C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF MONTRÉAL
LOCALITY OF MONTRÉAL

No: 500-06-001004-197

SUPERIOR COURT
(Class Action)

RICCARDO CAMARDA

Plaintiff

v.

ABBOTT LABORATORIES, LIMITED

APOTEX INC.

ARALEZ PHARMACEUTICALS CANADA INC.

BGP PHARMA ULC

BOEHRINGER INGELHEIM (CANADA) LTD.

BRISTOL-MEYERS SQUIBB CANADA CO.

CHURCH & DWIGHT CANADA CORP.

COBALT PHARMACEUTICALS INC.

ETHYPHARM INC.

GLAXOSMITHKLINE INC.

HIKMA LABS INC.

JANSSEN INC.

JODDES LIMITED

LABORATOIRE ATLAS INC.

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SANIS HEALTH INC.

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SUN PHARMA CANADA INC.

TEVA CANADA LIMITED

VALEANT CANADA LIMITED

VALEANT CANADA LP

4490142 CANADA INC., F.K.A. AS MEDA VALEANT PHARMA CANADA INC.

Defendants

APPLICATION OF SANDOZ CANADA INC. FOR AUTHORIZATION TO ADDUCE RELEVANT EVIDENCE
(574 CCP)

TO THE HONOURABLE JUSTICE GARY D.D. MORRISON OF THE SUPERIOR COURT, ACTING AS THE DESIGNATED JUDGE IN THE PRESENT CASE, THE DEFENDANT SANDOZ CANADA INC. RESPECTFULLY SUBMITS AS FOLLOWS:

1. The Defendant Sandoz Canada Inc. ("**Sandoz**") hereby seeks the authorization of this Honourable Court to adduce relevant evidence pursuant to article 574, paragraph 3 of the *Code of Civil Procedure*, RLRQ c C-25.01 ("**CCP**").

2. More specifically, Sandoz seeks authorization to adduce as relevant evidence a Sworn Statement of Sonia Gallo, Director-Regulatory Affairs, dated March 31, 2021, a copy of which is filed herewith as **Exhibit SZ-1**.

3. As further detailed below, the Sworn Statement (Exhibit SZ-1) is relevant and necessary for the Court's analysis of the criteria of art. 575 CCP, providing essential information regarding the unique regulatory approval process of the generic drugs manufactured by Sandoz and the significant differences between each opioid drug product, as well as serving to correct a false allegation advanced by the Plaintiff.

I. THE AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION

4. On or about May 23, 2019, EV (a pseudonym used to protect the anonymity of the plaintiff) filed an *Application for Authorization to Institute a Class Action*.

5. On or about October 25, 2019, an *Amended Application for Authorization to Institute a Class Action* (the "**Amended Authorization Application**") was filed, in which, among other things, the original plaintiff was replaced with Mr. Riccardo Camarda (the "**Plaintiff**"), and additional defendants were added, bringing the total number to 34 named defendants.

6. The Plaintiff seeks the authorization to represent the following proposed class (the "**Class**" or the "**Class Members**"):

> "All persons in Quebec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the Defendants between 1996 and the present day ("**Class Period**") and who suffer or have suffered from Opioid Use Disorder, according to the diagnostic criteria herein described.
>
> The Class includes the direct heirs of any deceased persons who met the above-mentioned description. The Class excludes any person's claim, or any portion thereof, subject to the settlement agreement entered into in the court file no 200-06-000080-070, provided that such settlement agreement becomes effective as a result of the issuance of the requisite court approvals."

7. Without making any distinction whatsoever between the Defendants or the panoply of opioid drug products they are alleged to have manufactured, marketed, distributed and/or sold, the Amended Authorization Application alleges that in an effort to increase the sales of their products, the Defendants deliberately misrepresented that:

   a) opioids are not as addictive as they truly were;

b) opioids resulted in improved function and were more effective than other pain relief treatment;

c) the withdrawal that could occur when taking opioids could easily be managed;

d) opioids were appropriate for long-term use;

e) opioids had less adverse effects than other pain management drugs;

f) certain opioids provided 12-hour pain relief;

g) increased dosages of opioids could be prescribed to combat the effects of end-of-dose failure, without disclosing the risks of the increased dosage; and

h) "abuse deterrent" formulations of opioids were effective to prevent abuse.

8. The Amended Authorization Application further alleges, again without making any distinction between the Defendants or the multitude of opioid drug products they are said to have manufactured, sold and/or distributed, that they engaged in aggressive marketing and sales tactics for the distribution of their drugs, and that they were negligent in the research, development, manufacture, testing and regulatory licensing of opioid products in Quebec.

9. The Plaintiff seeks compensatory damages for each Class Member in the amount of $30,000, punitive damages in the amount of $25,000,000 from each Defendant as well as pecuniary damages for each Class Member's personal losses.

II. THE RELEVANCE OF THE SWORN STATEMENT OF SONIA GALLO

10. Sandoz seeks this Honourable Court's permission to file the Sworn Statement of Sonia Gallo, Director-Regulatory Affairs (Exhibit SZ-1), in order to provide this Court with the relevant and necessary factual context regarding the some material differences in the regulatory approval process for an innovator drug and the generic versions of those innovator drugs, and between each of Sandoz's multiple named opioid drug products, as well as to correct one of the false allegations advanced in the Amended Authorization Application.

11. Indeed, the Amended Authorization Application completely ignores the rigorous regulatory approval process by Health Canada that precedes the sale of drugs in Canada.

12. The Amended Authorization Application also ignores the differences between the 34 Defendants named in the Amended Authorization Application, which includes innovator and generic drug manufacturers, sellers and/or distributors, as well as the many differences between the exceedingly large number of drug

products and/or categories of drugs they are said to have manufactured marketed and/or sold, and falsely assumes and alleges that they have all committed the same alleged faults or misrepresentations.

13. The Sworn Statement (Exhibit SZ-1) serves to:

    a) explain some material differences between "brand name" drugs - also referred to as "innovator" or "original" drugs, and "generic" drugs;

    b) demonstrate that each specific drug requires a different regulatory approval process and that Sandoz had to go through this regulatory process for each of its opioid drug products;

    c) demonstrate that the opioid drug products differ from one another in many different respects, including notably their use, dosage, forms and strengths, the ways they administered/ingested and regarding their specific contraindications, precautions and warnings;

    d) correct a false statement regarding the manufacture of Fiorinal by Sandoz during the Class Period.

14. With respect to the regulatory process of drug approval, the Sworn Statement (Exhibit SZ-1) clarifies that:

    a) The process for an innovator drug to obtain approval from Health Canada to sell its drugs in Canada differs from the regulatory approval process applicable to suppliers of generic versions of those innovator drugs;

    b) The innovator drug regulatory approval process includes assessing information and data about the drug's safety, effectiveness, and quality;

    c) The product monograph of a drug is also approved by Health Canada;

    d) The regulatory review process for a generic drug does **not** require the generic drug supplier to provide safety and efficacy studies. Instead, the generic drug supplier only needs to establish that its proposed generic drug is a bioequivalent of the innovator drug;

    e) Sandoz underwent the regulatory process for each of the generic opioid drugs it manufactures and/or sells and obtained from Health Canada regulatory approval to manufacture and sell those drugs; and;

    f) Generic opioid drug products differ in various respects: they are indicated for different purposes, produced in different dosages,

administered/ingested differently, and they each have a different product monograph.

15. The important distinctions between the regulatory approval process of Health Canada with respect to generic drugs and innovator drugs and between the different opioid drug products are relevant and essential to this Court's determination of whether the Amended Authorization Application has demonstrated that the claims of the Class Members in fact raise identical, similar or related issues of law or fact pursuant to article 575(1) CCP, and whether the Plaintiff has in fact demonstrated an arguable case against each of the 34 Defendants as required by article 575(2) CCP.

16. As drafted, the Amended Authorization Application is based on the patently false assumption, among other things, that:

    a) any and all opioid drug products and product monographs are interchangeable (as demonstrated by the conscious choice of the Plaintiff not to include in its Amended Authorization Application all the product monographs of the different drugs for the different Defendants);

    b) the risks of the different opioid drug products are the same for any opioid drug product;

    c) the marketing of any opioid drug product and/or by each of the Defendants is done in the same way;

    d) the obligations of all of the 34 named Defendants are exactly the same, regardless of the nature of a given Defendant's business and the nature of the opioid drug product at issue;

    e) the Defendants have all committed the same alleged faults.

17. The Plaintiff plainly ignores and/or diminishes the very real and important differences between the Defendants and each of the many different opioid drug products they are alleged to have manufactured, sold and/or distributed.

18. As such, the Sworn Statement (Exhibit SZ-1) provides the relevant and necessary information and the complete factual matrix regarding the important differences between the Defendants, their obligations, and the various opioid drug products that Sandoz manufactures, sells and/or distributes, thus assisting this Honourable Court in its analysis of the criteria of article 575 CCP.

19. In addition to providing these essential explanations, Sonia Gallo's Sworn Statement also serves to correct a false allegation of the Amended Authorization Application.

20. Specifically, the Sworn Statement (Exhibit SZ-1) confirms that contrary to the allegations of the Amended Authorization Application, Sandoz did not manufacture, market and/or sell Fiorinal C1/2 or Fiorinal C1/4 during the Class Period.

21. The Sworn Statement (Exhibit SZ-1) will thus assist this Honourable Court in its analysis of the authorization criteria, and specifically in its determination of whether the claims of the Class Members raise identical, similar or related issues of law or fact pursuant to article 575 (1) CCP, and whether Plaintiff has established an appearance of right pursuant to article 575 (2) CCP.

22. The relevant evidence, which Sandoz seeks this Court's authorization to submit, also satisfies the principle of proportionality required by article 18 and 19 CCP.

23. The present Application is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THIS COURT TO:

GRANT the present Application;

AUTHORIZE the Defendant Sandoz Canada Inc. to file the Sworn Statement of Sonia Gallo, Director-Regulatory Affairs, dated March 31, 2021, a copy of which is filed herewith as **Exhibit SZ-1**;

THE WHOLE without legal costs, unless the present Application is contested.

Montréal, this March 31, 2021

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LIST OF EXHIBITS

EXHIBIT SZ-1. : Copy of the Sworn Statement of Sonia Gallo, Director-Regulatory Affairs, dated March 31, 2021

Montréal, this March 31, 2021

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APPLICATION FOR AUTHORIZATION TO ADDUCE RELEVANT EVIDENCE (ART. 574 CCP), LIST OF EXHIBITS AND EXHIBIT SZ-1

(Class Action)

ORIGINAL

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