C A N A D A

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

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

N° : 500-06-000734-158

JOSEE BERGERON, [redacted];

and

JOSEE BERGERON, *ès qualité* tutor to her minor child [redacted];

and

JOSEE BERGERON, *ès qualité* tutor to her minor child [redacted];

Petitioner

vs

LUNDBECK CANADA INC., a legal person, having its principal place of business at [redacted];

and

H. LUNDBECK A/S, a legal person, having its principal place of business at [redacted];

Respondents

MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE THE STATUS OF REPRESENTATIVE
(Art. 1002 C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT OF QUEBEC, SITTING IN AND FOR THE DISTRICT OF MONTREAL, THE PETITIONER STATES THE FOLLOWING:

GENERAL PRESENTATION

1. Petitioner wishes to institute a class action on behalf of her children, herself, and others similarly affected, as members of the proposed class, defined as follow:

> Any person in Canada (including their estates, executors, personal representatives, and family members) born with defects, to women who ingested Celexa while pregnant;

(hereinafter, referred to as "**Class Member(s)**", "**Group Member(s)**", the "**Group**", the "**Class**", the "**Member(s)**");

The Respondents:

2. Respondent H. Lundbeck A/S, is a Danish international corporation with its headquarters located at [redacted], Denmark;

3. H. Lundbeck A/S, originally founded in 1915, is a pharmaceutical company primarily concerned with the treatment of disorders in the central nervous system. For this purpose, it is engaged in the research and development, production, marketing, and sale of pharmaceuticals across the world, including Celexa;

4. Respondent Lundbeck Canada Inc., is a subsidiary of H. Lundbeck A/S, with its head office located at [redacted], Montreal, Québec, Canada;

5. Lundbeck Canada Inc. has been active in the Canadian pharmaceutical industry for almost two decades, marketing products for the treatment of depression, anxiety, and other mental and physical ailments;

6. "Lundbeck" hereinafter refers to a partnership, joint venture, or other common enterprise carrying on business in Canada and throughout the world, between H. Lundbeck A/S, Lundbeck Canada Inc., and any of their other affiliates or subsidiaries;

General Facts:

7. Known pharmaceutically as Citalopram, Celexa is part of a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medications work by increasing the amount of serotonin in the brain. Celexa is prescribed most commonly to treat depression, anxiety, panic disorder, and generalized anxiety disorders;

8. Children in the proposed Class are, and have been, permanently disabled as a result of birth defects caused by the use of Celexa by their mothers when pregnant;

9. Celexa has been associated with an increased risk of serious adverse cardiovascular and other complications for newborns when taken by women during or immediately before pregnancy, including but not limited to premature birth, miscarriage, withdrawal symptoms, clubbed foot, cleft lip or palate, delayed development, Persistent Pulmonary Hypertension of the Newborn ("PPHN"), gastroschisis, enlarged heart, septal heart defects, left outflow tract heart defects, macroephaly, craniosynostosis, neural tube defects, autism and spina bifida;

10. A Danish study published on November 17, 2006, identified 1051 women who filled prescriptions for SSRIs from 30 days before conception to the end of the first trimester, and concluded that there exists an increased risk of congenital malformations after exposure to SSRIs in early pregnancy. A copy of the study is attached hereto as **Exhibit P-1**. This belief was further accepted and confirmed with respect to Citalopram specifically, in another Danish study dated September 23, 2009, attached hereto as **Exhibit P-2**;

11. A different study published on February 9, 2006 in the *New England Journal of Medicine* showed a significant association between exposure of a mother to an SSRI during late pregnancy and the occurrence of PPHN, a commonly deadly defect, in her infant. This finding was consistent with an earlier observation in a small cohort study. A copy of the study is attached hereto as **Exhibit P-3**;

12. Further, an article published by MEDSAFE in May 2008, citing a number of sources, claimed that studies suggest that SSRI antidepressant use in pregnancy may increase the risk of congenital abnormalities. This article reinforced the possibility of an increased risk of congenital malformations with first trimester SSRI use, and listed a number of potential malformations including cleft palate, hypospadias, and cardiovascular abnormalities such as septal defects. A copy of the study is attached hereto as **Exhibit P-4**;

13. Women who have taken SSRIs including Celexa during pregnancy are also reported to be at higher risk of having a baby with a clubfoot birth defect. This has been confirmed by a study conducted by the Institute of Reproductive Toxicology at the University of Ulm, Germany and the authors of a July 2007 article in the *New England Journal of Medicine*, as it appears in a copy of an article attached hereto as **Exhibit P-5**. This concern was confirmed in another population-based case-control study published on November 25, 2014. A copy of an abstract of the study is attached hereto as **Exhibit P-6**;

14. Additionally, recent studies have linked the use of SSRIs during pregnancy to late development; lower language competence at age 3, and Citalopram specifically to Craniosynostosis, malformation of the infant's skull. Attached hereto as **Exhibits P-7** and **P-8** respectively;

15. Lundbeck did not adequately research or test the use of Citalopram by pregnant mothers, and ignored the large stream of medical evidence linking SSRI use, and specifically Citalopram, in such a capacity, to infant birth defects;

16. At all material times, Lundbeck failed to adequately warn the medical community and consumers of the risks associated with the use of Celexa by pregnant women;

17. The earliest product monograph from 1999 contains no reference to risks associated with pregnancy. As of the February 2002 product monograph, there is a section titled "Precautions" (not "Warnings") which states that "safety of Celexa during pregnancy and lactation has not been established. Therefore, Celexa should not be used during pregnancy, unless, in the opinion of the physician, the expected benefits to the patient markedly outweigh the possible hazards to the fetus". This statement is found in all future revisions of the product monograph;

18. For the first time, the November 2004 product monograph links citalopram ingestion during the third trimester to only withdrawal symptoms in the infant;

19. The inadequacy of this precaution was not all addressed until the product monograph was again updated in May 2011. This update combined the "Warning" and "Precaution" sections and contained the following:

> ***Citalopram Treatment during Pregnancy – Effects on Newborns***
>
> *In animal reproduction studies, citalopram has been shown to have adverse effects on embryo/fetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic dose. There are no adequate and well-controlled studies in pregnant women; therefore, citalopram should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.*
>
> *Post-marketing reports indicate that some neonates exposed to SSRIs and other antidepressants late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. When treating a pregnant woman with citalopram during the third trimester, the physician should carefully consider the potential risks and benefits of treatment.*

20. Since the 2011 revision, no substantial changes were made to the product monograph with respect to warning against the ingestion of Celexa during pregnancy and associated birth defects. Copies of the May 2004, May 2011, and June 2012 product monographs are attached hereto as **Exhibits P-9**, **P-10** and **P-11** respectively;

21. Had the true facts been disclosed by Lundbeck, namely, that Celexa is associated with an increased risk of birth defects when ingested by mothers during or immediately before pregnancy, the Petitioner and Class members in common would not have used Celexa;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

22. The Petitioner, Ms. Josee Bergeron is a resident of Gatineau, Quebec;

23. Ms. Bergeron was prescribed Celexa to treat symptoms of depression. She took Celexa from 2001 until 2008, including throughout both of her pregnancies. As a result, both of Ms. Bergeron's children suffer from birth defects;

24. M[redacted] was born on May 27, 2004 with physical and psychological defects, including a club foot. While M[redacted] was an infant, doctors instructed Ms. Bergeron to use two diapers on her, in an attempt to help her legs develop and grow in a manner that would allow her to walk normally. Her condition improved as a result;

25. M[redacted] is now 10 years old and suffering from depression and obsessive-compulsive disorder (OCD);

26. J[redacted] was born on May 30, 2006 demonstrating severe withdrawal symptoms. She was extremely lethargic, abnormally irritable, and lost a significant amount of weight as a result of feeding problems;

27. J[redacted] is now 8 years old and suffering from Attention Deficit Hyperactivity Disorder (ADHD), which requires ongoing treatment. Further, she was born with a club foot. Similarly to M[redacted], Ms. Bergeron was advised to use two diapers on J[redacted] to aid the development of her legs. However, this did not help her at all, and she continues to have a visible limp;

28. All of these birth defects were caused by Ms. Bergeron having been prescribed and having ingested Celexa during pregnancy. Her children have been forced to live with the negative health consequences;

29. M[redacted] and J[redacted]'s injuries have required ongoing and onerous burdens of time and effort on their mother and other family members. For example, M[redacted] has required visits to a psychiatrist to treat her depression and obsessive-compulsive disorder (OCD). Also, J[redacted] has undergone therapy for her ADHD symptoms. Ms. Bergeron has missed work in order to take her daughters to these appointments;

30. M[redacted] and J[redacted]'s physical and mental suffering, as well as the caregiving and financial burdens that their injuries have imposed upon their mother and family, are an ongoing reality. The costs generated to ensure proper monitoring and subsequent treatment, all of which have been and will continue to be, incurred as a result of Ms. Bergeron having ingested Celexa during pregnancy;

31. The damages suffered by the Petitioner are a direct and proximate result of the Respondents' conduct;

32. As a consequence of the foregoing, the Petitioner is justified in claiming damages;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

33. Consumers reasonably relied and rely upon the Respondents to ensure that Celexa is safe for human consumption and that all potential health risks are properly warned; risks such as *inter alia* premature birth, miscarriage, withdrawal symptoms, club foot, cleft lip or palate, delayed development, persistent pulmonary hypertension of the newborn ("PPHN"), gastroschisis, enlarged heart, septal heart defects, left outflow tract heart defects, macrocephaly, craniosynostosis, neural tube defects, autism, and spina bifida;

34. The injuries and damages of the Petitioner and the Group as described herein were caused by the negligence and misrepresentations of the Respondents;

35. As a result of the Respondents' faults described herein, Group Members have suffered and claim damages for the following:

a) compensatory damages as may be proved in this Honourable Court for:

(i) personal injury or death;

(ii) economic loss;

(iii) pain and suffering;

(iv) loss of income and earning capacity;

(v) loss of amenities and enjoyment of life;

(vi) loss of guidance, care and companionship;

(vii) costs of past and future care and related expenses;

36. exemplary and punitive damages;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

The composition of the group makes the application of Article 59 or 67 C.C.P. impractical or impossible for the reasons detailed below:

37. The number of potential Group Members is so numerous that joinder of all Members is impracticable. While the exact number of Group Members is unknown to Petitioner at the present time and can only be ascertained from sales

and distribution records maintained by the Respondents and its agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Canada;

38. Based on the number of potential Group Members, it is impossible for the Petitioner to identify all potential Group Members and obtain a mandate from each of them;

39. In addition, given the costs and risks inherent in an action before the Courts, many people will hesitate to institute an individual action against the Respondents. Even if the Group Members themselves could afford such individual litigation, the Court system could not as it would be overloaded;

40. In these circumstances, a class action is the only appropriate procedure for all of the Members of the Group to effectively pursue their respective rights and have access to justice;

The questions of fact and law which are identical, similar, or related with respect to each of the Class Members:

41. The recourses of the members raise identical, similar or related questions of fact or law, namely:

a) Does the ingestion of Celexa during pregnancy cause or increase the risk of birth defects?

b) Did Respondents know or ought to have known that the ingestion of Celexa during pregnancy could cause birth defects?

c) Did Respondents conduct adequate research or test for the use of Celexa during pregnancy?

d) Did Respondents adequately inform the medical community and consumers of the risks associated with the ingestion of Celexa during pregnancy?

e) Are Respondents liable to pay compensatory damages to the Group Members, and if so, in what amount?

f) Are Respondents liable to pay moral damages to the Group Members, and if so, in what amount?

g) Are Respondents liable to pay punitive damages to the Group Members, and if so, in what amount?

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

42. The action that the Petitioner wishes to institute for the benefit of the members of the Group is an action in damages for product liability;

43. The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings are:

GRANT Petitioners' action against Respondents;

GRANT the class action of Petitioner on behalf of all the Members of the Group;

CONDEMN Respondents to pay an amount in compensatory damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in moral damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

ORDER the treatment of individual claims of each Member of the Group in accordance with Articles 1037 to 1040 C.C.P.;

THE WHOLE with interest and additional indemnity as provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members;

44. Petitioner suggests that this class action be exercised before the Superior Court in the District of Montreal for the following reasons:

a) The Respondents sell Celexa in the District of Montreal;

b) Many Group Members are domiciled in the District of Montreal;

c) The Respondents have a business establishment in the District of Montreal;

d) The Petitioner's legal counsel practices law in the District of Montreal;

45. The Petitioner, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the Members of the Group, since Petitioner:

a) ingested Celexa for 7 years, including during pregnancies, and her daughters were born with birth defects;

b) understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;

c) is available to dedicate the time necessary for the present action before the Courts of Quebec and to collaborate with Class attorneys in this regard;

d) is ready and available to manage and direct the present action in the interest of the Group Members that the Petitioner wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class;

e) does not have interests that are antagonistic to those of other members of the Group;

f) has given the mandate to the undersigned attorneys to obtain all relevant information to the present action and intend to keep informed of all developments;

g) is, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Members of the Group and to keep them informed;

46. The present motion is well-founded in fact and in law;

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the bringing of a class action in the form of a motion to institute proceedings in damages;

ASCRIBE the Petitioner the status of representative of the persons included in the Group herein described as:

> *Any person in Canada (including their estates, executors, personal representatives, and family members) born with defects, to women who ingested Celexa while pregnant;*

IDENTIFY the principle questions of fact and law to be treated collectively as the following:

a) Does the ingestion of Celexa during pregnancy cause or increase the risk of birth defects?

b) Did Respondents know or ought to have known that the ingestion of Celexa during pregnancy could cause birth defects?

c) Did Respondents conduct adequate research or test for the use of Celexa during pregnancy?

d) Did Respondents adequately inform the medical community and consumers of the risks associated with the ingestion of Celexa during pregnancy?

e) Are Respondents liable to pay compensatory damages to the Group Members, and if so, in what amount?

f) Are Respondents liable to pay moral damages to the Group Members, and if so, in what amount?

g) Are Respondents liable to pay punitive damages to the Group Members, and if so, in what amount?

IDENTIFY the conclusions sought by the class action to be instituted as being the following:

GRANT Petitioners' action against Respondents;

GRANT the class action of Petitioner on behalf of all the Members of the Group;

CONDEMN Respondents to pay an amount in compensatory damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in moral damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

ORDER the treatment of individual claims of each Member of the Group in accordance with Articles 1037 to 1040 C.C.P.;

THE WHOLE with interest and additional indemnity as provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members;

FIX the delay of exclusion at 60 days from the date of the publication of the notice to the Members;

DECLARE that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

ORDER the publication of a notice to the Members of the Group in accordance with Article 1006 C.C.P.;

THE WHOLE with costs to follow.

Montréal, March 10, 2015

Merchant Law Group LLP

MERCHANT LAW GROUP LLP
Attorneys for the Petitioner

CERTIFIED COPY

MERCHANT LAW GROUP LLP
Attorneys for the Petitioner