

Application for authorization to institute a class action

Canada
Province of Quebec
District of Montreal

No. 500-06-001004-197

(Class Action)
Superior Court

EV, with an elected domicile for the purpose hereof at 1250
Rene-Levesque Boulevard West, Suite 4100, Montreal,
Quebec H3B 4W8

Plaintiff

v.

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

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

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

and

COBALT PHARMACEUTICALS INC., a legal person, having
a place of business at 6500 Kitimat Road, Mississauga,

Ontario L5N 2B8

and

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

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

MYLAN PHARMACEUTICALS ULC, a legal person, having a place of business at 450 1st Street SW, Suite 2500, Calgary, Alberta T2P 5H1

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 22 Adelaide Street West, Suite 3400, Toronto, Ontario M5H 4E3

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

and

STANLEY PHARMACEUTICALS, a division of **Vita Health Products Inc.**, a legal person, having an elected domicile at 1501 McGill College Avenue, Suite 26E, Montreal, Quebec H3A 3N9

and

STERIMAX INC., a legal person, having a place of business at 2770 Portland Drive, Oakville, Ontario L6H 6R4

and

SUN PHARMA CANADA INC., legal person having a place of business at 170 Steelwell Road, Unit 100, Brampton Ontario, L6T 5T3

and

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

and

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

**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 nos. 200-06-000089-071 and 200-06-000080-070.

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 her 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 sold opioids in Quebec, including Dilaudid and Fentanyl Citrate injections.
 - 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 sold opioids in Quebec, including Dilaudid.
- 2.6. Defendant Apotex Inc. ("**Apotex**") is an Ontario corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Apo-Oxycodone CR, Apo-Fentanyl Matrix and Apo-Hydromorphone.
- 2.7. Defendant BGP Pharma ULC ("**BGP Pharma**") is a Nova Scotia corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Kadian.
- 2.8. Defendant Bristol-Myers Squibb Canada Co. ("**Bristol-Myers**") is a Nova Scotia corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Percocet.

- 2.9. Defendant Cobalt Pharmaceuticals Inc. ("**Cobalt**") is an Ontario corporation which, during the Class Period, manufactured, marketed, and sold opioids in Quebec, including CO Fentanyl.
- 2.10. Defendant Ethypharm Inc. ("**Ethypharm**") is a Quebec corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including M-eslon and M-ediat.
- 2.11. Defendant Janssen Inc. ("**Janssen**") is an Ontario corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Jurnista and Duragesic.
- 2.12. 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 sold opioids in Quebec, including Hydromorphone tablets.
- 2.13. Defendant Laboratoire Atlas Inc. ("**Laboratoire Atlas**") is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Linctus Codeine Blanc, Codeine Phosphate syrups and Doloral.
- 2.14. Defendant Laboratoire Riva Inc. ("**Riva**") is a Quebec corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Codeine tablets.
- 2.15. Defendant Mylan Pharmaceuticals ULC ("**Mylan**") is an Alberta corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Mylan-Fentanyl Matrix patches.
- 2.16. Defendant Paladin Labs Inc. ("**Paladin**") is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Abstral, Metadol, Metadol-D and Statex.
- 2.17. Defendant Pfizer Canada ULC ("**Pfizer Canada**") is a British Columbia corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Hydromorphone Hydrochloride injections.
- 2.17.1. Hospira Healthcare Corporation ("**Hospira**") was a Canadian corporation that amalgamated with Pfizer Canada in 2018 which, during the Class Period, manufactured, marketed and

sold opioids in Quebec, including Morphine Sulfate injections, Codeine Phosphate injections and Fentanyl Citrate injections.

- 2.17.2. David Bull Laboratories (Canada) Inc. (“**David Bull Lab**”) was a Canadian corporation that amalgamated with Hospira in 2007, which then amalgamated with Pfizer Canada in 2018 which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Morphine Sulphate injections and Fentanyl Citrate injections.
- 2.18. Defendant Pharmascience Inc. (“**Pharmascience**”) is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including pms-Oxycodone, pms-Morphine Sulfate, pms-Hydromorphone and pms-Fentanyl MTX.
- 2.19. Defendant Pro Doc Limitée (“**Pro Doc**”) is a Quebec corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Oxycodone and Fentanyl patches.
- 2.20. 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 sold opioids in Quebec, including Codeine, Contin, Dilaudid, Hydromorph Contin, MS Contin, MS.IR and OxyIR.
- 2.21. Defendant Purdue also produces OxyContin and OxyNeo, and claims related to the use of these products are part of the settlements entered into in connection with the court file nos. 200-06-000089-071 and 200-06-000080-070.
- 2.22. 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 sold opioids in Quebec, including Hydromorphone Hydrochloride tablets and Oramorph.
- 2.23. Defendant Sandoz Canada Inc. (“**Sandoz Canada**”) is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Sepeudol, Codeine Phosphate injections, Fentanyl patches, Fentanyl Citrate injections, Morphine Sulfate injections, Hydromorphone and Hydromorphone HP.

- 2.24. Defendant Sanis Health Inc. ("**Sanis**") is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Morphine SR tablets.
- 2.25. Defendant Stanley Pharmaceuticals ("**Stanley**"), a division of Vita Health Products Inc., is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, mainly Codeine syrups.
- 2.26. Defendant Sterimax Inc. ("**Sterimax**") is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Hydromorphone Hydrochloride injections.
- 2.27. Defendant Sun Pharma Canada Inc. ("**Sun Pharma Canada**"), formerly known as Ranbaxy Pharmaceuticals Canada Inc., is an Ontario corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Ren-Fentanyl Matrix Patch and Ren-Fentanyl Transdermal System.
- 2.28. Defendant Teva Canada Limited ("**Teva Canada**") is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Codeine syrups and tablets, Hydromorphone and Hydrochloride tablets, Ratio-Codeine, Ratio-Morphine, Fentora, Teva-Fentanyl, Teva Hydromorphone, Teva-Codeine and Teva-Morphine.
- 2.28.1. Actavis Pharma Inc. ("**Actavis**") was a Nova Scotia corporation that amalgamated with Teva Canada in 2017 which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Oxycodone CR tablets.
- 2.29. Defendant Valeant Canada LP ("**Valeant Canada**") is a Quebec limited partnership which, during the Class Period, manufactured, marketed and sold opioids in Quebec, including Morphine Hydrochloride (M.O.S.).
- 2.30. Defendant Meda Valeant Pharma Canada Inc., now 4490142 Canada Inc. ("**4490142**"), is a Canadian corporation which, during the Class Period, manufactured, marketed and sold opioids in Quebec, namely Onsolis.

The Defendants' Faults

- 2.31. 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**.

- 2.32. 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.
- 2.33. 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**.
- 2.34. 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.
- 2.35. 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.
- 2.36. The new narrative concerning the use of opioids, which was promoted by the Defendants, misrepresented that:
 - 2.36.1. the risk of opioid addiction was low, and that doctors could use screening tools to exclude patients who might become addicted;
 - 2.36.2. use of opioids resulted in improved function;
 - 2.36.3. withdrawal from opioids could easily be managed;
 - 2.36.4. opioids were appropriate for long-term use;
 - 2.36.5. opioids had less adverse effects than other pain management drugs;
 - 2.36.6. use of certain opioids provided patients with long-lasting pain relief;

2.36.7. increased dosages of opioids could be prescribed, without disclosing the increased risks; and

2.36.8. that “abuse deterrent” formulations of opioids were effective.

(collectively the “**Misrepresentations**”).

Misrepresentations of the addictive nature and likelihood of abuse

2.37. In their marketing efforts, the Defendants persuaded health care professionals that the risk of addiction to opioids was largely unfounded.

2.38. 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**.

2.39. 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 there is very little risk of addiction from the proper uses of these drugs for pain relief.*”

2.40. 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.

2.41. 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.

2.42. 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**.

- 2.43. 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**.
- 2.44. 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

- 2.45. 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.
- 2.46. 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.
- 2.47. 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.
- 2.48. 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.
- 2.49. 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

- 2.50. 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.
- 2.51. 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

- 2.52. The Defendants marketed their drugs as being safe for long-term use, a claim which was not backed up by any scientific evidence.
- 2.53. 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.*”
- 2.54. The Defendants pushed the prescription of their drugs for use in the non-malignant pain markets. On this subject, the 2000 Purdue Marketing Budget (EXHIBIT P-6) states:

In 2000, OxyContin Tablets will be more aggressively promoted 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. The promotional efforts will focus on specific disease syndromes such as back pain, osteoarthritis, reflex sympathetic dystrophy, trauma/injury, neuropathic type pains, etc.

- 2.55. 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

- 2.56. 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.
- 2.57. For example, the Defendants failed to disclose the risks of overdose, addiction, respiratory depression and death.
- 2.58. 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.
- 2.59. Hyperalgesia can further cause sufferers to experience hormonal dysfunction, a decline in immune function, mental clouding, confusion and dizziness.
- 2.60. 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

- 2.61. 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.
- 2.62. The Defendants, however, knew that these claims were false and that their drugs would not provide 12-hours of pain relief for most patients.

- 2.63. 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.
- 2.64. 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.
- 2.65. 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.
- 2.66. 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

- 2.67. 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 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**.
- 2.68. 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.
- 2.69. 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

- 2.70. 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.

- 2.71. 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.
- 2.72. 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

- 2.73. The Defendants engaged in aggressive marketing and sales practices which were entirely inappropriate for the distribution of dangerous, addictive drugs.
- 2.74. 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**”).
- 2.75. The Defendants also engaged in aggressive sales’ tactics in order to spread their Misrepresentations:
 - 2.75.1. to health care professionals;
 - 2.75.2. to medical students;
 - 2.75.3. by funding patient advocacy groups; and
 - 2.75.4. to the public.

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

- 2.76. 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.
- 2.77. 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**.

- 2.78. 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**.
- 2.79. 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.*”
- 2.80. 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**.
- 2.81. 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.*”
- 2.82. 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 même 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**.
- 2.83. These warnings were clearly insufficient, as appears from the way that they have evolved over time. Indeed, the recent Product Monographs furthermore include bolded sections containing precautions, 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**.

- 2.84. In addition to the limitations on use, the current warnings and precautions are now in bold in the Product Monographs and they 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.

The spreading of Misrepresentations to health care professionals

- 2.85. 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.
- 2.86. 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.
- 2.87. 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.
- 2.88. Many examples of these types of advertisements can be found in the CPS.
- 2.89. 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 pouvez l’aider.*” The ad gently warned in fine print that prudence was required when prescribing medications that have a “*potential 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**.
- 2.90. In the 2007 CPS, Defendant Purdue advertised Hydromorph Contin for non-cancer 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.**

- 2.91. 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 “*potential 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.
- 2.92. 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.
- 2.93. 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 opiacés avec l’**extrême** prudence qu’exige ce type de médicament, car il présente un **fort** 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.**
- 2.94. 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.**

- 2.95. 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**
- 2.96. 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**.
- 2.97. 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**.
- 2.98. 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.

- 2.99. 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

- 2.100. The aggressive marketing of opioids was not limited to health care professionals, but also targeted medical students.
- 2.101. 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

- 2.102. The Defendants provided financial support to Canadian patient advocacy groups, such as the Canadian Pain Society, the Canadian Pain Coalition 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.
- 2.103. 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

- 2.104. 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.
- 2.105. For example, starting in 1997, one such medical professional, Dr. Russell Portenoy, 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**.

The Resulting Opioid Crisis in Quebec

- 2.106. As a result of the Defendants’ Misrepresentations, failure to inform and failure to warn, an opioid crisis has ensued.
- 2.107. 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.
- 2.108. 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**.

- 2.109. 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**.
- 2.110. 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**.
- 2.111. 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.
- 2.112. 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.
- 2.113. 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

- 2.114. 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**.
- 2.115. 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**.
- 2.116. On January 31, 2019, Health Canada sent a follow up letter to fifteen companies who market and distribute opioid products in Canada.
- 2.117. 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**.
- 2.118. 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**.
- 2.119. The required warning label clearly indicates that opioids can cause dependence, addiction and overdose, as appears from the reproduction of the warning below:



2.120. The information handout provides patients with a serious and explicit warning about opioid use, including that the use of opioids can result in overdose (which can lead to death), addiction, physical dependence, life-threatening 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

- 2.121. 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).
- 2.122. In particular, the Defendants' Misrepresentations caused the Opioid Use Disorders that the Class Members have suffered from, or continue to suffer from.
- 2.123. Sufferers of Opioid Use Disorder experience at least two of the following diagnostic symptoms:
- 2.123.1. Opioids are often taken in larger amounts or over a longer period than was intended;
 - 2.123.2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use;
 - 2.123.3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects;

- 2.123.4. Craving or a strong desire to use opioids;
- 2.123.5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home;
- 2.123.6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids;
- 2.123.7. Important social, occupational, or recreational activities are given up or reduced because of opioid use;
- 2.123.8. Recurrent opioid use in situations in which it is physically hazardous;
- 2.123.9. 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;
- 2.123.10. 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.
- 2.123.11. 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**.

- 2.124. Opioid Use Disorder has crippling effects on its victims, including in the form of:

- 2.124.1. personal injury, including addiction;
 - 2.124.2. severe emotional distress, social stigma, prejudice and discrimination resulting from addiction;
 - 2.124.3. a lack of awareness that they are suffering from Opioid Use Disorder;
 - 2.124.4. overdose, serious injury, and death;
 - 2.124.5. out of pocket expenses relating to their drug dependence, including for treatment and recovery; and
 - 2.124.6. loss of income.
- 2.125. 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

The Plaintiff's request to use a pseudonym

- 2.126. Due to the personal nature of her story, as described herein, the Plaintiff requests permission to use a pseudonym for all legal proceedings and court documents in the present Court file.
- 2.127. The Plaintiff also requests that all Class Members be granted the right to use pseudonyms in connection with all legal proceedings and court documents in the present Court file as well.
- 2.128. The disclosure of the Plaintiff's identity would have negative consequences on her personally, as intimate details of her personal struggle with opioid use and addiction would become public.
- 2.129. The Plaintiff, in particular, does not want her name to be published in the media in connection with this proceeding, although she strongly feels that her story needs to be told.
- 2.130. The Plaintiff does not want to forever be associated with her addiction to opioids, which would be the consequence of the public disclosure of her name in connection with this case.

- 2.131. Furthermore, the Plaintiff, who still suffers from chronic pain, is concerned that if her name and story are made public, it could impact her relationship with medical professionals in the future.
- 2.132. In protecting her identity, the Court will also ensure that other class members, who are similarly fearful of the stigma of addiction, would be more likely to come forward.
- 2.133. Allowing the Plaintiff and the Class Members to use pseudonyms will provide greater access to justice.
- 2.134. The Plaintiff is prepared to provide her name to the Court and to counsel for the Defendants, provided such information is kept confidential.

The facts giving rise to the Plaintiff's claim

- 2.135. The Plaintiff is a resident of the Province of Quebec.
- 2.136. Until she retired in 2008, the Plaintiff was employed by a Montreal university in a management capacity for over 30 years. She was always a highly effective and productive employee.
- 2.137. Approximately 9 years ago, the Plaintiff visited her family physician to seek treatment of her chronic pain, caused by polymyalgia-rheumatica, fibromyalgia and osteo-arthritis.
- 2.138. At that time the Plaintiff was prescribed Hydromorph Contin, which she then became addicted to, along with other opioids, for approximately 7 years.
- 2.139. The Plaintiff remembers meeting with her family doctor when the decision to prescribe this drug was made. The doctor very clearly told her that they, implying family physicians, had been advised that they had been under-prescribing opioids and that opioids were the drug of choice to treat pain. She said, as the Plaintiff recalls, that there was "*no reason to hold back*" and that they had been advised to "*feel free to prescribe opioids more liberally.*"
- 2.140. This information was provided to the Plaintiff without equivocation, such that Plaintiff perceived it as being a recommendation of the Canadian Medical Association or the Royal College of Physicians and Surgeons of Canada.

- 2.141. The Plaintiff was not informed of any risks that might be associated with the use of opioids, and fully trusted that the prescription of an opioid was appropriate for the treatment of her pain.
- 2.142. As mentioned above, the Plaintiff was addicted to opioids for approximately 7 years.
- 2.143. As her tolerance to the drug increased, so did the dosages that she was prescribed, since she required the increased dosages in order to obtain the same relief. As well, the Plaintiff was prescribed the opioid Dilaudid as a rescue medication to alleviate pain caused by end-of-dose failure.
- 2.144. At one point, her total daily dose had increased to 30mg per day, in two doses being 12mg and 18mg. She was later told that this is the equivalent of 150mg of morphine, whereas the recommended maximum daily dose of morphine is only 90mg.
- 2.145. With her dosage of opioids increasing and her pain getting worse, the Plaintiff's family physician, in consultation with the Plaintiff's son, who is also a physician, determined that she was suffering from opioid-induced hyperalgesia.
- 2.146. Unable to simply stop taking these addictive drugs on her own, and after unsuccessfully trying to taper under the care of her physician, the Plaintiff was entered into a month-long, grueling, in-patient medical detox in the psychiatry ward at the Montreal General Hospital in August 2017, where her addiction to opioids was treated with yet another opioid, methadone, marketed and sold by Defendant Paladin.
- 2.147. At the time, there were only two other beds in the psychiatry ward dedicated to detoxification, and the other patients were an individual suffering from a 14-year crystal meth addiction, and an alcoholic.
- 2.148. The detoxification process was excruciating for the Plaintiff and lasted for a period of more than six months after her release from the hospital. In particular, the Plaintiff could not sleep, and her body and mind were, in her words, "*as weak as a baby.*"
- 2.149. The Plaintiff has only been able to ascertain the devastating impact her addiction to opioids had on her life since the drugs have left her system.
- 2.150. She describes her time under the influence of opioids as a seven-year sentence of "*brain fog,*" depression and suicidal ideation.

- 2.151. She stopped seeing friends and taking care of herself, for example, she no longer went to the gym or physical therapy.
- 2.152. The Plaintiff's dependence on opioids impacted her quality of life, the quality of her relationships and her decision making, and caused her significant prejudice and harm.
- 2.153. While under the influence of opioids, her decision-making was careless and devoid of critical thinking, which led her to make bad decisions that seriously and negatively impacted her life.
- 2.154. In particular, the bad financial decisions that she made as a result of her opioid addiction, led her to seek protection from the bankruptcy court, and to file a consumer proposal to settle the significant claims she faced from creditors, which lasted from 2013 to 2018.
- 2.155. Since her treatment from opioid dependence, the Plaintiff feels "*brighter, smarter and younger.*" She feels her life has been returned.
- 2.156. The Plaintiff describes her time on prescription opioids as horrific, and as having caused her to lose more than 7 years of her life, which she can never get back.
- 2.157. Although Plaintiff still experiences pain, she says that the pain is far better than the treatment with opioids.

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 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:
 - 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 and 300 deaths between January and September 2018, as appears from the 2019 National Report on Opioid-Related Deaths (EXHIBIT P-27).
 - 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).
 - 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 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 she be ascribed the status of representative.**
- 11. The Plaintiff is in a position to represent the members adequately, for the following reasons:**
 - 11.1. She was prescribed opioids, as described herein;
 - 11.2. She became addicted to opioids, as described herein, and in fact, has suffered from Opioid Use Disorder, having experienced several of the Diagnostic Criteria;
 - 11.3. She has suffered damages as a result of her Opioid Use Disorder;
 - 11.4. She feels that the opioid crisis is a story that needs to be told to alert people suffering of Opioid Use Disorder and to break the stigma associated with addiction;
 - 11.5. She understands the nature of the action; and
 - 11.6. She is willing to devote the time necessary to the dispute and has already taken steps in that direction by obtaining her 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 nos. 200-06-000089-071 and 200-06-000080-070.

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 non-pecuniary 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 (6) 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, May 23, 2019

MONTREAL, May 23, 2019

(s) Fishman Flanz Meland Paquin

(s) Trudel Johnston & Lespérance

FISHMAN FLANZ MELAND PAQUIN LLP

Co-Counsel for Petitioner
4100-1250 René-Lévesque Blvd. West
Montreal QC H3B 4W8
Tel. 514-932-4100
Fax 514-932-4170
afishman@ffmp.ca
mmeland@ffmp.ca
msiminovitch@ffmp.ca
tsilverstein@ffmp.ca

TRUDEL JOHNSTON & LESPÉRANCE

Co-Counsel for Petitioner
750 Côte de la Place d'Armes
Montréal, QC H2Y 2X8
Tel. 514-871-8385
Fax 514-871-8800
andre@tjl.quebec
gabrielle@tjl.quebec

COPIE CONFORME

TRUDEL JOHNSTON & LESPÉRANCE

LIST OF EXHIBITS

- EXHIBIT P-1.** Ifan 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. Juurlink, “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, “Hydromorph Contin” in *Compendium des produits et spécialités pharmaceutiques*, 35th ed (Ottawa: 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).

- EXHIBIT P-11.** Association des pharmaciens du Canada, “Supeudol” in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2004).
- EXHIBIT P-12.** Association des pharmaciens du Canada, “Jurnista” in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2018); Association des pharmaciens du Canada, “Hydromorph Contin” in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2018); Sandoz Canada Inc., “Product Monograph Including Patient Medication Information - Supeudol” (23 March 2018).
- EXHIBIT P-13.** Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2004)
- EXHIBIT P-14.** Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2007)
- EXHIBIT P-15.** Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2010)
- EXHIBIT P-16.** OxyContin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2004)
- EXHIBIT P-17.** OxyContin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2007)
- EXHIBIT P-18.** OxyNeo ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2013)

- EXHIBIT P-19.** Duragesic ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2003)
- EXHIBIT P-20.** Letter from Thomas W. Abrams (US Department of Health and Human Services) to Ajit Shetty (Janssen Pharmaceutica, Inc.) (2 September 2004)
- EXHIBIT P-21.** Navindra Persaud, “Questionable Content of an Industry-Supported Medical School Lecture Series: A Case Study”, (2014) *J Med Ethics*, 40:414-418
- EXHIBIT P-22.** Itai Bavli and Joel Lexchin, “Why Big Pharma must disclose payments to patient groups”, *The Conversation* (13 January 2019).
- EXHIBIT P-23.** Kelly Crowe, “Following the money between patient groups and Big Pharma”, *CBC* (17 February 2018).
- EXHIBIT P-24.** Christian Noel, “Des groupes de patients financés en secret par des pharmaceutiques”, *Radio-Canada* (6 May 2019).
- EXHIBIT P-25.** Arthur H. Gale, “Drug Company Compensated Physicians Role in Causing America’s Deadly Opioid Epidemic: When Will We Learn?”, (July-August 2016) *Mo Med* 113(4):244-246
- EXHIBIT P-26.** Christian McPhate, “Upshur County Is First in Texas to File a Lawsuit Holding Drug Makers Responsible for Opioid Epidemic”, *Dallas Observer* (6 October 2017).
- EXHIBIT P-27.** Government of Canada, Special Advisory Committee on the Epidemic of Opioid Overdoses, “National Report: Apparent opioid-related deaths in Canada” (April 2019).
- EXHIBIT P-28.** Canadian Institute for Health Information, “Opioid-Related Harms in Canada” (December 2018).
- EXHIBIT P-29.** Gouvernement du Québec, Institut national de santé publique, “Opioid-related Poisoning Deaths in Québec: 2000-2009” (October 2013).
- EXHIBIT P-30.** Karl Rettino-Parazelli, “L’usage d’opioïdes est en forte hausse”, *Le Devoir* (25 April 2016)
- EXHIBIT P-31.** Megan Martin, “Large portion of Quebec population unaware of the risks with opioids”, *Montreal Gazette* (26 March 2019).

EXHIBIT P-32. Kalina Laframboise, “Quebec government unveils action plan to fight opioid overdoses, addiction”, Global News (25 July 2018).

EXHIBIT P-33. Government of Canada, Health Canada, “Notice of Intent to Restrict the Marketing and Advertising of Opioids” (19 June 2018)

EXHIBIT P-34. Government of Canada, “Opioid Warning Sticker and Patient Information Handout, and Risk Management Plans” (15 March 2019).

EXHIBIT P-35. Government of Canada, Health Canada, “Opioids List” (2 May 2018).

EXHIBIT P-36. Government of Canada, Health Canada, “Patient Information Handout” (15 March 2019).

EXHIBIT P-37. American Psychiatric Association, “Opioid Use Disorder” in *Diagnostic and statistical manual of mental disorders*, 5th ed (Arlington: American Psychiatric Publishing, Inc., 2013).

MONTREAL, May 23, 2019

MONTREAL, May 23, 2019

(s) Fishman Flanz Meland Paquin

(s) Trudel Johnston & Lespérance

FISHMAN FLANZ MELAND PAQUIN LLP

Co-Counsel for Petitioner
4100-1250 René-Lévesque Blvd. West
Montreal QC H3B 4W8
Tel. 514-932-4100
Fax 514-932-4170
afishman@ffmp.ca
mmeland@ffmp.ca
msiminovitch@ffmp.ca
tsilverstein@ffmp.ca

TRUDEL JOHNSTON & LESPÉRANCE

Co-Counsel for Petitioner
750 Côte de la Place d'Armes
Montréal, QC H2Y 2X8
Tel. 514-871-8385
Fax 514-871-8800
andre@tjl.quebec
gabrielle@tjl.quebec

COPIE CONFORME

TRUDEL JOHNSTON & LESPÉRANCE