKENZIE

Plaintiffs

- and -

APOTEX INC., APOTEX PHARMACEUTICAL HOLDINGS, INC., BRISTOL-MYERS SQUIBB CANADA, BRISTOL-MYERS SQUIBB COMPANY, PALADIN LABS, ENDO PHARMACEUTICALS INC., ENDO INTERNATIONAL PLC, JANSSEN INC., JOHNSON & JOHNSON, PHARMASCIENCE INC., JODDES LIMITED, MYLAN PHARMACEUTICALS ULC, PURDUE PHARMA INC., PURDUE PHARMA L.P., PURDUE FREDERICK COMPANY INC., PURDUE FREDERICK INC., RANBAXY PHARMACEUTICALS CANADA INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SANIS HEALTH INC., SANDOZ CANADA INC., TEVA CANADA LIMITED, TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS PHARMA COMPANY, VALEANT CANADA LP/ VALEANT CANADA S.E.C, BAUSCH HEALTH COMPANIES INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

SECOND FRESH AS AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS

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

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the *Rules of Civil Procedure*, serve it on the Plaintiffs' lawyer or, where the Plaintiffs do not have a lawyer, serve it on the Plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the *Rules of Civil Procedure*. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

IF YOU PAY THE PLAINTIFF'S CLAIM, and $5,000.00 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 $400.00 for costs and have the costs assessed by the court.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court**.**

Date: May 15, 2019

Issued by _____
Local Registrar

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

TO: **APOTEX INC.**
2700-700 West Georgia Street
Vancouver, BC V7Y 1B8

AND TO: **APOTEX PHARMACEUTICAL HOLDINGS, INC.**
150 Signet Drive
Weston, ON M9L 1T9

AND TO: **BRISTOL-MYERS SQUIBB CANADA**
1959 Upper Water Street, Suite #900
Halifax, NS B3J 2X2

AND TO: **BRISTOL-MYERS SQUIBB COMPANY**
1209 Orange Street
Wilmington, Delaware, USA 19801

AND TO: **PALADIN LABS**
Suite 1800-510 West Georgia Street
Vancouver, BC V6B 0M3

AND TO: **ENDO PHARMACEUTICALS INC.**
1400 Atwater Drive
Malvern, Pennsylvania, USA 19355

AND TO: **ENDO INTERNATIONAL PLC**
First Floor, Minerva House
Simmonscourt Road
Ballsbridge Dublin 4, Ireland

AND TO: **JANSSEN INC**.
595 Burrard Street
Suite 2600, PO Box 49214
Vancouver, BC V7X 1L3

AND TO: **JOHNSON & JOHNSON**
1 Johnson & Johnson Plaza
New Brunswick, New Jersey, USA 08933

AND TO: **PHARMASCIENCE INC.**
6111 Royalmount Avenue, Suite 100
Montreal, QC H4P 2T4

AND TO: **JODDES LIMITED**
6111 Royalmount Avenue, Suite 100
Montreal, QC H4P 2T4

AND TO: **MYLAN PHARMACEUTICALS ULC**
85 Advance Road
Etobicoke, ON M8Z 2S6

AND TO: **PURDUE PHARMA INC.**
1200 Waterfront Centre
200 Burrard Street, PO Box 48600
Vancouver, BC V7X 1T2

AND TO: **PURDUE PHARMA L.P.**
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut, USA 06901-3431

AND TO: **THE PURDUE FREDERICK COMPANY INC.**
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut, USA 06901-3431

AND TO: **PURDUE FREDERICK INC.**
40 King Street West, Suite 4400
Toronto, ON M5H 3Y4

AND TO: **RANBAXY PHARMACEUTICALS CANADA INC.**
2680 Matheson Blvd. East, Suite 200
Mississauga, ON L4W 0A5

AND TO: **SUN PHARMACEUTICAL INDUSTRIES LTD.**
Sun Pharma Advanced Res.Centre,
Tandalja, Vadodara, India GJ-390020

AND TO: **SANIS HEALTH INC.**
Suite 200, Phoenix Square
371 Queen Street
Fredericton, NB E3B 1B1

AND TO: **SANDOZ CANADA INC.**
800-885 West Georgia Street
Vancouver BC V6C 3H1

AND TO: **TEVA CANADA LIMITED**
Suite 2200, 1055 West Hastings Street
Vancouver, BC V6E 2E9

AND TO: **TEVA PHARMACEUTICALS USA, INC.**
1090 Horsham Road
North Wales, Pennsylvania USA 19454

AND TO: **TEVA PHARMACEUTICAL INDUSTRIES LTD.**
5 Basel St., Petach Tikva
Israel, 49131

AND TO: **ACTAVIS PHARMA COMPANY**
30 Novopharm Court
Toronto, ON M1B 2K9

AND TO: **VALEANT CANADA LP/ VALEANT CANADA S.E.C.**
2700-700 West Georgia Street
Vancouver, BC V7Y 1B8

AND TO: **BAUSCH HEALTH COMPANIES INC.**
25th floor
700 West Georgia Street
Vancouver, BC V7Y 1B3

CLAIM

1. The Plaintiffs claim on their own behalf, and on behalf of the Class described herein:

   (a) an order certifying this action as a class proceeding and appointing the Plaintiffs as representative Plaintiffs for the Class Members;

   (b) a declaration that the Defendants have breached the *Competition Act*, R.S.C. 1985, c. C-35, section 52;

   (c) a declaration that the Defendants made fraudulent and/or negligent misrepresentations in relation to Opioids;

   (d) a declaration that the Defendants breached their duty to warn consumers of the risk of harm caused by Opioids;

   (e) a declaration that each of the Defendants is vicariously liable for the acts and omissions of its officers, directors, agents, employees and representatives;

   (f) an accounting of the profits each Defendant earned during the class period from the sale of Opioids to the Class and disgorgement to the Class of such profits;

   (g) damages under section 36 of the *Competition Act* for loss or damage suffered as a result of conduct contrary to section 52;

   (h) pecuniary damages in the amount of $1,000,000,000.00 for Class Members who suffered injuries and damages as a result of the Defendants' fraudulent misrepresentations, negligent misrepresentation, and breach of the duty to warn;

   (i) non-pecuniary damages in an amount to be assessed for each Class Member who suffered damages as a result of the Defendants' fraudulent misrepresentation, negligent misrepresentation, and breach of the duty to warn;

(j) damages pursuant to the *Family Law Act*, R.S.O. 1990, c F.3 s.61 and similar legislation (and common law) in other provinces, in the amount of $100,000.00 for each Family Law Class Member;

(k) punitive damages in the amount of $100,000,000.00;

(l) the costs of distributing all monies received to Class Members;

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

(n) costs on a substantial indemnity basis, plus applicable taxes; and

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

A. DEFINITIONS

2. The capitalized terms used in the Statement of Claim have the meanings indicated below:

(a) "**Class**" and "**Class Members**" means all persons in Canada, save for excluded persons, who were prescribed Opioids manufactured or marketed by the Defendants from January 1, 1996 to the present day ("**Class Period"**) and who suffer or have suffered from Opioid Use Disorder, according to the diagnostic criteria hereafter described;

(b) The Class includes the direct heirs of any deceased persons who met the above-mentioned criteria;

(c) "**Excluded Persons**" means:

(i) any person who was prescribed OxyContin® or OxyNEO® in Canada at any time between January 1, 1996 and April 15, 2016 inclusive, and was not prescribed any other Opioids, as defined below, at any time during the Class Period: and,

(ii) any officer or director of any of the Defendants;

(d) "**Family Law Class**" and "**Family Law Class Members**" means all persons within Canada, except for excluded persons, who by reason of his or her relationship to a Class Member have standing pursuant to s. 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, or equivalent legislation in other provinces and territories, or the common law;

(e) **"Opioids"** means opioid drugs or opioid products which are a class of drugs that are defined by a chemical compound that is naturally found in the opium poppy plant or which are synthetically made using the same chemical structure, and include (but are not limited to) butorphanol, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, normethadone, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol, codeine, Dilaudid/Dilaudid HP, Belbuca, BuTrans, Targin, Fentora, Duragesic, Abstral, Metadol, Statex, Tridural, Nucynta, Nucynta CR, Nucynta ER, Nucynta IR, Lazanda, Ultram, Opana ER, Tramacet, Percocet, Percocet-DEMI, Endocet, Percodan, Kadian, and generic versions of oxycodone, oxymorphone, hydromorphone, hydrocodone, and fentanyl transdermal systems. Opioids does not include OxyContin® or OxyNEO®.

(f) "**Opioid Use Disorder**" means use of Opioids resulting in:

i. giving up important social occupation or recreational activities;

ii. persistent desire or unsuccessful efforts to reduce Opioid use;

iii. failure to fulfill occupational, scholastics or home life obligations;

iv. persistent or recurrent social or interpersonal problems;

v. impairment in physically hazardous situations;

vi. tolerance requiring use of larger amounts of Opioids than intended;

vii. a persistent or recurrent physical or psychological problem that is caused or exacerbated by Opioids; or

viii. Opioids withdrawal syndrome.

B. NATURE OF THE ACTION

3. Starting in the mid-1990s, the Defendants marketed Opioids as less addictive than they knew them to be in order to encourage the long-term use of Opioids for widespread chronic conditions and, as a result, expand the market for Opioids. The Defendants promoted Opioids as safe, effective, and appropriate for long-term use in routine pain conditions, when they knew or should have known that they were not.

4. In so doing, the Defendants breached their statutory and common law duties to the Plaintiffs and Class Members, who became addicted to Opioids. The Defendants profited from these breaches. They owe damages for the harm they have caused to the Class Members.

C. THE DEFENDANTS

5. The Defendants manufacture, market, and sell Opioids in Canada.

i. The Apotex Defendants

6. Apotex Inc. is a Canadian company. During the Class Period, Apotex Inc. manufactured, marketed, and sold Opioids in Canada.

7. Apotex Pharmaceutical Holdings, Inc. is a Canadian company. During the Class Period, Apotex Pharmaceutical Holdings, Inc., directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada.

8. The businesses of each of the Defendants Apotex Inc. and Apotex Pharmaceutical Holdings, Inc. (collectively, "**Apotex**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to Apo-Tramadol, Apo-Fentanyl Matrix, Apo-Hydromorphone, and Apo-Oxycodone CR.

ii. The Bristol-Myers Defendants

9. Bristol-Myers Squibb Canada is a Canadian company. During the Class Period, Bristol-Myers Squibb Canada manufactured, marketed and sold Opioids in Canada.

10. Bristol-Myers Squibb Company is an American company. During the Class Period, Bristol-Myers Squibb Company, directly or through its subsidiaries or affiliates, manufactured, marketed, and sold Opioids in Canada and in the United States of America.

11. The businesses of each of the Defendants Bristol-Myers Squibb Canada and Bristol-Myers Squibb Company (collectively, "**Bristol-Myers**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada during the Class Period, including but not limited to Endocet, Percocet, Percocet-DEMI, Percodan, and Percodan-Demi.

iii. The Endo Defendants

12. Paladin Labs is a Canadian company. It is affiliated with and/or controlled by Endo Pharmaceuticals Inc. ("**Endo USA**") and Endo International PLC ("**Endo International**"). During the Class Period, Paladin Labs manufactured, marketed and sold Opioids in Canada.

13. Endo USA is an American company. During the Class Period, Endo USA, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada and in the U.S.A.

14. Endo International is an Irish company, with its principal place of business in Dublin, Ireland. Paladin Labs and Endo USA are subsidiaries of Endo International. During the Class Period, Endo International, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada.

15. The businesses of each of the Defendants Paladin Labs, Endo USA and Endo International (collectively, "**Endo**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to Opana ER, Abstral, Metadol, Statex, Tridural, PMS-Methadone, and Nucynta.

iv. The Janssen Defendants

16. Janssen Inc. (formerly known as Janssen-Ortho Inc.) is a Canadian company. During the Class Period, Janssen Inc. manufactured, marketed and sold Opioids in Canada.

17. Johnson & Johnson is an American company. Janssen Inc. is a subsidiary of Johnson & Johnson. During the Class Period, Johnson & Johnson, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada and the U.S.A.

18. The businesses of each of the Defendants Janssen Inc. and Johnson & Johnson (collectively, "**Janssen**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to Duragesic, Tramacet, Ultram, Nucynta CR, PAT-Tramadol/Acet, Tylenol with Codeine No. 2, Tylenol with Codeine No. 3, Tylenol with Codeine No. 4, and Tylenol with Codeine Elixir.

v. The Pharmascience Defendants

19. Pharmascience Inc. is a Canadian company. During the Class Period, Pharmascience Inc. manufactured, marketed and sold Opioids in Canada.

20. Joddes Limited is a Canadian company. Pharmascience Inc. is a subsidiary of Joddes Limited. During the Class Period, Joddes Limited, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada.

21. The businesses of each of the Defendants Pharmascience Inc. and Joddes Limited (collectively, "Pharmascience") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to PMS-Butorphanol, PMS-Oxycodone CR, PMS-Fentanyl MTX, PMS-Hydromorphone, PMS-Morphine Sulfate SR, and PDP-Hydrocodone.

vi. Mylan

22. Mylan Pharmaceuticals ULC ("**Mylan**") is a Canadian company. During the Class Period, Mylan Pharmaceuticals ULC manufactured, marketed and sold Opioids in Canada, including but not limited to Mylan-Fentanyl Matrix Patch, and Mylan-Tramadol/Acet.

vii. The Purdue Defendants

23. Purdue Pharma Inc. is a Canadian company. During the Class Period, Purdue Pharma Inc. manufactured, marketed and sold Opioids in Canada.

24. Purdue Pharma L.P. is an American company. During the Class Period, Purdue Pharma L.P. directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada and the U.S.A.

25. The Purdue Frederick Company Inc. is an American company. It is a signatory to a plea agreement in the United States District Court for the Western District of Virginia in which it admitted to the felony of misbranding the Opioid Product OxyContin with the intent to defraud or mislead.

26. Purdue Frederick Inc. is a Canadian company. During the Class Period, Purdue Frederick Inc., directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada.

27. The businesses of each of the Defendants Purdue Pharma Inc., Purdue Pharma L.P., The Purdue Frederick Company Inc. and Purdue Frederick Inc. (collectively, **"Purdue"**) are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to Dilaudid, Belbuca, BuTrans, Targin, MS Contin, MS-IR, Hydromorph Contin, Oxycontin, and OxyNEO.

viii. The Ranbaxy Defendants

28. Ranbaxy Pharmaceuticals Canada Inc. is a Canadian company. During the Class Period, Ranbaxy Pharmaceuticals Canada Inc. manufactured, marketed and sold Opioids in Canada.

29. Sun Pharmaceutical Industries Ltd. ("**Sun**") is an Indian company. Ranbaxy Pharmaceuticals Canada Inc. is a subsidiary of Sun. During the Class Period, Sun, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada and the U.S.A.

30. The businesses of each of the Defendants Ranbaxy Pharmaceuticals Canada Inc. and Sun (collectively, "**Ranbaxy**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to RAN-Fentanyl Matrix Patch and RAN-Oxycodone CR.

ix. Sanis

31. Sanis Health Inc. ("**Sanis**") is a Canadian company. During the Class Period, Sanis manufactured, marketed and sold Opioids in Canada, including but not limited to Oxycodone/Acet, Tramadol/Acet, and Morphine SR.

x. Sandoz

32. Sandoz Canada Inc. ("**Sandoz**") is a Canadian company. During the Class Period, Sandoz Canada Inc. manufactured, marketed and sold Opioids in Canada including but not limited to Supeudol, Sandoz Fentanyl Patch, Sandoz Oxycodone, Fentanyl Citrate Injection SDZ, Morphine HP 25, Morphine HP 50, Sandoz Opium & Belladonna, Sandoz Methadone, Sandoz Morphine SR, Morphine Sulfate Injection USP, and Meperidine Hydrochloride Injection USP.

xi. The Teva Defendants

33. Teva Canada Limited is a Canadian company. During the Class Period, Teva Canada Limited manufactured, marketed and sold Opioids in Canada.

34. Actavis Pharma Company (formerly Cobalt Pharmaceutical Company) is a Canadian company. During the Class Period, Actavis Pharma Company manufactured, marketed and sold Opioids in Canada.

35. Teva Pharmaceuticals USA, Inc., ("**Teva USA**") is an American company. During the Class Period, Teva USA, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada and the U.S.A.

36. Teva Pharmaceutical Industries Ltd. ("**Teva Pharmaceutical**") is an Israeli company. Teva Canada Limited, Actavis Pharma Company and Teva USA are subsidiaries of Teva Pharmaceutical. During the Class Period, Teva Pharmaceutical, directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada.

37. The businesses of each of the Defendants Teva Canada Limited, Actavis Pharma Company, Teva USA and Teva Pharmaceutical (collectively, "**Teva**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to Teva-Oxycocet, Teva-

Tramadol/Acetaminophen, Teva-Fentanyl, Teva-Hydromorphone, Teva-Morphine SR, ACT Oxycodone CR, and CO Fentanyl.

xii. The Valeant Defendants

38. Valeant Canada LP/Valeant Canada S.E.C. ("**Valeant Canada**") is a Canadian company. During the Class Period, Valeant Canada manufactured, marketed and sold Opioids in Canada.

39. Bausch Health Companies Inc. ("**Bausch**") is a Canadian company. Valeant Canada is a division of Bausch. During the Class Period, Bausch directly or through its subsidiaries or affiliates, manufactured, marketed and sold Opioids in Canada.

40. The businesses of each of the Defendants Valeant Canada and Bausch (collectively, "**Valeant**") are inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing and sale of Opioids in Canada, including but not limited to M.O.S.-SR (Morphine Hydrochloride), Cophylac, and Cophylac Drops.

41. Apotex, Bristol-Myers, Endo, Janssen, Pharmascience, Mylan, Purdue, Ranbaxy, Sanis, Sandoz, Teva, and Valeant have during the Class Period manufactured, marketed and sold in Canada prescription pain medications that contained Opioids under brand-names and generic counterparts.

D. THE PLAINTIFFS

42. The Plaintiffs are Darryl Gebien, Stephen Pye, Michael Roelofsen, Rebecca Stinton, Amanda Canella, Megan Brayshaw, and Siobhan Mackenzie. The Plaintiffs were prescribed Opioids produced by the Defendants for chronic pain conditions and injuries as a result of, and in reliance on, misrepresentations made by the Defendants to the Plaintiffs and their healthcare

providers, which includes prescribing physicians, treating physicians, pharmacists, and nurse practitioners. As a result, the Plaintiffs each developed Opioid Use Disorder.

i. Darryl Gebien

43. Dr. Darryl Gebien lives in Toronto, Ontario. He was prescribed Percocet, an Opioid produced by Bristol-Myers, for a ligament injury in his thumb. Shortly thereafter, he became addicted to Opioids. Dr. Gebien's addiction had a significant and lasting impact on his life. Dr. Gebien lost his license to practice medicine. He lost his job. He was incarcerated. He lost custody of his children.

44. Dr. Gebien relied on information that Bristol-Myers provided to him and to his healthcare providers in choosing to consume Percocet. Dr. Gebien's healthcare providers did not inform him that Percocet was addictive and dangerous when prescribed for chronic conditions and/or long-term use. Dr. Gebien trusted that his healthcare providers were fully informed by Bristol-Myers regarding the risks and dangers of Opioid use. He relied on information provided to him and to his healthcare providers in choosing to take Percocet.

45. In consuming Percocet, Dr. Gebien trusted his healthcare providers and the accuracy of the information they relied on when prescribing Percocet for his condition. Dr. Gebien's healthcare providers and, consequently, Dr. Gebien, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Bristol-Myers to promulgate the New Narrative. Dr. Gebien would not have consumed Percocet for his condition had he been informed that Percocet was addictive or dangerous, in the manner set out in paragraphs 70 to 74.

ii. Stephen Pye

46. Stephen Pye lives in Grand Falls-Windsor, Newfoundland. He worked as a Junior High School teacher for 24 years. Mr. Pye was prescribed Opioids for chronic pain resulting from hernia surgeries. He was prescribed Teva-Morphine, produced by Teva; Sandoz-Morphine, produced by Sandoz; MS-IR, produced by Purdue; and APO-Oxycodone and APO-Hydromorphone, produced by Apotex.

47. Mr. Pye developed Opioid Use Disorder. Mr. Pye's addiction had a significant and lasting impact on his life. His relationships with his wife and sons were irreparably damaged. He retired early and is therefore not entitled to a full pension. His addiction caused serious mental health issues, resulting in two suicide attempts.

48. Mr. Pye relied on information that Teva, Sandoz, Purdue, and Apotex provided to him and to his healthcare providers in choosing to consume their Opioids. Mr. Pye's healthcare providers did not inform Mr. Pye that the Opioids he was prescribed were addictive and dangerous when prescribed for chronic conditions and/or long-term use. He trusted that his healthcare providers were fully informed by Teva, Sandoz, Purdue, and Apotex regarding the risks and dangers of Opioid use. Mr. Pye relied on information provided to him and to his healthcare providers in choosing to take Opioids manufactured by Teva, Sandoz, Purdue, and Apotex.

49. In consuming Opioids manufactured by Teva, Sandoz, Purdue, and Apotex, Mr. Pye trusted his healthcare providers and the accuracy of the information they relied on when prescribing Opioids for his condition. Mr. Pye's healthcare providers and, consequently, Mr. Pye, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Teva, Sandoz, Purdue, and Apotex

to promulgate the New Narrative. Mr. Pye would not have consumed Opioids for his condition had he been informed that they were addictive or dangerous, in the manner set out at paragraphs 70 to 74.

iii. Michael Roelofsen

50. Michael Roelofsen lives in St. Thomas, Ontario. He worked in law enforcement for over 40 years. He was prescribed Opioids for chronic neck pain. Mr. Roelofsen was prescribed Sandoz-Morphine, produced by Sandoz; Endocet, produced by Bristol-Myers; Tylenol with Codeine No. 2 and Tylenol with Codeine No. 3, produced by Janssen; and Teva-Oxycocet and Teva-Morphine, produced by Teva.

51. Mr. Roelofsen developed Opioid Use Disorder. His addiction had a significant and lasting impact on his life. He was diagnosed with hypogonadism as a result of Opioid use. He did not feel like himself without taking multiple Opioids a day. He experienced severe anxiety, depression, and insomnia.

52. Mr. Roelofsen relied on information that Sandoz, Bristol-Myers, Janssen, and Teva provided to him and to his healthcare providers in choosing to consume their Opioids. Mr. Roelofsen's healthcare providers did not inform him that the Opioids he was prescribed were addictive and dangerous when prescribed for chronic conditions and/or long-term use. Mr. Roelofsen trusted that his healthcare providers were fully informed by Sandoz, Bristol-Myers, Janssen, and Teva regarding the risks and dangers of Opioid use. Mr. Roelofsen relied on information provided to him and to his healthcare providers in choosing to take Opioids manufactured by Sandoz, Bristol-Myers, Janssen, and Teva.

53. In consuming Opioids manufactured by Sandoz, Bristol-Myers, Janssen, and Teva, Mr. Roelofsen trusted his healthcare providers and the accuracy of the information they relied on when prescribing Opioids for his condition, Mr. Roelofsen's healthcare providers and, consequently, Mr. Roelofsen, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Sandoz, Bristol-Myers, Janssen, and Teva to promulgate the New Narrative. Mr. Roelofsen would not have consumed Opioids for his condition had he been informed that it was addictive or dangerous, in the manner set out at paragraphs 70 to 74.

iv. Rebecca Stinton

54. Rebecca Stinton lives in Calgary, Alberta. She was a nursing student when she was prescribed Opioids for chronic migraines. Ms. Stinton was prescribed Tylenol with Codeine No. 3, produced by Janssen; APO-Tramadol, produced by Apotex; Teva-Oxycocet produced by Teva; PMS-Oxycodone produced by Pharmascience; and MS-IR produced by Purdue.

55. Ms. Stinton developed Opioid Use Disorder. Ms. Stinton’s addiction had a significant and lasting impact on her life. She was unable to work as a registered nurse and remains on Long Term Disability to this day. She experienced homelessness and estrangement from her family.

56. Ms. Stinton relied on information that Janssen, Apotex, Teva, Pharmascience, and Purdue provided to her and to her healthcare providers in choosing to consume their Opioids. Ms. Stinton's healthcare providers did not inform her that the Opioids she was prescribed were addictive and dangerous when prescribed for chronic conditions and/or long-term use. Ms. Stinton trusted that her healthcare providers were fully informed by Janssen, Apotex, Teva, Pharmascience, and Purdue regarding the risks and dangers of Opioid use. Ms. Stinton relied on information provided

to her and to her healthcare providers in choosing to take Opioids manufactured by Janssen, Apotex, Teva, Pharmascience, and Purdue.

57. In consuming Opioids manufactured by Janssen, Apotex, Teva, Pharmascience, and Purdue, Ms. Stinton trusted her healthcare providers and the accuracy of the information they relied on when prescribing Opioids for her condition. Ms. Stinton's healthcare providers and, consequently, Ms. Stinton, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Janssen, Apotex, Teva, Pharmascience, and Purdue to promulgate the New Narrative. Ms. Stinton would not have consumed Opioids for her condition had she been informed that they were addictive or dangerous, in the manner set out at paragraphs 70 to 74.

v. Amanda Cannella

58. Amanda Cannella currently lives in Ottawa, Ontario. She was 15 years old when she was first prescribed Opioids for chronic pain following arm surgery. Ms. Canella was prescribed Percocet, produced by Bristol-Myers; Targin (Oxycodone Hydrochloride), produced by Purdue; and Metadol, produced by Endo.

59. Ms. Cannella developed Opioid Use Disorder. Her addiction had a significant and lasting impact on her life. It took her nearly eight years to complete her four-year undergraduate degree. She suffered from depression, anxiety, suicidal ideation, and insomnia. She faced difficulty maintaining positive close relationships. Her addiction resulted in a diagnosis of hyperalgesia, causing an increased sensitivity to pain.

60. Ms. Cannella relied on information that Bristol-Myers, Purdue and Endo provided to her and to her healthcare providers in choosing to consume their Opioids. Ms. Cannella's healthcare providers did not inform her that the Opioids she was prescribed were addictive and dangerous when prescribed for chronic conditions and/or long-term use. Ms. Cannella trusted that her healthcare providers were fully informed by Bristol-Myers, Purdue and Endo regarding the risks and dangers of Opioid use. Ms. Cannella relied on information provided to her and her healthcare providers in choosing to take Opioids manufactured by Bristol-Myers, Purdue and Endo.

61. In consuming Opioids manufactured by Bristol-Myers, Purdue and Endo, Ms. Cannella trusted her healthcare providers and the accuracy of the information they relied on when prescribing Opioids for her condition. Ms. Cannella's healthcare providers and, consequently, Ms. Cannella, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Bristol-Myers, Purdue and Endo to promulgate the New Narrative. Ms. Cannella would not have consumed Opioids for her condition had she been informed that they were addictive or dangerous, in the manner set out at paragraphs 70 to 74.

vi. Megan Brayshaw

62. Megan Anne Brayshaw lives in Calgary, Alberta. She works as a real estate transaction coordinator. Ms. Brayshaw was prescribed Opioids in or around 2010 for the long-term treatment of chronic pain. She quickly became addicted to Opioids. Ms. Brayshaw was prescribed Percocet, produced by Bristol-Myers; Supeudol, produced by Sandoz; Hydromorph Contin, produced by Purdue; Fentanyl patches, produced by Mylan; Fentanyl patches, produced by Teva; Fentanyl patches, produced by Ranbaxy, and M.O.S.-SR, produced by Valeant.

63. Ms. Brayshaw developed Opioid Use Disorder. Her addiction had a significant and lasting effect on her life. Ms. Brayshaw suffered from debilitating lethargy and became socially withdrawn. She was unable to hold steady employment or raise her children.

64. Ms. Brayshaw relied on information that Bristol-Myers, Sandoz, Purdue, Mylan, Teva, Ranbaxy and Valeant provided to her and to her healthcare providers in choosing to consume their Opioids. Ms. Brayshaw's healthcare providers did not inform her that the Opioids she was prescribed were addictive and dangerous when prescribed for chronic conditions and/or long-term use. Ms. Brayshaw trusted that her healthcare providers were fully informed by Bristol-Myers, Sandoz, Purdue, Mylan, Teva, Ranbaxy and Valeant regarding the risks and dangers of Opioid use. Ms. Brayshaw relied on information provided to her and to her healthcare providers in choosing to take Opioids manufactured by Bristol-Myers, Sandoz, Purdue, Mylan, Teva, Ranbaxy and Valeant.

65. In consuming Opioids manufactured by Bristol-Myers, Sandoz, Purdue, Mylan, Teva, Ranbaxy and Valeant, Ms. Brayshaw trusted her healthcare providers and the accuracy of the information they relied on when prescribing Opioids for her condition. Ms. Brayshaw's healthcare providers and, consequently, Ms. Brayshaw, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Bristol-Myers, Sandoz, Purdue, Mylan, Teva, Ranbaxy and Valeant to promulgate the New Narrative. Ms. Brayshaw would not have consumed Opioids for her condition had she been informed that they were addictive or dangerous, in the manner set out at paragraphs 70 to 74.

vii. Siobhan Mackenzie

66. Siobhan Mackenzie lives in Cranbrook, British Columbia. She was a Support Worker. Ms. Mackenzie was prescribed Tylenol with Codeine No. 3, produced by Janssen; Teva-Oxycocet and Teva-Fentanyl, produced by Teva; APO-Tramadol, produced by Apotex; PMS-Oxycodone and PMS-Hydromorphone, produced by Pharmascience; Hydromorph-Contin, Dilaudid, and MS-IR, produced by Purdue; Metadol, produced by Endo; and SAN-Oxycodone/Acet, produced by Sanis.

67. Ms. Mackenzie developed Opioid Use Disorder. Her addiction had a significant and lasting impact on her life. Ms. Mackenzie's addiction resulted in broken relationships with her family and drove her kids farther away from her. She was unable to work and receives Canada Pension Plan disability benefits to this day. She was labelled as being unfit to parent her son while taking Opioids, resulting in British Columbia Child Protection Services removing her son from her custody.

68. Ms. Mackenzie relied on information that Janssen, Teva, Apotex, Pharmascience, Purdue, Endo, and Sanis provided to her and to her healthcare providers in choosing to consume their Opioids. Ms. Mackenzie's healthcare providers did not inform her that the Opioids she was prescribed were addictive and dangerous when prescribed for chronic conditions and/or long-term use. Ms. Mackenzie trusted that her healthcare providers were fully informed by Janssen, Teva, Apotex, Pharmascience, Purdue, Endo, and Sanis regarding the risks and dangers of Opioid use. Ms. Mackenzie relied on information provided to her and her healthcare providers in choosing to take Opioids manufactured by Janssen, Teva, Apotex, Pharmascience, Purdue, Endo, and Sanis.

69. In consuming Opioids manufactured by Janssen, Teva, Apotex, Pharmascience, Purdue, Endo, and Sanis, Ms. Mackenzie trusted her healthcare providers and the accuracy of the

information they relied on when prescribing Opioids for her conditions. Ms. Mackenzie's healthcare providers and, consequently, Ms. Mackenzie, were influenced and informed by the misrepresentations, statements, and omissions in product packaging, labelling, or monographs, or other media created by Janssen, Teva, Apotex, Pharmascience, Purdue, Endo, and Sanis to promulgate the New Narrative. Ms. Mackenzie would not have consumed Opioids for her conditions had she been informed that they were addictive or dangerous, in the manner set out at paragraphs 70 to 74.

E. THE DEFENDANTS' CONDUCT IN MARKETING & SELLING OPIOIDS

i. BACKGROUND

70. Opioids are pain-management medications that carry serious risks of addiction, overdose, and death. Most Opioids are controlled substances listed under Schedule I of the *Controlled Drugs and Substances Act,* SC 1996, c 19.

71. Opioids are addictive. As agonists, they bind with opioid receptors on the spinal cord and in the brain, numbing pain reception and encouraging the release of dopamine, lessening the perception of pain. In addition to their pain controlling effects, Opioids can also induce a euphoric high, which increases their addiction potential.

72. With continued use, patients grow tolerant to Opioids, resulting in a decrease in the release of dopamine causing cravings for Opioids. As patients become tolerant, they require progressively higher doses over time, increasing the risks of withdrawal, addiction, and overdose.

73. Opioids are dangerous. In higher doses, they slow a user's breathing, causing potentially fatal respiratory depression. Patients who delay or discontinue long-term Opioid use often

experience extended withdrawal symptoms including nausea, muscle pain, depression, anxiety, diarrhea, vomiting, restlessness, and chills.

74. Until the mid-1990s, clinical and pharmacological standards dictated that Opioids were too addictive to be prescribed for long-term treatment. Opioids help manage pain when properly prescribed for appropriate conditions. Opioids were prescribed sparingly and only for short-term conditions such as acute injury or illness, and for post-surgical or palliative care.

ii. THE DEFENDANTS PROMOTE A "NEW NARRATIVE"

75. Starting in the mid-1990s, the Defendants developed and promoted a false and misleading new narrative about Opioids (the "**New Narrative**"), intended to broaden the market for, and increase sales of, Opioids. The New Narrative encouraged the long-term use of Opioids for chronic conditions, including back pain, migraines, sports injuries, and arthritis, for which Opioids would not previously have been prescribed.

76. The New Narrative consisted of a series of characteristic misrepresentations and omissions that downplayed the risk of addiction and represented Opioids as necessary, effective, and safe for long-term use in the treatment of chronic pain. The New Narrative was aimed at both healthcare professionals and the public, commandeering the existing methods of communicating information about drugs to disseminate the New Narrative.

77. The Defendants knew, or ought to have known, that doctors rely on them for current, accurate and complete information about Opioids' risks, and their ability to exercise fully informed medical judgment in prescribing Opioids would be fundamentally altered by the New Narrative. The Defendants knew, or ought to have known, that promoting Opioids as safe and effective for long-term use through the New Narrative would change how doctors prescribe them to patients.

78. The Defendants knew, or ought to have known, that regulators, including Health Canada, rely on the Defendants for current, accurate and complete information about Opioids' risks. The Defendants knew, or ought to have known, that promoting Opioids as safe and effective for long-term use through the New Narrative would influence regulatory oversight, and enforcement. This, in turn, altered physicians and the public's perception of their safety and efficacy.

79. The Defendants created and promulgated the New Narrative deceitfully, or alternatively, negligently. The Defendants knew, or ought to have known, at all material times that the New Narrative was false or misleading, that the New Narrative was not supported by data or science, that their Opioid products were dangerous, highly addictive, and had high abuse potential, and that marketing them as safe for long-term use would cause Opioid addiction and death. The Defendants nonetheless promoted the New Narrative for the purpose of expanding the market for Opioid drugs.

80. The Defendants were aware of, and ignored, both public and private warnings regarding the risks of long-term Opioid use. For example, staff at Janssen repeatedly advised senior management that Janssen's advertising, marketing, and labelling of Opioids was misleading and misrepresented the scientific evidence of addiction, which was known to Janssen management and staff.

81. The Defendants, through the New Narrative, concealed the risks of new and expanded Opioid use from regulators, healthcare professionals, the Plaintiffs, and Class Members. Through the New Narrative, the Defendants downplayed those risks to displace the medical orthodoxy that Opioids were too addictive and too dangerous for widespread or long-term use.

82. The particulars of the New Narrative are set out below. The Defendants knew or ought to have known that the following representations were false or misleading and were not supported by

legitimate peer-reviewed studies. They nonetheless promoted the New Narrative to increase sales of Opioids.

1. Minimal risk of addiction

83. The Defendants' marketing and other communications aimed to and did persuade healthcare professionals and patients that any risk of addiction to Opioids could be alleviated through careful supervision by doctors. The Defendants' marketing and other communications represented that:

a. concerns about addiction to Opioids had been exaggerated;
b. Opioids were not addictive, or less addictive, when taken as prescribed by a physician for genuine pain;
c. it was unfair to stigmatize patients as addicts when they just needed higher Opioid doses to alleviate their "pain", labelling genuine addiction as "pseudoaddiction";
d. the risk of addiction for patients prescribed appropriate doses of Opioids was minimal and should not prevent prescriptions of Opioids;
e. the risk of addiction could easily be managed including through screening and monitoring tools;
f. only certain types of patients were at risk for addiction, primarily illegitimate patients, recreational users, or those with inadequate medical supervision;
g. even high-risk patients could be closely managed in order to reduce or eliminate the risk of addiction;
h. if a patient exhibited symptoms of addiction, this was only a sign that their pain was undertreated, and that additional or higher doses of Opioids were required; and
i. abuse-deterrent formulations of Opioids made addiction unlikely.

84. The New Narrative, through these communications, aimed to and did persuade healthcare professionals that Opioids could be safely prescribed to appropriate patients without fear that such patients would become addicted.

2. Opioids would improve patient function and quality of life

85. The Defendants, in the New Narrative:

a. Claimed that long-term Opioid use would improve the function and quality of life for patients experiencing pain;
b. Failed to inform patients and healthcare providers of the known risks of chronic Opioid therapy; and
c. Exaggerated the risks of competing analgesics such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen.

86. These claims, which were made to promote Opioid use and increase sales, were not supported by peer-reviewed clinical or scientific evidence. The Defendants knew, or ought to have known, that these claims were false.

3. Withdrawal from Opioids could be easily managed

87. Long-term Opioid use causes withdrawal in many or most patients. Symptoms of withdrawal are severe and include nausea, muscle pain, depression, anxiety, diarrhea, vomiting, restlessness, and chills. Symptoms of withdrawal are difficult to manage, can occur between prescribed doses of Opioids, and can continue long after Opioid use is discontinued.

88. The Defendants asserted that:

a. certain Opioids were less likely to cause withdrawal symptoms than other pain medications;
b. physical dependence could be easily addressed by gradually decreasing dosages to avoid withdrawal symptoms; and
c. the signs and symptoms of withdrawal were indications that a patient's pain was undertreated and required additional or higher doses of Opioids.

89. The Defendants failed to disclose the actual risk and symptoms of withdrawal, or their severity. The Defendants knew or should have known both the risk and severity of withdrawal. The Defendants misrepresented these risks, and the ease of managing patients' withdrawal from Opioids, knowing that healthcare professionals would be more likely to prescribe chronic Opioid therapy if they believed that withdrawal would not be problematic.

4. Long-term use of Opioids was beneficial

90. The Defendants sponsored and published inaccurate reports that suggested that Opioids provide effective long-term treatment for chronic pain conditions. The Defendants claimed and promoted claims that there were significant upsides to long-term Opioid use. They falsely suggested that these so-called benefits were supported by proper scientific evidence. Opioids were consistently promoted by the Defendants as safe for the treatment of chronic pain and other long-term conditions.

5. Failure to warn of adverse effects and to disclose risks of Opioid use

91. The Defendants' promotion of their Opioid products failed to warn and inform medical professionals and patients of the adverse effects, risks and dangers associated with Opioid use, including the risks of overdose, addiction, respiratory depression, and death.

92. The Defendants knew, or should have known, of the risk of hyperalgesia linked to Opioid use. Long-term Opioid use can cause hyperalgesia, which causes a patient to become more sensitive to pain over time. A patient with hyperalgesia may experience hormonal dysfunction, decline in immune function, mental clouding, confusion and dizziness, increased falls and fractures, and potentially fatal interactions with alcohol or benzodiazepines. The Defendants failed to warn patients and healthcare providers of this risk.

93. Alternatively, whatever warnings were provided by the Defendants in relation to Opioids were insufficient in the face of the well-known risks of long-term use of Opioids and in the face of the promotion of the New Narrative, by the Defendants or others. The Defendants were required to tell the whole story regarding the dangers of Opioid use and bring that warning home to physicians and patients. Through the New Narrative, the Defendants did the opposite.

6. Long-acting Opioids would provide long-term pain relief

94. The Defendants marketed long-acting Opioids as providing 12 hours of pain relief. The Defendants knew that this representation was false and that long-acting Opioids were not effective for 12 hours in many, if not most, patients.

95. When the impact of an Opioid dose diminishes before a patient takes their next dose, patients experience end-of-dose failure and, as a result, begin to experience withdrawal symptoms, pain, and an intense craving for Opioids, and experience a euphoric high with the next dose. End-of-dose failure exacerbates the risks and symptoms of Opioid Use Disorder.

96. The Defendants encouraged medical professionals to prescribe higher doses of Opioids to their patients, rather than more frequent doses, and to prescribe additional rescue medication doses in response to end-of-dose failure. The Defendants knew or ought to have known that this was not a safe response to end-of-dose failure. The Defendants made this misrepresentation because higher dosing was more profitable on a per pill basis and in order to increase profits from Opioid sales.

7. Minimal risk of developing tolerance

97. Continued use of Opioids causes patients to develop a tolerance for Opioids. Patients then need increased doses of Opioids to obtain the same level of pain-management. This in turn increases the risk of withdrawal, addiction, respiratory depression, overdose and death.

98. The Defendants falsely claimed that Opioids were unlikely to cause tolerance, or less likely to cause tolerance than other pain medications, in order to encourage prescriptions of Opioids and increase sales. The Defendants knew or ought to have known that long-term Opioid use would lead patients to develop a dangerous tolerance for Opioids. Despite this knowledge, the Defendants

misled healthcare professionals and patients by failing to warn them of the increased risks and dangers associated with increased doses of Opioids.

iii. AGGRESSIVE PROMOTION AND DISSEMINATION OF THE NEW NARRATIVE

99. The Defendants marketed and promoted the representations and omissions in the New Narrative, in the following ways and through the following specific practices.

100. The Defendants failed to properly warn consumers and healthcare professionals of the risks and dangers associated with Opioid use in the Information for Patients and Product Monographs found in the Compendium of Pharmaceuticals and Specialties ("**CPS**"). Through the New Narrative, the Defendants drowned out or explained away any cautionary language in the CPS regarding the risk of and dangers associated with Opioid use.

101. In 2003, the Janssen defendants published a product monograph for Duragesic in *Le médecin du Québec* that falsely stated that Opioid addiction was relatively rare with appropriate dosage for chronic pain, and that this risk should not discourage prescriptions.

102. The Defendants targeted physicians and healthcare practitioners with false and misleading statements, containing the misrepresentations described above, in order to encourage increased prescribing of Opioids, through:

a) Advertisements in publications aimed at physicians including, inter alia, *Canadian Family Physician*, and in medical journals, that promoted the sale of Opioids by falsely understating the risk of addiction in patients prescribed Opioids, and that included inaccuracies and false claims.

b) Marketing efforts that targeted, in particular, family doctors and medical students, who frequently treated patients with chronic pain and who, due to their level of training and experience, were less able to verify the Defendants' claims.

c) Aggressive direct marketing strategies that emphasized in-person contact with physicians by pharmaceutical sales representatives.

d) Information provided to prescribers on the Defendants' own websites.

e) Additional promotional material provided to physicians, including material produced by the Defendants in the United States.

f) Enlisting Key Opinion Leaders ("**KOL**"s) - peer physicians purportedly focused on patient health – to espouse pro-opioid positions and campaign on behalf of Opioid drugs.

g) Schemes developed by the Defendants to financially reward healthcare providers who prescribed their Opioid drugs, including speakers' bureaus whereby high prescribers were paid to give presentations on the need to prescribe Opioid drugs and/or consult them.

h) Creating, funding and controlling medical societies, think tanks, and/or patient advocacy groups ("**Front Groups**"), with the purpose of advancing the New Narrative and encouraging physicians to combat untreated pain with Opioid drug prescriptions. Front Groups funded by the Defendants, including the Canadian Pain Coalition, the Chronic Pain Association of Canada, and People in Pain Network, that produced educational materials containing information that appeared independent and reliable, but was in fact, false and misleading.

i) Funding, either directly or indirectly through Front Groups and KOLs, marketing presentations that were deceptively presented as unbiased continuing medical education programs ("**CMEs**"), a requirement for many physicians to retain their licenses.

j) Marketing campaigns targeting students in their medical training, including through donations to medical schools and efforts to control and influence course materials in medical programs.

103. The Defendants were aware, and intended, that promoting the New Narrative in the manner described above would render physicians more likely to prescribe Opioids to their patients and increase sales of Opioids. They knew, or ought to have known, that doctors rely heavily on educational materials, such as treatment guidelines, continuing medical education seminars,

articles and websites to inform their treatment decisions, and that doctors are heavily influenced by their peers, apparently independent groups, and contact with sales representatives.

104. The Defendants also targeted potential consumers of Opioids with false and misleading statements, containing the misrepresentations described above, in order to encourage patients to seek, accept and comply with prescriptions of Opioids, through:

a) The foregoing conduct aimed at healthcare professionals, which was also intended to and did influence consumers/patients. The Defendants intended that healthcare professionals would accept the New Narrative and convey it to their patients, who would as a result request and comply with prescriptions for opioids.

b) The Defendants also pushed the New Narrative on consumers by funding Front Groups that purported to be patient advocacy groups. These groups downplayed the danger of Opioid addiction, while encouraging patients to seek medical treatment for chronic pain.

c) The Defendants sponsored documents targeting patients and their families that communicated the misrepresentations in the New Narrative. In 2001, the Janssen defendants funded the "Patient Pain Manifesto," a document aimed at hospital patients and their families that denied the risk of addiction.

105. The Defendants knew or ought to have known that these efforts to influence consumer/patient behaviour through the New Narrative would be successful and would lead to inappropriate and dangerous prescriptions of Opioids.

106. As a result of the Defendants' activities promoting the New Narrative and the misrepresentations it contained, and their failure to warn of the risks of Opioids, the prescribing of Opioids as a long-term treatment for chronic pain became routine and widespread. Perceptions of Opioids in the medical community changed drastically, and the prescribing of Opioids for

treatment of minor and sports injuries, chronic pain and other long-term conditions increased significantly.

107. As a result of the Defendants' conduct, Class Members were prescribed Opioids for conditions other than palliative care and short-term post-surgical care, consumed prescription Opioids, and developed Opioid Use Disorder. The rate at which individuals developed and died from Opioid Use Disorder following the New Narrative led to the "Opioid Epidemic".

108. As a result of the Opioid Epidemic, and growing evidence of the harms suffered by Class Members, the Minister of Health sent a letter to manufacturers and distributors of Opioids in Canada in June 2018 calling on them to stop all marketing and advertising of Opioids to healthcare professionals on a voluntary basis.

109. On October 23, 2018, Health Canada added requirements under the Food and Drug regulations in order to ensure that patients would finally “receive clear information about the safe use of opioids and the risks associated with their use.”

110. The new regulations require the Defendants to include a warning sticker and information handout with prescriptions for all Opioids that appear in Part A of Health Canada’s “List of Opioids” dated May 2, 2018. The required warning label clearly indicates that Opioids can cause dependence, addiction, and overdose. The information handout provides patients with a serious and explicit warning about Opioid use, including that the use of Opioids can result in overdose, addiction, physical dependence, life-threatening breathing problems, worsening rather than improving pain and withdrawal.

111. The Defendants' misrepresentations and failures to warn, which changed how Opioids were prescribed and used, caused Class Members to develop Opioid Use Disorder and suffer damages as a result.

F. CAUSES OF ACTION

i. Breach of the *Competition Act*

112. Each of the Defendants, as a result of their promotion and dissemination of the New Narrative, are liable under sections 36 and 52 of the *Competition Act*, R.S.C. 1985, c. C-34, for knowingly or recklessly making a representation to the public that is false or misleading in a material respect.

113. By creating, promoting and disseminating the New Narrative, the Defendants' misrepresentations included the following (the "**Opioid Misrepresentations**"):

(a) That the risk of Opioid addiction was low, and that doctors could use screening tools to exclude patients who might become addicted;

(b) That use of Opioids resulted in improved function;

(c) That withdrawal from Opioids could easily be managed;

(d) That Opioids were appropriate for long-term use;

(e) That Opioids had fewer and less significant adverse effects than other pain management drugs;

(f) That use of certain Opioids provided patients with long-lasting pain relief;

(g) That increased dosages of Opioids could be prescribed without disclosing the increased risks; and

(h) That "abuse deterrent" formulations of Opioids were effective.

114. As a result of the conduct described in section E above, the Defendants breached s. 52 of the *Competition Act,* and thereby committed an unlawful act because these misrepresentations:

(a) were made for the purpose of promoting the business interests of the Defendants;

(b) were made to the public; and

(c) were false and misleading in a material respect.

115. The Plaintiffs and Class Members suffered damages as a result of the Defendants' unlawful breach of s. 52 of the *Competition Act* and seek those damages, as well as their costs of investigation, pursuant to s. 36 of the *Competition Act.*

ii. Fraudulent Misrepresentation and Deceit

116. As described above, the Defendants created and promoted the New Narrative despite knowing that it was false, materially misleading, and deficient. Alternatively, the Defendants were indifferent as to whether the New Narrative was true or false. The New Narrative included the Misrepresentations described in paras. 83 to 98, above, which were fraudulent misrepresentations.

117. The Defendants promoted the Opioid Misrepresentations to the public at large, including the Plaintiffs and Class Members, as part of a uniform and consistent sales, advertising, and marketing campaign. The Defendants intended and encouraged the public, including the Plaintiffs and Class Members, to rely on them.

118. The Plaintiffs and Class Members reasonably relied on the Opioid Misrepresentations in making personal healthcare decisions, including whether to take Opioids.

119. The Defendants also made the Opioid Misrepresentations to healthcare professionals, intending that these healthcare professionals would believe the misrepresentations and in turn repeat them to their patients, who would rely on them. Knowing that healthcare professionals

would repeat the Opioid Misrepresentations to their patients, the Defendants deliberately abstained from intervening to prevent or correct this.

120. The Plaintiffs and Class Members suffered damages as a result of their reliance on the Opioid Misrepresentations, which caused Class Members to consume Opioids and develop Opioid Use Disorder.

iii. Negligent Misrepresentation

121. The Defendants were negligent in the sale and marketing of Opioids in Canada. The Defendants knew or ought to have known at all material times that the New Narrative and Opioid Misrepresentations were false or misleading. The Defendants, at all material times, knew or ought to have known that Opioids pose serious health risks, including addiction, which risks were concealed by the New Narrative. The Defendants negligently misrepresented Opioids.

122. As manufacturers of dangerous pharmaceutical products, the Defendants owed a duty of care to the Plaintiffs and the Class, as consumers of their Opioid products, in what they said and did not say about their Opioid products. In particular, at all material times, the Defendants owed a duty of care to the Plaintiffs and the Class Members to refrain from making representations, directly or indirectly, to consumers, potential consumers, and healthcare providers that downplayed, concealed, or failed to adequately state the dangers of Opioid use; that encouraged the prescription of Opioids for dangerous uses, including the treatment of chronic and long-term conditions; that encouraged the prescription of Opioids for ineffective uses; or that encouraged that Opioids be prescribed or consumed in a dangerous manner.

123. The Defendants breached the standard of care owed to the Plaintiffs and Class Members by making negligent misrepresentations in relation to their Opioid products, including the

misrepresentations detailed at paras. 83 to 98 above. Through those misrepresentations, the Defendants breached their standard of care by:

(a) asserting false statements and omitting material facts regarding the benefits of and evidence for the use of Opioids for chronic pain, while understating their very serious risks, including the risk of addiction;

(b) marketing and promoting Opioids for the treatment of long-term pain without any or adequate research proving that such use is safe and effective, and/or that the benefits of such use outweigh the risks;

(c) failing to adequately train sales representatives to provide only accurate information regarding appropriate use of Opioids and risks associated with their use;

(d) deliberately or recklessly misstating research findings regarding the risks and benefits of Opioids; and

(e) knowingly misstating research findings, knowing that the Plaintiffs, Class Members, and their healthcare providers would rely on their misrepresentations and omissions, and knowing that such reliance would cause the Plaintiffs and Class Members to suffer damages.

124. The Defendants knew, or ought to have known, their statements were misleading. Feedback from the market, including reports as early as in or around 1997-1998 that Opioids were being abused and were associated with a high risk of addiction, should have alerted the Defendants to the falsity of their statements.

125. The Plaintiffs, Class Members and their healthcare providers relied on the Defendants' misrepresentations, which reliance caused Class Members to consume the Defendants' Opioid products and to develop Opioid Use Disorder.

iv. Breach of the Duty to Warn

126. The Defendants were negligent in the sale and marketing of Opioids in Canada by failing to adequately warn healthcare providers and patients of the dangers of Opioids. The Defendants knew, or ought to have known, at all material times that inappropriate prescriptions of Opioids, including for long-term pain, pose serious health risks, including addiction, which risks were not disclosed.

127. The Defendants, as manufacturers of pharmaceutical products, owed a duty to the Class to warn Class Members and healthcare providers of the risks of Opioids. These manufacturers were obligated to be forthright and tell the whole story about the dangers of Opioid use, and to ensure that their warnings and the steps taken to bring the warning home to consumers were commensurate with the danger of Opioid use.

128. At all material times, the Defendants owed a duty of care to the Plaintiffs and the Class Members to, among other things:

(a) label, market, and sell Opioids only with proper and fulsome warnings of the risks of Opioid use;

(b) adequately test their Opioid drugs in a manner that would fully disclose the magnitude of the risks associated with their use, particularly the risk of addiction;

(c) monitor, investigate, evaluate and follow up on improper or adverse reaction to the use of Opioids in Canada, in order to provide proper and updated warnings to healthcare providers and patients;

(d) warn the Plaintiffs and Class Members of dangers inherent in the use of Opioids, including the significant risk of addiction, side-effects, tolerance, and overdose;

(e) provide adequate, updated and current warnings and information on the risks associated with the use of Opioids as such information became available;

(f) ensure that warnings were reasonably communicated and provided a full indication of the specific dangers that arose from Opioid Use;

(g) ensure that healthcare professionals were kept fully and completely informed of all risks associated with the use of Opioids, including their addictive properties;

(h) warn healthcare professionals and patients of the precautions to be taken, so as to avoid injury or damage from Opioids.

129. The Defendants breached the duty to warn that they owed to the Plaintiffs and Class Members. The Defendants' breaches of the duty to warn include, but are not limited to:

(a) failing to provide proper warnings in product monographs and materials provided to patients and healthcare providers;

(b) causing materials to be circulated that understated the risks of Opioid use;

(c) failing to monitor feedback from the market, including reports as early as in or around 1997-1998 that Opioids were being abused and were associated with the high risk of addiction;

(d) failing to warn doctors and the general public about the risks associated with Opioid use, even after it became apparent that the New Narrative was false and misleading;

(e) failing to conduct the necessary research and testing to determine the risks associated with Opioid use, particularly for the treatment of long-term pain;

(f) failing to conduct follow up testing or monitor Opioid use once Opioids began to be consistently prescribed for long-term pain; and

(g) failing to adequately train sales representatives to provide accurate information regarding appropriate use of Opioids and risks associated with their use.

130. As a result of these failures, Class Members consumed Opioids without knowledge of their dangers, developed Opioid Use Disorder, and suffered foreseeable harms.

v. Statutory Support for Negligent Misrepresentation and Duty to Warn

131. The duties owed by the Defendants in making representations about their Opioid products, and in providing proper warnings about their Opioid products, are further supported by the statutory requirements imposed on them, including as "manufacturers" under the *Food and Drugs Act*, R.S.C. 1985, c. F-27 [the "***FDA***"], and the *Food and Drug Regulations*, CRC, c. 870 [the "***FDR***"], and as "licensed dealers" under the *Controlled Drugs and Substances Act*, SC 1996, c19 and the *Narcotic Control Regulations*, CRC, c. 1041 [the "***NCR***"]. These requirements include:

(a) The prohibition in s. 9(1) of the *FDA*, against labelling, packaging, selling or advertising drugs in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety;

(b) The requirement imposed by s. C.01.012 of the *FDR* to conduct all necessary investigations before making representations regarding the site, rate or extent of release to the body of a medicinal ingredient of a drug, or the availability to the body of a medicinal ingredient of the drug;

(c) The requirement imposed by s C.01.017 of the *FDR* to report serious drug reactions within 15 days after receiving or becoming aware of the information;

(d) The requirements imposed by s. C.01.018(1) of the *FDR* to prepare annual summary reports of all information relating to adverse drug reactions, and to report whether there has been a significant change in what is known about the risks and benefits of the drug;

(e) The requirements imposed by s. C.02.020(1) of the *FDR* to maintain records of product testing and completion thereof;

(f) The requirements imposed by s. C.02.022(1) of the *FDR* to maintain records of the sale of drugs; and

(g) The requirements imposed by s. C.02.023(1) of the *FDR* to record, investigate, and if applicable, take corrective action in respect of complaints regarding the quality, deficiencies, or hazards of a drug.

vi. Fraudulent Concealment

132. The Defendants intentionally and fraudulently concealed the existence of their unlawful conduct from the public, including the Plaintiffs and the Class Members. The Defendants represented to the Plaintiffs, the Class Members, and the general public that the Opioid Misrepresentations were true and accurate, thereby misleading the Plaintiffs and the Class Members. The affirmative acts of the Defendants alleged herein were fraudulently concealed and carried out in a manner that precluded detection.

133. Because the Defendants' conduct was kept secret, the Plaintiffs and the Class Members were unaware of the Defendants' unlawful conduct.

G. RELIEF SOUGHT

i. Damages Suffered by Class Members

134. As a result of the Defendants' statutory breaches and common law tortious conduct, the Plaintiffs and Class have suffered and will continue to suffer damages including, but not limited to, damages for personal injuries, mental anguish, pain and suffering, loss of employment income and benefits, loss of enjoyment of life, possible death, and special damages and expenses.

135. As a result of the Defendants' conduct described above, the Plaintiffs and Class have suffered damages and losses, including but not limited to:

(a) personal injury, including addiction;

(b) severe emotional distress related to the pain and suffering associated with addiction;

(c) the risk of death or other serious injuries;

(d) out of pocket expenses incurred by the Class; and

(e) loss of income.

136. The Plaintiffs and Class have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life, as well as the need for lifelong medical treatment.

137. As a result of the Defendants' conduct described above, the Family Law Class have suffered damages, including but not limited to:

(a) actual expenses reasonably incurred for the benefit of Class Members;

(b) travelling expenses incurred while visiting Class Members during treatment or recovery;

(c) loss of income or the value of services provided for Class Members where services, including nursing and housekeeping have been provided; and

(d) compensation for loss of support, guidance, care, and companionship that they might reasonably have expected to receive from Class Members.

ii. Punitive Damages

138. The Plaintiffs claim punitive damages in the sum of $100,000,000.00 as a result of the egregious, outrageous and unlawful conduct of the Defendants, and in particular, their callous disregard for the health and lives of vulnerable patients in Canada.

139. In particular, the Defendants' conduct in the distribution, sale and marketing of Opioids after obtaining knowledge that Opioids were addictive showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages in a sum which will serve to deter the Defendants from similar conduct in the future.

iii. Disgorgement

140. The Plaintiffs claim an accounting of all profits earned by the Defendants during the class period from the sale of Opioids pursuant to the New Narrative and disgorgement thereof. Such a remedy is fair and just in the circumstances.

H. REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

141. The Plaintiffs plead that this action has a real and substantial connection with Ontario because, among other things:

(a) the Defendants distribute and sell their products in Ontario and derive substantial revenue from such sales;

(b) the Defendants' head offices are located in Ontario;

(c) the Defendants' advertised their products, including Opioids, in Ontario;

(d) the torts were committed in Ontario;

(e) Plaintiffs and Class Members were administered Opioids in Ontario and sustained consequent damages in Ontario; and

(f) the Defendants are necessary and proper parties to the action.

I. STATUTES RELIED UPON

142. The Plaintiffs rely upon the following statutes:

(a) *Class Proceedings Act*, 1992, SO 1992, c 6;

(b) *Family Law Act*, R.S.O. 1990, c. F.3;

(c) *Courts of Justice Act*, R.S.O. 1990, c. C.43;

(d) *Competition Act*, RSC 1985, c C-34;

(e) *Food and Drugs Act*, R.S.C. 1985, c. F-27;

(f) *Food and Drug Regulations*, C.R.C., c. 870;

(g) *Controlled Drugs and Substances Act*, SC 1996, c 19; and

(h) *Narcotic Control Regulations*, CRC, c 104.1

143. The Plaintiffs and Class request that this action be tried in Toronto, ON.

May 15, 2019

Amended: February 9, 2022

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Darryl Gebien Plaintiff and **Apotex Inc. et al.** Defendants

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ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding commenced at Toronto
Proceeding under the *Class Proceedings Act, 1992*

SECOND FRESH AS AMENDED STATEMENT OF CLAIM

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