CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

No.: 500-06-

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

KIM PARKER, residing and domiciled at [redacted]

and

JÉRÉMIE LAFOND, residing and domiciled at [redacted]

The Petitioners

vs.

APOTEX INC, a legal person duly constituted, with its principal establishment located at 150 Signet Drive, Toronto, Province of Ontario, M9L 1T9;

and

LABORATORIOS LEÓN FARMA, a legal person duly constituted, having its principal establishment located at Polígono Industrial Navatejera C/ La Vallina, s/n 24008 Navatejera, León, Spain;

The 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 QUÉBEC, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PETITIONERS STATE THE FOLLOWING:

1. The Petitioners wish to institute a class action on behalf of the following Group, of which they are members, namely:

   All persons in Canada who purchased or ingested Alysena 28 with Lot numbers LF01899A, LF01898A, LF01894B, LF01901A, LF01900A, LF01980A, LF01982A, LF01981A, LF01979A, LF02037A, LF02036A, and LF02026A and Lots that were half placebo and half active medicinal ingredients ("**Defective Alysena 28**"), and all persons in Canada who will become a parent of an unplanned pregnancy due to Defective Alysena 28;

   (hereinafter referred to as the "Group Members" or the "Group");

THE RESPONDENTS

2. The Respondent Apotex Inc ("Apotex") is incorporated and carries on business in Canada, with offices located at 150 Signet Drive, Toronto, Ontario M9L 1T9, as it appears from a copy of a report from the Registre des Entreprises, hereby filed as **Exhibit P-1**;

3. The Respondent Laboratorios León Farma ("Laboratorios") is a company in Spain located at Polígono Industrial Navatejera C/ La Vallina, s/n 24008 Navatejera, León, Spain. Laboratorios produces Alysena 28, as it appears in a copy of the Chemo Group Official Web Page, hereby filed as **Exhibit P-2**;

4. Apotex and Laboratorios ("the Respondents") shared the common purpose of producing, manufacturing, marketing, selling, or distributing Alysena 28 in Canada for profit. The business and interests of the Respondents are interwoven and each is the agent of the other, as it appears in a copy of an article from iStockAnalyst, hereby filed as **Exhibit P-3**;

5. At all material times, the Respondents were involved in producing,

manufacturing, marketing, selling, or distributing Alysena 28 in Canada directly or through agent(s), affiliate(s), or subsidiaries;

6. Alysena 28 is a generic birth control pill produced, manufactured, marketed, and distributed by the Respondents. It is the generic birth control pill for the brand-name Alesse 28;

7. The active tablets in Alysena contain levonorgestrel – ethinyl estradiol, which is a progestin and estrogen combination birth control pill used to prevent pregnancy. The ingredients of this medication work by preventing ovulation (the release of an egg from an ovary). This medication also causes changes in the mucus of the cervix, which makes it difficult for sperm to penetrate and for an egg to implant;

8. The inactive tablets in Alysena are placebo tablets and do not contain levonorgestrel – ethinyl estradiol;

9. Patients prescribed this medication are to take one active tablet daily for 21 days, then take one reminder placebo tablet for 7 days, and then begin the next blister pack;

10. Typically, one week of the placebo tablets is included in a 28-day pack to help women remember to take the medication every day. If women took two weeks of placebo pills instead of one, it would significantly increase the risk of unplanned pregnancy;

11. The correct packaging of Alysena 28 is one row of white placebo tablets (7 tablets) and three rows of pink active contraceptive tablets (21 tablets) in the blister pack;

12. The blister packs of Defective Alysena 28 dispensed to the Petitioner, Ms. Parker, contained two rows of white placebo tablets (14 tablets) and two rows of pink active contraceptive tablets (14 tablets);

13. On April 8, 2013, Health Canada warned consumers that the Defective Alysena 28 contained two rows of white placebo tablets and two rows of pink active contraceptive tablets in the blister packs. As such, Health Canada issued a recall of one lot of Defective Alysena 28, namely, lot LF01899A, as it appears on a copy of a Recalls & Alerts notice from Health Canada, hereby filed as **Exhibit P-4**;

14. On April 12, 2013, Health Canada expanded the Defective Alysena 28 recall to another 11 lots, namely, lot numbers LF01901A, LF01980A, LF02037A, LF01900A, LF01982A, LF02036A, LF01898A, LF01981A, LF02026A, LF01894A, LF01979A, for a total of 50,000 blister packs, as it appears on a copy of a Recalls & Alerts notice from Health Canada, hereby filed as **Exhibit P-5**;

FAULTS COMMITTED BY THE RESPONDENTS

15. Defective Alysena 28 which was manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by the Respondents, was defective in its manufacture when it left the hands of the Respondents. In particular, the product grossly deviated from performance standards expected by the consumer, such that it caused the very outcome it was supposedly designed to prevent – unwanted pregnancy;

16. The Respondents communicated the purported benefits of Defective Alysena 28 while failing to disclose the eminent contraceptive failure with the intent that consumers, including the Petitioners, would purchase and ingest Defective Alysena 28;

17. The Respondents misled the Petitioners by and through statements made by the Respondents, their authorized agents, or sales representatives (or through doctors and pharmacists). These representations that Defective Alysena was

safe, effective, and fit and proper for its intended use were made orally and in publications, package inserts, and other written materials to the health care community and the general public;

18. In using Defective Alysena 28, the Petitioners relied on the representations made by the Respondents to the healthcare community and the public. As a direct result of the Respondents' faults, the Petitioners suffered physical and moral damages, and are entitled to be compensated;

19. Despite the fact that the Respondents knew or ought to have known that Defective Alysena 28 caused unwanted pregnancies and posed a serious increased risk of pregnancy, injury, or bodily harm to consumers, the Respondents did not notify consumers and Group Members of its recall. When the Respondents became aware of the defect, they did not act with the timeliness required to minimize the potential damages to the Petitioners and the Group Members;

20. Certain lots of Defective Alysena 28 were already being sold by mid-December of 2012. The Respondents allege to have learned on April 3, 2013 that Defective Alysena 28 blister packs may have contained an extra week of the placebo pills. Notifications of the recall were only sent to pharmacists (Class II recall). The Respondents did not notify customers of the initial recall for five days after the problem was identified. Because of their delayed response in informing the public, the Respondents jeopardized the consumers' ability to use alternative forms of birth control thereby causing unplanned pregnancies or greatly increasing the risk of pregnancy;

21. Based on their own assessment, the Respondents issued a Class II recall, which requires drugstores to remove the product from their stock, but not alert consumers;

22. A Class II recall was inadequate. The April 3, 2013 Class II recall was not timely. But for the Class I recall of Health Canada on April 8, 2013, the Petitioners and Group Members might never have been made aware of the potential harm flowing from the Respondents' wrongful actions;

23. As a direct and proximate result of the Respondents' negligence, the Petitioners and Group Members suffered injury, economic loss, and damages, for which the Respondents are solely liable;

24. Each Member of the Group is entitled to claim compensatory damages directly caused by the faults of the Respondents, as well as moral damages;

25. Moreover, pursuant to the *Consumer Protection Act*, R.S.Q., c. P-40.1, each Member of the Group is entitled to punitive damages due to the gravity of the faults committed by the Respondents;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONERS

26. The Petitioner, Kim Parker, is a resident of Montréal, Québec. Ms Parker was prescribed and began using the Defective Alysena 28, as it appears on the copy of her receipt hereby filed as **Exhibit P-6**;

27. The Petitioner, Jérémie Lafond, is a resident of Montréal, Québec, and is in a conjugal relationship with Ms. Parker;

28. Notwithstanding the fact that Ms. Parker was properly using Defective Alysena 28 in the manner for which it was intended, she discovered that she was pregnant with an unplanned pregnancy. Ms. Parker is currently 25 weeks pregnant;

29. The Petitioners did not plan to become pregnant, and in fact, took steps to

actively avoid pregnancy;

30. The unplanned pregnancy has caused the Petitioners great emotional distress and life-altering consequences. The Petitioners now face financial, ethical, moral, and health issues;

31. Further, if and when the child is born, it is unknown whether he or she will suffer any birth defects given that Ms. Parker was using Defective Alysena 28 during the first trimester of her pregnancy, and the use of artificial birth control pills, here Defective Alysena 28, after conception is dangerous for the unborn child;

32. Further, if and when the child is born, the Petitioners will necessarily incur great expenses to raise the child;

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

33. Each Member of the Group ingested the Defective Alysena 28 and/or has or will become pregnant due to an unplanned pregnancy. Thus, each Group Member have common claims that are founded on the same underlying facts as the Petitioners' as they pertain to the acts and omissions of the Respondents;

34. Each Member of the Group suffered damages directly related to the consumption of Defective Alysena 28;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

35. The composition of the Group makes the application of Articles 59 or 67 C.C.P. impractical for the following reasons:

a) 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 the Petitioners 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 in Québec and throughout Canada;

b) Based on the number of potential Group Members and issues concerning privacy, it is impossible for the Petitioners to identify all potential Group Members and obtain a mandate from each of them. The Petitioners do not possess the names and addresses of potential Group Members;

c) 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. Furthermore, individual litigation of the factual and legal issues raised by the conduct of the Respondents would increase delay and expense to all parties and to the judicial system;

d) Moreover, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province) risks having contradictory judgments on questions of fact and law that are similar or related to all Group Members;

36. The recourses of the Group Members raise identical, similar, or related questions of fact or law, namely:

a) Does the consumption of Defective Alysena 28 protect against unwanted pregnancies?

b) As a result of unwanted pregnancies, was Defective Alysena 28 unsound, defective, unsafe or unfit for the purpose for which it was intended?

c) Were the Respondents negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling, or selling of Defective Alysena 28 to the Group Members?

d) Did the Respondents know or ought to have known that Defective Alysena 28 was defective, and if so, from what time?

e) Did the Respondents adequately advise and warn the Group Members of the non-adequacy and risks of Defective Alysena 28?

f) Did the use of Defective Alysena 28 cause unwanted pregnancies and injuries?

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

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

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

40. The questions of fact and law particular to each member consist of:

a) The amount of damages suffered;

b) The amount of damages that each Group Member can claim from the Respondents;

41. The interests of justice favour that this motion be granted in accordance with its conclusions.

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

42. The action that the Petitioners wish to institute for the benefit of the Group Members is an action in damages for product liability;

43. The conclusions that Petitioners wish to introduce by way of a motion to institute proceedings are for the Court to:

GRANT the Petitioners' action against the Respondents;

AUTHORIZE the Petitioners to commence this action as a class action;

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

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

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

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

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

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

44. The Petitioners suggest that this class action be exercised before the Superior Court in the District of Montréal for the following reasons:

a) The Respondents have sold Defective Alysena 28 in the District of Montréal;

b) The Petitioners reside in the District of Montréal;

c) Many Group Members are domiciled or work in the District of Montréal;

d) The Petitioners' legal counsel practise law in the District of Montréal.

45. The Petitioners, who are requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the members of the Group since the Petitioners:

a) purchased, and in Ms. Parker's case, consumed Defective Alysena 28 multiple times over one month;

b) were not given the chance to make an informed consent before purchasing and consuming the product;

c) suffered damages from using Defective Alysena 28;

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

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

f) are ready and available to manage and direct the present action in the interest of the Class Members that the Petitioners wish to represent, and are determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Group;

g) do not have interests that are antagonistic or in conflict to those of other members of the Group;

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

i) are, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Group Members 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;

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

All persons in Canada who purchased or ingested Alysena 28 with Lot numbers LF01899A, LF01898A, LF01894B, LF01901A, LF01900A, LF01980A, LF01982A, LF01981A, LF01979A, LF02037A, LF02036A, and LF02026A and Lots that were half placebo and half active medicinal ingredients, and all persons in Canada who will become a parent of an unplanned pregnancy due to Defective Alysena 28;

or any other Group or Sub-Group to be determined by the Court.

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

a) Does the consumption of Defective Alysena 28 protect against unwanted pregnancies?

b) As a result of unwanted pregnancies, was Defective Alysena 28 unsound, defective, unsafe or unfit for the purpose for which it was intended?

c) Were the Respondents negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling, or selling of Defective Alysena 28 to the Group Members?

d) Did the Respondents know or ought to have known that Defective Alysena 28 was defective, and if so, from what time?

e) Did the Respondents adequately advise and warn the Group Members of the non-adequacy and risks of Defective Alysena 28?

f) Did the use of Defective Alysena 28 cause unwanted pregnancies and injuries?

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

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

i) Are the Respondents liable to pay exemplary or 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 the Petitioners' action against the Respondents;

AUTHORIZE the Petitioners to commence this action as a class action;

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

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

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

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

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

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

MONTRÉAL. September 26. 2013

Merchant Law Group LLP

MERCHANT LAW GROUP LLP
Attorneys for the Petitioners

NOTICE OF PRESENTATION

TO: **APOTEX INC**
150 Signet Drive
Toronto, Province of Ontario,
M9L 1T9;

and

LABORATORIOS LEÓN FARMA
Polígono Industrial Navatejera
C/ La Vallina, s/n 24008
Navatejera,
León, Spain;

TAKE NOTICE that the Petitioners have filed this MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE THE STATUS OF REPRESENTATIVE in the office of the Superior Court of the Judicial District of Montréal.

The Motion will be presented before one of the Honourable Judges of the Superior Court of Québec, District of Montréal, on **December 4, 2013** at **9:00 AM**, in room **2.16** of the Courthouse of Montréal situated at 1 Notre Dame East, Montréal, Québec. On that date, the Court may exercise such powers as are necessary to ensure the orderly progress of the proceeding or the Court may hear the case.

MONTRÉAL, September 26, 2013

Merchant Law Group LLP

MERCHANT LAW GROUP LLP
Attorneys for the Petitioners