Court File No. CV-19-627656-00CL

ONTARIO SUPERIOR COURT OF JUSTICE (COMMERCIAL LIST)

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. C-36, AS AMENDED

AND IN THE MATTER OF A PLAN OF AND IN THE MATTER OF PURDUE PHARMA L.P., PURDUE PHARMA INC., RHODES ASSOCIATES L.P., PAUL LAND INC., RHODES TECHNOLOGIES, RHODES PHARMACEUTICALS L.P., UDF LP, SVC PHARMA INC., BUTTON LAND L.P., SVC PHARMA LP, QUIDNICK LAND L.P., SEVEN SEAS HILL CORP., OPHIR GREEN CORP., PURDUE PHARMA OF PUERTO RICO, AVRIO HEALTH L.P., PURDUE TRANSDERMAL TECHNOLOGIES L.P., PURDUE PHARMACEUTICALS L.P., PURDUE PHARMA MANUFACTURING L.P., ALDON THERAPEUTICS L.P., IMBRIUM THERAPEUTICS L.P., GREENFIELD BIOVENTURES L.P., NAYATT COVE LIFESCIENCE INC., PURDUE NEUROSCIENCE COMPANY, PURDUE PHARMACEUTICALS PRODUCTS L.P.

RESPONDING MOTION RECORD OF THE QUEBEC OPIOID CLASS ACTION PLAINTIFF

(Re: Related Party Stay Returnable November 28, 2019)

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André Lespérance Gabrielle Gagné

Lawyers for Riccardo Camarda, the Quebec Opioid Class Action Plaintiff

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| А. | Exhibit "A" – Amended Application for Authorization to Institute a Class Action dated October 25, 2019 |

Court File No. CV-19-62765600CL

ONTARIO SUPERIOR COURT OF JUSTICE (COMMERCIAL LIST)

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. C-36, AS AMENDED

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AFFIDAVIT OF TINA SILVERSTEIN (sworn November 22, 2019)

I, Tina Silverstein, of the City of Montreal, in the Province of Quebec, MAKE OATH AND SAY:

1. I am one of the attorneys representing the plaintiff (the "Quebec Plaintiff") in the proposed class action proceedings instituted before the Superior Court of Quebec in Court file number 500-06-001004-197 (as amended on October 25, 2019) (the "Quebec Opioid Class Action") against, *inter alia*, the defendants Purdue Pharma, a limited partnership, and Purdue Frederick Inc. (collectively, the "Quebec Purdue Defendants").

2. This Affidavit is sworn to support the Quebec Plaintiff's opposition to the request being made pursuant to the Notice of Motion filed by Purdue Pharma L.P. in its capacity as the foreign

representative (the "Foreign Representative") on behalf of itself and the 23 other debtors-inpossession (collectively, the "Chapter 11 Debtors") returnable November 28, 2019 (the "Related Party Stay Motion").

3. As counsel for the Quebec Plaintiff, I have knowledge of the matters to which I herein depose, except where I have obtained information from others. Where I have obtained information from others, I have stated the source of the information and believe it to be true.

4. Unless otherwise indicated, the defined terms used in the present Affidavit have the same meaning as ascribed to them in the Foreign Representative's Related Party Stay Motion.

5. On May 23, 2019, an application for authorization to institute a class action (the "Authorization Application") was filed in the Superior Court of Quebec, District of Montreal by an anonymous plaintiff, designated as EV.

6. The Authorization Application explains that Quebecers are facing a serious health crisis and alleges that this was as a result of misrepresentations made by the defendant drug companies about opioids and as a result of their failure to adequately warn users of serious and potentially fatal consequences of opioid use.

7. Subsequently, on October 25, 2019, an amended application was filed (the "Amended Authorization Application") in which, most notably, a change was made to substitute the class representative (due to the initial class representative's health) for the Quebec Plaintiff, Mr. Riccardo Camarda, and to effect certain changes to the list of defendants identified therein. A copy of the Amended Authorization Application is attached hereto as **Exhibit "A"**.

The Quebec Plaintiff is a resident of the Province of Quebec who alleges in paragraphs
2.152 and 2.153 of the Amended Authorization Motion that he:

"... was prescribed opioids for a period of 12 years and was treated for severe Opioid Use Disorder in early 2018 ... [and that while he] is presently in early remission from his Opioid Use Disorder ... he will always be vulnerable to relapses for this chronic illness caused by prescription opioids."

9. As stated in the Amended Authorization Application in paragraph 2.209, he has decided to act as representative class plaintiff because he believes "*that no person should ever have to experience the horrible effects that opioids have had on his life and well-being*" and is seeking compensation for himself and all members of the proposed class in Quebec (the "**Quebec Class**"), described in the Amended Authorization Application as follows:

"All persons in Quebec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the Defendants between 1996 and the present day ("Class Period") and who suffer or have suffered from Opioid Use Disorder, according to the diagnostic criteria herein described.

The Class includes the direct heirs of any deceased persons who met the above-mentioned description.

The Class excludes any person's claim, or any portion thereof, subject to the settlement agreement entered into in the court file no. 200-06-000080-070, provided that such settlement agreement becomes effective as a result of the issuance of the requisite court approvals."

10. There are presently 34 defendants in the Quebec Opioid Class Action, which include the two Quebec Purdue Defendants.

11. The Quebec Opioid Class Action does not name any of the Chapter 11 Debtors as defendants, nor does it name as defendants any of the related parties against whom an injunction has been ordered in the Preliminary Injunction Order before the US Bankruptcy Court.

12. While no date has as yet been set for a certification (authorization) hearing for the Amended Authorization Application, carriage of the file was recently assigned by the Coordinating Judge for the Class Action Division of the Quebec Superior Court, the Honorable Chantal Chatelain J.S.C, to the Honourable Justice Gary D. D. Morrison, J.S.C.

13. On November 15, 2019, Justice Morrison requested that the parties advise him as to their readiness to schedule a hearing date. As a result of certain developments, most notably the Related Party Stay Motion, counsel for the Quebec Plaintiff advised Justice Morrison that they would provide his Lordship with an update in mid-December 2019 as to their readiness to schedule the certification hearing, after the hearing on the Related Party Stay Motion.

14. A stay of proceedings against the Quebec Purdue Defendants would cause significant delays in respect of the fixing of a hearing date for the certification of their class action. It would also be highly prejudicial to the Quebec Class, and would create enormous difficulties in respect of the prosecution of the litigation against the other 32 defendants.

15. A stay of proceedings could also result in a requirement for the unnecessary duplication of work and substantial additional costs in the event that multiple certification hearings are required due to the stay (assuming that a court in Quebec would permit multiple hearings).

16. Since the Quebec Opioid Class Action was served in May, 2019, neither the Foreign Representative, nor the Quebec Purdue Defendants, have ever made any overtures to counsel for the Quebec Plaintiff regarding a potential settlement of their claims or otherwise.

17. Neither the Foreign Representative, nor the Quebec Purdue Defendants, or their legal counsel, contacted counsel for the Quebec Plaintiff to advise them of their intent to seek a stay of

the Quebec Opioid Class Action, or to discuss any matters related thereto, prior to the service of the motion record in connection with the Related Party Stay Motion.

18. All of the facts alleged herein are true.

AND I HAVE SIGNED

Tina Silverstein

Solemnly declared before me at Montreal, Province of Quebec, this 22nd day of November, 2019

Commissioner of Oaths for Quebec



| IN THE MATTER OF THE <i>COMPANIES' CREDITORS ARRANGEMENT ACT</i> , R.S.C. 1985, c. C-36, AS AMENDED AND IN THE MATTER OF A PLAN OF AND IN THE MATTER OF PURDUE PHARMA L.P., PURDUE PHARMA INC., RHODES ASSOCIATES L.P., PAUL LAND INC., RHODES TECHNOLOGIES, RHODES PHARMACEUTICALS L.P., UDF LP, SVC PHARMA INC., BUTTON LAND L.P., SVC PHARMA LP, QUIDNICK LAND L.P., SEVEN SEAS HILL CORP., OPHIR GREEN CORP., PURDUE PHARMA OF PUERTO RICO, AVRIO HEALTH L.P., PURDUE TRANSDERMAL TECHNOLOGIES L.P., PURDUE PHARMACEUTICALS L.P., PURDUE PHARMA MANUFACTURING L.P., ALDON THERAPEUTICS L.P., IMBRIUM THERAPEUTICS L.P., GREENFIELD BIOVENTURES L.P., NAYATT COVE LIFESCIENCE INC., PURDUE NEUROSCIENCE COMPANY, PURDUE PHARMACEUTICALS PRODUCTS L.P. | Court I | File No. CV-19-627656-00CL |
|--|--|--|
| | ONTARIO SUPERIOR COURT OF JUSTICE – COMMERCIAL LISTProceeding commenced at TorontoAFFIDAVIT OF TINA SILVERSTEIN (Sworn November 22, 2019)Fishman Flanz Meland Paquin LLP 4100-1250 René-Lévesque Blvd. West Montreal, Quebec H3A 3H3 Tel: (514) 932-4100 | |
| | | |
| | | |
| | Mark E. Meland mmeland@ffmp.ca | Avram Fishman afishman@ffmp.ca |
| | Tina Silverstein tsilverstein@ffmp.ca | Margo R. Siminovitch msiminovitch@ffmp.ca |
| | Trudel Johnston & Lespérance 90-750, Côte de la Place d'Armes Montréal, Quebec H2Y 2X8 Tel: 514 871-8385 | |
| | André Lespérance andre@tjl.quebec | Gabrielle Gagné gabrielle@tjl.quebec |

Canada

Province of Quebec

District of Montreal

No. <u>500-06-001004-197</u>

(Class Action) Superior Court

(...) **RICCARDO CAMARDA**, with an elected domicile for the purpose hereof at 1250 René-Lévesque Boulevard West, Suite 4100, Montreal, Quebec H3B 4W8

Plaintiff

۷.

ABBOTT LABORATORIES, LIMITED, a legal person, having its principal place of business at 75 boul. Pierre-Roux Est, CP 307, Victoriaville, Quebec G6P 6S9

and

APOTEX INC., a legal person, having a place of business at 2970 André Avenue, Dorval, Quebec H9P 2P2

<u>and</u>

ARALEZ PHARMACEUTICALS CANADA INC., a legal person having a place of business at 7100 West Credit Avenue, Suite 101, Mississauga, Ontario L5N 0E4

and

BGP PHARMA ULC, a legal person, having a place of business at 1959 Upper Water Street, Suite 900, Halifax, Nova Scotia B3J 2X2

and

BOEHRINGER INGELHEIM (CANADA) LTD., a legal person,

having a place of business at 5180 South Service Road, Burlington, Ontario L7L 5H4

<u>and</u>

BRISTOL-MYERS SQUIBB CANADA CO., a legal person, having its principal place of business at 2344 Alfred-Nobel Boulevard, Montreal, Quebec H4S 0A4

<u>and</u>

CHURCH & DWIGHT CANADA CORP., a legal person, having its principal place of business at 5485 Ferrier Street, Mont-Royal, Quebec H4P 1M6

and

COBALT PHARMACEUTICALS INC., a legal person, having a place of business at <u>17800 Lapointe Street</u>, <u>Mirabel</u>, <u>Quebec</u> <u>J7J 1P3</u>

and

ETHYPHARM INC., a legal person, having a place of business at 1000 De La Gauchetière, Suite 2400, Montreal, Quebec H3B 4W5

<u>and</u>

<u>GLAXOSMITHKLINE INC.</u>, a legal person, having its principal place of business at 245 Armand-Frappier Boulevard, Laval, Quebec H7V 4A7

and

HIKMA LABS INC., a legal person, having a place of business at 1809 North Wilson Road, Hilliard, Ohio 43026, U.S.A.

and

JANSSEN INC., a legal person, having a place of business at 14 Place du Commerce, Suite 620, Montreal, Quebec H3E 1T5

and

JODDES LIMITED, a legal person, having a place of business at 6111 Royalmount Avenue, Suite 100, Montreal, Quebec H4P 2T4

and

LABORATOIRE ATLAS INC., a legal person, having a place of business at 9600 des Sciences Boulevard, Montreal, Quebec H1J 3B6

and

LABORATOIRE RIVA INC., a legal person, having a place of business at 660 Industriel Boulevard, Blainville, Quebec J7C 3V4

and

LABORATOIRES TRIANON INC., a legal person, having a place of business at 660 Industriel Boulevard, Blainville, Quebec J7C 3V4

<u>and</u>

MERCK FROSST CANADA & CO., a legal person, having a place of business at 16750 Route Trans-Canada Highway, Kirkland, Quebec H9H 4M7

<u>and</u>

MYLAN PHARMACEUTICALS ULC, a legal person, having a place of business at <u>85 Advance Road, Etobicoke, Ontario,</u> <u>M8Z 2S6</u>

<u>and</u>

NOVARTIS PHARMACEUTICALS CANADA INC., a legal person, having a place of business at 385 Bouchard Boulevard, Suite 518, Dorval, Quebec H9S 1A9

and

PALADIN LABS INC., a legal person, having a place of business at 100 boul. Alexis-Nihon, Suite 600, Montreal, Quebec H4M 2P2

and

PFIZER CANADA ULC, a legal person, having a place of business at 17300 Trans-Canada Highway, Kirkland, Quebec H9J 2M5

and

PHARMASCIENCE INC., a legal person, having a place of business at 6111 Royalmount Avenue, Suite 100, Montreal, Quebec H4P 2T4

and

PRO DOC LTÉE, a legal person, having a place of business at 2925 Industriel Boulevard, Laval, Quebec H7L 3W9

and

PURDUE FREDERICK INC., a legal person, having a registered office address at <u>1000, De La Gauchetière West,</u> <u>Suite 900, Montreal, Quebec H3B 5H4</u>

and

PURDUE PHARMA, a limited partnership, having a place of business at 575 Court Granite, Pickering, Ontario L1W 3W8

and

ROXANE LABORATORIES INC., a legal person, having its registered office address at 5180 South Service Road, Burlington, Ontario L7L 5H4

and

SANDOZ CANADA INC., a legal person, having a place of business at 110 De Lauzon Street, Boucherville, Quebec J4B 1E6

and

SANIS HEALTH INC., a legal person, having a place of business at 1250 Guy Street, La Tour du Faubourg, 11th Floor, Montreal, Quebec H3H 2T4

(...Defendants Stanley Pharmaceuticals and Sterimax Inc. removed...)

and

SANOFI-AVENTIS CANADA INC., a legal person, having a place of business at 2905 Place Louis-R. Renaud, Laval, Quebec H7V 0A3

and

SUN PHARMA CANADA INC., legal person having a place of business at <u>126 East Drive</u>, Brampton, Ontario L6T 1C1

and

TEVA CANADA LIMITED, a legal person, having a place of business at 17800 Lapointe Street, Mirabel, Quebec J7J 1P3

and

VALEANT CANADA LIMITED, a legal person, having a place of business at 2150 Saint-Elzéar Boulevard West, Laval, Quebec H7L 4A8

<u>and</u>

VALEANT CANADA LP, a limited partnership, having a place of business 2150 Saint-Elzéar Boulevard West, Laval, Quebec H7L 4A8

and

4490142 CANADA INC., F.K.A. AS MEDA VALEANT PHARMA CANADA INC., a legal person, having a place of business at 2150 Saint-Elzéar Boulevard West, Laval, Quebec H7L 4A8

Defendants

<u>Amended</u> Application for authorization to institute a class action, and to obtain the status of representative

PLAINTIFF ALLEGES RESPECTFULLY:

Along with the rest of Canada, Quebec is facing a serious opioid crisis.

Opioids are a class of drugs which resemble naturally occurring opiates that are prescribed to treat pain. However, these drugs are dangerously addictive, and the growing number of addictions, overdoses and deaths in Quebec and Canada caused by opioids has been declared by the Government of Canada to be a public health emergency.

1. The Plaintiff wishes to institute a class action on behalf of the natural persons forming part of the class hereinafter described and of which the Plaintiff is a member, namely:

All persons in Quebec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the Defendants between 1996 and the present day ("**Class Period**") and who suffer or have suffered from Opioid Use Disorder, according to the diagnostic criteria herein described.

The Class includes the direct heirs of any deceased persons who met the above-mentioned description.

The Class excludes any person's claim, or any portion thereof, subject to the settlement agreement entered into in the court file no (...). (...) 200-06-000080-070, provided that such settlement agreement becomes effective as a result of the issuance of the requisite court approvals.

2. The facts on which the Plaintiff's personal claim against the Defendants are based, are as follows:

- 2.1. As more fully described herein, in an effort to increase sales of their dangerous products, and in wanton disregard for the health and safety of the members of the class (the "**Class**" or "**Class Members**"), the Defendants deliberately misrepresented that opioids were less addictive than they knew them to be, more effective than they actually are, and had a wider range of applications than those approved by health authorities.
- 2.2. The Defendants were also negligent in connection with the research, development, manufacture, testing, regulatory licensing, distribution, sale, marketing, and after-market surveillance of opioids in Quebec, and failed to

adequately warn users of the serious and potentially fatal harms associated with opioid use.

- 2.3. As a result of these actions, which contravene the provisions of the *Competition Act* (R.S.C., 1985, c. C-34) (the "**Competition Act**"), the *Civil Code of Quebec*, CQLR c CCQ-1991 ("**CCQ**") and the Quebec *Charter of Human Rights and Freedoms*, CQLR c C-12 (the "**Charter**"), the Plaintiff requests that the Defendants compensate (...) him and the other Class Members, as follows:
 - 2.3.1. Compensatory damages for each Class Member in the amount of \$30,000 plus interest and additional indemnity from the date of the commencement of their addictions;
 - 2.3.2. Punitive damages in the amount of \$25,000,000 from each Defendant plus interest and additional indemnity from the date of institution of the proceedings; and
 - 2.3.3. Pecuniary damages for each Class Member's personal losses, recoverable on an individual basis.

The Defendants

- 2.4. The Defendants are all manufacturers, marketers and/or distributors of opioid drugs, including but not limited to, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone and oxymorphone in Quebec.
- 2.5. Defendant Abbott Laboratories, Limited ("**Abbott**") is a Canadian corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including <u>Codeine Phosphate Injection USP</u>, <u>Demerol (injections)</u>, Dilaudid, (...) <u>Dilaudid-HP</u>, <u>Dilaudid-HP-Plus</u>, <u>Dilaudid-XP</u>, <u>Dilaudid Sterile Powder</u>, Kadian, (...), <u>Meperidine Hydrochloride Injection</u>, <u>Morphine Forte</u>, <u>Morphine Extra-Forte</u>, <u>Morphine-EPD Preservative-free and Talwin injections</u>.
 - 2.5.1. Knoll Pharma Inc. ("**Knoll**") was a Canadian corporation that amalgamated with Abbott in 2001 which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Dilaudid, <u>Dilaudid-HP</u>, <u>Dilaudid-HP-Plus</u>, <u>Dilaudid-XP</u>, <u>Dilaudid Sterile Powder and Kadian</u>.
- 2.6. Defendant Apotex Inc. ("**Apotex**") is an Ontario corporation which, during the Class Period, manufactured, marketed and<u>/or</u> sold opioids in Quebec,

including A<u>PO</u>-Fentanyl Matrix, (...) A<u>PO</u>-Hydromorphone, <u>APO-</u> <u>Hydromorphone CR, APO-Oxycodone CR, APO-Oxycodone/Acet and</u> <u>APO-Tramadol/Acet</u>.

- 2.7 Defendant Aralez Pharmaceuticals Canada Inc. ("Aralez"), formerly Tribute Pharmaceuticals Canada Inc., is an Ontario corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Fiorinal C1/2 and Fiorinal C1/4.
- <u>2.8</u> Defendant BGP Pharma ULC ("**BGP Pharma**") is a Nova Scotia corporation which, during the Class Period, manufactured, marketed and<u>/or</u> sold opioids in Quebec, including Kadian.
- 2.9 Defendant Boehringer Ingelheim (Canada) Ltd. ("**Boehringer**") is a Canadian corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Hydromorphone HCL (tablets), Oramorph SR and Roxicet.
- 2.10 Defendant Bristol-Myers Squibb Canada Co. ("**Bristol-Myers**") is a Nova Scotia corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including <u>Endocet</u>, <u>Endodan</u>, <u>Numorphan</u>, Percocet, <u>Percocet-Demi</u>, <u>Percodan and Percodan-Demi</u>.
 - 2.10.1 Du Pont Merck Pharma Inc. was a Quebec limited partnership, which, in 1998, became DuPont Pharma Inc., a Canadian corporation, which amalgamated with Bristol-Myers in 2002, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Endocet, Endodan, Numorphan, Percocet, Percocet-Demi, Percodan and Percodan-Demi.
- 2.11 Defendant Church & Dwight Canada Corp. ("Church & Dwight") is a Nova Scotia corporation which, during the Class Period, manufactured, marketed, and/or sold opioids in Quebec, including Atasol-15 and Atasol-30.
 - 2.11.1 Frank W. Horner Inc. was a Canadian corporation, which amalgamated into Carter-Horner Inc. in 1996, which then amalgamated into Carter-Horner Corp. in 2002, who in turn amalgamated into Church & Dwight in 2004, and which, during the Class Period, manufactured, marketed, and/or sold opioids in Quebec, including Atasol-15 and Atasol-30.

- <u>2.12</u> Defendant Cobalt Pharmaceuticals Inc. ("**Cobalt**") is an Ontario corporation which, during the Class Period, manufactured, marketed and<u>/or</u> sold opioids in Quebec, including CO Fentanyl.
- <u>2.13</u> Defendant Ethypharm Inc. ("**Ethypharm**") is a Quebec corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including M-<u>E</u>diat and M-<u>E</u>slon.
- 2.14 Defendant GlaxoSmithKline Inc. ("**GSK**") is a Canadian corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Empracet-30 and Empracet-60.
 - 2.14.1 <u>Glaxo Wellcome Inc. was an Ontario corporation which</u> <u>amalgamated into GSK in 2001, and which, during the Class</u> <u>Period, manufactured, marketed and/or sold opioids in Quebec,</u> <u>including Empracet-30 and Empracet-60.</u>
 - 2.14.2 Smithkline Beecham Inc., also known as Smithkline Beecham Pharma, was a Canadian corporation that amalgamated into GSK in 2001, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Opium & Belladonna Suppositories.
- 2.15 Defendant Janssen Inc. ("Janssen"), also known as Janssen-Ortho and/or Patriot, is an Ontario corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Duragesic, Jurnista, Nucynta CR, Nucynta Extended-Release, Nucynta IR, PAT-Tramadol/Acet, Tramacet, Tylenol with Codeine No. 2, Tylenol with Codeine No. 3, Tylenol with Codeine No. 4, Tylenol with Codeine Elixir and Ultram.
- <u>2.16</u> Sorres Pharma Inc. ("**Sorres Pharma**") was a Canadian corporation and a subsidiary of Defendant Joddes Limited ("**Defendant Joddes**") which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Hydromorphone tablets.
- <u>2.17</u> Defendant Laboratoire Atlas Inc. ("**Laboratoire Atlas**") is a Canadian corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Codeine Phosphate <u>Syrup</u>, Doloral and Linctus Codeine Blanc.
- <u>2.18</u> Defendant Laboratoire Riva Inc. ("<u>Laboratoire</u> Riva") is a Quebec corporation which, during the Class Period, manufactured, marketed and/<u>or</u>

sold opioids in Quebec, including (...) <u>Codeine 15, Codeine 30, Rivacocet</u>, <u>RIVA-Tramadol/Acet and Triatec-30</u>.

- 2.19 Defendant Laboratoires Trianon Inc. ("Laboratoires Trianon") is a Quebec corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Codeine 15, Codeine 30 and Triatec-30.
- 2.20 Defendant Merck Frosst Canada & Co. ("Merck & Co."), also known as Frosst, is an Nova Scotia corporation, which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including 282 Mep Tab, 282 Tab, 292 Tab, Exdol-15 and Exdol-30.
- 2.21 Defendant Mylan Pharmaceuticals ULC ("**Mylan**") is an Alberta corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Mylan-Fentanyl Matrix <u>Patch</u> and <u>Mylan-Tramadol/Acet</u>.
- 2.22 Defendant Novartis Pharmaceuticals Canada Inc. ("Novartis") is a Canadian corporation, which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Fiorinal C1/2 and Fiorinal C1/4.
- 2.23 Defendant Paladin Labs Inc. ("**Paladin**") is a Canadian corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Abstral, <u>Fiorinal C1/2</u>, <u>Fiorinal C1/4</u>, <u>Metadol, (...)</u> <u>Nucynta Extended-Release</u>, <u>Nucynta IR</u>, Statex <u>and Tridural</u>.
 - 2.23.1 Labopharm Inc. was a Canadian corporation that amalgamated with Paladin in January 2013, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Tridural.
- 2.24 Defendant Pfizer Canada ULC ("**Pfizer Canada**") is a British Columbia corporation which (...) has acquired various Canadian corporations that manufactured, marketed and/or sold opioids in Quebec during the Class Period.
 - 2.24.1 Pfizer Canada Inc. was a Canadian corporation that amalgamated with Pfizer Canada in October 2010, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including HYDROmorphone Hydrochloride Injection, Morphine Forte, Morphine Extra-Forte, Morphine Sulfate Injection, USP, Robaxisal C1/2 and Robaxisal C1/4.

- 2.24.2 Hospira Healthcare Corporation ("**Hospira**") was a Canadian corporation that amalgamated with Pfizer Canada in (...) 2015 and was dissolved in 2018, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Codeine Phosphate injections, Demerol (injections), Meperidine Hydrochloride Injection, Morphine Forte, Morphine Extra-Forte, Morphine-EPD, Morphine Sulfate Injection, USP, (...) and Talwin (injections).
- 2.24.3 (...) Mayne Pharma (Canada) Inc. ("**Mayne**"), also known as Faulding (Canada) Inc., was a Canadian corporation that amalgamated with Hospira in 2007, which then amalgamated with Pfizer Canada in (...) 2015 and was dissolved in 2018, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Morphine Sulfate Injection BP and (...) Pethidine Injection BP.
- 2.24.4 Wyeth Consumer Healthcare ULC (formerly Wyeth Consumer Healthcare Inc., and formerly Whitehall-Robins Inc.) was an Ontario corporation that amalgamated with Pfizer Canada in August 2010, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Robaxisal C1/2 and Robaxisal C1/4.
- 2.25 Defendant Pharmascience Inc. ("Pharmascience"), also known as Pendopharm, a Division of Pharmascience Inc., is a Canadian corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including 282 Tablets, 292 Tablets, Acet-2, Acet-3, Acet Codeine 30, Acet Codeine 60, Exdol-15, Exdol-30, Metadol, pms-Acetaminophen with Codeine Elixir, pms-Butorphanol, pms-Codeine, pms-Fentanyl MTX, pms-Hydromorphone, pms-Morphine Sulfate <u>SR</u>, pms-Opium and Belladonna, pms-Oxycodone, pms-Oxycodone CR, pms-Oxycodone-Acetaminophen and pms-Tramadol-Acet.
- 2.26 Defendant Pro Doc Limitée ("**Pro Doc**") is a Quebec corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Fentanyl <u>Patch</u>, Oxycodone <u>(tablets)</u>, <u>Oxycodone-Acet</u>, <u>Procet-30</u>, <u>Pronal C1/2</u>, <u>Pronal C1/4</u>, and <u>Tramadol-Acet</u>.
- 2.27 Defendants Purdue Pharma and Purdue Frederick Inc. (collectively "**Purdue**") are respectively a partnership pursuant to the laws of Ontario and a Canadian corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including <u>Belbuca, BuTrans 5</u>,

<u>BuTrans 10, BuTrans 15, BuTrans 20,</u> Codeine Contin, Dilaudid, <u>Dilaudid-HP</u>, <u>Dilaudid-HP-Plus</u>, <u>Dilaudid-XP</u>, <u>Dilaudid Sterile Powder</u>, Hydromorph Contin, <u>Hydromorph.IR</u>, MS Contin, MS.IR, Oxy.IR, <u>Palladone XL</u>, <u>Targin and Zytram XL</u>.

- 2.28 Defendant Purdue also produces OxyContin and OxyNeo (...). While claims related to the use of these products between January 1, 1996 and February 28, 2017 are part of the settlement (...) entered into in connection with the court file no (...) 200-06-000080-070, it remains to be seen whether such settlement agreement (the "Quebec Settlement Agreement"), which was part of a national settlement initiative (the "National Settlement Agreement"), will become effective as a result of the issuance of the requisite court approvals.
 - 2.28.1 As appears from the April 4, 2017 judgment of the Honourable Justice Claude Bouchard, J.S.C ("Justice Bouchard"), which authorized the class action for the sole purpose of the settlement agreement, the provisions of such judgment are without effect if the required approvals in other jurisdictions are not issued:

[24] **DÉCLARE** que le présent jugement est rendu sous réserve que des ordonnances similaires soient également rendues par les tribunaux de l'Ontario, de la Nouvelle-Écosse, et de la Saskatchewan, et que les dispositions du présent jugement seront sans effet tant que ces ordonnances ne seront pas rendues;

2.28.2 Similarly, the August 21, 2017 judgment of Justice Bouchard approving the Quebec Settlement Agreement was also conditional, *inter alia*, upon a similar order being rendered by the court in Saskatchewan:

> [22] **DECLARE** que l'approbation de l'Entente est conditionnelle à ce qu'une ordonnance d'approbation soit également émise par le tribunal de la Saskatchewan. <u>Si une</u> telle ordonnance n'est pas rendue, le présent jugement sera nul et sans effet ;

Copies of the April 4, 2017 and August 21, 2017 judgments of Justice Bouchard are communicated herewith, *en liasse*, as **EXHIBIT P-38**.

2.28.3 On March 15, 2018, the court in Saskatchewan did not approve the National Settlement Agreement, which is attempting to settle the claims relating to the use of OxyContin and OxyNeo in Canada for the total amount of \$20,000,000, as the judge was "not satisfied that the Settlement Agreement is fair, reasonable and in the best interests of the class," the whole as appears from a copy of the judgment of Justice Barrington-Foote (SKQB), communicated herewith as **EXHIBIT P-39**. Consequently, the Quebec Settlement Agreement is not yet effective, and may never be effective.

- 2.28.4 While proceedings are still ongoing in connection with the efforts to have the National Settlement Agreement approved in Saskatchewan, if same is not approved, the claims of Class Members relating to the use of OxyContin and OxyNeo between January 1, 1996 and February 28, 2017 would appropriately be covered by the present proceedings since many Class Members may have been prescribed such drugs, along with a multitude of other drugs produced by Purdue and/or by other Defendants herein, which are covered by the present proceeding.
- 2.29 Defendant Roxane Laboratories, Inc. ("Roxane") is an Ohio corporation acquired by Defendant Hikma Labs Inc. ("Hikma") in 2015 which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Hydromorphone (...) HCL (tablets), and Oramorph SR.
- 2.30 Defendant Sandoz Canada Inc. ("Sandoz Canada") is a Canadian corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Codeine Phosphate injections, Fiorinal C1/2, Fiorinal C1/4, Hydromorphone HP 10, Hydromorphone HP 20, Hydromorphone HP 50, Hydromorphone HP Forte, HYDROmorphone Hydrochloride Injection USP, Meperidine Hydrochloride Injection USP, Morphine HP 25 (injection), Morphine HP 50 (injection), Morphine LP Epidural, Morphine Sulfate Injection USP, (...) Sandoz Fentanyl Patch, (...) Sandoz Morphine SR, Sandoz Opium & Belladonna, Sandoz Oxycodone/ Acetaminophen and Supeudol.
 - 2.30.1 Sabex Inc. (formerly Sabex 2002 Inc.) was a Canadian corporation that amalgamated with Sandoz Canada in 2004, which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Hydromorphone HP 10, Hydromorphone HP 20, Hydromorphone HP 50, Hydromorphone HP Forte, HYDROmorphone Hydrochloride Injection USP and Suppositories, Morphine HP injections, Morphine LP Epidural,

Morphine Sulfate Injection, Sab-Opium & Belladonna and Supeudol.

- 2.31 Defendant Sanofi-Aventis Canada Inc. ("Sanofi") (formerly, Sanofi-Synthelabo Canada Inc.) is a Canadian corporation, which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Demerol (tablets and injections) and Talwin (tablets and injections).
 - 2.31.1 Rhône-Poulenc Rorer Canada Inc. ("Rhône-Poulenc") was a Canadian corporation which, in 2000, amalgamated with Hoechst Marion Roussel Canada Inc., a Canadian corporation, to create Aventis Pharma Inc., which in turn amalgamated into Sanofi in 2004, and which, during the Class Period, Rhône-Poulenc manufactured, marketed and/or sold opioids in Quebec, including M-Eslon.
- <u>2.32</u> Defendant Sanis Health Inc. ("**Sanis**") is a Canadian corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including Morphine SR, (...) <u>Oxycodone-Acet and Tramadol/Acet</u>.
- <u>2.33 (...)</u>
- <u>2.34</u> Defendant Sun Pharma Canada Inc. ("Sun Pharma Canada"), formerly known as Ranbaxy Pharmaceuticals Canada Inc. (<u>"Ranbaxy"</u>), is an Ontario corporation which, during the Class Period, manufactured, marketed and<u>/or</u> sold opioids in Quebec, including <u>RAN</u>-Fentanyl Matrix Patch, <u>RAN</u>-Fentanyl Transdermal System <u>and RAN-Tramadol/Acet</u>.
- 2.35 Defendant Teva Canada Limited ("**Teva Canada**"), formerly Novopharm Limited, is a Canadian corporation which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including (...), Fentora, <u>Methoxisal-C ½</u>, <u>Methoxisal-C ¼</u>, <u>Novo-gesic C15</u>, <u>Novo-gesic C30</u>, Teva-Codeine, <u>Teva-Emtec-30</u>, <u>Teva-Fentanyl</u>, Teva-<u>HYDRO</u>morphone, <u>Teva-Lenoltec No. 2</u>, <u>Teva-Lenoltec No. 3</u>, <u>Teva-Lenoltec No. 4</u>, <u>Teva-Morphine SR</u>, <u>Teva-Oxycocet</u>, <u>Teva-Oxycodan</u>, and <u>Teva-Tramadol/Acetaminophen</u>.
 - 2.35.1 <u>Novopharm Limited was an Ontario corporation which</u> <u>amalgamated with Teva Canada in 2001, and which, during the</u> <u>Class Period, manufactured, marketed and/or sold opioids in</u> <u>Quebec, including Novo-gesic C15 and Novo-gesic C30.</u>
 - 2.35.2 Rougier Pharma Inc. was a Canadian corporation, which amalgamated into Ratiopharm Inc. in January 2001, and which,

during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Codeine Tab 15MG, Coryphen Codeine, Methoxisal-C ¹/₂, Methoxisal-C ¹/₄ and Paveral.

- 2.35.3 Ratiopharm Inc. was a Canadian corporation, which amalgamated into Teva Canada in August 2010, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including ratio-Codeine, ratio-Emtec-30, ratio-Fentanyl, ratio-Lenoltec No. 2, ratio-Lenoltec No. 3, ratio-Lenoltec No. 4, ratio-Morphine SR, ratio-Oxycocet and ratio-Oxycodan.
- 2.35.4 Technilab Pharma Inc. was a Canadian corporation which amalgamated into Teva Canada in August 2010, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Emtec-30, Lenoltec with Codeine No. 2, Lenoltec with Codeine No. 3, Lenoltec with Codeine No. 4, Methoxisal-C ½, Methoxisal-C ¼, Oxycocet and Oxycodan.
- 2.35.5 Actavis Pharma Inc. ("**Actavis**") was a Nova Scotia corporation that amalgamated with Teva Canada in 2017, <u>and</u> which, during the Class Period, manufactured, marketed and<u>/or</u> sold opioids in Quebec, including <u>ACT</u>Oxycodone CR (...) and ACT <u>Tramadol/Acet</u>.
- <u>2.36</u> Defendant Valeant Canada LP ("**Valeant** (...) <u>LP</u>") is a Quebec limited partnership which, during the Class Period, manufactured, marketed and/<u>or</u> sold opioids in Quebec, including (...) M.O.S., M.O.S.-SR, M.O.S.-Sulfate, <u>Onsolis and Ralivia</u>.
 - 2.36.1 Biovail Pharmaceuticals Canada, which was a division of Biovail Corporation, was a Canadian corporation that amalgamated with Valeant LP in September 2010, and which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including Ralivia.
- 2.37 Defendant Valeant Canada Limited ("Valeant Limited"), formerly known ICN Canada Limited, is a Canadian corporation which, during the Class Period, manufactured, marketed and/or sold opioids in Quebec, including M.O.S., M.O.S.-SR, M.O.S.-Sulfate, and Painex.
- <u>2.38</u> Defendant Meda Valeant Pharma Canada Inc., now 4490142 Canada Inc. ("4490142"), is a Canadian corporation which, during the Class Period, manufactured, marketed and<u>/or</u> sold opioids in Quebec, namely Onsolis.

The Defendants' Faults

- <u>2.39</u> Prior to the mid-1990s, opioids were primarily used to treat palliative care patients and for short-term treatment of acute pain, as appears from a 2011 article by Irfan A. Dhalla, Navindra Persaud and David N. Jurrlink entitled "Facing up to the prescription opioid crisis" (the "**Dhalla Article**"), communicated herewith as **EXHIBIT P-1**.
- <u>2.40</u> Opioids effectively treat pain by attaching to receptors in the brain, which block the feeling of pain, slow down breathing and result in a general calming effect; however, they carry great potential for misuse and abuse.
- 2.41 Indeed, opioids were initially thought to be too addictive to treat conditions requiring longer-term pain management, as appears from a 2016 article by Asim Alam and David N. Jurrlink entitled "The prescription opioid epidemic: an overview for anesthesiologists" (the "Alam Article"), communicated herewith as **EXHIBIT P-2**.
- 2.42 The prescribed uses of opioids changed in the mid-1990s; in particular, in 1996, when Defendant Purdue introduced a time-release formulation of oxycodone branded as OxyContin. Defendant Purdue claimed that the drug was safer because it could be taken less often, and it aggressively encouraged its widespread use for chronic conditions, such as back pain, migraines and arthritis.
- 2.43 While the Defendants may have competed with each other to increase their respective market shares, they generally acted in concert to promote the false and misleading narrative described more fully herein concerning the safety and efficacy of opioids in an effort to increase the acceptance of such drugs for treatment in a much larger patient population than that which was previously considered acceptable.
- 2.44 In their efforts to obtain market share and increase the prescription rate and sale of their drugs, the Defendants also failed to disclose the risks of using opioids.
- <u>2.45</u> The new narrative concerning the use of opioids, which was promoted by the Defendants, misrepresented that:
 - <u>2.45.1</u> the risk of opioid addiction was low, and that doctors could use screening tools to exclude patients who might become addicted;
 - <u>2.45.2</u> use of opioids resulted in improved function;

- <u>2.45.3</u> withdrawal from opioids could easily be managed;
- <u>2.45.4</u> opioids were appropriate for long-term use;
- <u>2.45.5</u> opioids had less adverse effects than other pain management drugs;
- <u>2.45.6</u> use of certain opioids provided patients with long-lasting pain relief;
- <u>2.45.7</u> increased dosages of opioids could be prescribed, without disclosing the increased risks; and
- <u>2.45.8</u> that "abuse deterrent" formulations of opioids were effective.

(collectively the "Misrepresentations").

Misrepresentations of the addictive nature and likelihood of abuse

- <u>2.46</u> In their marketing efforts, the Defendants persuaded health care professionals that the risk of addiction to opioids was largely unfounded.
- 2.47 A press release issued by Defendant Purdue in 1996 concerning the impending release of OxyContin stated that "one cause of patient resistance to appropriate pain treatment the fear of addiction is largely unfounded", the whole as appears from a copy of such press release (the "OxyContin **Press Release**"), communicated herewith as **EXHIBIT P-3**.
- 2.48 The OxyContin Press Release (EXHIBIT P-3) further quoted Dr. Max, then chairman of the American Pain Society and Quality Care Committee, as saying "*Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that <u>there is very little risk of addiction from the proper uses of these drugs for pain relief</u>."*
- 2.49 The message that was widely communicated was that addiction was not an issue when opioids were used by patients genuinely experiencing pain, as opposed to addicts seeking drugs to get high, that there was no risk to the general patient population, and that doctors could easily screen and rule out opioid therapies for patients prone to addiction.
- <u>2.50</u> The Misrepresentations in respect of addiction falsely induced health care professionals to believe that opioids could be safely prescribed to

appropriate patients, without the fear that such patients would become addicted.

- 2.51 This marketing strategy was particularly effective because it was able to "exploit gaps in physician knowledge and training relating to addiction medicine" and "led to unsafe prescribing practices and the failure to employ evidence-based treatments for addiction," as appears from the December 2016 Standing Committee on Health's report entitled "Report and Recommendations on the Opioid Crisis in Canada" (the "**2016 Standing Committee Report**"), communicated herewith as **EXHIBIT P-4**.
- 2.52 In furtherance of this message, the Defendants funded and/or improperly relied on studies that downplayed the risk of addiction by promoting the concept of "pseudoaddiction". Pseudoaddiction has been described in studies funded by pharmaceutical companies as "an iatrogenic disease resulting from withholding opioids for pain that can be diagnosed, prevented, and treated with more aggressive opioid treatment." Conversely, in studies without pharmaceutical funding, pseudoaddiction is described as nothing more than a clinical construct, which is no different from addiction, as appears from a 2015 article by Marion S. Greene and R. Andrew Chambers entitled "Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature", communicated herewith as EXHIBIT P-5.
- <u>2.53</u> The myth of pseudoaddiction encouraged healthcare professionals to increase the prescription of more opioids, in order to "cure" their patients from their pseudoaddictions.

Misrepresentations as to the improved function and efficacy of opioids over other pain relief treatment

- <u>2.54</u> Without proper clinical evidence, the Defendants purported in their marketing materials that long term use of opioids would improve patients' function and quality of life.
- <u>2.55</u> Opioids were misleadingly marketed by the Defendants as an appropriate choice for the treatment of chronic pain, and as both safe and effective for long-term use in connection with routine pain conditions.
- <u>2.56</u> As part of their marketing strategy, the Defendants exaggerated the risks of competing non-opioid products, in an effort to make treatment with opioids more popular than treatment with other therapies such as acetaminophen and nonsteroidal anti-inflammatory drugs ("**NSAIDs**"), like ibuprofen.

- 2.57 As indicated in the 2016 Standing Committee Report (EXHIBIT P-4), the marketing efforts employed by the Defendants were targeted in particular at family doctors, who commonly see patients with chronic pain conditions and who did not have the level of training to verify whether the Defendants' claims concerning the safe and effective nature of the drugs were correct.
- 2.58 In fact, a 2011 study reported that many physicians were unaware that there is no evidence from randomized controlled trials to support the assertion of the pharmaceutical companies that the benefits of long-term opioid therapy outweigh the risks, as appears in the Dhalla Article (EXHIBIT P-1).

Misrepresentations with respect to the management of withdrawal

- <u>2.59</u> The Defendants promoted the assertion that withdrawal from opioids was easily managed, in an effort to induce health care professionals to prescribe their drugs more liberally.
- <u>2.60</u> The message was that physical addiction could be easily managed by gradually decreasing the dosage; however, this ignored the fact that the actual symptoms of withdrawal can continue long after a patient stops using the drug. These side-effects, which include nausea, muscle pain, depression, anxiety, restlessness, chills, diarrhea and vomiting, make relapse and continued use more likely.

Misrepresentations regarding the appropriateness of long term use

- <u>2.61</u> The Defendants marketed their drugs as being safe for long-term use, a claim which was not backed up by any scientific evidence.
- 2.62 As appears from a 2000 marketing budget for Purdue (the "2000 Purdue Marketing Budget"), a copy of which is communicated herewith as **EXHIBIT P-6**, one of the objectives of Purdue with OxyContin was to promote it as the opioid "*to start with (...) and to stay with.*"
- <u>2.63</u> The Defendants pushed the prescription of their drugs for use in the nonmalignant pain markets. On this subject, the 2000 Purdue Marketing Budget (EXHIBIT P-6) states:

In 2000, <u>OxyContin Tablets will be more aggressively promoted</u> for use in the non-malignant pain market. The most common diagnoses for non-malignant pain are back pain, osteoarthritis, injury, and trauma pain. The major competitors for these diagnoses will be oxycodone and hydrocodone combination products, as well as Ultram. OxyContin Tablets will be positioned as providing the equivalent efficacy and safety of combination opioids, with early onset of pain relief and the benefit of a q12h dosing schedule. <u>The</u> <u>promotional efforts will focus on specific disease syndromes</u> <u>such as back pain, osteoarthritis, reflex sympathetic dystrophy,</u> <u>trauma/injury, neuropathic type pains, etc.</u>

2.64 The Dhalla Article (EXHIBIT P-1) states that there is no evidence from randomized control trials to support the affirmation that the benefits of long term opioid use outweigh the risks. Completed trials have generally been short term, used placebo instead of alternative therapies, and excluded high risk patients.

Misrepresentations relating to the adverse effects of opioids and failure to disclose risks

- <u>2.65</u> The Defendants virtually ignored the risks of opioid use in their promotion of their harmful products, and certainly failed to warn and inform both medical professionals and patients alike of the risks and dangers associated with opioid use.
- <u>2.66</u> For example, the Defendants failed to disclose the risks of overdose, addiction, respiratory depression and death.
- <u>2.67</u> The Defendants also ignored the risk of the development of hyperalgesia, which is an enhanced sensitivity to pain, leading a sufferer to feel pain more intensely, for pain to spread to different locations and to feel increased pain response to external stimuli. Unlike the case of increased tolerance, increased use of opioids by sufferers of hyperalgesia worsens the pain.
- <u>2.68</u> Hyperalgesia can further cause sufferers to experience hormonal dysfunction, a decline in immune function, mental clouding, confusion and dizziness.
- <u>2.69</u> In addition to failing to disclose these serious risks, the Defendants deceptively promoted the risks of alternative pain treatment therapies in an effort to convince health care professionals and patients that opioids were a better choice.

Misrepresentations as to the long-lasting nature of the pain relief provided by certain opioid formulations

<u>2.70</u> While the Defendants apparently knew that these claims were incorrect, they nevertheless promoted the misconception that certain slow-release opioid formulations provided 12-hour pain relief. This was advertised as

making opioids a better option, since patients would not have to take their medication as often in order to treat their pain.

- 2.71 The Defendants, however, knew that these claims were false and that their drugs would not provide 12-hours of pain relief for most patients.
- 2.72 Experiencing pain before it is time for the scheduled next dose of opioids, known as "end-of-dose failure", results in patients experiencing symptoms of withdrawal, intense cravings as well as euphoric highs with their next dose, all of which can promote addiction.
- 2.73 Patients may then exacerbate this vicious cycle by taking their next dose too early or by taking another short-acting opioid, known as rescue medication to alleviate pain and to tide them over until it is time for their next dose, which increases the overall opioids that they are taking.
- <u>2.74</u> The Defendants informed health care professionals that higher doses, rather than more frequent doses, were the appropriate treatment response to end-of-dose failure, which posed a greater risk to patients, including a greater risk of addiction, overdose and death.
- <u>2.75</u> This Misrepresentation played a key role in the creation of the opioid crisis because it resulted in some patients being prescribed higher doses rather than more frequent doses of opioids.

Misrepresentations relating to risk associated with developing tolerance to opioids

- 2.76 Continued use of opioids causes users to develop a tolerance for the drug and results in a need for higher doses to obtain the same effects. This in turn increases the risk of withdrawal, addiction, respiratory depression, overdose and death. Opioids <u>may</u> also induce an addictive, euphoric high for their users, as appears from the 2010 Canadian Guideline for Safe and Effective Use of Opioid for Chronic Non-Cancer Pain, communicated herewith as **EXHIBIT P-7**.
- 2.77 As mentioned above, the Defendants encouraged medical professionals to prescribe higher doses of their drugs to patients, rather than more frequent doses, and to prescribe additional rescue medication doses to combat the effects of end-of-dose failure.
- <u>2.78</u> The Defendants misled health care professionals and patients alike by failing to warn them that increased use of opioids also increases the risks and dangers associated with such use.

Misrepresentations relating to "abuse deterrent" opioid formulations

- <u>2.79</u> Abuse-deterrent formulations ("**ADF**") of opioid drugs have been marketed as a way to prevent abuse, by restricting the ability of a potential abuser to crush or chew the opioid pills.
- <u>2.80</u> When the patent for OxyContin was set to expire in 2013, Purdue produced an ADF version, OxyNeo, in an effort to convince doctors to continue to prescribe their product rather than the less expensive generic alternatives.
- <u>2.81</u> Defendant Purdue knew, however, that the ADF properties of this new drug would not prevent all tampering with the pills, and completely ignored that oral consumption of opioids, without crushing or chewing, is considered to be the most common form of opioid abuse.

The Spreading of the Misrepresentations

- <u>2.82</u> The Defendants engaged in aggressive marketing and sales practices which were entirely inappropriate for the distribution of dangerous, addictive drugs.
- <u>2.83</u> The Defendants failed to properly warn both health care professionals and consumers of the risks and dangers associated with opioid use in the Information for Patients and Product Monographs, as found in the Compendium of Pharmaceuticals and Specialties ("**CPS**").
- <u>2.84</u> The Defendants also engaged in aggressive sales' tactics in order to spread their Misrepresentations:
 - <u>2.84.1</u> to health care professionals;
 - <u>2.84.2</u> to medical students;
 - <u>2.84.3</u> by funding patient advocacy groups; and
 - <u>2.84.4</u> to the public.

The spreading of Misrepresentations in the Information for Patients and Product Monographs, as found in the CPS

<u>2.85</u> The Defendants failed to properly warn and inform of the serious risks and dangers associated with opioid use in their Information for Patients and Product Monographs in the CPS.

- 2.86 As an example, the Information for Patients generated by Defendant Purdue for the years 1996, 1998 and 2000 in respect of Hydromorph Contin contained no warnings about overdose or physical addiction. Copies of the extracts of the 1996, 1998 and 2000 CPS are communicated herewith, *en liasse*, as **EXHIBIT P-8**.
- <u>2.87</u> While in 2002 a warning was added to the Information for Patients, the addictive nature of the medication was downplayed: "*Les patients qui ont pris Hydromorph Contin pendant un certain temps peuvent développer une dépendance physique; cependant, ce n'est pas la même chose que la toxicomanie*", as appears from such extract communicated herewith as **EXHIBIT P-9**.
- 2.88 While the Product Monographs for Hydromorph Contin for the years 1996, 1998, 2000 and 2002 (EXHIBIT P-8 and EXHIBIT P-9) contained a warning, such warning indicated that "Le risque d'abus ne constitue pas un problème chez les patients présentant des douleurs intenses et chez qui l'hydromorphone est indiquée."
- 2.89 In the case of Supeudol, even though the CPS for 1996, 1998, 2000, and 2002 included a section for Information for Patients, such section did not contain any listing for Supeudol. Extracts of the 1996, 1998, 2000 and 2002 CPS are communicated herewith, *en liasse*, as **EXHIBIT P-10**.
- 2.90 Like with Hydromorph Contin, the Product Monograph for Supeudol contained warnings, however, these warnings were neither detailed nor forceful. Risks of respiratory depression, for example, were described as being limited to patients predisposed to such conditions. The warning regarding to tolerance, addiction and dependence is a general warning for all "analgésiques narcotiques" rather than being product specific: "La tolérance, la dépendance psychique et physique **peuvent** survenir chez les patients recevant des analgésiques narcotiques."
- 2.91 In 2004, the warnings with respect to Supeudol were modified. While they state that risks of secondary effects were less severe than with morphine products, they did acknowledge that the risk of dependence was *"sensiblement le meme que pour la morphine."* Furthermore, after the general warning that the use of narcotics may cause tolerance and dependence, there is a directive to consequently prescribe the drug in reduced doses and frequencies where dependence or risk of dependence is noted. Interestingly, it does not say not to prescribe the drug in such situations. The 2004 CPS is communicated herewith as **EXHIBIT P-11**.

- 2.92 These warnings were clearly insufficient, as appears from the way that they have evolved over time. Indeed, the recent Product Monographs (...) include bolded sections containing precautions, in the Serious Warnings and Precautions Boxes, advising that treatment using such drugs should be limited to "patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would otherwise be inadequate to provide appropriate management of pain," as appears from the 2018 Product Monograph for Jurnista, Hydromorph-Contin and Supeudol, copies of which are communicated herewith, *en liasse*, as **EXHIBIT P-12**.
- 2.93 In addition to the limitations on use, the<u>se</u> (...) <u>Serious Warnings and</u> <u>Precautions Boxes</u> refer to, *inter alia*, addiction, abuse and misuse of opioids, life threatening respiratory depression as well as to the risks of accidental death and neonatal opioid withdrawal. These warnings are much more complete than they were in earlier years.
- 2.94 While Health Canada issued guidance to the industry on October 1, 2003, effective October 1, 2004, wherein it advised that a Serious Warnings and Precautions Box should be included in the Product Monographs of pharmaceutical products in order to highlight "*Clinically significant or life-threatening safety hazards when taking the drug…*", as appears from a copy of such guidelines communicated herewith as **EXHIBIT P-40**, the Product Monographs for many of the drugs produced by the Defendants did not include Serious Warnings and Precautions Boxes until much later. As an example, a Serious Warnings and Precautions Box only appears to have been added to the Dilaudid Prescribing Information in October, 2016, as appears from the 2012 and 2016 Prescribing Information provided to the Undersigned attorneys by Health Canada in response to a request for all Dilaudid Product Monographs, communicated herewith as **EXHIBIT P-41**.

The spreading of Misrepresentations to health care professionals

- 2.95 In an effort to increase the sales of their opioid products, the Defendants employed sales representatives to meet with health care professionals in person to perpetuate the Misrepresentations. According to the Dhalla Article (EXHIBIT P-1), these sales representatives apparently were paid bonuses based on the number of prescriptions issued by health-care providers that they visited.
- 2.96 The Defendants also promoted the use of opioids by placing ads in medical journals and popular magazines, which deceptively downplayed the risks of addiction by omitting negative side-effects and overstated the benefits of the use of opioids for the treatment of chronic pain.

- 2.97 This aggressive marketing is evident in the 2000 Purdue Marketing Budget (EXHIBIT P-6), where Defendant Purdue stated that it will promote OxyContin tablets for use in the non-cancer pain management patient group through advertisements using a *"keep it simple"* message, promoting a humane, quality of life appearance by including pictures of patients with their pain under control with OxyContin tablets.
- <u>2.98</u> Many examples of these types of advertisements can be found in publications geared towards Quebec health professionals, including *Le* <u>médecin du Québec</u>, as well as the CPS.
- 2.99 The Defendant Purdue advertised Codeine Contin to medical professionals for light to moderate chronic pain, as appears from a 2005 advertisement in a publication called *Le médecin du Québec* and accompanying Product Monograph, communicated herewith as **EXHIBIT P-42**. The advertisement referred to a general risk of abuse relating to all opioid pain relievers, but did not mention a serious risk of addiction. The Product Monograph stated that "*Le risque d'abus ne constitue pas un probleme* chez les patients présentant des douleurs et chez qui la codéine est indiquée" and that withdrawal symptoms were "généralement légers si l'emploi médical des analgésiques opioïdes est justifié et si le sevrage est progressif".
- 2.100 By way of illustration, in the 2004 CPS, Defendant Purdue advertised Hydromorph Contin, in an ad which encouraged prescribing the drug due to its tagline "*C'est votre patient. Vous pouver l'aider*." The ad gently warned in fine print that prudence was required when prescribing medications that have a "*potentiel d'abus*", but did not highlight the serious risks of addiction, overdose or death. The 2004 Hydromorph Contin ad is communicated herewith as **EXHIBIT P-13**.
- 2.101 In the 2007 CPS, Defendant Purdue advertised Hydromorph Contin for noncancer pain relief with an image of an older woman with the caption that stated: "Il y a plusieurs raisons de prescrire Hydromorph Contin. Elle est la plus importante." The tagline under the name of the drug stated that Hydromorph Contin was "un premier choix efficace pour la douleur intense." The 2007 Hydromorph Contin ad is communicated herewith as EXHIBIT P-14.
- 2.102 The warnings contained in the fine print of the 2007 Hydromorph Contin ad (EXHIBIT P-14) mentioned again that prudence was required when prescribing medications that had a "*potentiel d'abus*." Although the ad mentioned the potential risk of fatal respiratory depression, this risk is stated as only being applicable to patients without a pre-established opioid

tolerance. The ad did not contain general warnings of the risks to all opioid users. While the ad stated that the "*monographie du produit* [sera] fournie *sur demande*", health care professionals were required to take positive steps to be fully aware of all of the significant negative side-effects of this drug.

- 2.103 Lastly, while the 2007 Hydromorph Contin ad (EXHIBIT P-14) stated that Hydromorph Contin should only be prescribed at an initial dose of 3mg every 12 hours, health care professionals were encouraged to increase the dose *"sans dose plafond"* after 48 hours.
- 2.104 In the 2010 CPS, the ad for Hydromorph Contin depicted a man walking in water with his dog with the caption "Éprouvé pour maîtriser la douleur...une étape à la fois." The information included was mostly the same as in the 2007 Hydromorph Contin ad, except for the additions of "extrême" and "fort" to the warning, which stated that: "On doit prescrire et utiliser les analgésiques opiaces avec l'<u>extrême</u> prudence qu'exige ce type de médicament, car il présente un <u>fort</u> potentiel d'abus." Although this is a stronger caution to physicians regarding prescription practices, the warning was still grossly insufficient. The 2010 Hydromorph Contin ad is communicated herewith as EXHIBIT P-15.
- 2.105 Another example of misrepresentative marketing is evident in the way that OxyContin was advertised. In the 2004 CPS, an ad for OxyContin was included that showed a father on crutches looking depressed while watching his children play with the caption "*Je veux me concentrer sur ma vie, et non sur ma douleur.*" In a 2007 ad for OxyContin, a man was shown sitting on a bed, cross-armed, with a tagline that reads "*La douleur laisse une impression durable*". Both of these ads contained a similar fine print warning to prescribe OxyContin with prudence, which mirrored the language of the 2004 Hydromorph Contin ad (EXHIBIT P-13). The 2004 and the 2007 OxyContin ad are communicated herewith respectively as **EXHIBIT P-16** and **EXHIBIT P-17**.
- 2.106 In the 2013 CPS, Defendant Purdue advertised OxyNeo as a replacement for OxyContin and encouraged medical practitioners to take action by prescribing OxyNeo. Interestingly, despite having somewhat emboldened its 2010 Hydromorph Contin warning that it should be prescribed with extreme caution because of a strong risk of abuse, the words "*extrême*" and "*fort*" are notably absent from the warning on this 2013 ad. The 2013 OxyNeo ad is communicated herewith as **EXHIBIT P-18**.

2.107 The Defendant Janssen (known at the time as Janssen-Ortho Inc.) advertised the Duragesic fentanyl patch to medical professionals to replace weaker opioids for chronic pain, as appears from a 2002 advertisement in Le médecin du Québec and accompanying Product Monograph, communicated herewith as **EXHIBIT P-43**. The caption reads "lorsque les opioïdes faibles ne suffisent plus à maîtriser la douleur chronique", and promised three days of balanced blood levels, less constipation, nausea and vomiting and asserted that patients preferred the patch over oral timereleased morphine. The fine print referred to a risk of abuse as well as a contra-indication for use in patients without prior tolerance to weaker opioids, but it did not mention the serious risk for all users of opioid products. In fact, the Duragesic Product Monograph contained at the rear of the same publication actively discouraged medical professionals from being influenced by the risk of addiction, which it characterized as rare:

Pharmacodependance et toxicomanie

Le fentanyl est une substance opioïde qui peut occasionner une pharmacodépendance semblable à celle causée par la morphine. Il existe donc un potentiel d'abus de DURAGESIC. Cependant, la tolérance ainsi que la dépendance physique et psychologique peuvent se développer après des administrations répétées d'opioïdes et ne sont pas par elles-mêmes une preuve de toxicomanie ou d'abus. La toxicomanie iatrogène à la suite d'une administration appropriée d'opioïdes pour le soulagement de la douleur chronique est relativement rare. Les médecins ne doivent pas laisser le souci d'une dépendance physique influencer leur décision de prescrire une posologie appropriée d'opioïdes pour contrôler une douleur intense lorsqu'un tel emploi est indiqué.

2.108 The Defendant Janssen produced similar ads to those of Defendant Purdue. As an example, in the 2003 CPS, the Defendant Janssen promoted a new use for the drug Duragesic, namely to treat chronic pain with the caption: "Les Canadiens n'ont plus à avaler la douleur chronique; vers une vie sans interruption". The fine print referred to a risk of abuse as well as a contra-indication for use in patients without prior tolerance to weaker opioids, but it did not mention the serious risk for all users of opioid products. The ad also mentioned, in larger print, that Duragesic had less risk of adverse secondary side-effects, like constipation, nausea and vomiting. The 2003 Duragesic ad is communicated herewith as **EXHIBIT P-19**.

- 2.109 Interestingly, in 2004, when Janssen Pharmaceutica Inc. ("Janssen USA") made similar statements in its ads, the USA Department of Health and Human Services (the "USA Department of Health") issued a warning letter to Janssen USA for making false and misleading claims about the lower potential of abuse compared to other opioid products. The letter also criticized Janssen USA for deceptively advertising Duragesic as "associated with less constipation, nausea, and vomiting than oral opioids, which are absorbed by the GI tract." The USA Department of Health maintained that it was "not aware of substantial evidence or substantial clinical experience to support this comparative claim" and requested that Janssen USA immediately cease the dissemination of promotional materials for Duragesic that were the same or similar to those indicated in the letter. The 2004 warning letter from the USA Department of Health is communicated herewith as **EXHIBIT P-20**.
- 2.110 In addition to meetings with professionals and advertising their drugs, the Defendants also sponsored presentations as part of the continuing medical education courses attended by physicians that purported to show that certain opioids could be used as effective treatments for chronic pain and breakthrough pain, even in circumstance where such uses were not approved or for which there had been no adequate studies that proved that they were appropriate.
- 2.111 As seen in the 2000 Purdue Marketing Budget (EXHIBIT P-6), Defendant Purdue also considered Residents and Fellows to be a promising secondary target audience, stating that this market "provides the ability to influence physicians still in training. Chief residents can be especially influential in teaching facilities."

The spreading of Misrepresentations to medical students

- <u>2.112</u> The aggressive marketing of opioids was not limited to health care professionals, but also targeted medical students.
- 2.113 For example, certain Defendants supported the pain curriculum for students at several Canadian universities, as appears from a 2014 article by Navindra Persaud entitled "Questionable Content of an Industry-Supported Medical School Lecture Series: A Case Study", communicated herewith as EXHIBIT P-21:

Medical students received information about opioids in educational sessions that were developed using funding from pharmaceutical companies that sell opioids. The course material contained information that aligned with the interests of these companies by minimizing opioid-related harms relative to those other analgesics, overstating the evidence for their effectiveness and, in at least one instance, provided a potentially dangerous characterization of the potency of a commonly used opioid.

The spreading of Misrepresentations by funding patient advocacy groups

- 2.114 The Defendants provided financial support to Canadian patient advocacy groups, such as the Canadian Pain Society, the Canadian Pain Coalition, the Association Québécoise de la Douleur Chronique (the "AQDC") and Chronic Pain Association of Canada in order to indirectly promote use of opioids to treat pain and to influence public opinion and policy in ways favorable to their drugs.
- 2.115 <u>As an example, Defendants Purdue, Janssen and Pfizer provided grants to</u> <u>sponsor the Canadian Pain Society's 2001 "Patient Pain Manifesto", which</u> <u>was announced at a conference at the Delta Hotel in Montreal. A</u> <u>backgrounder included with a press release on the subject stated:</u>

Fiction: Patients will become addicted to painkillers.

Fact: Pain killers given in a controlled way to people who are having moderate to severe levels of pain **almost never leads to addiction**. There are a variety of treatments available to help prevent pain, which include a wide range of drugs as well as non-pharmacological techniques such as heat or relaxation.

The whole as appears from a copy of such press release, backgrounder, fact sheet and bookmarks, dated May 11, 2001, communicated herewith as **EXHIBIT P-44**.

2.116 <u>As appears from such document, the Canadian Pain Society intended on</u> <u>distributing a million of the attached bookmarks, which list the names of the</u> <u>Defendants that funded the initiative, to patients, their families, and health</u> <u>professionals. The bookmark stated:</u>

Did you know that

It is extremely rare that people become addicted to the pain killers they are given for pain.

<u>Problems with pain killers (constipation, itching, nausea) can be</u> <u>controlled.</u>

- 2.117 The Canadian Pain Society also lists, as one of its goals, to "work more closely with industry to market educational materials" and to spread this message by providing "more continuing education opportunities to health professionals on the assessment and management of pain", and by distributing "10,000 posters to healthcare professionals and clinics."
- 2.118 In 2002, the Canadian Pain Society published a consensus statement and guidelines on the "Use of opioid analgesics for the treatment of chronic noncancer pain", a copy of which is communicated herewith as **EXHIBIT P-45**, which promoted, inter alia, that:
 - <u>"Pain of all types is undertreated in our society";</u>
 - <u>"Health professionals' fears regarding iatrogenic addiction...create a</u> <u>significant barrier to the optimum prescribing of opioids for pain";</u>
 - <u>"Tolerance and/or physical dependence on regular opioid use in a</u> patient in pain are not, by themselves, evidence of an addictive disorder";
 - <u>"A patient with a past history of, or risk factors for, addiction should not</u> <u>necessarily be precluded from a careful trial of opioid therapy..."; and</u>
 - <u>"Opioid analgesics are generally safe medications when prescribed with appropriate monitoring."</u>
- 2.119 <u>As another example, Defendants Purdue, Paladin, Pfizer, and Valeant</u> provided funding to the AQDC, which shared content on its website such as an article entitled "*La dépendence aux opiacés… mythe ou réalité*" which downplayed the risk of addiction to opioids, stating:

À l'opposé, l'apparition d'un problème de dépendance psychologique (addiction) à la suite d'une exposition thérapeutique aux opiacés est considérée comme un phénomène rare qui, s'il survient, affecte généralement un individu préalablement vulnérable sur le plan biologique et (ou) psychosocial.

the whole as appears from a list of the AQDC's partners from June 7, 2007 communicated herewith as **EXHIBIT P-46**, and a copy of such website's "Lexique de Maladies" with a 2003 article by Dominique Dion entitled "La dépendence aux opiacés....mythe ou réalité", communicated herewith en liasse as EXHIBIT P-47.

- 2.120 Similarly, in the United States, the Defendants' related and parent companies funded these types of groups, which spread similar content, namely that the under treatment of pain was a serious issue and that more liberal use of opioids was the solution, all of which content was available online in Quebec.
- 2.121 As an example, Pricara, a division of Ortho-McNeil Janssen Pharmaceuticals Inc. in the United States, gave funding for the website "Letstalkpain.org", which promoted the use of opioids and downplayed the risks of addiction. In a section of such website called "Understanding Tolerance, Physical Dependence and Addiction", a copy of which is communicated herewith as **EXHIBIT P-48**, the false notion of "pseudoaddiction" was promoted, as well as the false statement that for many patients, opioids were the only effective treatment option:

<u>A related term is pseudoaddiction, which refers to patient behaviors</u> that may occur when pain is under-treated. This includes an increased focus on obtaining medications ("drug seeking" or "clock watching") and even illicit drug use or deception. **Pseudoaddiction** is different from true addiction because such behaviors can be resolved with effective pain management.

For many people experiencing pain, **opioid analgesics** - when used as recommended by established pain management guidelines - **are** the most effective way to treat their pain, and often the only treatment option that provides substantial relief.

2.122 In some instances, the Defendants would cut-off funding if the information being conveyed by the patient advocacy groups did not align with their interests, as appears from a 2019 news article by Itai Bavli and Joel Lexchin entitled "Why Big Pharma must disclose payments to patient groups", a 2018 news article by Kelly Crowe entitled "Following the money between patient groups and Big Pharma" and a 2019 news article by Christian Noel entitled "Des groupes de patients financés en secret par des pharmaceutiques", communicated herewith respectively as EXHIBIT P-22, EXHIBIT P-23 and EXHIBIT P-24.

. . .

The spreading of Misrepresentations to the public

- 2.123 The Defendants recruited and paid professionals to advocate for the widespread use of opioids by consumers by writing books and articles and giving speeches on the benefits of opioid therapies, in which they downplayed the risks of addiction, while attempting to destigmatize the use of opioids.
- 2.124 For example, starting in 1997, one such medical professional, Dr. Russell Portenov, received research support, consulting fees and other payments from several of the Defendants. He, along with a number of other medical professionals solicited and supported by the Defendants, played a critical role in supporting the misleading claims about opioids in the medical literature and at presentations. Most specifically, Dr. Portenoy carried his message about opioids even beyond the medical community to the public, falsely stating in a television interview on Good Morning America on August 30, 2010 that less than 1% of patients would become addicted to opioids and "most doctors can feel very assured that the person is not going to become addicted" in the absence of a personal or family history of substance abuse, as appears in a 2016 article by Arthur H. Gale entitled "Drug Company Compensated Physicians Role in Causing America's Deadly Opioid Epidemic: When Will We Learn" (the "Gale Article") and a 2017 news article by Christian Mcphat entitled "Upshur County is First in Texas to File a Lawsuit Holding Drug Makers Responsible for Opioid Epidemic", which are communicated respectively herewith as **EXHIBIT P-25** and EXHIBIT P-26.

Liability in the United States

- 2.125 Opioid manufacturers in the United States, including many of the Defendants' parent and/or related corporations, made largely the same Misrepresentations, in ostensibly the same or similar manner to that described above.
- 2.126 In fact, the aggressive marketing and misinformation strategies employed by the Defendants were largely coordinated with and/or directed by their US parents and/or related corporations.
- 2.127 On August 26, 2019, a landmark decision was rendered in the state of Oklahoma, wherein Johnson & Johnson and its various pharmaceutical subsidiaries including Janssen Pharmaceuticals, Inc., were condemned to pay in excess of US\$460 million to the state, as a result of the role that such companies played in fueling the opioid epidemic experienced in that state,

as appears from a copy of such judgment, communicated herewith as **EXHIBIT P-49**.

- 2.128 In particular, Justice Balkman found:
 - Defendants, acting in concert with others, embarked on a major campaign in which they used branded and unbranded marketing to disseminate the messages that pain was being undertreated and "there was a low risk of abuse and a low danger" of prescribing opioids to treat chronic, non-malignant pain and overstating the efficacy of opioids as a class of drugs. (para. 18)
 - <u>A key element of Defendants' opioid marketing strategy to</u> <u>overcome barriers to liberal opioid prescribing was its</u> <u>promotion of the concept that pain was undertreated (creating</u> <u>a problem) and increased opioid prescribing was the</u> <u>solution.... Defendants' trained their Oklahoma sales</u> <u>representatives on how to use these campaigns, including</u> <u>though the use of "emotional selling" for opioids by convincing</u> <u>physicians that undertreated pain was harming patients.</u> <u>(para. 20)</u>
 - <u>Defendants used the phrase "pseudoaddiction" to convince</u> <u>doctors that patients who exhibited signs of addiction [...]</u> <u>were not actually suffering from addiction, but from the</u> <u>undertreatment of pain, and the solution, according to</u> <u>Defendants' marketing was to prescribe more opioids. (para.</u> <u>22)</u>
 - <u>Defendants trained their sales reps to target high-opioid</u> prescribing physicians, including pain specialists and primary care physicians.... Defendants particularly targeting primary care physicians with their opioid marketing, identifying them as "Key Customer[s]" for Defendants' pain franchise. (para. 30)</u>
 - <u>Defendants made substantial payments to a variety of</u> <u>different pain advocacy groups and organizations that</u> <u>influenced prescribing physicians and other health</u> <u>professionals. (para. 36)</u>

- <u>Defendants made claims, unsupported by any high quality</u> evidence, that opioids could be safely used for chronic, onterminal pain. Defendants used the phrase "pain as the 'fifth vital sign' to influence doctors to liberally prescribe opioids. (para. 57)
- 2.129 Prior to the trial, Purdue Pharma L.P. and its related companies, as well as Teva Pharmaceuticals USA Inc., and its related companies, settled with the state of Oklahoma for US\$270 million and US\$85 million respectively.
- 2.130 Following such settlement, on September 15, 2019, Purdue Pharma L.P. filed for Chapter 11 bankruptcy protection in the United States, in an effort to effect a global settlement of the more than 2600 claims against it and various related parties, for misleading doctors and patients alike by overstating benefits and downplaying the risks of opioids.
- 2.131 On October 21, 2019, Teva Pharmaceutical Industries Ltd., together with three US distributors, settled another claim with two Ohio counties on the eve of trial, for a combined amount of US\$260 million, which includes a contribution by Teva Pharmaceutical Industries Ltd. of \$20 million in cash and \$25 million at its wholesale acquisition cost of sublingual buprenorphine (a partial opioid agonist) and naloxone (a pure opioid agonist), known by the brand name Suboxone, which is commonly used in the treatment of Opioid Use Disorder.

The Resulting Opioid Crisis in Quebec

- <u>2.132</u> As a result of the Defendants' Misrepresentations, failure to inform and failure to warn, an opioid crisis has ensued.
- 2.133 The 2016 Standing Committee Report (EXHIBIT P-4) issued to the Government of Canada stated that Canadians are the second highest consumers of prescription opioids in the world, with 15% of Canadians over the age of 15 reporting having used opioids in 2013. It was further reported that approximately 10% of patients who are prescribed opioids for chronic pain become addicted.
- 2.134 In April 2019, the Public Health Agency of Canada issued a report that found that opioid use is responsible for an estimated 3,017 deaths in 2016, 4,034 deaths in 2017 and 3,286 deaths between January and September of 2018, as appears from the 2019 Report entitled "National Report: Apparent Opioid-related Deaths in Canada" (the "2019 National Report on Opioid-Related Deaths"), communicated herewith as EXHIBIT P-27.

- 2.135 In an earlier study conducted by the Canadian Institute for Health Information ("CIHI"), it was found that hospitalization rates for opioid-related harms increased by 27% over the past 5 years and between 2016 and 2017, opioid poisoning hospitalization went up by 8%, resulting in an average of 17 hospitalizations per day, as appears from the 2018 Report entitled "Opioid-Related Harms in Canada" (the "2018 CIHI Report on Opioid-Related Harms"), communicated herewith as EXHIBIT P-28.
- 2.136 A study conducted in Quebec on opioid-related deaths over a 20-year period from 1990 to 2009 found that the number of unintentional poisonings increased in the period of 1990 to 1994 and again from 2005 to 2009. The study further found that fatal poisonings caused by opioids increased by 40.9% during the 2005 to 2009 period, and that 91.3% of such fatal poisonings were caused by prescription opioids, as appears from the *Institut National de Santé Publique du Québec*'s 2013 report entitled "Opioid-related Poisoning Deaths in Québec: 2000-2009" (the "2013 Quebec Opioid-Related Death Report"), communicated herewith as EXHIBIT P-29.
- 2.137 The 2019 National Report on Opioid Related Deaths (EXHIBIT P-27) found that in Quebec, deaths relating to opioid and other illicit drug use resulted in 166 deaths in 2016, 181 deaths in 2017 and 300 deaths between January and September 2018. In 2018, the total number of deaths from opioid and other illicit drug use was 424, and in the first three months of 2019, 119, as appears from the updated figures of such National Report, communicated herewith as **EXHIBIT P-50**.
- 2.138 The impact of the opioid crisis in Quebec is being felt more urgently with each passing year, as the number of prescriptions for opioids has increased significantly in recent years.
- 2.139 Statistics provided by the *Régie de l'assurance maladie du Québec* ("RAMQ") to Le Devoir indicate that between 2011 and 2015, the number of new prescriptions for opioid medications has increased by 29% from 1.9 million in 2011 to 2.4 million in 2015, and the number of renewals of prescriptions climbed by 44%, as appears from a 2016 article by Karl Rettino-Parazelli entitled "L'usage d'opioïdes est en forte hausse" (the "Rettino-Parazelli Article") communicated herewith as EXHIBIT P-30.

Government Response to the Opioid Crisis

2.140 Despite these disturbing statistics, a 2017 Opioid Awareness Survey revealed that Quebecers have by far the lowest level of knowledge in

respect of the opioid crisis of all of the Canadian provinces, and as a consequence, in 2018, the government of Quebec embarked on a thirty-five million dollar action plan over the next 10 years in order to raise public awareness of this epidemic, as appears from a 2019 news article by Megan Martin entitled "Large portion of Quebec population unaware of the risks with opioids" and from a 2018 news article by Kalina Laframboise entitled "Quebec government unveils action plan to fight opioid overdoses, addiction", communicated herewith respectively as **EXHIBIT P-31** and **EXHIBIT P-32**.

- 2.141 In June 2018, the Minister of Health sent a letter to manufacturers and distributors of opioids in Canada calling on them to stop all marketing and advertising of opioids to health care professionals on a voluntary basis, as appears from the Government of Canada's webpage entitled "Notice of Intent to Restrict the Marketing and Advertising of Opioids", a copy of which is communicated herewith as **EXHIBIT P-33**.
- <u>2.142</u> On January 31, 2019, Health Canada sent a follow up letter to fifteen companies who market and distribute opioid products in Canada.
- 2.143 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*", as appears from the Government of Canada's webpage entitled "Opioid Warning Sticker and Patient Information Handout, and Risk Management Plans", communicated herewith as **EXHIBIT P-34**.
- <u>2.144</u> These new regulations require that a warning sticker and a patient information handout be provided with prescriptions for all opioids that appear in Part A of Health Canada's "List of Opioids" dated May 2, 2018, attached hereto together with the required warning label as **EXHIBIT P-35**.
- <u>2.145</u> The required warning label clearly indicates that opioids can cause dependence, addiction and overdose, as appears from the reproduction of the warning below:



The information handout provides patients with a serious and explicit 2.146 warning about opioid use, including that the use of opioids can result in overdose (which can lead to death), addiction, physical dependence, lifethreatening breathing problems, worsening rather than improving pain and withdrawal. It further warns of the risks of taking opioids while pregnant, and cautions users to take only as directed, and in particular, not to crush, cut, break, chew or dissolve pills. The provided information advises of the signs of overdose and directs users to the Product Monograph for further complete information about the prescribed drug, as appears in Health Canada's Patient Information Handout dated March 15. 2019. communicated herewith as EXHIBIT P-36.

Damages caused by Defendants' Faults

- 2.147 As a direct result of the Defendants' failure to adequately warn of the risks and dangers associated with use of their opioid products and their campaign to misinform the public as to both the effectiveness and risks relating to opioid use, the use of opioids to treat chronic pain became much more common, and this has caused the opioid crisis in Quebec today, as appears from the 2016 Standing Committee Report (EXHIBIT P-4).
- <u>2.148</u> In particular, the Defendants' Misrepresentations caused the Opioid Use Disorders that the Class Members have suffered from, or continue to suffer from.
- <u>2.149</u> Sufferers of Opioid Use Disorder experience at least two of the following diagnostic symptoms:
 - <u>2.149.1</u> Opioids are often taken in larger amounts or over a longer period than was intended;
 - <u>2.149.2</u> There is a persistent desire or unsuccessful efforts to cut down or control opioid use;
 - <u>2.149.3</u> A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects;
 - <u>2.149.4</u> Craving or a strong desire to use opioids;
 - <u>2.149.5</u> Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home;

- <u>2.149.6</u> Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids;
- <u>2.149.7</u> Important social, occupational, or recreational activities are given up or reduced because of opioid use;
- <u>2.149.8</u> Recurrent opioid use in situations in which it is physically hazardous;
- <u>2.149.9</u> Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids;
- <u>2.149.10</u> Tolerance*, as defined by either of the following:
 - 1. Need for markedly increased amounts of opioids to achieve intoxication or desired effect; and
 - 2. Markedly diminished effect with continued use of the same amount of opioid.
- 2.149.11 Withdrawal*, as manifested by either of the following:
 - 1. Characteristic opioid withdrawal syndrome; and
 - 2. Same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.

*Patients who are prescribed opioid medications for analgesia may exhibit these two criteria (withdrawal and tolerance), but would not necessarily be considered to have a substance use disorder.

A copy of the above clinical diagnostic criteria as per the DSM-5 ("**Diagnostic Criteria**") is communicated herewith as **EXHIBIT P-37**.

- 2.150 Opioid Use Disorder has crippling effects on its victims, including in the form of:
 - <u>2.150.1</u> personal injury, including addiction;
 - <u>2.150.2</u> severe emotional distress, social stigma, prejudice and discrimination resulting from addiction;

- <u>2.150.3</u> a lack of awareness that they are suffering from Opioid Use Disorder;
- <u>2.150.4</u> overdose, serious injury, and death;
- <u>2.150.5</u> out of pocket expenses relating to their drug dependence, including for treatment and recovery; and
- <u>2.150.6</u> loss of income.
- 2.151 The Defendants should be held liable for the consequences of their faults to the Class Members, as they had an obligation to both ensure the safety and the safe use of their products and to properly warn, rather than misinform, of the risks associated with their products.

The Designated Class Member

<u>(...)</u>

- 2.152 The Plaintiff, Riccardo Camarda, is a resident of the Province of Quebec, who was prescribed opioids for a period of 12 years and was treated for severe Opioid Use Disorder in early 2018 at an in-patient facility at the Montreal General Hospital.
- 2.153 While he is presently in early remission from his Opioid Use Disorder and is using Suboxone as maintenance therapy to support his remission, he will always be vulnerable to relapses for this chronic illness caused by prescription opioids.

Plaintiff's introduction to opioids

- 2.154 <u>After graduating from culinary school in 2001, the Plaintiff worked as an executive chef in a Montreal hotel.</u>
- 2.155 In 2004, as a result of extreme fatigue, he switched careers to work in telecom and, in 2005, his fatigue became so severe that he was unable to work and went on sick leave.
- 2.156 Later that year, after experiencing an unplanned 70-pound weight loss in addition to the on-going fatigue, he was diagnosed with thalassemia, an inherited blood disorder characterized by less hemoglobin and fewer red blood cells in the body than normal. The anemia resulted in a lack of oxygen and fatigue.

- 2.157 Although transfusions and other treatments alleviated his symptoms for a few weeks, the Plaintiff's condition soon worsened, and it was determined that he needed to have his spleen removed.
- 2.158 On March 1, 2006, he underwent a splenectomy at the Royal Victoria Hospital in Montreal and, as a result of this procedure, he is now able to maintain a stable level of hemoglobin without further transfusions.
- 2.159 During the two-week period of post-operative recovery at the hospital, the Plaintiff experienced significant pain and was given intravenous opioids administered using an infusion pump. Initially, he was given Morphine but was switched to Hydromorphone, which treated his pain more effectively. This was the Plaintiff's first encounter with opioids.

Plaintiff's continued use of prescription opioids

- 2.160 When he was released from the hospital on March 20, 2006, the Plaintiff was prescribed Dilaudid (2 mg) to be taken as needed.
- 2.161 The acute pain associated with the surgery lasted for about a month, including the time spent in the hospital. However, even when the pain associated with the surgery had subsided, the Plaintiff continued to experience pain and consequently was prescribed opioids as an out-patient.
- 2.162 The investigation into the reason for the Plaintiff's continued pain resulted in a diagnosis of extramedullary hematopoiesis. The team of doctors treating him considered his now chronic pain to be due to overactive bone marrow.
- 2.163 By early January 2007, the Plaintiff was being regularly prescribed both long acting Hydromorph Contin to be taken every 12 hours as well as short acting Dilaudid to be taken as a rescue medication, as needed. For the next 12 years, the hematologist who followed him for thalassemia continued to renew his prescriptions for opioids to treat his pain.
- 2.164 The Plaintiff was led to believe that he was being provided the standard treatment for the chronic pain he was experiencing and was told by his various physicians that he would have to stay on these drugs forever. He fully trusted that the use of opioids was appropriate for his condition and was not informed about the addictive and devastating effects that this treatment could cause.
- 2.165 Over time, the drugs became less effective in controlling his pain and the Plaintiff's dosages of opioids were periodically increased. As well, his

sensitivity to pain increased, and the pain which had been mostly in his lower back and thighs spread throughout his body, including to his rib cage, elbows and hands.

- 2.166 As a result, to obtain pain relief, the Plaintiff would go to the emergency room where he would be admitted to the hospital for two to three days at a time and treated with IV opioids as well as additional rescue-medication. In the earlier years, these crises, causing the Plaintiff to go to the emergency room to treat uncontrolled pain, occurred about 4 to 6 times a year; however, by 2017 the frequency of these crises had increased to about once a month.
- 2.167 On one occasion, in April 2017, he went to the emergency room because of unmanageable pain and was treated with additional opioids through a patient controlled analgesia (PCA) pump. A nurse told him that he had been seen manipulating the PCA pump and the use of the pump was stopped. He learned from seeing his discharge papers that he had been labelled as someone who "was already known with a drug-seeking behavior" and that he was never to be on a PCA pump again.
- 2.168 The Plaintiff suffered immensely when he only had his regular doses of opioids as they were no longer sufficient to control the pain. While using the combination of long-acting Hydromorph Contin and Dilaudid for breakthrough pain, he experienced convulsions and was feverish, lethargic and clammy. He stayed indoors, trying to remain still, to minimize his pain. He "lived through hell".
- 2.169 In October 2017, the Plaintiff was assessed at the Pain Clinic at the Montreal General Hospital, after obtaining a referral from his hematologist. The doctor he saw recommended that he start using Fentanyl patches. By this time, having heard of the risks associated with Fentanyl, the idea of using Fentanyl patches scared him. In particular, because he was so young and his tolerance to opioids was already so strong, he feared for his future, and the quantity of drugs that he would require to alleviate his pain.
- 2.170 When he first started taking opioids, and until he began exploring treatment for his addiction in late 2017, the only warnings that the Plaintiff recalls receiving were that the drugs could cause constipation and that he should wait to see how they affected him prior to driving or operating heavy machinery. In fact, when he switched pharmacies in October/November 2017, the patient information given to him by his pharmacy about the two drugs he was on, Hydromorph Contin and Dilaudid, contained **no warnings** of the highly addictive nature of such drugs.

Physical and emotional impact of Plaintiff's Opioid Use Disorder

- 2.171 The Plaintiff's addiction to opioids has had a horrific impact on his life.
- 2.172 In his words, opioids "took away each of the puzzle pieces of life one at a time", and the picture of what remained "was unrecognizable."
- 2.173 Prior to taking these drugs, he was a very social and outgoing person, an extroverted "life of the party" type; however, on the drugs he withdrew socially, suffered from brain-fog, and was both confused and exhausted all the time.
- 2.174 Despite being a chef, and having a passion for food, he rarely cooked and lost interest in eating.
- 2.175 All his life, he had been very active in his community and church, until he was on opioids and could not continue these activities. He stopped swimming and, one by one, he dropped out of everything.
- 2.176 He gradually lost interest in social and family gatherings. Every year at Christmas, the Plaintiff would normally play a very active role in a holiday gathering of 40 to 50 members of his family, including taking care of all of the food. No matter what else was going on in his life, he was always there and happily involved. In 2017, he felt so sick and apathetic that he skipped the Christmas celebration all together, which was extremely significant for him, being from a traditional Italian background.
- 2.177 He describes the effect of opioids as "taking the life right out of you". Taking on the simplest of tasks required significant time and effort –getting out of bed and dressing became a battle. He stopped his regular routines such as morning coffees and going out for lunch and even missed medical appointments.
- 2.178 While his symptoms of fatigue should have been alleviated after his splenectomy, the continued use of opioids caused him to experience such overwhelming mental and physical exhaustion that he could barely work and was, at times, on long-term disability.
- 2.179 Although he was told that the relief provided by slow-release Hydromorph Contin would extend over a 12-hour period, he consistently needed to supplement that medication with short-acting Dilaudid, as a rescue medication. While the Dilaudid was prescribed to be taken as needed every four hours, he would always need to take it, and would often adjust the dosing on his own in order to get through his daily activities. If he had

something important to do that day, he would take more than prescribed, and then take less later on so that he would not run out of his pills too quickly. When he was taking less to conserve his medication, he would stay home and "*try to stay as still as possible not to feel pain*".

- 2.180 The Plaintiff's life revolved around scheduling as to when he could take the next dose. He was consumed by the need to ration the pills over the month and found himself "juggling pills" to ensure he would have enough. Typically, he would run out of medication a few days before the month's end, and would renew his prescriptions at the pharmacy a few days early.
- 2.181 While on opioids, he "survived in four hour blocks", meaning that he would take the drugs, feel relief for about two hours and slowly the pain returned. After about three to three-and-a-half hours, the pain was debilitating; he would feel the sharp, intense pain, starting in his back, and travelling up his spinal cord, and down his thighs. He describes the pain he felt while on opioids as being like someone is stabbing you with a knife.
- 2.182 Towards the end of virtually every dose, he would feel the uncomfortable symptoms of withdrawal; he was constantly sneezing and his nose was always running, and he alternated between having chills and sweating so excessively that he would need to change his undershirt multiple times a day and his bedsheets almost every night.
- 2.183 He was never able to sleep for more than four hours at a time, as his withdrawal symptoms were so intense that he needed to take his medication throughout the night. On at least two occasions, he woke up choking and concerned for his life, as he was confused about how much opioids he had taken, and likely had taken too many pills.
- 2.184 In order to counteract the side effects of the opioids, he had to take many other medications, including Adderall as a stimulant, Elavil (amitriptyline) to help him to sleep and Ativan to calm him down. He estimates that he was taking more than 25 additional pills a day in an effort to offset the undesirable effects of the opioids.
- 2.185 Opioids affected his personal life immensely and all his relationships were compromised as a result. In 2010, after three years of marriage, the Plaintiff's then-wife left him because the situation had become too difficult for her. Although she was aware of his medical issues before they got married, the side effects that he suffered as a result of being addicted to opioids put too much stress on their marriage and ultimately led to their divorce.

- 2.186 Although the Plaintiff loves travelling and made sure he would visit his family in Italy at least 4 to 5 times a year, while addicted to opioids, he was not able to travel easily because of his fatigue and concerns related to the amount of and nature of the drugs he needed to bring with him. On one trip to Cuba in 2011, he was detained for nearly 4 hours by armed guards upon arrival at the airport, who believed he was carrying illegal drugs. The most terrifying part of that experience for him was not being held by armed guards but, rather, the prospect of being without his drugs for the duration of his trip. The Plaintiff luckily was able to convince the guards to leave him with just enough of opioids to get through one week, although he had packed enough for two weeks. Being far from home, without any back-up medication, was overwhelmingly stressful.
- 2.187 The effects of the prescribed opioids became so severe that between 2017 and early 2018, he stayed home in his pajamas, barely moving, and withdrew almost completely from his family and friends. It was almost impossible to muster the energy to brush his teeth, let alone move his car to avoid getting parking tickets. As a result, he got thousands of dollars of parking tickets that year. His only concern was when he would be able to take his next dose of opioids. The Plaintiff describes this period as "just like an entire year was completely gone".
- 2.188 While the Plaintiff tried to stop using opioids on his own, by stopping to take his medication "cold turkey", the side effects of doing so, being vomiting, sweating and convulsing, were too much for him to handle. The longest he was able to last on his own without opioids was 6 days. The Plaintiff also tried to use acupuncture and naturopathy as alternatives to opioids, but these treatments did not help him.

The road to recovery

- 2.189 By October 2017, the Plaintiff's daily dose of Hydromorph Contin had increased to 33 mg for the day and 36 mg for the night as well as 4 mg of Dilaudid to be taken as needed, which was all the time (about 240 tablets per month).
- 2.190 Despite this quantity of consumption of drugs, his pain was still not adequately managed and his visits to the emergency room became more frequent. In January 2018, the Plaintiff was admitted to the hospital but his requests for more opioids to control the pain were refused. Although the medical team was uncertain as to whether the severe pain was due to opioid hyperalgesia and/or opioid withdrawal, it was now clear to the Plaintiff that

he had a very serious problem that, if untreated, could become life-threatening.

- 2.191 At this time, the Plaintiff and his doctor specifically discussed his Opioid Use Disorder and the possibility of participating in an addiction treatment program. Given his despair, and his feeling that at that point he had "*no more life*", the Plaintiff was willing to be treated for his addiction in the hope of getting back his life.
- 2.192 On February 27, 2018, the Plaintiff entered into an inpatient treatment program at the Montreal General Hospital which took him 18 days to complete. The treatment program was part of the psychiatry unit at the hospital, where only three beds were dedicated to the treatment of addictions.
- 2.193 Upon admission to the Montreal General Hospital Addiction Unit, it was noted that for several months the Plaintiff had also been using IV Hydromorphone (Dilaudid) 4mg once every 2 days.
- 2.194 By this time, his increased pain symptoms appeared to be a consequence of withdrawal.
- 2.195 Even though the Plaintiff was admitted on a volunteer basis, he was strip searched upon arrival, given a pair of green scrubs to wear, and encouraged not to leave the psychiatric unit. His mother accompanied him into the hospital, and seeing her son in such a setting, surrounded by such severely mentally ill patients, made her cry and she did not even want to leave him there. When she left, he had an emotional breakdown.
- 2.196 In order to start therapy, the Plaintiff had to first rid his system of opioids completely for 12 to 18 hours. At times, the withdrawal process was excruciating for him, marked by vomiting, sweating or chills and constant sneezing, which made him feel like he was going to die.
- 2.197 <u>The Plaintiff then commenced an opioid maintenance treatment, and was given Suboxone.</u>
- 2.198 Once he began taking Suboxone, he started to feel much better, and for him, Suboxone has, for the most part, been an effective medication to support the remission of his Opioid Use Disorder.
- 2.199 <u>However, the Plaintiff has not been immune to relapse. Since being engaged in addiction treatment in February/March 2018, there have been</u>

two occasions when the Plaintiff returned to the emergency room for additional pain treatment.

- 2.200 During his most recent admission to the hospital in July 2019, the Plaintiff's Suboxone prescription was increased from 6 mg to 12 mg per day, which has enabled him to maintain a state of early remission from his severe Opioid Use Disorder, without increasing his pain.
- 2.201 While being on this maintenance treatment enables him to be in early remission of his Opioid Use Disorder, his body is still dependent on opioids and it will be several years, if ever, before he can be fully weaned off of these destructive drugs.

Life after addiction treatment

- 2.202 Since his treatment for severe Opioid Use Disorder, the Plaintiff feels that his life has been restored. He is now able to work full-time, travel and enjoy his life with energy and enthusiasm.
- 2.203 <u>He feels that he has accomplished more in the last year and a half after</u> treating his addiction than he had accomplished in the 12 years prior.
- 2.204 In fact, the Plaintiff has been able to return to his true vocation of cooking. In addition to being recently hired as the Food and Beverage Director for a major hotel chain in downtown Montreal, the Plaintiff has recorded 16 episodes of a cooking show for an Italian/English television program.
- 2.205 He has also gotten involved with his Church and started volunteering again.
- 2.206 On a personal level, since obtaining treatment for his severe Opioid Use Disorder, he started dating his now-wife. They were married civilly on March 1, 2019, and they had a religious celebration of their marriage in California on September 17, 2019.
- 2.207 The Plaintiff has only been able to fully ascertain the devastating impact that his addiction to opioids had on his life since he has been engaged in addiction treatment, and states that if he had known the life-altering effects of these prescription opioids, he would never have commenced taking them after leaving the hospital following his splenectomy in 2006.
- 2.208 <u>Although he continues to experience pain, since his addiction treatment, it</u> is no longer the debilitating stabbing pain he suffered for so many years.

2.209 The Plaintiff believes that no person should ever have to experience the horrible effects that opioids have had on his life and well-being. Accordingly, he has decided to act as the designated Class Member in this proceeding to seek compensation for Quebecers affected by Opioid Use Disorder and to raise awareness about the dangers of opioid use.

3. The facts giving rise to personal claims by each of the members of the Class against the Defendants are:

- 3.1. Each Class Member was prescribed and has consumed opioids, produced, manufactured, sold, marketed and/or distributed by the Defendants.
- 3.2. Each Class Member became addicted to opioids produced, manufactured, sold, marketed and/or distributed by the Defendants, and consequently suffers from, or has suffered from, Opioid Use Disorder, marked by having experienced symptoms of at least two of the Diagnostic Criteria.
- 3.3. Each Class Member has suffered substantially as result of their addiction.
- 3.4. The Defendants' faults in <u>failing to disclose the risks of, and in</u> disseminating the false and misleading information about opioids are the direct cause of the damages suffered by the Class Members.
- 3.5. The Defendants chose profits over the health of the consumers of their products, profits which are generated by the sale of opioids as well as drugs that treat addiction, overdose and other side-effects of opioids.
- 3.6. Accordingly, the Class Members are justified in seeking compensation for the damages suffered as a result of their Opioid Use Disorder.

4. The composition of the Class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings:

- 4.1. The Plaintiff is unaware of the precise number of Class Members, who reside all over Quebec.
- 4.2. The opioids produced, manufactured, sold, marketed and/or distributed by the Defendants have been more widely prescribed since at least 1996 when the Misrepresentations began.
- 4.3. As previously stated, <u>in Quebec</u>:

- 4.3.1. Fatal poisoning cause by opioids increased by 40.9% between 2005 and 2009 and 91.3% of these fatal poisonings were caused by prescription opioids, as appears from the 2013 Quebec Opioid-Related Death Report (EXHIBIT P-29).
- 4.3.2. Deaths relating to opioids and other illicit drug use resulted in 166 deaths in 2016, 181 deaths in 2017 (...) <u>424 deaths in 2018, and 119 deaths in the first three months of 2019</u>, as appears from the 2019 National Report on Opioid-Related Deaths <u>and its September 2019 update</u> (EXHIBIT P-27 <u>and EXHIBIT P-50</u>).
- 4.3.3. The number of new prescriptions for opioid medications has increased by 29%, from 1.9 million in 2011 to 2.4 million in 2015, as appears from the Rettino-Parazelli Article (EXHIBIT P-30), and it is estimated that approximately 10% of individuals prescribed opioids for chronic pain become addicted (EXHIBIT P-4).
- 4.4. The number of individuals who make up the Class can therefore reasonably be estimated to be several thousand people.
- 4.5. Due to the confidentiality of medical records, it is impossible for the Plaintiff to know the identity of the people who consumed <u>prescription</u> opioids, and who developed an Opioid Use Disorder.
- 4.6. It would be difficult, if not impossible, to find and contact the Class Members to obtain a mandate or for the consolidation of the proceedings.

5. The identical, similar or related questions of law or fact between each member of the Class and the Defendants which Plaintiff wishes to have decided by the class action are:

- 5.1. Do the opioid products manufactured, marketed, distributed and/or sold by the Defendants pose serious health risks to their users due to, *inter alia*, their addictive nature?
- 5.2. Do the opioid products manufactured, marketed, distributed and/or sold by the Defendants offer the safety that Class Members could normally expect?
- 5.3. Did the Defendants provide the Class Members with precise and complete warnings on the risks and dangers of using their opioid products?
- 5.4. Did the Defendants trivialize or deny the risks and dangers associated with the use of opioids?

- 5.5. Did the Defendants employ marketing strategies which conveyed false or misleading information, including by omission, about the characteristics of the opioid products they were selling?
- 5.6. Did the Defendants fail to properly monitor the safety of their opioid products and/or take appropriate corrective action to adequately inform users of such safety risks, as knowledge evolved as to such safety risks and side effects?
- 5.7. Have the Class Members suffered damages as a result of their Opioid Use Disorders?
- 5.8. What is the amount of non-pecuniary damages suffered by the Class Members?
- 5.9. Can the Class Members ask for collective recovery of their non-pecuniary damages?
- 5.10. Did the Defendants intentionally interfere with the right to life, personal security and inviolability of the Class Members?
- 5.11. Did the Defendants knowingly put a product on the market that creates addiction and Opioid Use Disorder?
- 5.12. Are the Defendants liable for punitive damages as a result their egregious conduct, and if so, in what amount?

6. The questions of law or fact which are particular to each of the members, are:

- 6.1. The nature of their Opioid Use Disorder, in particular, which of the Diagnostic Criteria they experience or have experienced;
- 6.2. Other than the damages recovered collectively, what other damages have the Class Members suffered?

7. It is expedient that the bringing of a class action for the benefit of the members of the class be authorized.

8. The nature of the recourse which the Plaintiff wishes to exercise on behalf of the members of the Class, is:

8.1. An action for damages based on the extra-contractual responsibility of the manufacturer, the *Competition Act* and the *Charter of Human Rights and Freedoms*.

9. The conclusions sought by the Plaintiff are:

GRANT the Plaintiff's Class Action;

CONDEMN the Defendants solidarily to pay to each of the Class Members the amount of \$30,000 in non-pecuniary damages with interest and additional indemnity since the service of the application for leave to institute a class action;

CONDEMN each of the Defendants to pay the sum of \$25,000,000, in punitive damages;

CONDEMN the Defendants to pay to each Class Member a sum as pecuniary damages to be determined on an individual basis, increased by interest at the legal rate and the additional indemnity provided for in article 1619 of the *Civil Code of Quebec*, since service of the *application for leave to institute a class action* and to be recovered individually;

CONDEMN the Defendants to pay the Plaintiff's full costs of investigation in connection with the misrepresentations made by the Defendants;

ORDER the collective recovery of these awards;

DETERMINE the appropriate measures for distributing the amounts recovered collectively and the terms of payment of these amounts to the Class Members;

ORDER the liquidation of the individual claims for any other damage sustained by the Class Members;

DETERMINE the process of liquidating the individual claims and the terms of payment of these claims pursuant to articles 599 to 601 CCP.

10. The Plaintiff requests that (...) he be ascribed the status of representative.

11. The Plaintiff is in a position to represent the members adequately, for the following reasons:

- 11.1. (...) <u>He</u> was prescribed opioids, as described herein;
- 11.2. (...) <u>He</u> became addicted to opioids, as described herein, and in fact, has suffered from <u>severe</u> Opioid Use Disorder, having experienced (...) virtually <u>all</u> of the Diagnostic Criteria;

- 11.3. (...) <u>He</u> has suffered damages as a result of (...) <u>his</u> Opioid Use Disorder, <u>which is a chronic condition that he will likely have to face for the rest of his</u> <u>life;</u>
- 11.4. (...) The Plaintiff would like to raise awareness about the dangers of opioid use, and feels so strongly about this issue that he is even willing to associate his name with these proceedings, despite any stigma which may still be associated with the issue of addiction;
- 11.5. <u>As previously mentioned, he believes that no person should ever have to</u> suffer the way that he has as a result of his addiction to prescription opioids, and has decided to act as the designated Class Member in this proceeding to seek compensation for all Quebecers affected by Opioid Use Disorder;</u>
- 11.6. (...) <u>He</u> understands the nature of the action; and
- 11.7. (...) <u>He</u> is willing to devote the time necessary to the dispute and has already taken steps in that direction by obtaining (...) <u>his</u> prescription history.

12. The Plaintiff suggests that the class action should be brought before the Superior Court of the district of Montreal for the following reasons:

- 12.1. Plaintiff resides in the district of Montreal;
- 12.2. The facts which give rise to the proceedings took place in Montreal; namely, the Plaintiff was prescribed, and became addicted to opioids in Montreal, and has suffered damages in Montreal;
- 12.3. The Plaintiff's attorneys practice their professions in Montreal; and
- 12.4. Many Class Members reside in Montreal.

WHEREFORE THE PLAINTIFF PRAYS:

That the present application be granted;

and

That the bringing of a class action be authorized, as described herein;

That the status of representative be granted to the Plaintiff for the purpose of bringing the said class action for the benefit of the following group of natural persons, namely:

All persons in Quebec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the Defendants between 1996 and the present day ("**Class Period**") and who suffer or have suffered from Opioid Use Disorder, according to the diagnostic criteria herein described.

The Class includes the direct heirs of any deceased persons who met the above-mentioned description.

The Class excludes any person's claim, or any portion thereof, subject to the settlement agreement entered into in the court file no (\dots) . (\dots) 200-06-000080-070, provided that such settlement agreement becomes effective as a result of the issuance of the requisite court approvals.

That the principal questions of law and fact to be dealt with collectively be identified as follows:

- i. Do the opioid products manufactured, marketed, distributed and/or sold by the Defendants pose serious health risks to their users due to, *inter alia*, their addictive nature?
- ii. Do the opioid products manufactured, marketed, distributed and/or sold by the Defendants offer the safety that Class Members could normally expect?
- iii. Did the Defendants provide the Class Members with precise and complete warnings on the risks and dangers of using their opioid products?
- iv. Did the Defendants trivialize or deny the risks and dangers associated with the use of opioids?
- v. Did the Defendants employ marketing strategies which conveyed false or misleading information, including by omission, about the characteristics of the opioid products they were selling?
- vi. Did the Defendants fail to properly monitor the safety of their opioid products and/or take appropriate corrective action to adequately inform users of such safety risks, as knowledge evolved as to such safety risks and side effects?

- vii. Have the Class Members suffered damages as a result of their Opioid Use Disorders?
- viii. What is the amount of non-pecuniary damages suffered by the Class Members?
- ix. Can the Class Members ask for collective recovery of their nonpecuniary damages?
- x. Did the Defendants intentionally interfere with the right to life, personal security and inviolability of the Class Members?
- xi. Did the Defendants knowingly put a product on the market that creates addiction and Opioid Use Disorder?
- xii. Are the Defendants liable for punitive damages as a result of their egregious conduct, and if so, in what amount?

That the conclusions sought with relation to such questions be identified as follows:

GRANT the Plaintiff's Class Action;

CONDEMN the Defendants solidarily to pay to each of the Class Members the amount of \$30,000 in non-pecuniary damages with interest and additional indemnity since the service of the application for leave to institute a class action;

CONDEMN each of the Defendants to pay the sum of \$25,000,000 in punitive damages;

CONDEMN the Defendants to pay to each Class Member a sum as pecuniary damages to be determined on an individual basis, increased by interest at the legal rate and the additional indemnity provided for in article 1619 of the *Civil Code of Quebec*, since service of the *application for leave to institute a class action* and to be recovered individually;

CONDEMN the Defendants to pay the Plaintiff's full costs of investigation in connection with the misrepresentations made by the Defendants;

ORDER the collective recovery of these awards;

DETERMINE the appropriate measures for distributing the amounts recovered collectively and the terms of payment of these amounts to the Class Members;

ORDER the liquidation of the individual claims for any other damage sustained by the Class Members;

DETERMINE the process of liquidating the individual claims and the terms of payment of these claims pursuant to articles 599 to 601 CCP.

THE WHOLE WITH COSTS, including experts' fees and notice costs.

That it be declared that any member who has not requested his exclusion from the Class be bound by any judgment to be rendered on the class action, in accordance with law;

That the delay for exclusion be fixed at sixty (60) days from the date of the notice to members and that at the expiry of such delay the members of the Class who have not requested exclusion be bound by any such judgment;

That it be ordered that a notice to the class members be published according to the terms to be determined by the Court;

That it be ordered that the class action should be brought before the Superior Court of the district of Montreal;

The whole with costs, including the costs of all notices.

MONTREAL, (...) October 25, 2019

MONTREAL, (...) October 25, 2019

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LIST OF EXHIBITS

- **EXHIBIT P-1.** Irfan A. Dhalla, Navindra Persaud and David N. Juurlink, "Facing up to the prescription opioid crisis", (2011) *BMJ* 343: d5142
- **EXHIBIT P-2.** Asim Alam and David N. Jurrlink, "The prescription opioid epidemic: an overview for anesthesiologists", (2016) *Can J Anaesth* 63(1):61-68
- **EXHIBIT P-3.** Purdue Pharma L.P., Press Release, "New Hope for Millions of Americans Suffering from Persistent Pain", PR Newswire (31 May 1996)
- **EXHIBIT P-4.** Canada, House of Commons, "Report and Recommendations on the Opioid Crisis in Canada", Report of the Standing Committee on Health, 1st sess., 42nd parliament, December 2016
- **EXHIBIT P-5.** Marion S. Greene and R. Andrew Chambers, "Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature", (2015) *Curr Addict Rep*, 2(4): 310-317
- **EXHIBIT P-6.** Purdue Pharma, "2000 Budget Plan OxyContin Tablets" (2000)
- **EXHIBIT P-7.** Canada, National Opioid Use Guideline Group, "Canadian Guideline for Safe and Effective Use of Opioid for Chronic Non-Cancer Pain" (2010).
- **EXHIBIT P-8.** Association pharmaceutique canadienne, "Hydromorph Contin" in *Compendium des produits et spécialités pharmaceutiques*, 31st ed (Ottawa: Association pharmaceutique canadienne, 1996); Association des pharmaciens du Canada, "Hydromorph Contin" in *Compendium des produits et spécialités pharmaceutiques*, 33rd ed (Ottawa: Association des pharmaciens du Canada, 1998); Association des pharmaciens du Canada, 1998); Association des pharmaciens du Canada, 2000)
- **EXHIBIT P-9.** Association des pharmaciens du Canada, "Hydromorph Contin" in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2002)
- **EXHIBIT P-10.** Association pharmaceutique canadienne, "Supeudol" in *Compendium des produits et spécialités pharmaceutiques*, 31st ed (Ottawa: Association pharmaceutique canadienne, 1996); Association des pharmaciens du Canada, "Supeudol" in *Compendium des produits et spécialités pharmaceutiques*, 33rd ed (Ottawa: Association des pharmaciens du Canada, 1998); Association des pharmaciens du

Canada, "Supeudol" in *Compendium des produits et spécialités pharmaceutiques*, 35th ed (Ottawa: Association des pharmaciens du Canada, 2000); Association des pharmaciens du Canada, "Supeudol" in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2002).

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No: 500-06-001004-197

| SUPERIOR COURT District of Montreal (Class Action Division) | | | |
|---|--|--|--|
| RICCARDO CAMARI | DA Plaintiff | | |
| ABBOTT LABORATORIES, LIMITED et als. | | | |
| | Defendants | | |
| <u>Amended</u> Application for authorization to institute a class action, and to obtain the status of representative | | | |
| ORIGINAL | | | |
| File: OPIOID-1 Nature: Class Action | | | |
| Mtre Avram Fishman (afishman@ffmp.ca) Mtre. Mark E. Meland (mmeland@ffmp.ca) Mtre. Margo R. Siminovitch (msiminovitch@ffmp.ca) Mtre. Tina Silverstein | Mtre Philippe H. Trudel (<u>philippe@tjl.quebec</u>) Mtre André Lespérance (<u>andre@tjl.quebec</u>) Mtre Gabrielle Gagné (<u>gabrielle@tjl.quebec</u>) | | |
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CODE: BM-0309

CODE: BT-1415

| IN THE MATTER OF THE <i>COMPANIES' CREDITORS ARRANGEMENT ACT</i> , R.S.C. 1985, c. C-36, AS AMENDED AND IN THE MATTER OF A PLAN OF AND IN THE MATTER OF PURDUE PHARMA L.P., PURDUE PHARMA INC., RHODES ASSOCIATES L.P., PAUL LAND INC., RHODES TECHNOLOGIES, RHODES PHARMACEUTICALS L.P., UDF LP, SVC PHARMA INC., BUTTON LAND L.P., SVC PHARMA LP, QUIDNICK LAND L.P., SEVEN SEAS HILL CORP., OPHIR GREEN CORP., PURDUE PHARMA OF PUERTO RICO, AVRIO HEALTH L.P., PURDUE TRANSDERMAL TECHNOLOGIES L.P., PURDUE PHARMACEUTICS L.P., IMBRIUM THERAPEUTICS L.P., GREENFIELD BIOVENTURES L.P., NAYATT COVE LIFESCIENCE INC., PURDUE NEUROSCIENCE COMPANY, PURDUE PHARMACEUTICALS PRODUCTS L.P. | Court | File No. CV-19-627656-00CL |
|---|---|--|
| | ONTARIOSUPERIOR COURT OF JUSTICE – COMMERCIAL LIST Proceeding commenced at TorontoRESPONDING MOTION RECORD OF QUEBEC OPIOID CLASS ACTION PLAINTIFF (Re: Related Party Stay – Returnable November 28, 2019)Fishman Flanz Meland Paquin LLP 4100-1250 René-Lévesque Blvd. West Montreal, Quebec H3A 3H3 Tel: (514) 932-4100 | |
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