C A N A D A

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL
Nº: 500-06-001004-197

S U P E R I O R C O U R T
(Class Action)

JEAN-FRANÇOIS BOURASSA, with an elected domicile for the purpose hereof at 1010 de la Gauchetière Street. West, suite 1600, Montreal, Quebec H3B 2N2

Representative Plaintiff

v.

ABBOTT LABORATORIES, CO., 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

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

and

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

and

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

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

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 1000, De La Gauchetière West, Suite 900, Montreal, Quebec H3B 5H4

and

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

and

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

and

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

and

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

Defendants

ORIGINATING APPLICATION TO INSTITUTE CLASS ACTION PROCEEDINGS
(Articles 141 and 583 *C.C.P.*)

TO THE HONOURABLE JUSTICE PIERRE NOLLET OF THE SUPERIOR COURT OF QUEBEC, SITTING IN AND FOR THE DISTRICT OF MONTREAL AND DESIGNATED TO PRESIDE OVER THE PRESENT MATTER, THE REPRESENTATIVE PLAINTIFF RESPECTFULLY STATES THE FOLLOWING:

I. INTRODUCTION

1 Prescription opioids have contributed to the serious opioid crisis in Canada. In Quebec, thousands of people suffer from, or have suffered from, Opioid Use Disorder ("**OUD**").

2 Opioids are a class of drugs which resemble naturally occurring opiates that are prescribed to treat pain. These drugs, even when used as prescribed, are dangerously addictive, and the growing number of addictions, overdoses and deaths caused by opioids has been declared by the Government of Canada to be a public health emergency.

3 The purpose of this class action is to provide compensation to persons in Quebec who were prescribed opioids and who suffer, or have suffered from, OUD.

4 On April 10, 2024, the Honourable Justice Gary D.D. Morrison, J.S.C. authorized the class action against the Defendants and appointed Jean-François Bourassa as the Representative Plaintiff (hereinafter, the "**Plaintiff**").

5 The authorization judgment was rectified on April 18, 2024 to correct an omission from the listing of Defendants' opioid products provided on Schedule I of the judgement. A copy of the authorization judgment and the rectifying judgment (collectively, the "**Authorization Judgment**") are communicated herewith, *en liasse*, as **EXHIBIT P-1**.[1]

6 Schedule I (as rectified) is a list of the opioid drugs, containing active ingredients such as fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, codeine, tapentadol, tramadol, opium, buprenorphine and butorphanol, that are, or have been, manufactured, marketed, distributed and/or sold by each of the Defendants in the Province of Quebec during the Class Period (the "**Subject Opioids**").[2]

7 All of the Subject Opioids can cause dependence, addiction or death and may result in a diagnosis of OUD.

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[1] The Plaintiff refers to, and relies upon, the Authorization Judgment as though recited at length herein.

[2] Schedule I (as rectified) reflects the Plaintiff's knowledge of the Defendants' opioid drugs at the time of the authorization hearing and the list of the Subject Opioids will require modification as additional information emerges about the Defendants' opioid products.

8 As appears from EXHIBIT P-1, the authorized class action is for the benefit of persons forming part of the following group (the "**Class**"):

> All persons in Quebec who have been prescribed and consumed any one or more of the opioid medications identified in Schedule I attached hereto, manufactured, marketed, distributed and/or sold by the Defendants between 1996 and the present day ("**Class Period**") and who have been diagnosed by a physician as suffering or having suffered from Opioid Use Disorder.
>
> The Class excludes any person whose claim, or any portion thereof, is in relation to the drugs OxyContin or OxyNeo, as well as in relation to opioid drugs that were solely and exclusively available for use in a hospital setting and not prescribed for use in the home.
>
> The Class also includes the direct heirs of any deceased person who during his or her lifetime met the above description, subject to the same exclusions.

9 The principal questions of law or fact to be dealt with collectively in the class action are as follows:

9.1 Did and/or do the opioid products manufactured, marketed, distributed and/or sold during the Class Period by the Defendants, as identified at Schedule I in the Authorization Judgment, cause opioid use disorder in class members and pose other serious health risks to them due to, *inter alia*, their addictive nature?

9.2 Do the opioid products manufactured, marketed, distributed and/or sold by the Defendants offer the safety that Class Members could normally expect and do they have a safety defect within the meaning of articles 1468-1469 CCQ?

9.3 Did the Defendants provide sufficient information on the risks and dangers of using their opioid products?

9.4 Did the Defendants trivialize or deny the risks and dangers associated with the use of opioids?

9.5 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?

9.6 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?

9.7 Have the Class Members suffered damages as a result of their Opioid Use Disorders?

9.8 What is the amount of non-pecuniary damages suffered by the Class Members?

9.9 Are the Class Members legally entitled to collective recovery of their non-pecuniary damages?

9.10 Did the Defendants intentionally interfere with the right to life, personal security and inviolability of the Class Members?

9.11 Did the Defendants knowingly put a product on the market that creates addiction and Opioid Use Disorder?

9.12 Are the Defendants liable for punitive damages as a result of their egregious conduct, and if so, in what amount?

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

10.1 The specific nature of their Opioid Use Disorder, in particular, which of the diagnostic criteria symptoms they experience or experienced; and

10.2 Other than the damages recovered collectively, what other damages have the Class Members suffered?

11 The Plaintiff alleges that the Defendants failed to sufficiently warn health care professionals and consumers of the serious and potentially fatal harms associated with opioid use, including the significant risk of developing addiction and OUD, such that each of the Subject Opioids have a safety defect within the meaning of articles 1468 and 1469 of the *Civil Code of Quebec*, CQLR c CCQ-1991 ("**CCQ**").

12 The Plaintiff further alleges that, starting in mid-1990s, the Defendants intentionally promoted the prescription of opioids for the treatment of chronic pain although, historically, opioids were primarily used for palliative care and for the short-term treatment of acute pain, and this despite the absence of independent and meaningful research indicating that the benefits outweighed the risks when opioids were prescribed for long-term use.

13 In wanton disregard for the health and safety of the members of the Class (the "**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 what was supported by independent research studies.

14 As a result of these actions, which contravene the relevant provisions of the CCQ, the *Competition Act* (R.S.C., 1985, c. C-34) (the "**Competition Act**"), the Quebec *Charter of Human Rights and Freedoms*, CQLR c C-12 (the "**Charter**") and, in light of the provisions of the *Opioid-related Damages and Health Care Costs Recovery Act*, chapter R-2.2.0.0.01 (the "**ORDA**"), the Plaintiff requests that the Defendants compensate him and the other Class Members, as follows:

14.1 Compensatory damages for each Class Member in the amount of $75,000 plus interest and additional indemnity from the date of institution of the proceedings;

14.2 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

14.3 Pecuniary damages for each Class Member's personal losses, recoverable on an individual basis.

II. THE PARTIES

The Plaintiff

15 The Plaintiff is a resident of Quebec who was prescribed opioids during the Class Period and was first diagnosed with OUD in 2017, as is more fully explained below at paragraphs 198 – 224.

The Defendants and their Opioid Drugs

16 Defendant Abbott Laboratories, Co. ("**Abbott**"), formerly known as Abbott Laboratories, Limited, is a Canadian corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Dilaudid (tablets) and Kadian.

16.1 Knoll Pharma Inc. ("**Knoll**") was a Canadian corporation that amalgamated with Abbott in 2001 which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Dilaudid (tablets), and Kadian.

17 Defendant Apotex Inc. ("**Apotex**") is an Ontario corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including APO-Fentanyl Matrix, APO-Hydromorphone, APO-Hydromorphone CR, APO-Oxycodone CR, APO-Oxycodone/Acet, and APO-Tramadol/Acet.

18 Defendant Bristol-Myers Squibb Canada Co. ("**Bristol-Myers**") is a Nova Scotia corporation which, during the Class Period, manufactured, marketed, distributed

and/or sold opioids in Quebec, including Endocet, Endodan, Numorphan, Percocet, Percocet-Demi, Percodan and Percodan-Demi.

18.1 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, distributed and/or sold opioids in Quebec, including Endocet, Endodan, Numorphan (suppository), Percocet, Percocet-Demi, Percodan and Percodan-Demi.

19 Defendant Ethypharm Inc. ("**Ethypharm**") is a Quebec corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including M-Ediat and M-Eslon.

20 Defendant Janssen Inc. ("**Janssen**"), also known as Janssen-Ortho and/or Patriot, is an Ontario corporation which, during the Class Period, manufactured, marketed, distributed 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.

21 Defendant Laboratoire Atlas Inc. ("**Laboratoire Atlas**") is a Canadian corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Codeine Phosphate Syrup, Doloral and Linctus Codeine Blanc.

22 Defendant Laboratoire Riva Inc. ("**Laboratoire Riva**") is a Quebec corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Codeine 15, Codeine 30, Rivacocet, RIVA-Tramadol/Acet, and Triatec-30.

23 Defendant Laboratoires Trianon Inc. ("**Laboratoires Trianon**") is a Quebec corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Codeine 15, Codeine 30 and Triatec-30.

24 Defendant Pharmascience Inc. ("**Pharmascience**"), also known as Pendopharm, a Division of Pharmascience, is a Canadian corporation which, during the Class Period, manufactured, marketed, distributed 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 SR, pms-Opium and Belladonna, pms-Oxycodone, pms-Oxycodone CR, pms-Oxycodone-Acetaminophen and pms-Tramadol-Acet.

25 Defendant Pro Doc Limitée ("**Pro Doc**") is a Quebec corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Fentanyl Patch, Oxycodone (tablets), Oxycodone-Acet, Procet-30, Pronal C1/2, Pronal C1/4, and Tramadol-Acet. In 2007, the Jean Coutu Group (PJC) Inc. acquired Pro Doc.

26 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, distributed and/or sold opioids in Quebec, including Belbuca, BuTrans 5, BuTrans 10, BuTrans 15, BuTrans 20, Codeine Contin, Dilaudid (tablets), Hydromorph Contin, Hydromorph.IR, MS Contin, MS.IR, Oxy.IR, Palladone XL, Targin and Zytram XL.

26.1 Defendant Purdue also produces OxyContin, which it stopped selling in 2012, and OxyNeo. Personal injury claims related to the use of these specific products between January 1, 1996 and February 28, 2017 are part of the settlement (the "**National Settlement Agreement**") for the total amount of $20 million entered into, *inter alia*, in connection with the court file no 200-06-000080-070.

26.2 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.

26.3 The parties to the National Settlement Agreement entered into an Agreement re: Interpretation of Settlement Agreement dated July 13-14, 2022 (the "**Interpretation Agreement**") with the Plaintiff (then the Applicant), which clarified that the National Settlement Agreement was exclusively limited to claims or portions of claims related to OxyContin and OxyNeo, the whole as appears from a copy of the Interpretation Agreement communicated herewith as **EXHIBIT P-2**.

26.4 The binding Interpretation Agreement irrevocably stipulates that claims asserted in these proceedings against (i) opioid manufacturers, distributors or suppliers other than Purdue for harms, losses or damages caused by opioids in Canada, and (ii) against Purdue for harms, losses or damages caused by opioids other than OxyContin or OxyNeo, are **not released** by the National Settlement Agreement.

26.5 On September 23, 2022, Chief Justice Popescul of the King's Bench for Saskatchewan approved the National Settlement Agreement, such that it is now effective, the whole as appears from a copy of the approval judgment communicated herewith as **EXHIBIT P-3**.

26.6 In addition to the foregoing, Purdue reached a $150 million settlement of a proposed class action brought by the Province of British Columbia on behalf of all Canadian governments seeking recovery of health care costs related to opioid-related wrongs and, on December 16, 2022, the Supreme Court of British Columbia approved, *inter alia*, the Governments' Settlement, the whole as appears from a copy of the settlement approval judgment communicated herewith as **EXHIBIT P-4.**

27 Defendant Sandoz Canada Inc. ("**Sandoz Canada**") is a Canadian corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Sandoz Fentanyl Patch, Sandoz Morphine SR, Sandoz Opium & Belladonna, Sandoz Oxycodone/ Acetaminophen and Supeudol.

27.1 Sabex Inc. (formerly Sabex 2002 Inc.) was a Canadian corporation that amalgamated with Sandoz Canada in 2004, which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including HYDROmorphone Hydrochloride Suppositories, Sab-Opium & Belladonna and Supeudol.

28 Defendant Sun Pharma Canada Inc. ("**Sun Pharma Canada**"), formerly known as Ranbaxy Pharmaceuticals Canada Inc. ("**Ranbaxy**"), is an Ontario corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including RAN-Fentanyl Matrix Patch, RAN-Fentanyl Transdermal System, and RAN-Tramadol/Acet.

29 Defendant Teva Canada Limited ("**Teva Canada**"), formerly Novopharm Limited, is a Canadian corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including, Fentora, Methoxisal-C ½, Methoxisal-C ¼, Novo-gesic C15, Novo-gesic C30, Teva-Codeine, Teva-Emtec-30, Teva-Fentanyl, Teva-HYDROmorphone, Teva-Lenoltec No. 2, Teva-Lenoltec No. 3, Teva-Lenoltec No. 4, Teva-Morphine SR, Teva-Oxycocet, Teva-Oxycodan, and Teva-Tramadol/Acetaminophen.

29.1 Novopharm Limited was an Ontario corporation which amalgamated with Teva Canada in 2001, and which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Novo-gesic C15 and Novo-gesic C30.

29.2 Rougier Pharma Inc. was a Canadian corporation, which amalgamated into Ratiopharm Inc. in January 2001, and which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including Codeine Tab 15MG, Coryphen Codeine, Methoxisal-C 1/2 Methoxisal-C 1/4 and Paveral.

29.3 Ratiopharm Inc. was a Canadian corporation, which amalgamated into Teva Canada in August 2010, and which, during the Class Period, manufactured, marketed, distributed 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.

29.4 Technilab Pharma Inc. was a Canadian corporation which amalgamated into Teva Canada in August 2010, and which, during the Class Period, manufactured, marketed, distributed 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.

29.5 Cobalt Pharmaceuticals Inc. ("**Cobalt**") was an Ontario corporation which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including CO Fentanyl. In 2009, Cobalt continued in Nova Scotia and changed its name to Cobalt Pharmaceuticals Company. In 2013, the latter changed its name to Actavis Pharma Company, and in 2014, amalgamated with Actavis Pharma OTC Company and Actavis Pharma Inc. and continued as Actavis Pharma Company ("**Actavis Pharma**"). In 2015, Actavis Pharma amalgamated with 3242038 Nova Scotia Company and Actavis Canada Company and continued as Actavis Pharma Inc. ("**Actavis**").

29.6 Actavis was a Nova Scotia corporation that amalgamated with Teva Canada in 2017, and which, during the Class Period, manufactured, marketed, distributed and/or sold opioids in Quebec, including ACT Oxycodone CR and ACT Tramadol/Acet.

III. SETTLEMENTS

30 Since the institution of the class action in May 2019, this Court has approved ten settlement agreements (collectively, the "**Settlement Agreements**") between the Plaintiff (formerly the Applicant) and fifteen manufacturers of opioids (the "**Settled Defendants**").

31 The Settlement Agreements and related judgments form part of this court record and are also posted on the websites of counsel for the Plaintiff. The opioid drugs manufactured, marketed, distributed and/or sold during the Class Period by the Settled Defendants, as well as those associated with another settling defendant and the Court will be asked to approve such settlement, and those of a putative defendant who was discharged as a result of proceedings instituted under Chapter 11 of the United States Bankruptcy Code, are listed on **Schedule I**.

IV. THE DEFENDANTS' LIABILITY

a. Opioids are a dangerously addictive class of drugs that can cause OUD

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 harm. Opioids may also induce an addictive, euphoric high for their users.

33 Even when used as prescribed, all the Subject Opioids contain an inherent danger and do not afford the expected safety to users. Opioids can cause dependence, addiction and may result in OUD and even death.

34 Sufferers of OUD experience at least two of the following diagnostic symptoms:

34.1 Opioids are often taken in larger amounts or over a longer period than was intended;

34.2 There is a persistent desire or unsuccessful efforts to cut down or control opioid use;

34.3 A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects;

34.4 Craving or a strong desire to use opioids;

34.5 Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home;

34.6 Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids;

34.7 Important social, occupational, or recreational activities are given up or reduced because of opioid use;

34.8 Recurrent opioid use in situations in which it is physically hazardous;

34.9 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;

34.10 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.

34.11 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-5**.

35 Previously, OUD was classified as Opioid Abuse or Opioid Dependence in the DSM-4 and has also been referred to as "opioid addiction", as appears from the CDC's Module 5 entitled "Assessing and Addressing Opioid Use Disorder (OUD)", a copy of which is communicated herewith as **EXHIBIT P-6**.

36 However, diagnostically, the term "OUD" is now preferred over other terms with similar definitions, such as "opioid abuse or dependence" or "opioid addiction", as appears from the glossary of commonly used terms published by the National Center for Disease Control and Prevention (dated April 19, 2024), communicated herewith as **EXHIBIT P-7**.

37 OUD has crippling effects on its victims, including in the form of:

37.1 personal injury, including addiction;

37.2 severe emotional distress, social stigma, prejudice and discrimination resulting from addiction;

37.3 a lack of awareness that they are suffering from Opioid Use Disorder;

37.4 overdose, serious injury, and death;

37.5 out of pocket expenses relating to their drug dependence, including for treatment and recovery; and

37.6 loss of income.

38 Long-term opioid use comes with an increased risk of harms, including addiction, dependence, OUD and death, especially at high doses.

b. The current warnings for the Subject Opioids

39 Health Canada issued guidance to the industry on September 22, 2003, effective October 1, 2004, wherein it advised that a Serious Warnings and Precautions Box (often referred to as a Black Box Warning) 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 Health Canada's guidance to the industry, communicated herewith as **EXHIBIT P-8**. However, it was only years later when the Defendants' Product Monographs for the Subject Opioids included Serious Warnings and Precautions Boxes which expressly warned that:

39.1 even at recommended doses and used as prescribed, the use of opioids may cause addiction and dependence;

39.2 opioid use carries the risk of abuse and misuse, life threatening respiratory depression, accidental death and neonatal opioid withdrawal.

40 In October 2018, Health Canada added provisions in the Food and Drug Regulations requiring: (1) a warning sticker and (2) a patient information handout to accompany all prescriptions of opioids that appear in Part A of Health Canada's "List of Opioids" dated May 2, 2018, together with the required warning label, communicated herewith as **EXHIBIT P-9**. No distinction is made by Health Canada as to whether the product is a brand-name or generic opioid, or is an extended-release or immediate-release product, or by its formulation or its purported strength.

41 The required warning label clearly indicates that opioids can cause dependence, addiction and overdose:

42 Additionally, the required 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-10**.

43 These new regulations were meant 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-11**.

c. The Subject Opioids contain a safety defect

44 Beginning in the mid-1990s, the Defendants manufactured, distributed, sold and/or marketed the Subject Opioids, inherently dangerous drugs, without sufficient serious warnings of the risks. While the warnings have evolved during the Class Period and have become more forceful, the current warnings remain insufficient.

45 For example, only a handful of the current Product Monographs warn specifically about the serious risk of OUD. Additionally, even in the Patient Medication Information section of these Product Monographs, they do not warn consumers that treatment of OUD may require lengthy consumption of another prescription opioid (such as suboxone) for extended periods, if not forever.

46 Moreover, the Defendants continue to downplay the risks of opioid use. For instance, many continue to mislead health care professionals and the public, notably in their Product Monographs (and comparable documents), by asserting that "*concerns about abuse, addiction, and diversion should not prevent the proper management of pain*" even with respect to patients with a history of alcohol and illicit/prescription drug abuse.

47 This was, and is, a violation of their legal duty to sufficiently warn which caused the Subject Opioids to contain a safety defect.

48 The safety defect in the Subject Opioids caused harm to Class Members.

49 Despite the ongoing national opioid crisis, the over-prescription of opioids in Quebec induced by the Defendants' improper promotion of opioids remains widespread and the resultant harm to Quebecers is devastating. More than 1 in 9 Quebecers received at least one prescription for opioids in 2023 and, in the same year, more than 13,000 Quebecers were prescribed opioids for the treatment of OUD, as appears from a 2024 report from private healthcare consultant IQVIA entitled "Prescription Opioid Trends in Canada – An independent IQVIA report on measuring and understanding the use of prescription opioids dispensed from 2019 to 2023", communicated herewith as **Exhibit P-12**.

d. The Defendants deliberately misrepresented the Subject Opioids' risks and alleged benefits

50 The Defendants went far beyond failing to sufficiently warn health care professionals and consumers of the risks posed by the Subject Opioids. They knowingly promoted the use of these drugs for the treatment of chronic pain in the absence of evidence that the benefits to patients outweigh the risks of addiction and other harms.

(1) Historical context

51 Prior to the mid-1990s, opioids were primarily used for palliative care and for the short-term treatment of acute pain. Indeed, opioids were initially thought to be too addictive to treat conditions requiring longer-term non-cancer pain management.

52 The prescribed uses of opioids changed in the mid-1990s; in particular, in 1996, when Defendant Purdue (through its parent company in the U.S.) 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 and knee pain, osteoarthritis and neuropathic pain.

53 Chronic pain is defined by Health Canada as pain that persists beyond 3 months, as appears from the document published on Health Canada's website as at November 6, 2023, a copy of which is communicated herewith as **EXHIBIT P-13**. However, opioid consumption can lead to physical dependence within as little as 4-8 weeks.

54 The new narrative concerning the use of opioids which first emerged in the mid-1990s and which was promoted by the Defendants misrepresented that:

54.1 the risk of opioid addiction was low, and that doctors could use screening tools to exclude patients who might become addicted;

54.2 use of opioids resulted in improved function;

54.3 withdrawal from opioids could easily be managed;

54.4 opioids were appropriate for long-term use;

54.5 opioids had less adverse effects than other pain management drugs;

54.6 use of certain opioids provided patients with long-lasting pain relief;

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

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

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

55 For example, when OxyContin was approved by Health Canada for the Canadian market in 1996, the manufacturer’s prescribing information misrepresented that:

- the drug was safe and effective for chronic pain;
- “*drug abuse is not a problem in patients with pain in whom oxycodone* [the active ingredient in OxyContin] *is appropriately indicated*”; and
- in the event of breakthrough pain, “*it is generally an indication for a dosage increase*”.

as appears from the extract of the 1997 Compendium of Pharmaceuticals and Specialties (“**CPS**”) related to OxyContin, communicated herewith as **EXHIBIT P-14**. Moreover, as no recommended maximum dose was provided by Purdue, OxyContin could be marketed with no upper dose threshold. Rather, as stated in EXHIBIT P-14, “*dosage limitations are imposed by the adverse effects*”.

56 On a global basis, the Purdue family of companies profited massively from the aggressive marketing of opioids for use to treat chronic pain: sales grew from $48 million in 1996 to almost $1.1 billion in 2000.

57 Defendants were eager to capitalize on the expanding market for opioid products. Those with opioids already being marketed to alleviate short-term acute pain or palliative care began marketing the same product for non-cancer chronic pain.

58 A number of the Defendants also sought to enter the market with generic versions of OxyContin, even though they knew that Purdue’s claims about the safety and efficacy of OxyContin lacked support from independent scientific data. In fact, despite later claiming that their own Subject Opioids were safe and effective, these Defendants denied the novelty, safety and efficacy of these drugs in order to challenge Purdue’s patent on OxyContin.

59 For example, Defendant Pharmascience asserted that Defendant Purdue’s claim that the formulation for OxyContin results in an improvement in the efficiency and quality of pain treatment “*was not proven at the time of the filing of the patent application and to this day* [December 2009]*, it has still not yet been proven*”, as appears from the Statement of Claim, communicated herewith as **EXHIBIT P-15.**

60 The attempts made to invalidate Defendant Purdue’s patent were unsuccessful. However, despite such attempts, Defendants Apotex and Pharmascience manufactured and sold generic versions of OxyContin (containing the active

ingredient oxycodone) in Quebec beginning in 2011/2012, making the same Misrepresentations in their respective Product Monographs about the safety and efficacy of their version of the drug that had been asserted by Defendant Purdue about OxyContin (EXHIBIT P-14), as appears from the Apotex Product Monograph for Apo-Oxycodone CR dated April 15, 2011 and the pms-Oxycodone CR dated November 23, 2012, communicated herewith, *en liasse*, as **EXHIBIT P-16**.

61 Similarly, Cobalt and Actavis, both now part of Defendant Teva, began to manufacture and sell generic versions of OxyContin, as appears from the November 8, 2012 Product Monograph for CO-Oxycodone CR and the June 23, 2014 Product Monograph for Act-Oxycodone CR (by Actavis, now part of Defendant Teva), communicated herewith, *en liasse*, as **EXHIBIT P-17**.

62 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.

63 Notably, such coordination is shown by the fact that many of the **same** misleading statements appear generally in the Defendants' documents, such as Product Monographs (or comparable documents). This is illustrated by a sample of commonly used misleading statements found in the Defendants' Product Monographs (or comparable documents), which are reproduced in **Schedule II**. A number of the documents referenced in Schedule II are exhibits communicated in connection to the allegations made in other paragraphs in this Application. The remaining documents are communicated as **EXHIBITS P-82 TO P-137**.

64 The broadening of the market for prescription opioids over the last few decades has resulted in a highly lucrative global market for the opioid pharmaceutical industry, being valued at US $22.8 billion in 2022; and the scale of the opioid crisis created by this industry is eloquently illustrated by the expansion of another market, namely that for OUD treatment. Indeed, the global market for OUD treatment was valued at US $4.59 billion in 2023, and is projected to continue to grow over the decade, as appears from the Market Analysis Reports entitled "Opioid Market Size, Share & Trends Analysis Report" and "Opioid Use Disorder Market Size, Share & Trends Analysis Report" both published by Grandview Research and communicated herewith, *en liasse*, as **EXHIBIT P-18.**

(2) The Nature of the Misrepresentations

65 The Defendants failed to disclose the risks associated with opioid use and made several misleading claims regarding:

65.1 The addictive nature and likelihood of abuse of opioids;

65.2 The improved function and efficacy of opioids over other pain relief treatment;

65.3 The management of withdrawal of opioids;

65.4 The appropriateness of long-term use of opioids;

65.5 The adverse effects of opioids.

Misrepresentations of the addictive nature and likelihood of abuse

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

67 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.

68 The Misrepresentations in respect of addiction falsely induced health care professionals to believe that opioids could be safely prescribed for long-term use to appropriate patients, without the fear that such patients would become addicted. However, in reality, and significantly, between 5.5 % and 10% of patients prescribed opioids for chronic pain develop OUD, 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-19** and from a report entitled "Canadian Drug Summary: Prescription Opioids" published in July 2020 by the Canadian Centre on Substance Use and Addiction, communicated herewith as **EXHIBIT P-20**.

69 As appears from EXHIBIT P-19, 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*".

70 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 (i.e., caused by medical treatment) 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.

71 The myth of pseudoaddiction encouraged health care professionals to increase the dose of opioids they were prescribing, in order to "cure" their patients from their pseudoaddiction.

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

72 Without proper clinical evidence, the Defendants claimed in their marketing materials that long term use of opioids, including both immediate release and controlled release products, would improve patients' function and quality of life.

73 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.

74 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 nonsteroidal anti-inflammatory drugs ("**NSAIDs**"), like ibuprofen.

75 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.

76 Many physicians were unaware that there was 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.

77 Moreover, the Defendants' influence in promoting opioid use for chronic pain resulted in the 2010 "Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-cancer Pain" widely recommending the prescribing of opioids and providing few suggestions about when not to prescribe them, as appears from the 2010 "Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-cancer Pain", communicated herewith as **EXHIBIT P-21**.

78 The 2010 Guideline (EXHIBIT P-21) relied upon clinical trials for chronic non-cancer pain that failed to follow patients for more than one year, used limited patient populations and did not provide a comprehensive assessment of outcomes.

79 In contrast, the updated 2017 Prescribing Guideline strongly recommends that "*patients with chronic non-cancer pain may be offered a trial of opioids only after they have been optimized on non-opioid therapy*", as appears from the 2017 Canadian Opioid Prescribing Guideline published by the Canadian Centre on Substance Use and Addiction, communicated herewith as **EXHIBIT P-22**.

Misrepresentations with respect to the management of withdrawal

80 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.

81 The message was that physical addiction could be managed simply 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

82 The Defendants marketed their drugs as being safe for long-term use, a claim which was not backed up by any independent scientific evidence.

83 The Defendants pushed the prescription of their drugs for use in the non-malignant pain markets.

84 In reality, there is no evidence from randomized control trials to support the statement 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

85 The Defendants virtually ignored the serious 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, particularly in the context of non-cancer chronic pain.

86 For much of the Class Period, the Defendants failed to disclose as a serious warning the risks of overdose, addiction, respiratory depression, OUD and death that are associated with opioid use. The Defendants continue to downplay the risk of being

diagnosed with OUD and the possibility of years of treatment of OUD that require the consumption of another prescription opioid.

87 The Defendants also ignored or downplayed the risk of the development of opioid-induced hyperalgesia ("**OIH**"). OIH 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 tolerance to a drug, increased use of opioids by sufferers of hyperalgesia worsens the pain.

88 OIH often induced physicians to mistakenly increase their patients' opioid dosage, as the defendants repeatedly claimed that this was the appropriate response to ineffective pain relief at a given dose. This increase in dosage, in turn, greatly increased these patients' risk of developing OUD.

89 The paradoxical nature of OIH has been described in scientific papers going back at least to 2011. However, information clearly explaining this response to opioids, and describing the symptoms that differentiate OIH from opioid tolerance and withdrawal, was only introduced years later by certain Defendants in documents such as their Product Monographs.

90 By way of example, Defendant Teva's 2017 Product Monograph for Teva-Oxycodan did not contain detailed information about hyperalgesia. In contrast, in May 2024, it was explained in the Product Monograph for this product that "*Opioid induced hyperalgesia (OIH) is a paradoxical response to an opioid in which there is an increase in pain perception despite stable or increased opioid exposure. It differs from tolerance, in which higher opioid doses are required to achieve the same analgesic effect or treat recurring pain*" and, in Part III, the Patient Medication Information, OIH was explained to patients for the first time: "*Taking opioids for pain can sometimes have the unintended effect of making your pain feel worse (opioid-induced hyperalgesia) even though your opioid dose has been unchanged or increased. This can also include feeling pain in new places in your body…*", as appears from the 2017 and 2024 Product Monographs for Teva-Oxycodan, communicated herewith, *en liasse*, as **EXHIBIT P-23**.

91 In the absence of evidence to support the safe use of their opioid products, Defendants marketed such products without sufficient warnings of the risks until they were directed to do so by Health Canada, even with regard to children. For example, in 2019, Health Canada published a summary of opioid-containing products indicated for cough and colds "*which found limited evidence to support the effectiveness of these products in children and adolescents*" and asked manufacturers to update their product safety information in this regard. A subsequent communication by Health Canada posted on August 24, 2020, included a list of the targeted opioid products and their manufacturers, as appears from the Health Canada Information update dated February 18, 2019 and the Health

professional risk communication from Health Canada posted on August 24, 2020, communicated herewith, *en liasse*, as **EXHIBIT P-24**.

92 It was only after this latter communication on August 24, 2020, that Defendants Teva, Sandoz, Pharmascience, Atlas and Riva, signed and published safety information about the risk of children and adolescents developing OUD from the use of their opioid medications containing narcotics such as codeine and hydrocodone, as appears from the 2020 publication entitled "Important Safety Information on Prescription Cough and Cold Products Containing Opioids and the Risk of Opioid Use Disorder in Children and Adolescents (< 18 years of age)", a copy of which is communicated herewith as **EXHIBIT P-25.**

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

93 While the Defendants knew that these claims were incorrect, they nevertheless promoted the misconception that certain slow-release opioid formulations provided 12-hour (or longer) 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.

94 The Defendants, however, knew that these claims were false and that their drugs would not provide such extended pain relief for most patients.

95 Experiencing pain before it is time for the scheduled next dose of opioids, known as "end-of-dose failure" or "breakthrough pain", results in patients experiencing symptoms of withdrawal, intense cravings as well as euphoric highs with their next dose, all of which can promote addiction.

96 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 breakthrough pain and to tide them over until it is time for their next dose, which increases the overall opioids that they are taking.

97 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.

98 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

99 Continued use of opioids causes users to develop tolerance to the drug and results in a need for higher doses to obtain the same effects. This in turn increases the risk of withdrawal, addiction, overdose, OUD and death.

100 Tolerance is defined as either of the following: the need for markedly increased amounts of opioids to achieve intoxication or desired effect; and/or a markedly diminished effect with continued use of the same amount of opioid (EXHIBIT P-5).

101 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.

102 The Defendants misled health care professionals and patients by failing to warn them that increased use of opioids also increases the risks and dangers associated with such use.

(3) The Spreading of the Misrepresentations

103 The Defendants engaged in aggressive marketing and sales practices which were entirely inappropriate for the distribution of dangerous, addictive drugs.

104 The Defendants spread their Misrepresentations:

104.1 to health care professionals;

104.2 to medical students;

104.3 by funding patient advocacy groups; and

104.4 to the public.

The spreading of Misrepresentations in Product Monographs and the CPS

105 As explained below, information about every prescription drug is made available to health care professionals and the public in Product Monographs and, in most cases, in the CPS.

Product Monographs

106 Prescription medicines in Canada are required to have a Product Monograph which contains prescribing information, warnings and safety information for the medication. The holder of the drug identification number (DIN) assigned by Health Canada to a drug product prior to it being marketed in Canada is responsible for the

drug's Product Monograph regardless of whether the holder is the manufacturer or the distributor of the drug.

107 Manufacturers of both brand name and generic drugs develop the Product Monographs for their drugs which are then reviewed by Health Canada, as appears from the Government of Canada's publication entitled "Access to Generic Drugs in Canada" (as modified on May 7, 2024) and communicated herewith as **EXHIBIT P-26**. As also appears from EXHIBIT P-26, the Food and Drug Regulations under the *Food and Drugs Act*, as well as the Narcotic Control Regulations apply to all drugs, including generic drugs.

108 As appears from EXHIBIT P-8, Product Monograph guidelines were first published by Health Canada in 1976 and revised in 1989. The objective of the 1989 revision was to make the information more useful and accessible to both health care professionals and consumers.

109 As set out in Health Canada's Guidance Document for Product Monographs adopted in 2013 and effective on June 1, 2014, communicated herewith as **EXHIBIT P-27**, "*the prime objective of a product monograph is to provide essential information for* ***healthcare professionals, patients and consumers*** *that may be required for the safe and effective use of a drug*."

110 The most recent Product Monograph guidelines were made effective as at December 23, 2024. A copy of the 2024 Product Monograph guidelines is communicated herewith as **EXHIBIT P-28**. As explained therein, Product Monographs are structured as follows:

- The title page provides information which includes the name of the manufacturer of the medication and, when appropriate, the name of the distributor/importer of the drug.

- Part I contains Health Professional Information required for the safe and appropriate prescribing, dispensing and administering of the medication. Part I identifies the information to be provided if a package insert is included with a new drug product, as well as the information to be provided as part of all professional material and that may be used for promotional and advertising purposes.

- Part II contains more in-depth and complete scientific/research information such as toxicology and data from animal studies and human clinical trials and microbiology. It complements and extends the information contained in Part I.

- Part III is entitled "Patient Medication Information". This section is intended to provide in plain language information that should be provided to the patient regarding the use of the drug and what the potential side effects are.

(In 2004, when it was first introduced, this section was entitled “Consumer Information” to specifically provide information for the consumer. In 2014, Part III was renamed “Patient Medication Information”).

111 Exceptionally, certain DIN holders may be allowed to provide information about the drug in another format. As explained on Health Canada’s website addressing frequently asked questions (effective date November 1, 2020), when a Product Monograph is not deemed necessary, *“In such circumstances other information, such as package labels and inserts, prescribing information, or other drug information are produced and these must be consistent with authorized conditions of use*”, a copy of said website is communicated herewith as **EXHIBIT P-29**.

112 Pursuant to requests made to Health Canada beginning in 2019, Product Monographs (or comparable documents) for the Subject Opioids during the Class Period have been communicated, and continue to be communicated, to the Plaintiff on a sporadic basis. References herein are to the Defendants’ Product Monographs (or comparable documents) if such have been obtained by the Plaintiff, otherwise references are made to the CPS for the product.

The Compendium of Pharmaceuticals and Specialties

113 Since 1960, the CPS has been published annually by the Canadian Pharmacists Association. The CPS is a reference book that contains drug monographs. The earlier CPSs contained a separate section entitled “Information for the Patient”, which was provided for health care professionals to use in keeping their patients informed, as appears, by way of example, an extract of the 1996 CPS, communicated herewith as **EXHIBIT P-30**.

114 The CPS is the most widely used source of drug information in Canada, and is heavily financed by the pharmaceutical industry. Distribution decreased somewhat when a price began to be charged for the CPS subscription.

115 For years, the CPS was published in a hard cover paper format and was provided, initially free of charge and, beginning in 1979, for a subscription fee, to all physicians and pharmacists in Canada annually. The CPS became available electronically in 2004 and, after 2022, was no longer available in a paper format, as appears from a document entitled “CPS: Drug Information 2022*”,* **EXHIBIT P-31.**

116 In most cases, the product information provided in the CPS is not identical to the Product Monograph for the Subject Opioid, although the CPS does contain the prescribing information for healthcare professionals (i.e., Part I of the Product Monograph).

117 Significantly, the CPS contains advertisements promoting the use of certain drugs, including, in the earlier part of the Class Period, advertisements for opioid products.

Misrepresentations in Product Monographs and in the CPS

118 The Defendants misrepresented the risks and benefits associated with opioid use in their Product Monographs (and comparable documents), including the Information for Patients, and in the CPSs.

119 Misrepresentations, whether assertions or omissions, within a Product Monograph (or comparable document) are particularly egregious because a Product Monograph is described by Health Canada to be "*a factual, scientific document on the drug product that, **devoid of promotional material**, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug*", as set out in the 2024 Health Canada Guidance Document for Product Monographs (EXHIBIT P-28).

120 In some cases, the Product Monographs for opioids already on the market for cancer pain were subsequently revised to advise that the same drug was safe and effective for chronic non-cancer pain, although there was little or no evidence to support such use. This misleading practice led to health care professionals and their patients being misinformed about the dangers inherent in the opioid drugs that were being prescribed.

121 By way of example, the fentanyl patch manufactured and sold by Defendant Janssen in Canada under the brand-name Duragesic was for many years indicated for use "*in the management of **chronic cancer pain** in patients requiring continuous opioid analgesia*", as appears from the Product Monograph dated April 1, 1997 communicated herewith as **EXHIBIT P-32**. This restriction on the use of the Duragesic patch was employed in Defendant Janssen's Product Monographs until 2001.

121.1 In June 2001, the Product Monograph for the Duragesic fentanyl patch was modified to indicate that it was for use "*in the management of **chronic pain** in patients requiring continuous opioid analgesia for pain that is not optimally managed with weak or short-acting opioids such as acetaminophen-opioid combinations or PRN ("as needed") dosing with short-acting opioids*", as appears from the Product Monograph dated June 28, 2001 communicated herewith as **EXHIBIT P-33**. As no recommended maximum dose was provided, Duragesic could be marketed with no upper dose threshold.

121.2 In EXHIBIT P-33, Defendant Janssen reproduced the following assertion that had appeared in its previous Product Monographs for Duragesic for cancer pain, although there was no independent evidence that the assertion was correct in the context of chronic non-cancer pain: "***Iatrogenic addiction following opioid administration is relatively rare**. Physicians*

should not let concerns of physical dependence deter them from using adequate amounts of opioids in the management of severe pain."

121.3 As appears from page 35 of EXHIBIT P-33, part of the "Bibliography (clinical)" section of the 2001 Product Monograph for Duragesic, articles were added to the list of references to suggest to the reader that there was scientific support for the use of opioids to treat chronic non-malignant pain (items 23 to 27). However, none of these additional articles constitute independent research: as appears in the Bibliography, the first three of these articles were published in a Janssen Research Report and, in all five of the cited articles, the lead author (as well as other authors) received support from a Janssen-related entity and/or was employed by a Janssen-related entity when the study was performed. With respect to the two cited articles where the relationship with a Janssen-related entity is not explicit in the Product Monograph:

- Item 26: the footnote to the paper states that the study was supported by a grant from Janssen Research Foundation, Belgium and that author LA [Laurie Allan] receives support from both Janssen-Cilag, the manufacturer of transdermal fentanyl (Durogesic) and author EK [Eija Kalso] has been reimbursed by Janssen-Cilag for participation at a meeting sponsored by Janssen-Cilag; and

- Item 27: it identifies author Ludo Haazen as affiliated with the Janssen Research Foundation.

the two articles are communicated herewith, *en liasse*, as **EXHIBIT P-34**.

121.4 In 2001, at the same time Defendant Janssen revised its Product Monograph to broaden the market for Duragesic, it adopted the same assertion that appeared in the 1997 CPS related to OxyContin, EXHIBIT P-14, that, in the event of breakthrough pain, "*it is generally an indication for a dosage increase*". Moreover, this message was further reinforced in the section entitled "Information for the Patient", where Defendant Janssen asserted that the doctor may prescribe additional pain medication if there is breakthrough pain or if the patient becomes tolerant to the drug and a higher dose is required to produce the same result.

122 Similarly, in 1995, with regard to the morphine capsules manufactured and sold under the brand-name Kadian the information provided was based only on studies in healthy and cancer patients and the potential for dependence was indicated as "*not a prime concern in the management of terminally ill patients or patients in severe pain*", as appears from Faulding Canada Inc.'s Product Monograph dated September 21, 1995 communicated herewith as **EXHIBIT P-35**.

122.1 However, by April 2000, the information being provided in the Product Monograph was modified to include a reference to breakthrough pain as being "*generally an indication for dosage increase" and, in the section entitled "Information for the Consumer*", the reply provided to the question "***Is Kadian addictive?***", is "*People who have taken Kadian for several weeks may develop physical dependence,* ***but this is not the same as addiction***", as appears from the Product Monograph dated April 27, 2000, by Knoll Pharma Inc. (which amalgamated with Defendant Abbott in 2001), communicated herewith as **EXHIBIT P-36**.

122.2 These misrepresentations remained in subsequent Product Monographs for the opioid drug Kadian and were only removed in August 2014 when a Serious Warnings and Precautions Box was introduced. See, for example, the Product Monograph dated August 1, 2014 distributed by Defendant Abbott, communicated herewith as **EXHIBIT P-37**.

122.3 However, despite introducing the Serious Warnings and Precautions Box, in 2014, the warnings in EXHIBIT P-37 were inappropriately obfuscated by the use of statements such as: "*Concerns about abuse, addiction, and diversion should not prevent the proper management of pain*"; and "*Tolerance and/or physical dependence on regular opioid use in a patient in pain are not, by themselves, evidence of an addictive disorder*".

123 As another example, the Information for Patients generated by Defendant Purdue for the years 1997 to 2001 in respect of Hydromorph Contin contained no warnings about overdose or physical addiction related to the use of the drug. By way of example, copies of the extracts of the 1997 to 2001 CPSs are communicated herewith, en liasse, as **EXHIBIT P-38**.

123.1 While in 2002 a warning was added to the Information for Patients, the addictive nature of the medication was downplayed: "*Patients who have taken Hydromorph Contin for a period of time may develop physical dependence, however, this is not the same as addiction*", as appears from the extract 2002 CPS communicated herewith as **EXHIBIT P-39**.

123.2 While the product information for Hydromorph Contin in the CPSs for the years 1997, 2001 and 2002 (EXHIBIT P-38 and EXHIBIT P-39) contained a warning, such warning indicated that "*Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated*." The product information also included assertion that there is no upper limit to the dose of the drug: "*There is no intrinsic limit to the analgesic effect of hydromorphone; like morphine, adequate doses will relieve even the most severe pain*."

124 In the case of Sandoz Oxycodone/Acetaminophen, even in late 2011, the warning provided in the Product Monograph was neither detailed nor forceful. The warning regarding tolerance, addiction and dependence was a general warning for all "oral medication containing opioids" rather than being product specific: "*Psychic dependence, physical dependence and tolerance **may develop** upon repeated administration of oxycodone and acetaminophen and should be prescribed and administered with the same degree of caution appropriate to the use of other oral medication containing opioids*", as appears from the Product Monograph dated November 11, 2011 communicated herewith as **EXHIBIT P-40**.

124.1 In contrast, by 2018, the Product Monograph for Sandoz Oxycodone/Acetaminophen contained a Serious Warnings and Precautions Box which indicates the risks of addiction, abuse, and misuse with opioids, even at recommended doses of this product. However, like the other Defendants, Defendant Sandoz also included the following statements downplaying the risks of harm from opioid use: "*However, concerns about abuse, addiction, and diversion should not prevent the proper management of pain*"; and "*Tolerance, as well as physical dependence, may develop upon repeated administration of opioids and are not by themselves evidence of an addictive disorder or abuse*", as appears from the Product Monograph dated July 23, 2018 communicated herewith as **EXHIBIT P-41**.

125 In the case of Supeudol manufactured by Defendant Sandoz, even though the CPSs for 1996, 1998, 2000, and 2002 included a section for Information for Patients for many of the Subject Opioids, the listing for Supeudol did not provide such section. Extracts of the 1996, 1998, 2000 and 2002 CPS are communicated herewith, *en liasse*, as **EXHIBIT P-42**.

125.1 Like with Hydromorph Contin, as appears from EXHIBIT P-42, the CPSs 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 tolerance, addiction and dependence is a general warning for all "analgésiques narcotiques" or "opiacés" rather than being product specific to Supeudol: "*La tolérance, la dépendance psychique et physique **peuvent** survenir chez les patients recevant des analgésiques narcotiques*".

125.2 The 2010 Product Monograph for Supeudol contains the following misleading statements, that: *"[t]here is no intrinsic limit to the analgesic effect of oxycodone; like morphine, adequate doses will relieve even the most severe pain";"[d]rug abuse is not a problem in patients with pain in whom oxycodone is appropriately indicated*"; and, if breakthrough pain occurs, "*it is generally an indication for a dosage increase*", as appears from

the Product Monograph for Supeudol dated October 12, 2010, communicated herewith as **EXHIBIT P-43**.

126 All these warnings were clearly insufficient. As mentioned above, without any admission regarding the sufficiency of the current warnings, almost all the Product Monographs for the Subject Opioids now contain Serious Warnings and Precautions Boxes that warns of the risk of addiction, dependence and overdose, even when the medication is used as prescribed.

127 Consistent with the updated 2017 Guidelines for prescribing opioids, more recent Product Monographs also indicate that opioids 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 2017 Canadian Opioid Prescribing Guideline (EXHIBIT P-22) and the 2018 Product Monographs for Hydromorph-Contin, Jurnista and Supeudol, copies of which are communicated herewith, *en liasse*, as **EXHIBIT P-44.**

128 Surprisingly, despite what is known today about the risks associated with prescription opioids, there remain examples of Product Monographs that do not include in the Serious Warnings and Precautions Boxes any warning that the use of opioids may cause addiction, dependence and overdose, as appears from the Product Monograph of Teva-Oxycodan dated May 22, 2024, communicated herewith as **EXHIBIT P-45**.

The spreading of Misrepresentations to health care professionals by ads and other promotional means

129 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. These sales representatives were paid bonuses based on the number of prescriptions issued by health-care providers that they visited. The Defendants also used a variety of other marketing strategies, such as free samples, direct physician payments and online advertising.

130 The Defendants also promoted the use of opioids by placing ads in medical journals and the CPSs which deceptively downplayed the risks of addiction, omitted negative side-effects and overstated the benefits of the use of opioids for the treatment of chronic pain.

131 Studies cited in these publications were almost always either funded by pharmaceutical organizations or directly authored by their employees.

132 Print advertisements of opioid drugs appeared in American and Canadian medical journals as well as in publications specifically geared towards Quebec health

professionals, including *Le médecin du Québec, Le journal de l'association médical canadienne* and in the CPSs which are published in French as well as in English.

133 In its ads introducing OxyContin to the Canadian market, Defendant Purdue promoted the drug's use as part of a strategy of "*opioid rotation*" to be used with its controlled-release opioid products MS Contin and Hydromorph Contin, products for use for "*patients with severe **cancer pain***", as appears from a copy of the ad published in the December 1996 issue of the Canadian Family Physician, communicated herewith as **EXHIBIT P-46**.

134 In mid-2000, the ads for Defendant Purdue's MS Contin stated clearly that this morphine containing opioid was "*for dependable 24 hour cancer pain control.*" However, by September 2000, the ads removed any reference to cancer pain, as appears from the ads published in the Canadian Medical Association Journal in the issues published on April 4 and September 5, 2000, communicated herewith, *en liasse*, as **EXHIBIT P-47**.

135 In contrast to the earlier ads, in 2004, Defendant Purdue advertised Hydromorph Contin without indicating that the drug was for the treatment of cancer pain. The ad encouraged health care professionals to prescribe the drug with its tagline "*C'est votre patient. Vous pouver l'aider*" and 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 Hydromorph Contin ad in the 2004 CPS is communicated herewith as **EXHIBIT P-48.**

136 In the 2007 CPS, Defendant Purdue expressly 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-49**.

137 The warnings contained in the fine print of the 2007 Hydromorph Contin ad (EXHIBIT P-49) 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.

138 While the 2007 Hydromorph Contin ad (EXHIBIT P-49) 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.

139 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-50**.

140 Similarly, in 2005 Defendant Purdue advertised Codeine Contin to medical professionals for light to moderate **chronic pain**, as appears from an advertisement in a publication called *Le médecin du Québec* and accompanying therapeutic classification, communicated herewith as **EXHIBIT P-51**. 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 therapeutic classification 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*".

141 The change in prescribed uses of their opioid products, from cancer pain to chronic pain, is also evident from the ads placed in medical journals by other Defendants.

142 As indicated earlier in the context of its Product Monographs, prior to December 2001, Defendant Janssen (known at the time as Janssen-Ortho Inc.) advertised the Duragesic fentanyl patch solely to alleviate **cancer pain** by providing relief that lasted 3 days, as appears from a 1998 Duragesic ad and accompanying abbreviated therapeutic information found in *Le médecin du Québec*, communicated herewith as **EXHIBIT P-52**. The ad contains no warnings about addiction, dependence or abuse.

143 However, beginning in December 2001, Defendant Janssen promoted a new use for the drug Duragesic, namely to replace weaker opioids prescribed for chronic pain, as appears from the December 2001 ad for Duragesic, communicated herewith as **EXHIBIT P-53**.

144 Similarly, the caption in a 2002 advertisement for Duragesic in *Le médecin du Québec* and accompanying CPS information, communicated herewith as **EXHIBIT P-54**, 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 time-released 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 CPS information

for Duragesic 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.*

145 Moreover, to give the appearance of scientific credibility to the asserted benefits of Duragesic, Defendant Janssen cited three published journal articles at the bottom of this ad found in the *Le médecin du Québec* (EXHIBIT P-54). However, the research reported in these studies was only related to cancer pain or was supported by grants from Janssen-related entities and/or authored by employees of Janssen-related entities.

146 The marketing strategy developed in the U.S. for Duragesic in the context of chronic pain highlighted the concept of patients returning to a more normal life, as more fully appears from the document entitled "Duragesic Ad Campaign Overview", included in a Duragesic Positioning Evolution Overview, June 1, 2002, communicated as **EXHIBIT P-55**.

147 As appears from EXHIBIT P-55, beginning in October 2000, the core campaign journal ads were to employ the tagline "**Life uninterrupted**". This strategy and tagline were also employed in the Canadian market, including in Quebec.

148 For example, as appears from EXHIBITS P-53 and P-54, the ads for Duragesic, employed the tagline: "*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 ads also mentioned, in larger print, that Duragesic had less risk of adverse secondary side-effects, like constipation, nausea and vomiting.

149 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 health care professionals that purported to show that certain opioids could be used as effective treatments for chronic pain and breakthrough pain. By way of example:

- Conference held at the University of Sherbrooke on April 8, 2011: under the theme "*Symposium 2011 sur la douleur – Les narcotiques*" (sponsors included Defendants Purdue and Janssen);

- the 13th World Congress devoted to pain research and treatment, held in Montreal in 2010 (sponsors included Defendants Purdue and Janssen); and

- 2013 Canadian Pharmacists Association's conference (sponsors included Defendants Teva, Johnson & Johnson (related to Defendant Janssen) and Apotex).

the whole as appears from a copy of such programs (extracts) communicated herewith, *en liasse*, **EXHIBIT P-56**.

150 Other collaborative promotional efforts were employed by the Defendants. For example, Defendant Pro Doc's monthly newsletters were used to encourage the purchase of products such as their fentanyl patch because of the "*risque de pertes d'inventaire*" and to inform readers of the "*conférences-causeries*" being launched collaboratively by Defendants Pro Doc, Apotex and Pharmascience, as appears by way of example from the newsletter published in September 2014 entitled "Quoi de neuf chez Pro Doc?" communicated herewith as **EXHIBIT P-57**.

The spreading of Misrepresentations to medical students

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

152 Certain Defendants supported the pain curriculum for students at several Canadian universities. Medical students received information about opioids in educational sessions that were developed using funding from these Defendants. The course material contained information that aligned with the interests of these companies by minimizing opioid-related harms relative to other analgesics and overstating the evidence for their effectiveness.

153 For example, the textbook "*Managing Pain – The Canadian Healthcare Professional's Reference*", was provided to students free of charge. The textbook contained false assertions, such as the statement that "… ***it is exceedingly unlikely that a physician can create an addict from an opioid-naïve patient by the prescription of opioids for pain***" and promoted the legitimacy of pseudoaddiction (i.e., patients are not addicted they just need increased pain relief), as appears from

chapter 8 entitled Opioids, Pain and Addiction written by Dr. Roman Jovey of the textbook "*Managing Pain – The Canadian Healthcare Professional's Reference*" copyrighted in 2002 by Defendant Purdue, as appears from an extract of the textbook communicated herewith as **EXHIBIT P-58**.

154 The forward to the textbook was written by Dr. Russell Portenoy whom, as explained more fully below, was a non-independent key opinion leader advocating for the greater use of opioids. Dr. Portenoy asserted in EXHIBIT P-58 that, because of the stigma associated with opioids, they were being under-prescribed to treat chronic pain.

The spreading of Misrepresentations by funding patient advocacy groups

155 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.

156 Indeed, the Defendants attempted to expand the prescription of opioids by financing organizations who promoted this practice in the name of effective treatment of chronic pain. One of the campaigns led by these organizations was to attack doctors who had concerns about the risk of addiction as suffering from "opiophobia". This term later found its way into guidelines of the World Health Organization. These guidelines were only discontinued almost a decade later, in June 2019, when it was recognized that the content had been influenced by the pharmaceutical industry.

157 The Johnson & Johnson family of companies (which includes Defendant Janssen) both manufactures opioids and supplies active ingredients to other pharmaceutical companies and, therefore, was incentivized to use both competitive and coordinated corporate strategies of influence.

158 Defendants including Purdue and Janssen provided grants to sponsor the Canadian Pain Society's 2001 "Patient Pain Manifesto", which was announced at a conference at the Delta Hotel in Montreal. A backgrounder included with a press release on the subject stated:

> ***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 (in English and French), dated May 11, 2001, communicated herewith as **EXHIBIT P-59**.

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

> *Did you know that*
>
> ***It is extremely rare that people become addicted to the pain killers they are given for pain****.*
>
> *Problems with pain killers (constipation, itching, nausea) can be controlled.*

160 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*".

161 In 2002, the Canadian Pain Society published a consensus statement and guidelines on the "*Use of opioid analgesics for the treatment of chronic non-cancer pain*", a copy of which is communicated herewith as **EXHIBIT P-60**, which promoted, *inter alia*, that:

- *"Pain of all types is undertreated in our society";*
- *"Health professionals' fears regarding iatrogenic addiction…create a significant barrier to the optimum prescribing of opioids for pain";*
- *"Tolerance and/or physical dependence on regular opioid use in a patient in pain are not, by themselves, evidence of an addictive disorder";*
- *"A patient with a past history of, or risk factors for, addiction should not necessarily be precluded from a careful trial of opioid therapy…"; and*
- *"Opioid analgesics are generally safe medications when prescribed with appropriate monitoring."*

162 As another example, some Defendants 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-61**, 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-62**.

163 The Misrepresentations were also spread specifically in Quebec by the Société Québécoise de la douleur (the "**SQD**"), a group financed by the opioid pharmaceutical industry. In fact, the President of SQD confirmed that: *"… the finances of the Society are excellent, in large part due to the generous support by a few of those pharmaceutical companies whose products include pain-related medications …",* as appears from the President's letter published in the SQD's newsletter for May 2000 (Vol. 5, no. 2), communicated herewith as **EXHIBIT P-63**.

164 The SQD downplayed the risk of addiction in the information communicated to its members. For example, in another letter written by the President of the SQD in July 2000, he stated that the risk of opioid addiction was less than 0.1%, and championed the use of opioids stating that "*nous pouvons et devons utilizer ces médicaments pour tenter de soulager nos patients,"* as appears from a letter, published in the SQD's newsletter for July 2000 (Vol. 5, no. 4), communicated herewith as **EXHIBIT P-64**.

165 In 2004, the SQD newsletter's editor published an article in which he asserted that: "*Les opioïdes: ce sont les meilleurs analgésiques dont on dispose, par contre ils peuvent parfois causer une dépendance,* ***mais rarement en douleur chronique***", as appears from the SQD's newsletter for September 2004 (Vol. 9, no. 2), communicated herewith as **EXHIBIT P-65**.

166 As appears from this newsletter, the editor had recently attended a joint meeting of the American Pain Society and the Canadian Pain Society, and links to "useful" websites containing publications by American organizations were provided to the more than a hundred members of the SQD.

167 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.

168 The Defendants with American affiliates employed the same messages to promote their opioid products as were being used in the U.S. and many such promotions

were available in Canada. For example, Pricara (the American division of Ortho-McNeil Janssen Pharmaceuticals Inc.) provided funding for the website "*Letstalkpain.org*", which promoted the use of opioids and downplayed the risks of addiction. In a section of such website titled "Understanding Tolerance, Physical Dependence and Addiction", a copy of which is communicated herewith as **EXHIBIT P-66**, the false notion of "*pseudoaddiction*" was promoted, as well as the false statement that for many patients, opioids were the only effective treatment option:

> *A related term is pseudoaddiction, which refers to patient behaviors 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.

169 Similarly, Teva Pharmaceutical Industries Limited (one of the shareholders of Defendant Teva) provided financial support, clinical input and other expertise for "Pain Matters", a television program produced by the Discovery Channel in 2015 in collaboration with 7 advocacy organizations. This program purported to provide expertise about pain management, including the science behind chronic pain and the effects of untreated pain. In fact, it falsely claimed that:

169.1 Increased opioid prescriptions since the 1990s were due to "*improved abilities to assess pain and our willingness to treat chronic pain with a treatment regimen that includes opioids".*

169.2 Although they exist, risks of addiction and abuse are relatively low, especially for patients without a history of abuse and addiction, and patients can be effectively screened to identify these risks.

170 In some instances, the Defendants withdrew their funding from patient advocacy groups who were no longer willing to promote their misrepresentations.

The spreading of Misrepresentations to the public

171 The Defendants recruited and paid professionals to advocate for the widespread use of opioids 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. Many of the medical studies cited in support of

the misleading information included in the Defendants' Product Monographs were conducted by such medical professionals, including Drs. Russell Portenoy.

172 Notably, Dr. 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 conferences.

173 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.

174 On January 17, 2019, Dr. Portenoy acknowledged in a sworn statement that his work had been used by the pharmaceutical industry to promote a strongly positive message about opioid therapy to prescribers by overstating the benefits and understating the risks, although ***"[A]ddiction and overdoses were certainly known risks*** **[to the manufacturers]**, *since they were key in discouraging the use of opioids in clinical practice at the start of my career* [in 1980]", as appears from the Declaration of Dr. Portenoy executed in New York on January 17, 2019 (identified as Ex. S0879 in proceedings instituted in the State of Oklahoma) communicated herewith as **EXHIBIT P-67**.

e. Litigation in the U.S. against the opioid pharmaceutical industry

175 The opioid crisis in the U.S. is well documented and continues to devastate that population. There have been countless lawsuits instituted against the U.S. opioid pharmaceuticals industry, including against many companies that are related to the Defendants in the present action. Almost all of these actions have settled for very significant amounts.

176 Two of the most publicized cases involve the parent entities of Defendants Purdue and Janssen.

177 In December 2024, the U.S. Supreme Court refused to allow a multi-billion-dollar bankruptcy plan for U.S. Purdue debtors to proceed, siding with those who objected to the plan on the basis that it improperly protected the very individuals who had played a significant role in contributing to the opioid epidemic. As a result, the negotiations to develop a new plan are still on-going.

178 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 ordered 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-68**.

179 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)*

- *A key element of Defendants' opioid marketing strategy to overcome barriers to liberal opioid prescribing was its promotion of the concept that pain was undertreated (creating a problem) and increased opioid prescribing was the solution…. Defendants trained their Oklahoma sales representatives on how to use these campaigns, including through the use of "emotional selling" for opioids by convincing physicians that undertreated pain was harming patients. (para. 20)*

- *Defendants used the phrase "pseudoaddiction" to convince doctors that patients who exhibited signs of addiction […] were not actually suffering from addiction, but from the undertreatment of pain, and the solution, according to Defendants' marketing was to prescribe more opioids. (para. 22)*

- *Defendants trained their sales reps to target high-opioid prescribing physicians, including pain specialists and primary care physicians…. Defendants particularly [targeted] primary care physicians with their opioid marketing, identifying them as "Key Customer[s]" for Defendants' pain franchise. (para. 30)*

- *Defendants made substantial payments to a variety of different pain advocacy groups and organizations that influenced prescribing physicians and other health professionals. (para. 36)*

- *Defendants made claims, unsupported by any high quality evidence, that opioids could be safely used for chronic, non-terminal pain. Defendants used the phrase "pain as the 'fifth vital sign' " to influence doctors to liberally prescribe opioids. (para. 57)*

180 Although on November 9, 2021, a majority of the Supreme Court of Oklahoma overturned the decision of Justice Balkman on the basis that the state's public nuisance statute could not be extended to the manufacturing, marketing and selling

of a product, the findings of fact were not contradicted, as appears from a copy of such judgment, communicated herewith as **EXHIBIT P-69**.

f. The national opioid crisis and its impact in Quebec

181 The safety defect in the Subject Opioids and the Defendants' Misrepresentations with regard to their opioid products have led to an opioid crisis in Canada. Both the federal and provincial governments have taken action intended to mitigate the extensive harm to Canadians caused by opioid use.

182 In addition to mandating warning labels about the significant risks associated with prescription opioid use, 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-70**. The letter states that "*evidence suggests that the marketing and advertising of opioids has contributed to increased prescription sales and availability of opi*oids".

183 As stated in EXHIBIT P-70:

> *The pharmaceutical industry's marketing practices can take many forms of direct and indirect activities and incentives, including, for example, manufacturer-sponsored presentations at conferences, continuing education programs, advertisements in medical journals, and personal visits from sales representatives. It can also include use of promotional brochures, fees for research, consulting or speaking, reimbursement for travel and hospitality expenses to attend industry-sponsored events, and gifts of meals, equipment, and medical journals and texts.*

184 As it was not mandatory for the companies to reply, there were no sanctions for failing to do so.

185 Many of these responses that were provided to the Minister of Health were framed to distinguish "marketing and advertising" from "information provision", as appears from the response letters provided by Defendants Purdue and Pro Doc, copies of which are communicated herewith as **EXHIBIT P-71**. This response was an attempt to distinguish marketing from the information provided in Product Monographs, although, as indicated above, Misrepresentations in such documents during the Class Period were intended to influence healthcare professionals and the public and promote the use of their opioid products.

186 Notably, a number of the manufacturers of generic opioid products asserted that they did not market or promote opioid products to "doctors" or "prescribers" but were

silent with regard to the issue of promotion to other health care professionals such as pharmacists. By way of example, copies of the response letters sent by Defendants Rambaxy (Sun Pharma), Apotex, Pharmascience and Teva are communicated herewith, *en liasse*, as **EXHIBIT P-72**.

187 As a consequence of years of the false promotion of prescription opioids "*as low-risk, non-addictive, effective treatments*" for pain, by 2018, almost one in eight Canadians were being prescribed opioids, as appears from a July 2020 publication by the Canadian Centre on Substance Use and Addiction (**CCSA**) entitled "*Prescription Opioids*", communicated herewith as **EXHIBIT P-73**.

188 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 study conducted by the Canadian Institute for Health Information ("**CIHI**") (the "**2018 CIHI Report on Opioid-Related Harms**"), communicated herewith as **EXHIBIT P-74**.

189 Between January 2016 and June 2024, there were a total of 49,105 apparent opioid toxicity deaths reported by the Government of Canada on its webpage entitled "Opioid- and Stimulant-Related harms in Canada: Key Findings (updated December 23, 2024)", as appears from a copy of the webpage communicated herewith as **EXHIBIT P-75**.

190 The situation in Quebec is no less dire.

191 Unintentional poisonings in Quebec increased between 1990 and1994 and again from 2005 to 2009, with fatal opioid poisonings rising by 40.9% during the latter period. Notably, 91.3% of these deaths were caused by prescription opioids. These findings are documented in the Institut National de Santé Publique du Québec's 2013 report, "Opioid-related Poisoning Deaths in Québec: 2000-2009", communicated herewith as **EXHIBIT P-76**.

192 In Quebec, deaths related to opioid and other illicit drug use totaled 166 in 2016, 181 in 2017, and 300 between January and September 2018. By the end of 2018, this number had reached 424, with an additional 119 deaths recorded in the first three months of 2019. These figures are documented in the 2019 National Report on Opioid Related Deaths, 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-77**.

193 The impact of the harms caused by opioids in Quebec is being felt more urgently with each passing year. Indeed, between 2011 and 2015, the number of new prescriptions for opioid medications in Quebec rose by 29%, increasing from 1.9 million to 2.4 million, while prescription renewals surged by 44%,

194 Opioid drugs continue to be widely prescribed and dispensed in Quebec. Indeed, in each of the years between 2019 and 2023, Hydromorph Contin and pms-Hydromorphone were among the drugs most often reimbursed by RAMQ, as appears from the publicly available publication entitled “Les 10 médicaments les plus fréquemment payés par la RAMQ” (from 2019 – 2023), communicated herewith as **EXHIBIT P-78**.

195 Notably, the role of generic manufacturers of opioids has become more significant during the Class Period, as the patents on brand-name opioid drugs expired.

196 In Quebec, the market share for generic drugs increased after April 24, 2015 when new rules came into effect which prohibited pharmacists from dispensing the innovator version of the drug rather than the generic version unless the prescribing physician indicated a therapeutic consideration that was recognized by the *Régie de l'assurance maladie du Québec* (RAMQ) or the patient was willing to pay the difference in price.

197 In 2023, almost 77% of all prescription drugs dispensed were generics, as appears from the website of the Canadian Generic Manufacturers Association (the “**CGPA**”), communicated herewith as **EXHIBIT P-79**. The member companies of the CGMA included Defendants Apotex, Sandoz, Pharmascience and Teva.

V. THE PLAINTIFF’S PERSONAL EXPERIENCE

(the French language version of this section is attached hereto as Annex A)

198 The Plaintiff, Jean-François Bourassa, is a resident of the Province of Quebec, and has been treated for OUD since 2017, in both in-patient and out-patient programs, run by the Centre hospitalier de l'Université de Montréal, (the “**CHUM**”), after having been prescribed opioids for more than a decade.

199 Mr. Bourassa was the owner of a roofing business operating in the Laurentian region of Quebec. Prior to the events described below, Mr. Bourassa was active in his business, enjoyed playing sports, and had a full and rewarding life with his young family.

200 On November 27, 2005, at age 34, he was injured due to a fall from a roof. His injuries included multiple fractures to his left fibula and ankle. He was brought by ambulance to the emergency department at the Hôpital Hôtel-Dieu de Saint-Jérôme.

201 While being treated for his injuries at the hospital, Mr. Bourassa was initially given the opioid drug Supeudol (active pharmaceutical ingredient oxycodone) manufactured by Sandoz. Very shortly thereafter, the hospital doctors switched his medicine from Supeudol to the immediate-release drug Dilaudid (active pharmaceutical ingredient hydromorphone), at that time manufactured by Abbott.

202 Mr. Bourassa remained on prescription Dilaudid after his discharge from the hospital on November 28, 2005.

203 Beginning in January 2006 and until mid-2017, Mr. Bourassa was followed by a physician at a private clinic in Saint-Sauveur, specialized in the treatment of pain.

204 From 2006 until he was admitted to the CHUM in May 2017, Mr. Bourassa was dispensed by pharmacies the following prescription opioids for the pain which persisted after his fall :

(i) Dilaudid, manufactured by Abbott and then, starting in or around 2009 by Purdue Pharma, and

(ii) controlled-release Hydromorph Contin (active pharmaceutical ingredient hydromorphone) manufactured by Purdue Pharma.

205 In 2010 and 2013, the immediate-release hydromorphone was periodically dispensed to him as a generic version, PMS-Hydromorphone manufactured by Pharmascience.

206 Over this eleven (11) year period, the prescribed dosages of Dilaudid and Hydromorph Contin increased as Mr. Bourassa became tolerant to these drugs and required ever greater amounts of the medication to obtain some degree of pain relief.

207 In early 2017, Mr. Bourassa acknowledged that despite the large amounts of opioids he was taking, his pain was not being relieved and had become more widespread. He realized he had to do something to try to get some semblance of his life back. After eleven (11) years of taking Dilaudid and Hydromorph Contin, Mr. Bourassa decided that he needed to get treatment to address his dependency on opioids.

208 On March 22 and on April 28, 2017, Mr. Bourassa's doctors sent requisitions on his behalf to the Addiction Unit of Hôpital St-Luc (part of the CHUM since 2017) (the "**Addiction Unit**"). Following these requests, Mr. Bourassa was admitted to the hospital and stayed for eight-days from May 25 to June 2, 2017.

209 During this hospital stay, Mr. Bourassa was, for the first time, diagnosed as suffering from OUD (described as severe), as appears from his hospital admission records in respect of his May 25 to June 2, 2017 in-patient treatment at the CHUM communicated herewith under seal as **EXHIBIT P-80**.

210 During this stay at the hospital in 2017, his doctors began the withdrawal management process by decreasing his daily consumption of prescription opioids. From that time to the present, Mr. Bourassa has been monitored by physicians associated with the CHUM.

211 Following his discharge from the Hôpital St-Luc, Mr. Bourassa continued, as part of the treatment process, to be prescribed Dilaudid and Hydromorph Contin, each in lower dosages.

212 Between November 1 and December 4, 2017, Mr. Bourassa's medication was briefly switched by his doctor to a sustained-release morphine, which was dispensed to him as Teva-Morphine SR manufactured by Teva, and Morphine SR manufactured by Sanis. As well, he was prescribed and dispensed Statex manufactured by Paladin.

213 However, because he did not tolerate the morphine well, on December 4, 2017 his prescriptions were switched back to the combination of Hydromorph Contin and Dilaudid (including the generic versions of Dilaudid).

214 In February 2018, he agreed to be re-admitted to the hospital to embark on a process of Metadol (methadone) induction to treat his OUD.

215 On March 13, 2018, Mr. Bourassa was admitted for a four-day stay at the Addiction Unit. Mr. Bourassa's hospital admission records in respect of his March 13 to 17, 2018 in-patient treatment at the CHUM, communicated herewith under seal as **EXHIBIT P-81**, indicate once again his diagnosis of severe OUD.

216 During his stay at the hospital, he was given Metadol to treat his OUD and manage the withdrawal process, which he has continued to take in various quantities following his discharge from the hospital.

217 On the Metadol substitution treatment, Mr. Bourassa experienced withdrawal symptoms, including cravings, headaches, musculoskeletal pain, chills, episodes of severe sweating, and insomnia.

218 In April 2019, Mr. Bourassa began to be treated at the Clinique Antidouleur du CHUM and his dosages of Metadol were slowly decreased. His treating physician introduced him to certain alternative therapies for pain, including ketamine injections.

219 Mr. Bourassa's physicians have informed him that he will require Metadol treatment for his OUD for the rest of his life. He continues to be prescribed and to use Metadol in combination with small doses of other opioids to manage the symptoms of withdrawal.

The Consequences of his Use of Prescription Opioids and his OUD

220 Mr. Bourassa has greatly suffered, and continues to do so to this very day, from his OUD and its side effects, including severe muscle and bone pain, debilitating

fatigue, chronic insomnia, anxiety, depression, chills, excessive water retention, bloating and sweating.

221 His OUD prevents him from thinking properly, concentrating, sleeping, relaxing and even from enjoying simple pleasures such as reading or watching television. When he takes Metadol, he is only somewhat functional for 9 to 10 hours a day and the rest of the time is unbearable.

222 His addiction to opioids has also caused him to miss many of life's important moments with his children and put great strains on his marriage.

223 Although he was able to work intermittently after a lengthy recovery from his accident in November 2005, he ultimately was unable to continue working due to his OUD.

224 In November 2020, Mr. Bourassa applied for disability benefits under the Quebec Pension Plan, which application was supported by his family doctor, as he does not believe that Mr. Bourassa will ever be able to work again.

VI. CLASS MEMBERS' CAUSE OF ACTION AGAINST THE DEFENDANTS

225 Like the Plaintiff, each Class Member was prescribed and has consumed opioids, produced, manufactured, sold, marketed and/or distributed by the Defendants during the Class Period.

226 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, OUD, marked by having experienced symptoms of at least two of the Diagnostic Criteria.

227 Each Class Member has suffered substantially as a result of their addiction.

228 The safety defect in the Subject Opioids, along with the Defendants' misrepresentations about their products, caused the damages suffered by the Class Members. The Defendants are thus liable to repair the injuries caused to Class Members pursuant to the relevant provisions of the *CCQ*, the *Competition Act* and the *ORDA*.

229 Further, as demonstrated above, 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, OUD and the other side-effects of opioids.

230 Class Members are thus entitled to punitive damages pursuant to the relevant provisions of the *Québec Charter*.

VII. MODE OF RECOVERY

231 The Plaintiff claims $75,000 per Class Member in compensation for non-pecuniary injuries, and claims collective recovery of these amounts.

232 The Plaintiff also claims punitive damages in the amount of $25,000,000$ per Defendant, and also claims collective recovery of these amounts.

233 The Plaintiff proposes that damages awarded to compensate pecuniary injuries suffered by Class Members be adjudicated by individual recovery.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the Class Action of the Plaintiff and the members of the Class against the Defendants;

CONDEMN the Defendants solidarily to pay to each of the Class Members the amount of $75,000 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 institutes 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 at all levels, including the cost of all exhibits, experts, expertise reports and publication of notices.

MONTREAL, January 23, 2025

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ANNEX A

French language version of the section entitled "The Plaintiff's Personal Experience" (paras. 198 to 224):

198. Le Demandeur, Jean-François Bourassa, est un résident de la province de Québec. Il est traité depuis 2017 dans des programmes internes et externes, gérés par le Centre hospitalier de l'Université de Montréal (le « **CHUM** ») pour un trouble lié à la consommation d'opioïdes (« **TCO** »), après s'être fait prescrire des opioïdes pendant plus d'une décennie.

199. M. Bourassa était propriétaire d'une entreprise de toiture opérant dans la région des Laurentides au Québec. Avant les événements décrits ci-après, M. Bourassa était actif dans son entreprise, aimait pratiquer des sports et avait une vie bien remplie avec sa jeune famille.

200. Le 27 novembre 2005, à l'âge de 34 ans, il s'est blessé en tombant d'un toit. Ses blessures comprenaient des fractures multiples au péroné et à la cheville gauche. Il a été amené en ambulance à l'urgence de l'hôpital Hôtel-Dieu de Saint-Jérôme.

201. Pendant qu'il était traité pour ses blessures à l'hôpital, M. Bourassa a d'abord reçu le médicament opioïde Supeudol (ingrédient pharmaceutique actif oxycodone) fabriqué par Sandoz. Puis, peu de temps après, les médecins de l'hôpital ont remplacé le Supeudol par du Dilaudid (ingrédient pharmaceutique actif hydromorphone à libération immédiate), fabriqué à l'époque par Abbott.

202. M. Bourassa est resté sous prescription de Dilaudid après sa sortie de l'hôpital le 28 novembre 2005.

203. À partir de janvier 2006 et jusqu'à la mi-2017, M. Bourassa a été suivi par un médecin d'une clinique privée de Saint-Sauveur, spécialisé dans le traitement de la douleur.

204. De 2006, jusqu'à son admission au CHUM en mai 2017, M. Bourassa s'est vu prescrire et délivrer par des pharmacies des opioïdes pour des douleurs résultant de sa chute, à savoir:

    (i) Dilaudid, fabriqué par Abbott, puis à partir de 2009 par Purdue Pharma; et

    (ii) Hydromorph Contin (ingrédient pharmaceutique actif hydromorphone à libération contrôlée) fabriqué par Purdue Pharma.

205. En 2010 et 2013, l'hydromorphone à libération immédiate lui a été périodiquement délivré par les pharmacies sous la forme d'une version générique, le PMS-Hydromorphone fabriqué par Pharmascience.

206. Au cours de cette période de onze (11) ans, les doses prescrites à M. Bourassa de Dilaudid et d'Hydromorph Contin ont augmenté, car il est devenu tolérant à ces médicaments et n'obtenait plus le même degré de soulagement de la douleur.

207. Au début de 2017, M. Bourassa s'est rendu compte que malgré les quantités importantes d'opioïdes qu'il consommait, sa douleur n'était pas soulagée et s'était généralisée. Il a réalisé qu'il devait faire quelque chose pour essayer de retrouver un semblant de vie. Après onze (11) ans à prendre du Dilaudid et de l'Hydromorph Contin, M. Bourassa a décidé de rentrer en cure de désintoxication.

208. Le 22 mars et le 28 avril 2017, des demandes de cure pour sevrage ont été transmises par ses médecins à l'Unité de toxicomanie de l'Hôpital St-Luc (faisant partie du CHUM depuis 2017) (« l'Unité de toxicomanie ») au nom de M. Bourassa. Suite à ces demandes, M. Bourassa a été admis et a séjourné huit jours à l'Hôpital St-Luc du 25 mai au 2 juin 2017.

209. Lors de cette hospitalisation, M. Bourassa a été diagnostiqué pour la première fois avec un TCO (décrire comme sévère), tel qu'il appert du dossier d'admission pour son hospitalisation au CHUM du 25 mai au 2 juin 2017 produit aux présentes sous scellé comme **PIÈCE P-51.**

210. Lors de son séjour à l'hôpital en 2017, ses médecins ont entamé le processus de sevrage en diminuant sa consommation quotidienne d'opioïdes sur ordonnance. M. Bourassa continue à ce jour à être suivi par des médecins associés au CHUM.

211. Ce processus s'est poursuivi après son congé de l'Hôpital St-Luc et M. Bourassa a donc continué à recevoir du Dilaudid et de l'Hydromorph Contin à de plus faible dose. Le Dilaudid lui a été délivré par les pharmacies en forme de marque ou en forme générique, soit Apo-Hydromorphone fabriqué par Apotex ou PMS-Hydromorphone fabriqué par Pharmascience.

212. Entre le 1er novembre et le 4 décembre 2017, M. Bourassa s'est fait prescrire brièvement par son médecin de la morphine à libération contrôlée, qui lui a été délivrée sous les noms de Teva-Morphine SR fabriquée par Teva, et Morphine SR fabriquée par Sanis. De même, il s'est vu prescrire et délivrer du Statex fabriqué par Paladin.

213. Le 4 décembre 2017, comme il ne tolérait pas bien la morphine, il s'est vu represcrire la combinaison d'Hydromorph Contin et de Dilaudid, pour ce dernier, il a reçu également les versions génériques.

214. En février 2018, il a accepté d'être hospitalisé pour entreprendre un traitement de substitution au Metadol (méthadone) pour son TCO.

215. Le 13 mars 2018, M. Bourassa a été admis pour un séjour de quatre jours à l'Unité de toxicomanie où il a de nouveau reçu le diagnostic de TCO sévère, tel qu'il

appert du dossier d'admission pour son hospitalisation au CHUM du 13 mars au 17 mars 2018 produit aux présentes sous scellé comme **PIÈCE P-52**.

216. Pendant son séjour à l'hôpital, on lui a administré du Metadol pour traiter son TCO et entreprendre son sevrage, qu'il a continué à prendre en diverses quantités depuis sa sortie de l'hôpital.

217. Le traitement de substitution au Metadol a causé à M. Bourassa des symptômes de sevrage, dont des envies impérieuses (cravings), des maux de tête, des douleurs musculo-squelettiques, des frissons, des crises de sudation et de l'insomnie.

218. En avril 2019, M. Bourassa a commencé à être traité à la Clinique Antidouleur du CHUM et ses doses de Métadol ont lentement été diminuées. Son médecin traitant l'a initié à plusieurs thérapies alternatives contre la douleur, dont des perfusions de kétamine.

219. Les médecins de M. Bourassa l'ont informé qu'il aura besoin d'un traitement au Metadol pour son trouble lié à l'utilisation d'opioïdes pour le restant de ses jours. Il continue donc à en consommer, en combinaison avec des petites doses d'autres opioïdes afin de contrôler ses symptômes de sevrage.

Les conséquences de sa consommation d'opioïdes sur ordonnance et de son TCO.

220. M. Bourassa a beaucoup souffert, et continue de souffrir jusqu'à ce jour, du TCO et de ses effets secondaires, y compris de graves douleurs musculaires et osseuses, une fatigue invalidante, une insomnie chronique, de l'anxiété, une dépression, des frissons, une rétention d'eau excessive, des ballonnements et des crises de sudation.

221. Son TCO l'empêche de se concentrer, de dormir, de se détendre et même de profiter de plaisirs simples comme lire ou regarder la télévision. Suite à la prise de Metadol, il n'est que quelque peu fonctionnel pendant 9 à 10 heures par jour et que le reste du temps, sa condition est insupportable.

222. Sa dépendance aux opioïdes lui a fait manquer de nombreux moments importants de la vie avec ses enfants et ait mis son mariage à rude épreuve.

223. Bien qu'il ait pu travailler par intermittence après un long rétablissement à la suite de son accident en novembre 2005, il est présentement incapable de continuer à travailler en raison de son TCO.

224. En novembre 2020, M. Bourassa a fait une demande de prestations d'invalidité en vertu du Régime de rentes du Québec, laquelle demande a été appuyée par son médecin de famille, car il ne croit pas être en mesure de travailler de nouveau un jour.

LIST OF EXHIBITS

EXHIBIT P-1 (***en liasse***)	Authorization Judgment and the rectifying judgment
EXHIBIT P-2	Interpretation Agreement entered into on July 13-14, 2022 by the parties to the National Settlement Agreement
EXHIBIT P-3	Judgment of the Saskatchewan Court dated September 23, 2022 approving the National Settlement Agreement
EXHIBIT P-4	Settlement approval judgment of the Supreme Court of British Columbia dated December 16, 2022 (S189395) (*British Columbia v. Purdue Pharma Inc.,* 2022 BCSC 2288)
EXHIBIT P-5	American Psychiatric Association, "Opioid Use Disorder" in *Diagnostic and statistical manual of mental disorders*, 5th ed (DSM-5) (Arlington: American Psychiatric Publishing, Inc., 2013)
EXHIBIT P-6	CDC Module 5: Assessing and Addressing Opioid Use Disorder (OUD)
EXHIBIT P-7	Glossary of commonly used terms published by the Centers for Disease Control and Prevention (last reviewed on April 19, 2024)
EXHIBIT P-8	Government of Canada, Health Canada, "Guidance for Industry: Product Monograph" (adopted: September 22, 2003)
EXHIBIT P-9	Government of Canada, Health Canada, "Opioids List" (2 May 2018)
EXHIBIT P-10	Government of Canada, Health Canada, "Patient Information Handout" (15 March 2019)
Exhibit P-11	Government of Canada, "Opioid Warning Sticker and Patient Information Handout, and Risk Management Plans" (15 March 2019)
EXHIBIT P-12	IQVIA Report, "Prescription Opioid Trends in Canada – An independent IQVIA report on measuring and understanding the use of prescription opioids dispensed from 2019 to 2023" (April 2024)
EXHIBIT P-13	Government of Canada's publication entitled "About chronic pain" (as at November 6, 2023)

EXHIBIT P-14	Extract of the 1997 CPS for OxyContin
EXHIBIT P-15	Statement of Claim filed by Pharmascience in December 2009 in court file No. T-2050-09
EXHIBIT P-16 (***en liasse***)	Product Monograph for Apo-Oxycodone CR dated April 15, 2011 and Product Monograph for pms-Oxycodone CR dated November 23, 2012
EXHIBIT P-17 (***en liasse***)	Product Monograph for CO-Oxycodone CR (by Cobalt, now part of Defendant Teva) dated November 8, 2012 and the Product Monograph for Act-Oxycodone CR (by Actavis, now part of Defendant Teva) dated June 23, 2014
EXHIBIT P-18 (***en liasse***)	Market Analysis Reports entitled “Opioid Market Size, Share & Trends Analysis Report By Product (IR/ Short Acting Opioids, ER/Long-Acting Opioids), By Application (Pain Relief, Anesthesia), By Route Of Administration, By Distribution Channel, By Region, And Segment Forecasts, 2023 – 2030”; and “Opioid Use Disorder Market Size, Share & Trends Analysis Report By Drug (Naltrexone, Buprenorphine, Methadone), By Route Of Administration, By Distribution Channel, By Region, And Segment Forecasts, 2024 – 2030”
EXHIBIT P-19	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-20	Report entitled “Canadian Drug Summary: Prescription Opioids” published in July 2020 by the Canadian Centre on Substance Use and Addiction
EXHIBIT P-21	Canadian Guideline for Safe and Effective Use of Opioids for Chronic and Effective Use of Opioids (2010)
EXHIBIT P-22	2017 Canadian Opioid Prescribing Guideline published by the Canadian Centre on Substance Use and Addiction
Exhibit P-23 (***en liasse***)	Product Monographs for Teva-Oxycodan dated December 21, 2017 and May 22, 2024

EXHIBIT P-24 (***en liasse***)	Information update, "Health Canada recommends that children and youth not use cough and cold products that contain opioids" dated February 18, 2019; and Health professional risk communication, "Prescription Cough and Cold Products Containing Opioids & the Risk of OUD in Children and Adolescents (< 18 years of age)" dated August 24, 2020
EXHIBIT P-25	Defendants, Teva, Sandoz, Pharmascience, Atlas and Riva, signed and published "Important Safety Information on Prescription Cough and Cold Products Containing Opioids and the Risk of Opioid Use Disorder in Children and Adolescents (< 18 years of age)", dated August 24, 2020
EXHIBIT P-26	Government of Canada's publication entitled "Access to Generic Drugs in Canada" (as modified on May 7, 2024)
EXHIBIT P-27	Health Canada's Guidance Document for Product Monographs adopted in 2013 and effective on June 1, 2014
EXHIBIT P-28	Guidance Document for Product Monograph (Effective date: 2024-12-23)
EXHIBIT P-29	Government of Canada's publication entitled: "Product monographs: Frequently asked questions" (as at November 1, 2020)
EXHIBIT P-30	Extract of the 1996 CPS containing a section entitled "Information for the Patient"
EXHIBIT P-31	CPS: Drug Information 2022
EXHIBIT P-32	Product Monographs for Duragesic (by Janssen-Ortho) dated April 1, 1997
EXHIBIT P-33	Product Monographs for Duragesic (by Janssen-Ortho) dated June 28, 2001

EXHIBIT P-34 (***en liasse***)	Allan L, Hays H, Jensen N-H, Le Polain de Waroux B, Bolt M, Donald R, Kalso E., "Randomised crossover trial of transdermal fentanyl and oral morphine in chronic non-cancer pain", British Medical Journal, Vol. 322, 12 MAY 2001:1154-58
	Milligan K, Lanteri-Minet M, Borchert K, Helmers H, Donald R. Kress H-G, Adriaensen H, Moulin D, Jarvimaki V, Haazen L., "Evaluation of long-term efficacy and safety of transdermal fentanyl in the treatment of chronic non-cancer pain", Journal of Pain (in press), Vol 2, No 4 (August), 2001: pp 197-204.
EXHIBIT P-35	Product Monograph for Kadian (by Faulding/Pfizer) dated September 21, 1995
EXHIBIT P-36	Product Monograph for Kadian (by Knoll/Abbott) dated April 27, 2000
EXHIBIT P-37	Product Monograph for Kadian (by Abbott) dated August 1, 2014
EXHIBIT P-38 (***en liasse***)	Canadian Pharmacists Association, "Hydromorph Contin" in *Compendium of Pharmaceuticals and Specialities*, 32nd ed. (Ottawa: Canadian Pharmacists Association, 1997);
	Canadian Pharmacists Association, "Hydromorph Contin" in *Compendium of Pharmaceuticals and Specialities*, 33rd. (Ottawa: Canadian Pharmacists Association, 1998);
	Canadian Pharmacists Association, "Hydromorph Contin" in *Compendium of Pharmaceuticals and Specialities*, 34th ed. (Ottawa: Canadian Pharmacists Association, 1999);
	Canadian Pharmacists Association, "Hydromorph Contin" in *Compendium of Pharmaceuticals and Specialities*, 35th ed. (Ottawa: Canadian Pharmacists Association, 2000);
	Canadian Pharmacists Association, "Hydromorph Contin" in *Compendium of Pharmaceuticals and Specialities*, 36th ed. (Ottawa: Canadian Pharmacists Association, 2001)
EXHIBIT P-39	Canadian Pharmacists Association, "Hydromorph Contin" in *Compendium of Pharmaceuticals and Specialities*, 37th ed. (Ottawa: Canadian Pharmacists Association, 2002)
EXHIBIT P-40	Product Monograph for Sandoz Oxycodone/Acetaminophen (by Sandoz) dated November 11, 2011
EXHIBIT P-41	Product Monograph for Sandoz Oxycodone/Acetaminophen (by Sandoz) dated July 23, 2018

EXHIBIT P-42 (***en liasse***)	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); and Association des pharmaciens du Canada, "Supeudol" in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2002)
EXHIBIT P-43	Product Monograph for Supeudol dated October 12, 2010
EXHIBIT P-44 (***en liasse***)	Product Monograph for Hydromorph-Contin dated February 13, 2018; Product Monograph for Jurnista dated March 1, 2018; and Product Monograph for Supeudol dated March 23, 2018
EXHIBIT P-45 (***en liasse***)	Product Monographs for Teva-Oxycodan dated December 21, 2017 and May 22, 2024
EXHIBIT P-46	OxyContin ad published in the December 1996 issue of the Canadian Family Physician
EXHIBIT P-47 (***en liasse***)	MS Contin ad and accompanying therapeutic classification in the Canadian Medical Association Journal, (April 4, 2000), Vol. 162-7; and MS Contin ad and accompanying therapeutic classification in the Canadian Medical Association Journal, (September 5, 2000), Vol. 163-5
EXHIBIT P-48	Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2004)
EXHIBIT P-49	Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2007)

EXHIBIT P-50 Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2010)

EXHIBIT P-51 Codeine Contin ad and accompanying therapeutic classification in *Le médecin du Québec*, (March 2005) Vol. 40-3

EXHIBIT P-52 Duragesic ad and accompanying abbreviated therapeutic information in *Le médecin du Québec*, (May 1998)

EXHIBIT P-53 Duragesic ad and accompanying abbreviated therapeutic information in *Le médecin du Québec*, (December 2001)

EXHIBIT P-54 Duragesic ad and accompanying therapeutic information in *Le médecin du Québec*, (January 2002) Vol. 37-1

EXHIBIT P-55 Duragesic ad campaign, "Duragesic Positioning Evolution Overview" dated June 1, 2002 (Source: from the Oklahoma Trial (Opioid Industry Documents)).

EXHIBIT P-56

- Conference held at the University of Sherbrooke on April 8, 2011: under the theme "*Symposium 2011 sur la douleur – Les narcotiques*" (sponsors included Defendants Purdue and Janssen);

- the 13th World Congress devoted to pain research and treatment, held in Montreal in 2010 (sponsors included Defendants Purdue and Janssen); and

- 2013 Canadian Pharmacists Association's conference (sponsors included Defendants Teva, Johnson & Johnson (related to Defendant Janssen) and Apotex

EXHIBIT P-57 (***en liasse***) Extract of Pro Doc Newsletters announcing new products, including opioid products

EXHIBIT P-58 Extract of textbook written by Dr. Roman Jovey: "*Managing Pain – The Canadian Healthcare Professional's Reference*", Chapter 8 entitled "Opioids, Pain and Addiction"

EXHIBIT P-59 Canadian Pain Society, Press Release, "Canadian Pain Society Launches 'Patient Pain Manifesto'" with book marks in English and French (May 11, 2001)

EXHIBIT P-60	Dr. Roman D. Jovey, et al., "Use of opioid analgesics for the treatment of chronic noncancer pain - A consensus statement and guidelines from the Canadian Pain Society, 2002" (Spring 2003) *Pain Manage* Vol 8 Suppl A
EXHIBIT P-61	List of the AQDC's Partners (June 7, 2007)
EXHIBIT P-62	AQDC, "Lexique de Maladies" (June 2, 2007) and Dominique Dion, "*La dependence aux opiacés…mythe ou réalité*" (June 2003), *Le médecin du Québec*, Vol 38-6 (online), ***en liasse***
EXHIBIT P-63	Letter from SQD's President published in the SQD's newsletter for May 2000 (Vol. 5, no. 2)
EXHIBIT P-64	Letter from SQD's President published in the SQD's newsletter for July 2000 (Vol. 5, no. 4)
EXHIBIT P-65	Letter from SQD's President published in the SQD's newsletter for September 2004 (Vol. 9, no. 2)
EXHIBIT P-66	Letstalkpain.org, "Understanding Tolerance, Physical Dependence and Addiction" (24 January 2009)
EXHIBIT P-67	Declaration of Dr. Portenoy executed in New York on January 17, 2019 (Source: Identified as Ex. S0879 in proceedings instituted in the State of Oklahoma)
EXHIBIT P-68	Judgment rendered by Justice Thad Balkman on August 26, 2019 in case number CJ-2017-816 (*State of Oklahoma* v. *Purdue Pharma L.P. et al.*)
EXHIBIT P-69	Judgment rendered on November 9, 2021 by the Oklahoma Supreme Court in case number 118474 (*State of Oklahoma v. Johnson & Johnson*, 2021 OK 54)
EXHIBIT P-70	Government of Canada, Health Canada, "Notice of Intent to Restrict the Marketing and Advertising of Opioids" (19 June 2018)
EXHIBIT P-71 (*en liasse*)	Response letters to the Minister of Health of Canada provided by Defendants Purdue and Pro Doc, respectively dated June 27 and July 6, 2018
EXHIBIT P-72 (*en liasse*)	Response letters to the Minister of Health of Canada provided by Defendants Rambaxy (Sun Pharma), Teva, Pharmascience and Apotex, respectively dated June 21, September 14 and 21, 2018 and February 13, 2019

EXHIBIT P-73 Canadian Centre on Substance Use and Addiction ("**CCSA**") – Prescription Opioids (July 2020)

EXHIBIT P-74 Canadian Institute for Health Information ("**CIHI**") (the "**2018 CIHI Report on Opioid-Related Harms**")

EXHIBIT P-75 Health Canada's webpage entitled "Opioid- and Stimulant-Related harms in Canada: Key Findings (updated December 23, 2024)"

EXHIBIT P-76 Gouvernement du Québec, Institut national de santé publique, "Opioid-related Poisoning Deaths in Québec: 2000-2009" (October 2013)

EXHIBIT P-77 Government of Canada, Special Advisory Committee on the Epidemic of Opioid Overdoses, "National Report: Apparent opioid-related deaths in Canada" (April 2019)

EXHIBIT P-78 Les 10-medicaments fréquemment payes par la RAMQ (from 2019 - 2023)

EXHIBIT P-79 Website of the Canadian Generic Manufacturers Association (the "**CGPA**")

EXHIBIT P-80 Plaintiff's CHUM hospital admission records from May 25 to June 2, 2017 (with bates stamps) **(Under Seal)**

EXHIBIT P-81 Plaintiff's CHUM hospital admission records from March 13 to 17, 2018 (with bates stamps) **(Under Seal)**

MONTREAL, January 23, 2025

(s) Fishman Flanz Meland Paquin

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MONTREAL, January 23, 2025

(s) Trudel Johnston & Lespérance

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SUMMONS
(articles 145 and following C.C.P.)

Filing of a judicial application

Take notice that the Plaintiff has filed this originating application in the office of the court of Montreal in the judicial district of Montreal.

Defendant's answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at **1 Notre-Dame Street East, Montreal, Québec, H2Y 1B6** within 15 days of service of the application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the plaintiff's lawyer or, if the plaintiff is not represented, to the plaintiff.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the cases required by the Code, cooperate with the plaintiff in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Québec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Change of judicial district

You may ask the court to refer the originating application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the plaintiff.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

Transfer of application to Small Claims Division

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Calling to a case management conference

Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

Exhibits supporting the application

EXHIBIT P-1 (***en liasse***)	Authorization Judgment and the rectifying judgment
EXHIBIT P-2	Interpretation Agreement entered into on July 13-14, 2022 by the parties to the National Settlement Agreement
EXHIBIT P-3	Judgment of the Saskatchewan Court dated September 23, 2022 approving the National Settlement Agreement
EXHIBIT P-4	Settlement approval judgment of the Supreme Court of British Columbia dated December 16, 2022 (S189395) (*British Columbia v. Purdue Pharma Inc.,* 2022 BCSC 2288)

EXHIBIT P-5	American Psychiatric Association, "Opioid Use Disorder" in *Diagnostic and statistical manual of mental disorders*, 5th ed (DSM-5) (Arlington: American Psychiatric Publishing, Inc., 2013)
EXHIBIT P-6	CDC Module 5: Assessing and Addressing Opioid Use Disorder (OUD)
EXHIBIT P-7	Glossary of commonly used terms published by the Centers for Disease Control and Prevention (last reviewed on April 19, 2024)
EXHIBIT P-8	Government of Canada, Health Canada, "Guidance for Industry: Product Monograph" (adopted: September 22, 2003)
EXHIBIT P-9	Government of Canada, Health Canada, "Opioids List" (2 May 2018)
EXHIBIT P-10	Government of Canada, Health Canada, "Patient Information Handout" (15 March 2019)
Exhibit P-11	Government of Canada, "Opioid Warning Sticker and Patient Information Handout, and Risk Management Plans" (15 March 2019)
EXHIBIT P-12	IQVIA Report, "Prescription Opioid Trends in Canada – An independent IQVIA report on measuring and understanding the use of prescription opioids dispensed from 2019 to 2023" (April 2024)
EXHIBIT P-13	Government of Canada's publication entitled "About chronic pain" (as at November 6, 2023)
EXHIBIT P-14	Extract of the 1997 CPS for OxyContin
EXHIBIT P-15	Statement of Claim filed by Pharmascience in December 2009 in court file No. T-2050-09
EXHIBIT P-16 (***en liasse***)	Product Monograph for Apo-Oxycodone CR dated April 15, 2011 and Product Monograph for pms-Oxycodone CR dated November 23, 2012
EXHIBIT P-17 (***en liasse***)	Product Monograph for CO-Oxycodone CR (by Cobalt, now part of Defendant Teva) dated November 8, 2012 and the Product Monograph for Act-Oxycodone CR (by Actavis, now part of Defendant Teva) dated June 23, 2014

EXHIBIT P-18 (***en liasse***)	Market Analysis Reports entitled “Opioid Market Size, Share & Trends Analysis Report By Product (IR/ Short Acting Opioids, ER/Long-Acting Opioids), By Application (Pain Relief, Anesthesia), By Route Of Administration, By Distribution Channel, By Region, And Segment Forecasts, 2023 – 2030”; and “Opioid Use Disorder Market Size, Share & Trends Analysis Report By Drug (Naltrexone, Buprenorphine, Methadone), By Route Of Administration, By Distribution Channel, By Region, And Segment Forecasts, 2024 – 2030”
EXHIBIT P-19	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-20	Report entitled “Canadian Drug Summary: Prescription Opioids” published in July 2020 by the Canadian Centre on Substance Use and Addiction
EXHIBIT P-21	Canadian Guideline for Safe and Effective Use of Opioids for Chronic and Effective Use of Opioids (2010)
EXHIBIT P-22	2017 Canadian Opioid Prescribing Guideline published by the Canadian Centre on Substance Use and Addiction
EXHIBIT P-23 (***en liasse***)	Product Monographs for Teva-Oxycodan dated December 21, 2017 and May 22, 2024
EXHIBIT P-24 (***en liasse***)	Information update, “Health Canada recommends that children and youth not use cough and cold products that contain opioids” dated February 18, 2019; and Health professional risk communication, “Prescription Cough and Cold Products Containing Opioids & the Risk of OUD in Children and Adolescents (< 18 years of age)” dated August 24, 2020
EXHIBIT P-25	Defendants, Teva, Sandoz, Pharmascience, Atlas and Riva, signed and published “Important Safety Information on Prescription Cough and Cold Products Containing Opioids and the Risk of Opioid Use Disorder in Children and Adolescents (< 18 years of age)”, dated August 24, 2020
EXHIBIT P-26	Government of Canada’s publication entitled “Access to Generic Drugs in Canada” (as modified on May 7, 2024)
EXHIBIT P-27	Health Canada’s Guidance Document for Product Monographs adopted in 2013 and effective on June 1, 2014

EXHIBIT P-28	Guidance Document for Product Monograph (Effective date: 2024-12-23)
EXHIBIT P-29	Government of Canada's publication entitled: "Product monographs: Frequently asked questions" (as at November 1, 2020)
EXHIBIT P-30	Extract of the 1996 CPS containing a section entitled "Information for the Patient"
EXHIBIT P-31	CPS: Drug Information 2022
EXHIBIT P-32	Product Monographs for Duragesic (by Janssen-Ortho) dated April 1, 1997
EXHIBIT P-33	Product Monographs for Duragesic (by Janssen-Ortho) dated June 28, 2001
EXHIBIT P-34 (***en liasse***)	Allan L, Hays H, Jensen N-H, Le Polain de Waroux B, Bolt M, Donald R, Kalso E., "Randomised crossover trial of transdermal fentanyl and oral morphine in chronic non-cancer pain", British Medical Journal, Vol. 322, 12 MAY 2001:1154-58 Milligan K, Lanteri-Minet M, Borchert K, Helmers H, Donald R. Kress H-G, Adriaensen H, Moulin D, Jarvimaki V, Haazen L., "Evaluation of long-term efficacy and safety of transdermal fentanyl in the treatment of chronic non-cancer pain", Journal of Pain (in press), Vol 2, No 4 (August), 2001: pp 197-204.
EXHIBIT P-35	Product Monograph for Kadian (by Faulding/Pfizer) dated September 21, 1995
EXHIBIT P-36	Product Monograph for Kadian (by Knoll/Abbott) dated April 27, 2000
EXHIBIT P-37	Product Monograph for Kadian (by Abbott) dated August 1, 2014

EXHIBIT P-38 (***en liasse***)	Canadian Pharmacists Association, “Hydromorph Contin” in *Compendium of Pharmaceuticals and Specialities*, 32nd ed. (Ottawa: Canadian Pharmacists Association, 1997);
	Canadian Pharmacists Association, “Hydromorph Contin” in *Compendium of Pharmaceuticals and Specialities*, 33rd. (Ottawa: Canadian Pharmacists Association, 1998);
	Canadian Pharmacists Association, “Hydromorph Contin” in *Compendium of Pharmaceuticals and Specialities*, 34th ed. (Ottawa: Canadian Pharmacists Association, 1999);
	Canadian Pharmacists Association, “Hydromorph Contin” in *Compendium of Pharmaceuticals and Specialities*, 35th ed. (Ottawa: Canadian Pharmacists Association, 2000);
	Canadian Pharmacists Association, “Hydromorph Contin” in *Compendium of Pharmaceuticals and Specialities*, 36th ed. (Ottawa: Canadian Pharmacists Association, 2001)
EXHIBIT P-39	Canadian Pharmacists Association, “Hydromorph Contin” in *Compendium of Pharmaceuticals and Specialities*, 37th ed. (Ottawa: Canadian Pharmacists Association, 2002)
EXHIBIT P-40	Product Monograph for Sandoz Oxycodone/Acetaminophen (by Sandoz) dated November 11, 2011
EXHIBIT P-41	Product Monograph for Sandoz Oxycodone/Acetaminophen (by Sandoz) dated July 23, 2018
EXHIBIT P-42 (***en liasse***)	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); and
	Association des pharmaciens du Canada, “Supeudol” in *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2002)
EXHIBIT P-43	Product Monograph for Supeudol dated October 12, 2010

EXHIBIT P-44 (***en liasse***)	Product Monograph for Hydromorph-Contin dated February 13, 2018; Product Monograph for Jurnista dated March 1, 2018; and Product Monograph for Supeudol dated March 23, 2018
EXHIBIT P-45 (***en liasse***)	Product Monographs for Teva-Oxycodan dated December 21, 2017 and May 22, 2024
EXHIBIT P-46	OxyContin ad published in the December 1996 issue of the Canadian Family Physician
EXHIBIT P-47 (***en liasse***)	MS Contin ad and accompanying therapeutic classification in the Canadian Medical Association Journal, (April 4, 2000), Vol. 162-7; and MS Contin ad and accompanying therapeutic classification in the Canadian Medical Association Journal, (September 5, 2000), Vol. 163-5
EXHIBIT P-48	Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2004)
EXHIBIT P-49	Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2007)
EXHIBIT P-50	Hydromorph Contin ad in Association des pharmaciens du Canada, *Compendium des produits et spécialités pharmaceutiques* (Ottawa: Association des pharmaciens du Canada, 2010)
EXHIBIT P-51	Codeine Contin ad and accompanying therapeutic classification in *Le médecin du Québec*, (March 2005) Vol. 40-3
EXHIBIT P-52	Duragesic ad and accompanying abbreviated therapeutic information in *Le médecin du Québec*, (May 1998)
EXHIBIT P-53	Duragesic ad and accompanying abbreviated therapeutic information in *Le médecin du Québec*, (December 2001)
EXHIBIT P-54	Duragesic ad and accompanying therapeutic information in *Le médecin du Québec*, (January 2002) Vol. 37-1

EXHIBIT P-55 Duragesic ad campaign, "Duragesic Positioning Evolution Overview" dated June 1, 2002 (Source: from the Oklahoma Trial (Opioid Industry Documents)).

EXHIBIT P-56

- Conference held at the University of Sherbrooke on April 8, 2011: under the theme "*Symposium 2011 sur la douleur – Les narcotiques*" (sponsors included Defendants Purdue and Janssen);

- the 13th World Congress devoted to pain research and treatment, held in Montreal in 2010 (sponsors included Defendants Purdue and Janssen); and

- 2013 Canadian Pharmacists Association's conference (sponsors included Defendants Teva, Johnson & Johnson (related to Defendant Janssen) and Apotex

EXHIBIT P-57 (***en liasse***) Extract of Pro Doc Newsletters announcing new products, including opioid products

EXHIBIT P-58 Extract of textbook written by Dr. Roman Jovey: "*Managing Pain – The Canadian Healthcare Professional's Reference*", Chapter 8 entitled "Opioids, Pain and Addiction"

EXHIBIT P-59 Canadian Pain Society, Press Release, "Canadian Pain Society Launches 'Patient Pain Manifesto'" with book marks in English and French (May 11, 2001)

EXHIBIT P-60 Dr. Roman D. Jovey, et al., "Use of opioid analgesics for the treatment of chronic noncancer pain - A consensus statement and guidelines from the Canadian Pain Society, 2002" (Spring 2003) *Pain Manage* Vol 8 Suppl A

EXHIBIT P-61 List of the AQDC's Partners (June 7, 2007)

EXHIBIT P-62 AQDC, "Lexique de Maladies" (June 2, 2007) and Dominique Dion, "*La dependence aux opiacés…mythe ou réalité*" (June 2003), *Le médecin du Québec*, Vol 38-6 (online), *en liasse*

EXHIBIT P-63 Letter from SQD's President published in the SQD's newsletter for May 2000 (Vol. 5, no. 2)

EXHIBIT P-64 Letter from SQD's President published in the SQD's newsletter for July 2000 (Vol. 5, no. 4)

EXHIBIT P-65	Letter from SQD's President published in the SQD's newsletter for September 2004 (Vol. 9, no. 2)
EXHIBIT P-66	Letstalkpain.org, "Understanding Tolerance, Physical Dependence and Addiction" (24 January 2009)
EXHIBIT P-67	Declaration of Dr. Portenoy executed in New York on January 17, 2019 (Source: Identified as Ex. S0879 in proceedings instituted in the State of Oklahoma)
EXHIBIT P-68	Judgment rendered by Justice Thad Balkman on August 26, 2019 in case number CJ-2017-816 (*State of Oklahoma* v. *Purdue Pharma L.P. et al.*)
EXHIBIT P-69	Judgment rendered on November 9, 2021 by the Oklahoma Supreme Court in case number 118474 (*State of Oklahoma v. Johnson & Johnson*, 2021 OK 54)
EXHIBIT P-70	Government of Canada, Health Canada, "Notice of Intent to Restrict the Marketing and Advertising of Opioids" (19 June 2018)
EXHIBIT P-71 (*en liasse*)	Response letters to the Minister of Health of Canada provided by Defendants Purdue and Pro Doc, respectively dated June 27 and July 6, 2018
EXHIBIT P-72 (*en liasse*)	Response letters to the Minister of Health of Canada provided by Defendants Rambaxy (Sun Pharma), Teva, Pharmascience and Apotex, respectively dated June 21, September 14 and 21, 2018 and February 13, 2019
EXHIBIT P-73	Canadian Centre on Substance Use and Addiction ("**CCSA**") – Prescription Opioids (July 2020)
EXHIBIT P-74	Canadian Institute for Health Information ("**CIHI**") (the "**2018 CIHI Report on Opioid-Related Harms**")
EXHIBIT P-75	Health Canada's webpage entitled "Opioid- and Stimulant-Related harms in Canada: Key Findings (updated December 23, 2024)"
EXHIBIT P-76	Gouvernement du Québec, Institut national de santé publique, "Opioid-related Poisoning Deaths in Québec: 2000-2009" (October 2013)
EXHIBIT P-77	Government of Canada, Special Advisory Committee on the Epidemic of Opioid Overdoses, "National Report: Apparent opioid-related deaths in Canada" (April 2019)

EXHIBIT P-78	Les 10-medicaments fréquemment payes par la RAMQ (from 2019 - 2023)
EXHIBIT P-79	Website of the Canadian Generic Manufacturers Association (the "**CGPA**")
EXHIBIT P-80	Plaintiff's CHUM hospital admission records from May 25 to June 2, 2017 (with bates stamps) **(Under Seal)**
EXHIBIT P-81	Plaintiff's CHUM hospital admission records from March 13 to 17, 2018 (with bates stamps) **(Under Seal)**

These exhibits are available on request.

Notice of presentation of an application

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

MONTREAL, January 23, 2025

(s) Fishman Flanz Meland Paquin

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MONTREAL, January 23, 2025

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NOTICE OF PRESENTATION
(Article 574 C.C.P.)

TO:

ABBOTT LABORATORIES, CO.
75, boulevard Pierre-Roux Est
Victoriaville, Québec G6P 6S9

APOTEX INC.,
2970 André Avenu
Dorval, Quebec H9P 2P2

BRISTOL-MYERS SQUIBB CANADA CO.
2344 Alfred-Nobel Boulevard
Montreal, Quebec H4S 0A4

ETHYPHARM INC.,
2400-1000 De La Gauchetière
Montreal, Quebec H3B 4W5

JANSSEN INC.,
14 Place du Commerce, Suite 620
Montreal, Quebec H3E 1T5

LABORATOIRE ATLAS INC.,
9600 des Sciences Boulevard
Montreal, Quebec H1J 3B6

LABORATOIRE RIVA INC.,
660 Industriel Boulevard
Blainville, Quebec J7C 3V4

LABORATOIRES TRIANON INC.,
660 Industriel Blvd.
Blainville, Quebec J7C 3V4

PHARMASCIENCE INC.
6111 Royalmount Avenue, Suite 100
Montreal, Quebec H4P 2T4

PRO DOC LTÉE,
2925 Industriel Boulevard
Laval, Quebec H7L 3W9

PURDUE FREDERICK INC.
22 Adelaide Street West, Suite 3400,
Toronto, Ontario M5H 4E3

PURDUE PHARMA,
575 Court Granite
Pickering, Ontario L1W 3W8

SANDOZ CANADA INC.,
110 De Lauzon Street
Boucherville, Quebec J4B 1E6

SUN PHARMA CANADA INC.,
170, Steelwell Road, Unit 100
Brampton, Ontario, L6T 5T3

TEVA CANADA LIMITED,
17800 Lapointe Street
Mirabel, Quebec J7J 1P3

TAKE NOTICE that the *Originating Application to Institute Class Action Proceedings* will be presented at the Superior Court at the Courthouse of Montréal, located at 1 Notre-Dame Street East, at a date and time to be determined by the Coordinating Judge for the Class Action Division

PLEASE ACT ACCORDINGLY.

MONTREAL, January 23, 2025

(s) Fishman Flanz Meland Paquin

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MONTREAL, January 23, 2025

(s) Trudel Johnston & Lespérance

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louis-alexandre@tjl.quebec

ATTESTATION THAT THE APPLICATION WILL BE ENTERED IN THE NATIONAL CLASS ACTION REGISTER

(Article 55 of the *Regulation of the Superior Court of Québec in civil matters)*

The Plaintiff, through his attorneys, the undersigned, certifies that the *Originating Application to Institute Class Action Proceedings* will be registered in the National Register of Class Actions.

MONTREAL, January 23, 2025

(s) Fishman Flanz Meland Paquin

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Co-Counsel for Plaintiff
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MONTREAL, January 23, 2025

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SCHEDULE I

A. List of Settled and Settling Defendants and their respective opioid products that were manufactured, marketed, distributed and/or sold during the Class Period:

Settled Defendants	***Respective Opioid Drugs***	***Settlement Judgment***
Roxane Laboratories, Inc. / Hikma Labs Inc.	Hydromorphone HCL (tablets); Oramorph SR; and Roxicet	Justice Morrison, August 9, 2022 [*Bourassa c. Roxane Laboratories Inc.*, 2022 QCCS 2976]
Boehringer Ingelheim (Canada) Ltd.		
BGP Pharma ULC	Kadian	
Mylan Pharmaceuticals ULC	Mylan-Fentanyl Matrix Patch; and Mylan-Tramadol/Acet	
Merck Frosst Canada & Co.	282 Mep Tab; 282 Tab; 292 Tab; Exdol-15; Exdol-30; 642 Tab; 692 Tab Leritin (tablets); and Leritin (injection)	
Sanis Health Inc.	Morphine Sulf SR; Oxycodone/Acet; and Tramadol/Acet	
Aralez Pharmaceuticals Canada Inc.	Fiorinal-C ¼; Fiorinal-C ½; and Durela	Justice Bisson, May 18, 2023 [*Bourassa c. Abbott Laboratories*, Limited, 2023 QCCS 1680]
Valeant Canada Limited, Valeant Canada LP and 4490142 Canada Inc., F.K.A. as Meda Valeant Pharma Canada Inc.	M.O.S. products; Onsolis; Ralivia; Kadian; and Cophylac	
Church & Dwight	Atasol 15 mg; and Atasol 30 mg	
GlaxoSmithKline Inc.	Empracet-30; Empracet-60; Opium and Belladonna Suppositories; Robaxisal C ½ Robaxisal C ¼ Robitussin AC Coactified (in various tablet and syrup forms)	Justice Bisson, September 6, 2024 [*Bourassa c. GlaxoSmithKline inc.*, 2024 QCCS 3295]
Novartis Pharmaceuticals Canada Inc.	Fiorinal-C ¼; and Fiorinal-C ½	
sanofi-aventis Canada Inc.	Demerol (tablets); Talwin (tablets); and M-Eslon	

SCHEDULE I

Discharged Defendants	***Respective Opioid Drugs***	***Judgment***
Pfizer Canada ULC	Robaxisal C1/2; and Robaxisal C1/4	Motion for Approval of the Settlement Agreement will be presented to the Court shortly.

B. Putative defendant who was discharged under the CCAA

Paladin Labs Inc.[1]	Abstral; Fiorinal C1/2; Fiorinal C1/4; Metadol; Metadol D; Nucynta Extended-Release; Nucynta IR; Statex; and Tridural	Justice Morawetz, April 16, 2024 [Plan Recognition Order (CV-22-00685631-00CL) and Justice Morawetz, April 17, 2024 [*Paladin Labs Canadian Holding Inc.*, 2024 ONSC 2224]

[1] Paladin was purchased by a global specialty pharmaceutical group ("**Endo**"). On August 16, 2022, Endo International plc ("**Endo Parent**") and certain of its affiliates, including Paladin filed for protection under Chapter 11 of the United States Bankruptcy Code. On March 22, 2024, the fourth amended joint Chapter 11 plan of reorganization was confirmed by Justice Garrity of the U.S. Court (the "**Plan Confirmation Order**"). On April 16, 2024, the CCAA Court recognized and enforced the Plan Confirmation Order and on April 17, 2024, the CCAA Court discharged and dismissed the litigation instituted by the Quebec Class Representative (then Applicant) against Paladin.

Extracts of Defendants' Documents Containing Misleading Information About the Subject Opioids

Common Misleading Statements / Downplaying the Risks of Opioids in the Product Monographs (and comparable documents)

Example 1: Abuse / addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated

Opioid / Defendant	**Exhibits**[1]	**<u>Example 1</u> – Abuse / addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-38** Extract of 1997 CPS p. 680	Under "*Warnings*": **<u>Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated.</u>**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-38** Extract of 1998 CPS p. 724	Under "*Warnings*": **<u>Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated.</u>**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-38** Extract of 1999 CPS p. 786	Under "*Warnings*": **<u>Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated.</u>**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-38** Extract of 2000 CPS p. 706	Under "*Warnings*": **<u>Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated.</u>**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-38** Extract of 2001 CPS p. 690	Under "*Warnings*": **<u>Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated.</u>**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-39** Extract of 2002 CPS p. 756	Under "*Warnings*": **<u>Drug abuse is not a problem in patients with severe pain in which hydromorphone is appropriately indicated.</u>**

[1] Product Monographs ("**PM**) / Prescribing Information ("**PI**") / Compendium of Pharmaceuticals and Specialties ("**CPS**").

Opioid / Defendant	**Exhibits**[1]	**<u>Example 1</u> – Abuse / addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated**
Dilaudid [**Purdue**]	**EXHIBIT P-82** PI (Apr. 5, 2012) pp. 6 of 30	Under "*Dependence/Tolerance*": **<u>Addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated.</u>**
Codeine Contin [**Purdue**]	**EXHIBIT P-51** Therapeutic Information with an Ad (2005) p. 3 of 5	Under "*Mise en garde*": **<u>Le risque d'abus ne constitue pas un problème chez les patients présentant des douleurs intenses et chez qui la codéine est indiquée.</u>**
Duragesic [**Janssen**]	**EXHIBIT P-54** Therapeutic Information, with an Ad (2002) p. 3 of 5	Under "*Pharmaco dépendance et toxicomanie*": **<u>La toxicomanie iatrogène à la suite d'une administration appropriée d'opioïdes pour le soulagement de la douleur chronique est relativement rare</u>**.
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-83** PM (Feb. 19, 2010) p. 7 of 42	Under "*Dependence/Tolerance*": <u>Drug Dependence vs. Abuse</u>: **<u>Iatrogenic addiction following appropriate opioid administration for relief of severe pain is relatively rare.</u>**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-84** PM (Aug. 7, 2012) pp. 7 of 43	Under "*Dependence/Tolerance*": **<u>Iatrogenic addiction following appropriate opioid administration for relief of severe pain is relatively rare.</u>**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-85** PM (Feb. 6, 2013) p. 7 of 43	Under "*Dependence/Tolerance*": **<u>Iatrogenic addiction following appropriate opioid administration for relief of severe pain is relatively rare.</u>**
Fentanyl Patch [**Pro Doc**]	**EXHIBIT P-86** PM (May 21, 2013) p. 7 of 45	Under "*Dependence/Tolerance*": <u>Drug Dependence vs. Abuse</u>: **<u>Iatrogenic addiction following appropriate opioid administration for relief of severe pain is relatively rare.</u>**
pms-Oxycodone [**Pharmascience**]	**EXHIBIT P-87** PM (Nov. 28, 2008) p. 4 (of 19)	Under "*Warnings*": <u>Drug Dependence</u>: **<u>Drug abuse is usually not a problem in patients with pain in whom oxycodone is appropriately indicated.</u>**

Opioid / Defendant	**Exhibits**[1]	**Example 1 – Abuse / addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated**
pms-Oxycodone [**Pharmascience**]	**EXHIBIT P-88** PM (Feb. 22, 2012) p. 9 of 32	Under "*Dependence/Tolerance*": **Addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated.**
Oxycodone [**Pro Doc**]	**EXHIBIT P-89** PM (May 6, 2009) p. 4 (of 19)	Under *"Warnings*" : Drug Dependence: **Drug abuse is usually not a problem in patients with pain in whom oxycodone is appropriately indicated**.
Oxycodone [**Pro Doc**]	**EXHIBIT P-90** PM (Feb. 6, 2013) p. 9 of 31	Under *"Warnings*" : Dependence/Tolerance: **Addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated**.
Oxycodone-Acet [**Pro Doc**]	**EXHIBIT P-91** PM (Jan. 16, 2018) p. 28 of 33	Under "*Dependence and withdrawal*": **Abuse is not a problem with people who require this medication for pain relief.**
Rivacocet [**Laboratoire Riva**]	**EXHIBIT P-92** PI (Dec. 9, 2013) p. 9 (of 11)	Under "*Dependence and withdrawal*": **Abuse is not a problem with people who require this medication for pain relief.**
Rivacocet [**Laboratoire Riva**]	**EXHIBIT P-93** PI (May 3, 2016) p. 10 of 12	Under "*Dependence and withdrawal*": **Abuse is not a problem with people who require this medication for pain relief.**
Rivacocet [**Laboratoire Riva**]	**EXHIBIT P-94** PM (Sept. 14, 2017) p. 28 of 33	Under "*Dependence and withdrawal*": **Abuse is not a problem with people who require this medication for pain relief.**
Apo-Tramadol/ Acet [**Apotex**]	**EXHIBIT P-95** PM (Oct. 28, 2013) p. 5 of 38	Under "*Drug, Abuse, Addiction and Dependence*": **The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare**.

Opioid / Defendant	**Exhibits**[1]	**<u>Example 1</u> – Abuse / addiction is not usually a problem in patients with pain in whom opioid analgesics are appropriately indicated**
Tramadol-Acet [**Pro Doc**]	**EXHIBIT P-96** PM (Oct. 28, 2013) p. 5 of 38	Under "*Drug, Abuse, Addiction and Dependence*": **<u>The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare</u>**.

[1] Product Monographs ("**PM**) / Prescribing Information ("**PI**") / Compendium of Pharmaceuticals and Specialties ("**CPS**"). **The CPSs attached herewith are extracts**.

Example 2: Concerns about abuse, addiction and diversion should not prevent the proper management of pain

Opioid / Defendant	**Exhibit**	**Example 2 – Concerns about abuse, addiction and diversion should not prevent the proper management of pain**
Hydromorph Contin [**Purdue**]	**EXHIBIT P-44** PM (Feb. 13, 2018) p. 7 of 46	Under "*Addiction, Abuse and Misuse*": However, **concerns about abuse, addiction, and diversion should not prevent the proper management of pain**.
Dilaudid [**Purdue**]	**EXHIBIT P-97** PI (April 5, 2012) p. 6 of 30	Under "*Warnings and Precautions*": Dependence/Tolerance: **Concerns about abuse, addiction, and diversion should not prevent the proper management of pain**.
Tylenol with Codeine No. 2 and No. 3 [**Janssen**]	**EXHIBIT P-98** PM (Mar. 8, 2019) p. 7 of 39	Under "*Abuse and Misuse*": However, **concerns about abuse, addiction, and diversion should not prevent the proper management of pain.**
Tylenol with Codeine No. 4 [**Janssen**]	**EXHIBIT P-99** PM (Mar. 8, 2019) p. 7 of 39 (sic)	Under "*Abuse and Misuse*": However, **concerns about abuse, addiction, and diversion should not prevent the proper management of pain.**
Jurnista [**Janssen**]	**EXHIBIT P-44** PM (Mar. 1, 2018) p. 7 of 52	Under "*Addiction, Abuse and Misuse*": However, **concerns about abuse, addiction, and diversion should not prevent the proper management of pain.**
Duragesic [**Janssen**]	**EXHIBIT P-54** Therapeutic Info. with an Ad (2002) p. 3 of 5	Under "*Pharmacodépendance et toxicomanie"*: **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.
Duragesic [**Janssen**]	**EXHIBIT P-100** PM (Dec. 16, 2019) p. 8 of 55	Under "*Addiction, Abuse and Misuse*": However, **concerns about abuse, addiction, and diversion should not prevent the proper management of pain.**
Tramacet [**Janssen**]	**EXHIBIT P-101** PM (Jan. 22, 2020) p. 7 of 61	Under "*Abuse and Misuse*": However, **concerns about abuse, addiction, and diversion should not prevent the proper management of pain.**

Opioid / Defendant	**Exhibit**	**<u>Example 2</u> – Concerns about abuse, addiction and diversion should not prevent the proper management of pain**
Ultram [**Janssen**]	**EXHIBIT P-102** PM (Dec. 9, 2020) pp. 7 of 54	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Nucynta CR [**Janssen**]	**EXHIBIT P-103** PM (Aug. 5, 2014) p. 7 of 46	Under "*Abuse, Addiction and Misuse*": **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain</u>**.
Nucynta ER [**Janssen**]	**EXHIBIT P-104** PM (Aug. 5, 2014) p. 7 of 48	Under "*Abuse, Addiction and Misuse*": **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Nucynta IR [**Janssen**]	**EXHIBIT P-105** PM (Oct. 21, 2016) p. 6 of 50	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Supeudol [**Sandoz**]	**EXHIBIT P-44** PM (Mar. 23, 2018) p. 6 of 38	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain</u>**.
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-106** PM (Aug. 7, 2012) p. 7 of 43	Under "*Potential for Abuse and Diversion*": **<u>Concerns about abuse, addiction and diversion should not prevent the proper management of pain.</u>**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-107** PM (Feb. 6, 2013) p. 7 of 43	Under "*Potential for Abuse and Diversion*": **<u>Concerns about abuse, addiction and diversion should not prevent the proper management of pain</u>**.
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-108** PM (Sept. 22, 2014) p. 7 of 48	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-109** PM (Jan. 7, 2016) p. 7 of 48	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**

Opioid / Defendant	**Exhibit**	**<u>Example 2</u> – Concerns about abuse, addiction and diversion should not prevent the proper management of pain**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-110** PM (June 22, 2017) p. 7 of 50	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain</u>**.
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-111** PM (June 22, 2018) p. 8 of 54	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-113** PM (May 21, 2019) p. 8 of 54	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Sandoz Fentanyl Patch [**Sandoz**]	**EXHIBIT P-114** PM (Feb. 26, 2020) p. 8 of 55	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Fentanyl Patch [**Pro Doc**]	**EXHIBIT P-115** PM (May 21, 2013) p. 7 of 45	Under "*Potential for Abuse and Diversion*": **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Fentanyl Patch [**Pro Doc**]	**EXHIBIT P-116** PM (Nov. 7, 2014) p. 7 of 49	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Fentanyl Patch [**Pro Doc**]	**EXHIBIT P-117** PM (May 4, 2016) p. 7 of 49	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Fentanyl Patch [**Pro Doc**]	**EXHIBIT P-118** PM (Aug. 31, 2017) p. 7 of 50	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Fentanyl Patch [**Pro Doc**]	**EXHIBIT P-118** PM (Jan. 30, 2019) p. 8 of 53	Under "*Addiction, Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**

Opioid / Defendant	**Exhibit**	**<u>Example 2</u> – Concerns about abuse, addiction and diversion should not prevent the proper management of pain**
Oxycodone [**Pro Doc**]	**EXHIBIT P-119** PM (Feb. 6, 2013) p. 9 of 31	Under "Warnings": <u>Dependence/Tolerance</u>: **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain</u>**.
Oxycodone [**Pro Doc**]	**EXHIBIT P-120** PM (Dec. 21, 2018) p. 6 of 42	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Oxycodone-Acet [**Pro Doc**]	**EXHIBIT P-121** PM (Jan. 16, 2018) p. 6 of 33	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Oxycodone-Acet [**Pro Doc**]	**EXHIBIT P-122** PM (Feb. 7, 2019) p. 6 of 34	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Procet-30 [**Pro Doc**]	**EXHIBIT P-123** PI (Feb. 7, 2019) p. 6 of 33	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Tramadol-Acet [**Pro Doc**]	**EXHIBIT P-124** PM (Dec. 11, 2013) p. 5 of 38	Under "*Drug Abuse, Addiction and Dependence*": **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Tramadol-Acet [**Pro Doc**]	**EXHIBIT P-125** PM (Jan. 24, 2018) p. 7 of 63	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Tramadol-Acet [**Pro Doc**]	**EXHIBIT P-126** PM (Dec. 12, 2018) p. 7 of 65	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**

Opioid / Defendant	**Exhibit**	**<u>Example 2</u> – Concerns about abuse, addiction and diversion should not prevent the proper management of pain**
pms-Oxycodone [**Pharmascience**]	**EXHIBIT P-127** PM (Feb. 22, 2012) p. 9 of 32	Under "*Warnings*": <u>Dependence/Tolerance</u>: **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain</u>**.
pms-Oxycodone [**Pharmascience**]	**EXHIBIT P-128** PM (July 29, 2016) p. 4 of 30	Under "*Warnings and Precautions*": <u>Addiction, Abuse and Misuse</u>: However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
pms-Oxycodone [**Pharmascience**]	**EXHIBIT P-129** PM (Jan. 12, 2017) p.6 of 38	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
pms-Oxycodone [**Pharmascience**]	**EXHIBIT P-130** PM (May 28, 2018) p. 6 of 45	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Rivacocet [**Laboratoire Riva**]	**EXHIBIT P-131** PM (Sept. 14, 2017) p. 6 of 33	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Rivacocet [**Laboratoire Riva**]	**EXHIBIT P-132** PM (Dec. 4, 2018) p. 6 of 33	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Triatec-30 [**Laboratoire Riva**]	**EXHIBIT P-133** PI (Oct. 16, 2018) p. 6 of 33	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Apo-Tramadol/Acet [**Apotex**]	**EXHIBIT P-134** PM (Nov. 1, 2013) p. 5 of 38	Under "*Drug Abuse, Addiction and Dependence*": **<u>Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**

Opioid / Defendant	**Exhibit**	**<u>Example 2</u> – Concerns about abuse, addiction and diversion should not prevent the proper management of pain**
Apo-Tramadol/Acet [**Apotex**]	**EXHIBIT P-135** PM (Aug. 22, 2017) p. 7 of 63	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
Apo-Tramadol/Acet [**Apotex**]	**EXHIBIT P-136** PM (July 13, 2018) p. 7 of 65	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**
APO-HYDROmorphone [**Apotex**]	**EXHIBIT P-137** PI (July 13, 2018) p. 6 of 37	Under "*Abuse and Misuse*": However, **<u>concerns about abuse, addiction, and diversion should not prevent the proper management of pain.</u>**

No: 500-06-001004-197

SUPERIOR COURT
(Class Action)

JEAN-FRANÇOIS BOURASSA

Representative Plaintiff

v.

ABBOTT LABORATORIES, CO. et al.

Defendants

ORIGINATING APPLICATION TO INSTITUTE CLASS ACTION PROCEEDINGS
(Articles 141 and 583 C.C.P.)

ORIGINAL

File: OPIOID-1
Nature: Class Action

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