C A N A D A

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

(Class Action)
SUPERIOR COURT

No: 500-06-000821-161

PIERRE MARTEL

Petitioner

v.

MERCK CANADA INC.

-and-

SCHERING-PLOUGH CANADA INC.

-and-

DAIICHI SANKYO COMPANY LTD.

Respondents

APPLICATION FOR PERMISSION TO SUBMIT RELEVANT EVIDENCE
(Article 574 CCP)

TO THE HONOURABLE PIERRE-C. GAGNON, J.S.C., THE RESPONDENT DAIICHI SANKYO COMPANY LTD. RESPECTFULLY SUBMITS THE FOLLOWING:

1. The Respondent Daiichi Sankyo Company, Ltd. ("**Daiichi**") hereby seeks the permission of this Honourable Court to submit two expert reports as relevant evidence pursuant to article 574, para. 3 of the Code of Civil Procedure, CQLR, c. C-25.01 ("**CCP**").

I. THE APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT A REPRESENTATIVE

2. On or about November 4, 2016, Petitioner Pierre Martel filed a Motion to Authorize the Bringing of A Class Action & to Appoint the Petitioner As Representative (the "**Application**") on behalf of the following class:

> "all persons residing in Canada who were prescribed and have ingested the drug(s) OLMETEC® (Olmesartan Medoxomil) and/or OLMETEC PLUS® (Olmesartan Medoxomil and Hydrochlorothiazide) and their successors, assigns, family

members, and dependants, or any other group to be determined by the Court;"

Alternately (or as a subclass)

all persons residing in Quebec who were prescribed and have ingested the drug(s) OLMETEC® (Olmesartan Medoxomil) and/or OLMETEC PLUS® (Olmesartan Medoxomil and Hydrochlorothiazide) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court."

(hereinafter, the "**Proposed Class**").

3. In the Application, the Petitioner claims that the Respondents committed faults and that these faults caused damages to the Petitioner and to members of the Proposed Class.

4. More specifically, the Petitioner alleges, *inter alia*, that:

   a) The Respondents did not provide adequate warning to doctors and patients of the risks associated with the use of OLMETEC and OLMETEC PLUS (the "**Products**");

   b) The Respondents knew or should have known that the studies filed as Exhibit R-5 (the "**Studies**", R-5) suggest that there may be an association between the Products and the injuries allegedly suffered by the Proposed Class;

   c) The Respondents were negligent in the development of the Products in that they knew or should have known that the Products increased the risk of Gastrointestinal Disorders, as defined in paragraph 6 of the Application;

   d) The Respondents failed to ensure that the Products were not dangerous;

   e) The Respondents failed to conduct appropriate testing with regard to potential adverse effects of the Products;

5. Furthermore, the Petitioner claims that as a result of his use of one of the Products to treat his high blood pressure, he experienced chronic diarrhea, dehydration, weight loss, and abdominal and gastrointestinal pain for approximately 6 years.

6. While the Petitioner alleges having suffered from Gastrointestinal Disorders, as those are defined in paragraph 6 of the Application, both the Studies, R-5, and the Drug Safety Communication published by the United States Food and Drug Administration on July 3, 2013, filed as Exhibit R-7, focus more specifically on "sprue-like enteropathy."

7. Lastly, the Petitioner claims that, as a result of their use of the Products, each member of the Proposed Class suffered similar symptoms resulting in physical and mental injuries, pain, suffering, anxiety, fear, loss of quality and enjoyment of life, inflammation, chronic diarrhea, dehydration, weight loss, and abdominal and gastrointestinal pain.

II. THE RELEVANCE AND SCOPE OF THE EXPERT REPORTS

8. In order to convince the Court that the class action should be authorized and the Petitioner should be designated as representative plaintiff, the Petitioner must demonstrate, among other things:

   a) that the claims of the members of the class raise identical, similar or related issues of law or fact;

   b) that the facts alleged appear to justify the conclusions sought, and

   c) that the composition of the class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings (article 575 CCP);

   d) that the class member appointed as representative plaintiff is in a position to properly represent the class members.

9. On the one hand, the Petitioner's allegations rely heavily on the aforementioned Studies, which pertain to technical pharmaceutical information.

10. On the other hand, the Petitioner also relies on his own anecdotal experience using the Products.

11. Firstly, in order to determine whether the Petitioner's allegations justify the relief sought, the Court must be in a position to fully understand the allegations.

12. As is further explained below, the respondent Daiichi fully supports the application by respondents Merck Canada Inc. and Schering-Plough Canada Inc. (hereafter referred to, together, as "**Merck Canada**") seeking to obtain the Petitioner's relevant medical records.

13. Daiichi expects that the Petitioner's medical records will contain technical medical information as well as handwritten notes that will be difficult for those not in the medical and pharmaceutical fields to understand. Such information will need to be explained to the Court.

14. The primary objective of filing an expert report would therefore be to shed light on the Petitioner's allegations, thereby providing the Court with a sufficient scientific understanding to enable it to make a decision.

15. Secondly, the Petitioner has filed a curated selection of medical journal articles under Exhibit R-5 which the Defendant seeks to contextualize and to put in

layman's terms, with refutation of the papers to come at a later stage in the proceedings.

16. Thirdly, an expert report is necessary to educate the Court on the types of symptoms alleged by the Petitioner and their prevalence in the general population.

17. Indeed, the Court must be given the opportunity to consider the Petitioner's allegations against the backdrop of objective and non-controversial information regarding sprue-like enteropathy.

18. Lastly, in order to allow the Court to determine whether the claims of the Proposed Class members are sufficiently similar, the Petitioner's anecdotal experience must be analyzed within the context of his own medical history.

19. As such, an expert report prepared by a gastroenterologist is necessary to provide the Court with an understanding of the following subjects:

    a) Sprue-like enteropathy, its symptoms, potential causes, risk/confounding factors and diagnostic;

    b) The prevalence of sprue-like enteropathy;

    c) The current state of scientific knowledge as to whether sprue-like enteropathy is related to (or caused by) the use of the Olmetec drugs (including the Studies filed by the Petitioner as Exhibit R-5).

    d) The Petitioner's medical and pharmaceutical records, including:

        (i) His use of the Products;

        (ii) His need for medicine to treat his hypertension;

        (iii) The information provided by his treating physician in this regard;

        (iv) Other treatments discussed;

        (v) Other drugs used by the Petitioner that may have impacted his condition and other confounding factors;

        (vi) The Petitioner's symptoms;

        (vii) The consultations and tests performed to diagnose these symptoms and whether or not a physician diagnosed sprue-like enteropathy or other condition related to the Petitioner's alleged symptoms

        (viii) Any treatment prescribed to treat the Petitioner's symptoms.

20. In addition, the expert report of a cardiologist is necessary to provide greater clarity as to:

    a) The serious medical condition of hypertension, why and how it is treated and the consequences of failing to treat this potentially life-threatening condition, including:

        (i) the prevalence of hypertension;

        (ii) demonstrated benefits of pharmacological management, in general, and effectiveness of Angiotensin Receptor Blockers (ARBs), in particular; and

    b) The difference between Olmetec and Olmetec Plus, their use, efficacy, and position within the category of Angiotensin II Receptor Blockers (ARBs);

21. The expert reports that the applicant seeks to submit will help this Honorable Court in its analysis of the criteria for authorization of the Class Action pursuant to article 575 CCP.

22. It is in the interest of justice and the parties that Daiichi be granted permission to submit the expert reports of a gastroenterologist and a cardiologist.

III. MERCK CANADA INC. AND SCHERING-PLOUGH CANADA INC.'S *DEMANDE POUR PERMISSION DE PRODUIRE UNE PREUVE APPROPRIÉE ET POUR INTERROGER LE DEMANDEUR HORS COUR*

23. It is Daiichi's understanding that Merck Canada will file an application seeking to:

    a) Request permission to submit the affidavit of a regulatory expert and relevant statistics regarding prescription medicines in Canada over the relevant period;

    b) Request permission to examine the Petitioner with regard to the criteria for authorization of a class action, pursuant to article 575 CCP; and

    c) Obtain an order from the Court requiring the Petitioner to provide all of his relevant medical records as well as information regarding the Proposed Class.

24. Had Merck Canada not submitted such requests to the Court, Daiichi would have done so, as the above requests will no doubt prove to be productive in allowing the Court to make a decision with the fullest understanding of the issues.

25. In order to avoid duplication of requests and in accordance with the principle of proportionality, Daiichi will not make the same requests as Merck Canada and Shering.

26. Nevertheless, Daiichi fully supports Merck Canada's application.

27. The present application is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THIS COURT TO:

GRANT the present Application;

GIVE PERMISSION TO the Defendant Daiichi Sankyo Company, Ltd. to submit an expert report prepared by a gastroenterologist regarding the following subjects:

a) Sprue-like enteropathy, its symptoms, potential causes, risk/confounding factors and diagnostic;

b) The prevalence of sprue-like enteropathy;

c) The current state of scientific knowledge as to whether sprue-like enteropathy is related to (or caused by) the use of the Olmetec drugs (including the Studies filed by the Petitioner as Exhibit R-5):

d) The Petitioner's medical and pharmaceutical records, including:

(i) His use of the Products;

(ii) His need for medicine to treat his hypertension;

(iii) The information provided by his treating physician in this regard;

(iv) Other treatments discussed;

(v) Other drugs used by the Petitioner that may have impacted his condition and other confounding factors;

(vi) The Petitioner's symptoms;

(vii) The consultations and tests performed to diagnose these symptoms and whether or not a physician diagnosed sprue-like enteropathy or other condition related to the Petitioner's alleged symptoms

(viii) Any treatment prescribed to treat the Petitioner's symptoms.

GIVE PERMISSION TO the Defendant Daiichi Sankyo Company, Ltd. to submit an expert report prepared by a cardiologist to provide greater clarity as to:

a) The serious medical condition of hypertension, why and how it is treated and the consequences of failing to treat this potentially life-threatening condition, including:

(i) the prevalence of hypertension;

(ii) demonstrated benefits of pharmacological management, in general, and effectiveness of Angiotensin Receptor Blockers (ARBs), in particular; and

b) The difference between Olmetec and Olmetec Plus, their use, efficacy, and position within the category of Angiotensin II Receptor Blockers (ARBs);

GRANT Merck Canada Inc. and Schering-Plough Canada Inc.'s *Demande pour permission de produire une preuve appropriée et pour interroger le demandeur hors cour*;

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

Montréal, this October 31, 2017

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Amount in dispute: 0 $

ORIGINAL

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