SUPERIOR COURT

CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

No. : 500-06-000692-141

DATE : May 18, 2022

BY THE HONOURABLE PIERRE NOLLET, J.S.C.

Denis Lebel
Applicant
v.
Boehringer Ingelheim (Canada) Ltd./Ltée
and
Boehringer Ingelheim Auslandsbeteiligungs Gmbh
and
C.H. Boehringer Sohn Ag & Co. KG
Defendants

JUDGMENT

OVERVIEW

[1] The Applicant Lebel seeks the *Authorization to Institute a Class Action and to Appoint a Representative Plaintiff*[1] against the Defendants (**Application for Authorization**), on behalf of the following group:

[1] Version of March 19, 2020.

> All estates, successors, assigns, family members, and dependants of persons deceased prior to April 29, 2016 who, at the time of death, resided in Quebec, had taken the drug PRADAXA®, and whose death involved hemorrhage or exsanguination (**Proposed Class**);

[2] According to the Application for Authorization, Pradaxa is a prescription anticoagulant ("blood-thinner") developed and distributed by Defendants Boehringer since 2008. It aims at preventing venous thromboembolic events, stroke and systemic embolism in patients with atrial fibrillation

[3] Lebel alleges that his mother, Ms. Solange Lapointe, died from a massive cerebral hemorrhage after taking Pradaxa.

[4] Lebel also alleges that during the class period, Pradaxa would have caused a patient's blood to be excessively thinned, causing irreversible bleeding leading to hemorrhaging and death. No antidote to Pradaxa existed at the time.

[5] According to the allegations, Boehringer failed to adequately warn of the risk of life-threatening bleeding associated with Pradaxa[2]. It is his contention that no adequate warning of these facts in advertisements, with the medical community or on Pradaxa labeling or packaging existed. Furthermore, Defendants would have collectively withheld and suppressed this information worldwide, including in Canada and Quebec, preventing Class Members from making an informed decision as potential consumers of Pradaxa.

[6] The Defendant Boehringer Ingelheim (Canada) LTD. ("**Boehringer**") seeks leave to file relevant evidence to be used in the context of the hearing of the Application for Authorization.

[7] Boehringer proposes to file the following evidence:

- **Exhibit B-1** : Product Monographs for Boehringer's drug PRADAXA® dated June 10, 2008, March 11, 2009, July 31, 2009, October 26, 2010, June 13, 2011, January 27, 2012, July 6, 2012, September 5, 2012, November 28, 2012, December 24, 2012, May 14, 2013, May 30, 2014, June 24, 2014, October 28, 2014, and June 5, 2015;

- **Exhibit B-2** : Extract from the Government of Canada's website entitled *Canada Vigilance adverse reaction online database* and *Report a side effect*;

- **Exhibit B-3 (under seal)** : Translated medical records of Ms. Solange Lapointe;

[2] Paragraph 19 of the Application for Authorization.

- **Exhibit B-4 (under seal)** : Expert Report of Dr. Anil Chopra dated February 17, 2022;

- **Exhibit B-5 (under seal)** : Expert Report of Dr. Zaev Wulffhart dated February 18, 2022.

[8] Lebel consents to the filing of Exhibit B-1, subject to the comment that it is neither summary nor proportionate (849 pages). Lebel also consents to the filing of Exhibits B-2 and B-3 subject to any argument which could be raised at the hearing of the Application for Authorization.

[9] With respect to Exhibits B-4 and B-5, Lebel objects, deeming the evidence irrelevant at this stage.

ANALYSIS

1.1 Legal principles

[10] Boehringer has the burden of convincing the Court of the usefulness and appropriateness of the evidence it is requesting to file.

[11] At the authorization stage, if the judge finds himself faced with contradictory facts, he or she is to take as proven those facts of the application for authorization, unless they appear implausible or manifestly inaccurate. Given the presumption attached to the facts alleged, the evidence to be filed at this stage should be limited to what makes it possible to establish beyond dispute their implausibility or falsity.

[12] In addition, the filing of relevant evidence may aim at:

• understanding the nature of the defendant's operations;

• filling a factual void left by the application for authorization;

• completing, correcting or squarely contradicting the allegations of the application for authorization;

• allowing the court to have a better understanding of the factual context of the application; Where

[13] The proposed documentary evidence must also comply with the principles of reasonable conduct and proportionality set out in articles 18 and 19 CCP.

[14] The evidence is appropriate only if it is relevant and useful for verifying the criteria of article 575 CCP. The consent of Lebel to the filing of suggested evidence is not sufficient to authorize its introduction.

[15] A defendant may not put into evidence elements that fall within the nature of a defense on the merits. Except as otherwise stated above, the only defenses that can be decided by the authorization judge are those based on a "pure question of law if the fate of the proposed collective action depends on it[3].

[16] The Court must not allow the parties to produce voluminous evidence and must in no case examine in depth the evidence produced as if it were a question of assessing the merits of the case. The admissibility of relevant evidence must be done with moderation and be reserved for the essential and indispensable.

[17] The authorization of class actions is based on a liberal interpretation and application of the criteria for authorization, namely the demonstration of an arguable case. The court should be wary of allowing evidence that includes more than is strictly necessary to meet that threshold.

[18] Overall the proposed evidence must truly be useful to the authorization debate[4].

1.2 Discussion

1.2.1 The monographs

[19] The exhibit B-1 contains 15 different versions of product monographs related to Pradaxa over a period of 7 years. Each monograph contains at least 30 pages. The last pages are typically directed to the Consumers.

[20] The need to produce the 849 pages of monographs is not explained. The distinction between each version is not highlighted either, nor is there any indication as to how each monograph relate to a relevant period with respect to Ms. Lapointe's situation. As indicated in Boehringer submission, the monographs are mostly directed to professionals.

[21] The main claim made by Lebel is that there were no warning of a lack of antidote for Pradaxa, while other anticoagulant have antidotes such as Warfarin (Coumadin).

[22] At this stage, it is unclear as to how the presence of monographs will assist the Court in ascertaining whether the warnings contained in it were proper and sufficiently explicit for the consumer or for any other purposes. This is generally not the type of review to be conducted at the authorization stage.

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[3] *L'Oratoire Saint-Joseph du Mont Royal* c. *J.J.*, 2019 CSC 35, par. 55 ; *Desjardins Cabinet de services financiers inc.* c. *Asselin*, 2020 CSC 30, par. 154 ; *Conseil pour la protection des malades* c. *Centre intégré de santé et de services sociaux de la Montérégie-Centre*, 2019 QCCS 3934, par. 36.

[4] *Charbonneau* c. *Location Claireview*, 2019 QCCS 4196, par. 45 à 47 ; *Benizri* c. *Société canadienne des postes*, 2016 QCCS 454, par. 19 ; *Seigneur* c. *Netflix international*, 2018 QCCS 1275, par. 22, 24 et 26 ; *Ehouzou* c. *Manufacturers Life Insurance Company*, 2018 QCCS 4908, par. 22 à 27 ; *Société AGIL OBNL* c. *Bell Canada*, 2019 QCCS 4432, par. 20 à 22

[23] The Court will nonetheless allow the production of the monograph of June 13, 2011, the year Ms. Lapointe started taking Pradaxa in order to allow for the argument of the implausibility or false nature of certain allegations to be made. Without further explicit reasons for the filing of all the monographs or to distinguish between each of them, the Court is of the view that filing 849 pages does not meet the proportionality test nor the essential and indispensable criteria.

1.2.2 Extract from the Government of Canada's website entitled Canada Vigilance adverse reaction online database and Report a side effect

[24] The Applicant provides in support of his Application for Authorization an extract from the "*Health Canada database*" entitled *Summary of Reported Adverse Reactions*, filed as Exhibit P-1 and P-8.

[25] Boehringer wishes to demonstrate that the summary is an incomplete picture as it does not refer to certain specific warnings. The authorization to file Exhibit B-2 will be granted.

1.2.3 Filing of translated medical records of Ms. Solange Lapointe (B-3)

[26] It is alleged that prior to the surgery triggering the prescription of an anticoagulant, Ms. Lapointe had no other health issues. To succeed, the action may require that a causal link be established between Ms. Lapointe's circumstances including her death, the taking of Pradaxa and the warnings or alleged suppressions thereof. Her medical records may be of assistance to the Court in analysing whether or not the burden of demonstration is met. Accordingly the medical records (Exhibit B-3) are allowed to be filed under seal given the private nature of the information.

1.2.4 The content of the Expert reports (B-4 and B-5)

[27] Lebel makes various general allegations concerning the use and treatment regimens of Pradaxa including regarding the relative safety of Pradaxa when compared with the anticoagulant effect of Warfarin (Coumadin) which is reversible.

[28] Amongst the various claims made by Lebel, aside from the lack of antidote, is the significantly higher rate of major life threatening bleeding with Pradaxa, the increased risks of heart attack and a greater mortality rate.

[29] Boehringer wishes to file Expert reports (B-4 and B-5) to allow the Court to determine whether Lebel has a personal cause of action and whether he is an appropriate representative. The other stated purpose is to determine whether the Application for Authorization raises issues that can be addressed collectively. Boehringer suggests that

the Expert reports would allow for assessing whether the legal syllogism on which Lebel relies is supported by the facts.

[30] Boehringer finally alleges that the Expert reports will provide information concerning the different circumstances in which an anticoagulant (including Pradaxa) is properly prescribed, the emergency administration of reversal agents for Warfarin and Pradaxa and any causal relationship between the availability of a reversal agent and the death of Ms. Lapointe.

[31] In the first Expert report (Exhibit B-4), four questions were asked of the Expert. The Court also refers hereafter to some opinions given by the Expert:

> *1. Please comment on the emergency treatment and prognosis for a 79 year old female patient on warfarin or Pradaxa® who has experienced a massive cerebral hemorrhage and is found unresponsive at her home.*
>
> […] With respect to the case of Ms. Lapointe, had she been on warfarin, the treating physician would have had the option of using reversal agents (vitamin K and PCC) or could have chosen to withhold that therapy. However, using these reversal agents would not have changed her outcome. Ms. Lapointe had an unwitnessed fall, was likely unconscious for a considerable period of time on the floor and in a critical state by the time she reached the ED on April 27, 2013. In the ED, she was completely unreactive with a Glasgow Coma Scale score of 3 which represents the lowest level of consciousness (no ocular, verbal or motor response to stimuli). She required intubation and ventilation to keep her alive. A specialist consultation with a neurologist indicated "zero prognosis" based on the clinical presentation and neurological assessment which indicated a lack of brainstem reflexes. Ms. Lapointe had suffered a "massive" ICH with deviation of the brain by 16 mm on CT brain imaging. Survival was highly unlikely despite any available treatment and irrespective of the anticoagulant she was taking.
>
> *2. Having regard to ED practice related to bleeding and patient outcomes, did the absence of an approved specific reversal agent for Pradaxa® render Pradaxa® inferior to warfarin from a patient safety point of view and, if not, why not?*
>
> *3. Is there any scientific data or evidence that could be used to determine, with a reasonable degree of certainty, whether the proper use of Pradaxa® causes Pradaxa® patients as a group to experience worse outcomes related to bleeding than patients who use warfarin?*
>
> *4. Having regard to Part I of the Pradaxa® Product Monographs published since the product launch in Canada, are the risks of bleeding (including ICH) associated with the use of Pradaxa® fairly and reasonably disclosed?*
>
> […] Of course, the degree of risk of Pradaxa® to any given individual patient will differ according to the patient's specific characteristics, including age, comorbidity, weight, renal status, past medical history, and co-medications. For that reason, the

information in the product monograph will apply differently to each individual patient depending on these individual characteristics.

[32] In the second Expert report the questions asked were the following:

QUESTION #1 : Please describe the mortality and morbidity associated with atrial fibrillation ("AF") and the utility of anticoagulants like Warfarin (Coumadin) and Pradaxa® in the treatment of AF?

QUESTION #2 : Having particular regard to the risk of bleeding, please describe the risks and benefits associated with the use of Pradaxa® for the treatment of AF relative to the risks and benefits associated with the use of Warfarin.

QUESTION #3 : Having regard to the patient-specific facts alleged in paragraphs 35-40 of the Quebec Action 500-06-000692-141, and the available medical records of the late Ms. Solange Lapointe, please comment on whether the switch from warfarin to Pradaxa® was an appropriate treatment for Ms. Lapointe?

QUESTION #4 : What other individual patient-specific factors are relevant to decision-making related to a switch from Warfarin to Pradaxa®?

QUESTION #5 : Does the bleeding event experienced by Ms. Lapointe in April of 2013, or the medical outcome suggest that the switch from warfarin to Pradaxa® was not appropriate for Ms. Lapointe?

QUESTION #6 : Prior to the approval of Praxbind® for use in Canada, was it appropriate for a prescribing physician to have a general preference for prescribing warfarin over Pradaxa® because of the availability of a reversal agent for Warfarin?

QUESTION #7 : Was the absence of any specific reversal agent for Pradaxa® generally known to Canadian prescribing physicians prior to the marketing of Pradaxa® in Canada, and what impact, if any, did this knowledge have upon Canadian prescribing practices in the treatment of AF?

QUESTION #8 : Having regard to Part I of all the Pradaxa® Product Monographs published since the product launch in Canada, are the risks of bleeding associated with the use of Pradaxa® fairly and reasonably disclosed?

QUESTION #9 : Did the introduction of Pradaxa® have any material impact upon the management of AF in clinical practice and, if so, what was that impact?

[33] Overall, several of the questions as well as the answers provided by the Experts deal with the merit of the debate. None of the answers can be said to unequivocally counter the allegations or proving that the allegations are either implausible or manifestly inaccurate. The fact that the burden of proof may be difficult to meet for Lebel is irrelevant at the authorization stage. These Expert opinions might very well be countered by Applicant's own experts.

[34] While the Expert reports might have been useful in assisting to define the group, unfortunately they are not as they currently stands. The Expert reports cannot either demonstrate the absence of identical questions. Only one such question, if meaningful, is required. The fact that the degree of risk of Pradaxa to any given individual patient will differ according to the patient's specific characteristics, including age, comorbidity, weight, renal status, past medical history, and co-medications is insufficient to conclude that no group, no identical or common issues to be tried exist. Accordingly, these Experts reports are not useful to decide the issue of authorization.

FOR THESE REASONS, THE COURT:

[35] **GRANTS** in part the Application for leave to adduce relevant evidence;

[36] **AUTHORIZES** the Defendant Boehringer Ingelheim (Canada) Ltd to file the following Exhibits as evidence:

36.1. **Exhibit B-1** : Product Monographs for Boehringer's drug PRADAXA® dated June 13, 2011;

36.2. **Exhibit B-2** : Extract from the Government of Canada's website entitled *Canada Vigilance adverse reaction online database* and *Report a side effect*;

36.3. **Exhibit B-3 (under seal)** : Translated Medical Records of Ms. Solange Lapointe;

[37] **DENIES** the permission to file Exhibit B-4 (Expert Report of Dr. Anil Chopra dated February 17, 2022) and Exhibit B-5 **(**Expert Report of Dr. Zaev Wulffhart dated February 18, 2022);

[38] **WITH COSTS** to follow.

Signature numérique de Pierre Nollet
Date : 2022.05.18 11:28:30 -04'00'

PIERRE NOLLET, J.S.C.

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Hearing date: On file May 4, 2022