CANADA

PROVINCE OF QUÉBEC **DISTRICT OF MONTRÉAL**	SUPERIOR COURT (Class Actions Chamber)
NO: 500-06-001004-197	**JEAN-FRANÇOIS BOURASSA** Plaintiff v. **ABBOTT LABORATORIES, LIMITED** *et al.* Defendants

AMENDED APPLICATION OF THE DEFENDANT PFIZER CANADA ULC FOR LEAVE TO ADDUCE RELEVANT EVIDENCE
(Articles 574, 575 CCP)

TO THE HONOURABLE GARY D.D. MORRISON, J.S.C., THE DEFENDANT PFIZER CANADA ULC HEREBY SUBMITS THE FOLLOWING:

I. INTRODUCTION

1. Pfizer Canada ULC ("Pfizer") seeks permission to submit evidence which is both relevant to the authorization criteria applicable to the Plaintiff's *Amended Application for Authorization to Institute a Class Action* in this matter (the "Amended Application for Authorization") pursuant to art. 575 of the *Code of Civil Procedure* ("CCP") and necessary in order for the Court to undertake an informed analysis of those criteria.

2. As appears from the Court record, Pfizer's Application for leave to adduce relevant evidence was served on March 31, 2021. Since that time, the Plaintiff has served a Combined Plan of Argument in response to Pfizer's Application as well as a *Re-Amended Application for Authorization to Institute a Class Action dated December 17, 2021* (the "Re-Amended Application for Authorization"), as also appears from the Court record. This Amended Application is served in light of these developments.

3. Specifically, Pfizer seeks leave to submit the amended proposed affidavit of Lorella Garofalo attached hereto as Schedule A.1.

II. THE PROPOSED CLASS ACTION

4. As appears from the Re-Amended Application for Authorization, the Plaintiff seeks authorization to institute a class action on behalf of the following proposed class (the "Proposed Class"):

> *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.*

5. The proceeding generally asserts that the Defendants misrepresented the safety and efficacy of opioids to members of the Proposed Class.

6. Several medications are attributed to Pfizer, as appears more fully from paragraph 2.24 of the Re-Amended Application for Authorization. However, no information is provided regarding the nature of these medications, their approved indications, methods of administration or conditions of use.

III. THE CRITERIA FOR GRANTING AUTHORIZATION AND GRANTING LEAVE TO ADDUCE EVIDENCE

7. The criteria to determine whether the Re-Amended Application for Authorization should be granted are established in article 575 CCP.

8. In its analysis of these criteria, the Court assumes that the facts pleaded are true, unless they are clearly inaccurate and contradicted by other evidence. Further, the Court should not consider as true allegations those which are based on inferences, conclusions, unverified hypotheses, legal arguments or opinions.

9. Pursuant to article 574 CCP, the Court may permit the introduction of evidence, including documentary evidence, provided the evidence is relevant to the Court's analysis of the authorization criteria in article 575 CCP and necessary for purposes of the Court's application of those criteria.

IV. THE EVIDENCE PROPOSED IS RELEVANT AND NECESSARY

10. The evidence Pfizer seeks leave to adduce is both relevant to the authorization criteria and necessary to permit the Court to assess whether those criteria are met, in particular whether the proposed class action as against Pfizer presents an "appearance of right" and therefore justifies the granting of the authorization (article 575(2) CCP).

11. The Re-Amended Application for Authorization contains a number of very broad allegations concerning opioids. One of the impressions created is that all opioids are administered in the same manner, i.e., in pill or tablet form, prescribed by physicians to their patients on an individual basis, and therefore are associated with the same risks.

12. For example, at para. 2.42, the Plaintiff asserts that:

> *The prescribed uses of opioids changed in the mid-1990s; in particular, in 1996,* ***when Defendant Purdue introduced the time-release formulation of oxycodone branded as OxyContin****. Defendant Purdue claimed that the drug was safer because it could be taken less often, and it aggressively encouraged its widespread use for chronic conditions, such as back pain, migraines and arthritis.*

13. Paras. 2.43 and 2.44 further allege:

> *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.*
>
> ***In their efforts to increase market share and increase the prescription rate and sale of their drugs****, the Defendants also failed to disclose the risks of using opioids.*
>
> [emphasis added]

14. What this omits is:

a) the fact that there are different types and formulations of opioid medications;

b) the fact that certain opioid medications are marketed to hospitals only and, as such, have very specific indications and methods of administration; and

c) the indications and conditions of use of the medications that Plaintiff attributes to Pfizer.

15. The evidence Pfizer seeks to adduce in the form of Ms. Garofalo's affidavit will demonstrate that the injectable opioid medications attributed to Pfizer in the Re-Amended Application for Authorization are:

a) only sold to hospitals, as sterile liquids in vials or ampules;

b) only administered in hospitals by hypodermic needle or intravenous "drip"; and

c) are not prescribed to individuals or sold to them through retail pharmacies.

16. In its Combined Plan of Argument dated November 8, 2021, the Plaintiff asserts that the evidence Pfizer wishes to adduce – *viz.*, the Garofalo affidavit – is *"not sufficient to establish that Pfizer's injectable opioid drugs were used exclusively in a hospital setting."* The Plaintiff argues in this regard that Pfizer's evidence is contradicted by publicly available records. Specifically, the Plaintiff requests that it be allowed to reply to Pfizer's evidence, if that evidence is permitted, by adducing:

> *"[…] Pfizer's publicly available Prescribing Information for its injectable opioids such as HYDROmorphone Hydrochloride Injection USP that includes Patient Medication Information, with instructions for patients about refills, missed dose,storage and/or disposal of the drug in a home setting […]"*
>
> [Plaintiff's Combined Plan of Argument, para. 103 and fn. 70]

17. Ms. Garofalo's amended proposed affidavit is intended to respond to these arguments by explaining the reasons why the Product Monographs for the Pfizer medications at issue including HYDROmorphone Hydrochloride Injection USP contain the references on which the Plaintiff appears to rely.

18. The Re-Amended Application for Authorization also refers to Robaxisal, a medication available in two formulations, Robaxisal C ¼ and Robaxisal C ½ (para. 2.24.4).

19. As the amended proposed Garofalo affidavit demonstrates, Robaxisal is categorized by Health Canada as a skeletal muscle relaxant/analgesic and not as an opioid analgesic. Robaxisal is also considered an "old drug" by Health Canada. "Old drugs" are drugs that, according to Health Canada, have been sold in Canada for a specified use for a sufficient time and in sufficient quantity to establish in Canada their safety and effectiveness for that use.

20. The Re-Amended Application for Authorization also asserts, at para. 2.115 and following, that the alleged misrepresentations which are at the heart of the case were spread by Pfizer and others through unspecified funding in 2001 and 2007 of patient advocacy groups.

21. The evidence Pfizer wishes to adduce is that it was not involved in the sale of opioid medications at the times in question and that, in addition, any funding it provided was unconditional.

V. CONCLUSIONS

22. The evidence described above is necessary to permit the Court to assess whether the authorization criteria are met as against Pfizer.

23. It would be contrary to the interests of justice to refuse evidence directly relevant to understanding the proposed class action and assessing the criteria for authorization.

24. Pfizer further submits that the Court should have the benefit of the evidence described above, which is proportionate to the nature and the magnitude of the proposed class action, so that it might be in a position to make an informed decision at the authorization stage.

25. Without this evidence, the Court may be unable to properly assess whether the criteria for authorization are met and, if they are, how best to define the class and frame the common issues and conclusions sought.

26. The present Amended Application is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT TO:

GRANT the present Amended Application of the Defendant Pfizer Canada ULC for leave to adduce relevant evidence;

AUTHORIZE Pfizer Canada ULC to submit an affidavit from Pfizer's representative Lorella Garofalo in the form attached hereto as Schedule A.1, as well as Exhibits LG-1 to LG-3 in support thereof;

THE WHOLE without costs save in the event of contestation.

MONTRÉAL, January 10, 2022

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TAKE NOTICE that the present Application of the Defendant Pfizer Canada ULC for Leave to Adduce Relevant Evidence will be presented before the Superior Court at the Montréal Courthouse, located at 1 Notre-Dame Street East, in the City and District of Montréal, during the hearing scheduled for January 17-21, 2022.

PLEASE GOVERN YOURSELF ACCORDINGLY.

MONTRÉAL, January 10, 2022

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