CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

No.: 500-06-000512-109

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

YANN LEBRASSEUR, [redacted]

Petitioner

vs.

HOFFMANN-LA ROCHE LIMITÉE, [redacted]

Respondent

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 PETITIONER STATES THE FOLLOWING:

1. Petitioner wishes to institute a class action on behalf of the following Group, of which he is a member, namely:

SUB-GROUP A:

All persons in Canada (including their estates, executors, or personal representatives), who have ingested prescription medications containing an ingredient called Isotretinoin, manufactured, marketed or distributed by the Respondent, and who claim that they have suffered or are suffering from bowel injuries such as Crohn's disease, ulcerative colitis, proctitis, inflammatory bowel

disease (IBD), rectal bleeding and ileitis as a result of ingesting said prescription medications;

SUB-GROUP B:

All persons in Canada (including their estates, executors, or personal representatives), who have ingested prescription medications containing an ingredient called Isotretinoin, manufactured, marketed or distributed by the Respondent, and who claim that they have suffered or are suffering from any and all other side effects (not listed in Sub-Group A above), including but not limited to pancolitis, abdominal cramping and pain, pseudotumor cerebri of central nervous system (benign intracranial hypertension, intracranial hypertension), bone and muscle damage, hearing and vision impairment, liver damage, pancreatitis (including hemorrhagic pancreatitis), lupus, immunodeficiency (deficiency of immune system), glomerulonephritis (inflammatory disease of the kidneys), psychiatric side effects such as suicide, suicidal thoughts, suicide attempts, depression, aggression, paranoia, violent behaviors, psychosis, changes in personality, mood swings, withdrawal and abnormal behaviors, and birth defects;

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

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

2. Respondent **HOFFMANN-LA ROCHE LIMITÉE** does business under various other names, including but not limited to **HOFFMAN-LAROCHE LIMITED**, **ROCHE DIAGNOSTICS**, **ROCHE DIAGNOSTICS, DIVISION DE HOFFMANN-LA ROCHE LIMITÉE** and **ROCHE DIAGNOSTICS, DIVISION OF HOFFMANN-LA ROCHE LIMITED**;

3. Respondent (including its past and present related companies) is a pharmaceutical company that researches, develops, designs, tests, manufactures, distributes, labels, packages, supplies, markets, sells, advertises, and/or distributes various pharmaceutical products including products containing Isotretinoin, sold under the various brand names such as Accutane, Accutane Roche or Roaccutane in Canada and/or other countries (collectively referred to as "**Accutane**" hereinbelow).

4. Accutane (generically known as isotretinoin) is an acne medication alleged to cause serious injuries including but not limited to inflammatory disease of the intestines, an increased risk of colon cancer and psychiatric side effects such as suicide, depression and other serious conditions.

5. The Respondent, together with or through its parent companies, subsidiary companies or partners, has operations in numerous countries and sells its products worldwide. The Respondent offers and carries on business in the Province of Québec and throughout Canada, and derives revenue as a result of its presence and users located in Québec and throughout Canada (herein, references to the "Respondent" are intended to include the above mentioned corporation, subsidiaries, affiliates, predecessors and associated companies).

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

6. The Petitioner, **YANN LEBRASSEUR** is presently 24 years old and resides in the City of Châteauguay, Québec.

7. Approximately six years ago, Mr. Lebrasseur was prescribed and began taking Accutane for several months;

8. While taking Accutane, Petitioner suffered from extreme fatigue, extreme

dryness in the sinuses (to the point where they would bleed), extreme dryness of the lips and general skin dryness.

9. After discontinuing Accutane, Petitioner was diagnosed with Crohn's disease, which is an inflammatory disease of the intestines that may affect any part of the gastrointestinal tract.

10. The Petitioner is now living with Crohn's disease and suffers from regular abdominal cramping and pain, diarrhea and weight loss.

11. When being prescribed and ingesting Accutane, Petitioner was not made aware of and was not warned that the use of Accutane could lead him to such serious health problems. Had Petitioner been so warned, he would not have agreed to purchase and use Accutane.

12. The Petitioner suffered and continues to suffer pain and injuries as a result of using Accutane and claims damages as a result.

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

13. The prescription drugs containing an active ingredient called Isotretinoin, in the form of capsule, was researched, developed, designed, tested, manufactured, distributed, and marketed by the Respondent under different brand names.

14. Isotretinoin capsules are used for the treatment of severe acne among youth or young patients.

15. Isotretinoin was developed in 1982 by F. Hoffmann–La Roche Ltd., a Swiss global health-care company, which is a related company to the Respondent.

16. In April of 2001, the Respondent began to manufacture and sell the prescription drug containing Isotretinoin under various brand-names including Accutane, Accutane Roche, or Roaccutane, in Canada and other countries;

17. Accutane was prescribed to thousands of patients without clear, complete and current warning of the risk of serious side effects.

ACCUTANE'S RISKS

18. Patients who were administered Accutane containing Isotretinoin have been known to suffer from some of the following side effects (not an exhaustive list):

a) Inflammatory Bowel Disease (IBD);

b) Crohn's Disease;

c) Ulcerative Colitis;

d) Proctitis;

e) Rectal Bleeding;

f) Ileitis;

g) Increased risk of colon cancer;

h) Pancolitis;

i) Abdominal cramping and pain;

j) Pseudotumor Cerebri of Central Nervous System (Benign Intracranial Hypertension, Intracranial Hypertension);

k) Bone and muscle damage;

l) Hearing and vision impairment;

m) Liver damage;

n) Pancreatitis (including Hemorrhagic Pancreatitis);

o) Lupus;

p) Immunodeficiency (Deficiency of the immune system);

q) Glomerulonephritis (Inflammatory disease of the kidneys);

r) Psychiatric side effects such as suicide, suicidal thoughts, suicide attempts (Suicidal Ideation), depression, aggression, paranoia, violent behaviors, psychosis, changes in personality, mood swings, withdrawal and abnormal behaviors;

s) Birth defects;

t) Other Serious Conditions.

RESPONDENT'S CONDUCT

19. The Respondent researched, designed, tested, manufactured, marketed, labelled, distributed, promoted and sold Accutane in many countries including Canada.

20. Before and after Accutane was put on the Canadian market, numerous articles in leading scientific or medical journals and magazines were published in many countries, which revealed or suggested that Accutane is associated with an increased risk of causing the above-stated health problems.

21. Therefore, Respondent knew or should have known that Accutane is associated with increased risks of serious adverse medical events as described above but failed to fully inform the professionals and the public, including the Petitioner and putative Class Members, of such risks in a timely manner.

22. Respondent therefore ignored the potentially serious risks posed to the public and deliberately held back information from the public and the Class Members the whole in order to increase its own profits.

23. The Respondent knew or should have known the risks of using Accutane but portrayed Accutane as a safe drug. The Class Members relied on the Respondent's misrepresentations and were induced to use Accutane.

24. Had the true facts been disclosed that Accutane is associated with serious adverse effects as stated above, the use of Accutane on an objective Class wide basis would not have occurred.

25. The Respondent misled or deceived the Petitioner and the Class Members by representing in written labelling, written marketing materials, and advertising that Accutane does not pose the aforesaid risks to them during its normal use.

26. At all material times, the Respondent failed to provide the medical community and the general public with a clear, complete, and current warning of the risks associated with Accutane use, or failed to provide such warning in a timely manner, and the Respondent was negligent in that regard.

27. Further, or in the alternative, the Respondent did below standard research, design, and tests on Accutane, and made a defective drug product; thus, the Respondent was negligent in these regards.

28. In June 2009, Respondent pulled Accutane from the US market.

RESPONDENT'S LIABILITY

29. The Petitioner pleads that the Respondent is liable for the damages suffered by the Petitioner in that the Respondent was engaged in the business of researching, creating, designing, testing, manufacturing, labelling, packaging, supplying, marketing, selling, advertising, and distributing Accutane, when it knew or ought to have known about the serious risks but still sold and distributed

it in Canada and other countries.

30. Respondent deprived the Petitioner and the Class Members of their right to know what risks are involved in the use of Accutane and their right to make a meaningful choice between a number of alternative forms of drugs available to them.

31. The injuries and damages of the Petitioner and the Class as described herein were caused by the negligence and misrepresentations of the Respondent through its agents, representatives, and employees acting within the course and scope of their employment for which the Respondent is solely liable. Such negligence includes but is not limited to the following:

a) carelessly and negligently researching, designing, analyzing, manufacturing, testing, selling, merchandising, advertising, promoting, labelling, distributing, and marketing Accutane;

b) failing to fully disclose the results of the testing, learned articles and outside research, and other information in its possession regarding the possibility that Accutane can pose serious risks to the Class Members in a timely manner or at all;

c) being careless and negligent in that the Respondent knew or ought to have known that Accutane was a substance that would be causing injuries to the Class Members;

d) negligently and carelessly failing to appropriately and effectively warn the medical community and relevant authorities, the general public and the Class Members, in a timely manner, of the risks of using Accutane;

e) negligently and carelessly representing that Accutane was safe for use by the public including the Petitioner and Class Members, when in fact, the Respondent knew or ought to have known that it was unsafe;

f) negligently and carelessly failing to act as a reasonably prudent drug manufacturer; and

g) negligently and carelessly over promoting Accutane in a zealous and unreasonable way, without regard to the potential danger that it imposes to the public including the Petitioner and Class Members.

32. As a direct and proximate result of the Respondent's negligence, the Class Members suffered pain, damages and injuries for which the Respondent is solely liable.

33. The Respondent expressly warranted to the market, including Members of the Class, by and through statements made by the Respondent or its authorized agents or sales representatives, orally, or in publications, package inserts, product monographs or other written materials to the medical community or the public, as they marketed and did business in Canada and other countries, that Accutane was safe, effective, and fit and proper for its intended use.

34. In using Accutane, the Class Members relied on the skill, judgment, representations, and foregoing warranties of the Respondent. These warranties and representations proved to be false because the product was not safe or was unfit for the purposes for which it was intended.

35. By taking deliberate steps to preserve the relationship of informational inequality in its favour, and by wilfully and wantonly neglecting to inform and by intentionally misleading professionals and the public about the material risks associated with the use of Accutane, all for the sole purpose of increasing its own personal economic gain, Respondent preferred its own economic interest over the bodily interests and bodily security and integrity of Class Members.

36. Accordingly, the claims of each Group Member are founded on the same underlying facts as the Petitioner's claims.

37. Each Member of the Group has purchased and consumed Accutane;

38. Group Members were not adequately advised of the potential health effects of consuming Accutane;

39. Every member of the Group's consent when purchasing Accutane was vitiated as a result of the false or misleading statements made by Respondent, which are described hereinabove;

40. Every member of the Group would not have purchased the Accutane products in question if it weren't for Respondent's misleading marketing campaign described above;

41. Each Member of the Group is entitled to claim damages because of the faults committed by the Respondent;

42. The Petitioner therefore, on his behalf and on behalf of the Class Members, claims all appropriate remedies including restitution of all monies paid by Class Members for the purchase of Accutane, or in the alternative a monetary judgment in an amount equal to all benefits conferred and realized by the Respondent by reason of its conduct which alternative remedy would include all monies realized as profits from the sale of Accutane, and in the further alternative, monetary judgment based upon unjust enrichment.

43. Furthermore, and as a result of the Respondent's negligence and faults described herein, the Petitioner and Class Members have suffered and claim damages for the following:

a) personal injuries suffered;

b) economic and financial losses;

c) pain and suffering;

d) loss of amenities and enjoyment of life;

e) costs of future care and related expenses;

f) such further and other damages, the particular of which may be proven at trial.

44. Moreover, the Respondent's conduct, through actions or inactions, its awareness of the serious hazards of said drug, and its failure to fully, clearly, and in a timely way disclose and publicize the dangers of said drug, subjects the Respondent to punitive and exemplary damages.

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

45. The composition of the Group makes the application of Article 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 Petitioner at the present time and can only be ascertained from sales and distribution records maintained by the Respondent and its agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Canada;

b) 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. Petitioner does 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

Respondent. Even if the Class 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 Respondent would increase delay and expense to all parties and to the Court 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 Members of the Class;

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

a) Does the consumption of Accutane cause an increase in negative health effects, and to what extent?

b) As a result of negative health effects, was Accutane defective, unsafe, or unfit for the purpose for which it was intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce in Canada by the Respondent?

c) Was Respondent therefore negligent or did it commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of Accutane to the Group Members?

d) Did the Respondent adequately advise and warn the Group Members of the negative health effects associated with the consumption of Accutane?

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

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

g) Is Respondent liable to pay exemplary or punitive damages to the Group Members, and if so in what amount?

47. The majority of the issues to be dealt with are issues common to every Group Member.

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

49. The action that Petitioner wishes to institute for the benefit of the Members of the Group is an action in damages for product liability.

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

GRANT Petitioner's action against Defendant;

CONDEMN Defendant 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 Defendant 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 Defendant 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;

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

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 provided for in the *Civil Code of Québec* and with full costs and expenses including expert's fees and publication fees to advise members.

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

a) Respondent sells Accutane in the District of Montréal;

b) The Petitioner resides in the District of Montréal;

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

d) Petitioner's legal counsel practice law in the District of Montréal.

52. 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) purchased and consumed Accutane multiple times over many months, the whole as a result of Respondent's misleading marketing campaign described above;

b) was not given the chance to make an informed decision and give an informed consent before purchasing and consuming the said products, again due to Respondent's misleading marketing campaign described above;

c) suffered damages from using Accutane;

d) 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;

e) 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;

f) is ready and available to manage and direct the present action in the interest of the Class Members that 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;

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

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

i) 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;

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

SUB-GROUP A:

All persons in Canada (including their estates, executors, or personal representatives), who have ingested prescription medications containing an ingredient called Isotretinoin, manufactured, marketed or distributed by the Respondent, and who claim that they have suffered or are suffering from bowel injuries such as Crohn's disease, ulcerative colitis, proctitis, inflammatory bowel disease (IBD), rectal bleeding and ileitis as a result of ingesting said prescription medications;

SUB-GROUP B:

All persons in Canada (including their estates, executors, or personal representatives), who have ingested prescription medications containing an ingredient called Isotretinoin, manufactured, marketed or distributed by the Respondent, and who claim that they have suffered or are suffering from any and all other side effects (not listed in Sub-Group A above), including but not limited to pancolitis, abdominal cramping and pain, pseudotumor cerebri of central nervous system (benign intracranial hypertension, intracranial hypertension), bone and muscle damage, hearing and vision impairment, liver damage, pancreatitis (including hemorrhagic pancreatitis), lupus, immunodeficiency (deficiency of immune system), glomerulonephritis (inflammatory disease of the kidneys), psychiatric side effects such as suicide, suicidal thoughts, suicide attempts, depression, aggression, paranoia, violent behaviors, psychosis, changes in personality, mood swings, withdrawal and abnormal behaviors, and birth defects;

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 Accutane cause an increase in negative health effects, and to what extent?

b) As a result of negative health effects, was Accutane defective, unsafe or unfit for the purpose for which it was intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce in Canada by the Respondent?

c) Was Respondent therefore negligent or did it commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of Accutane to the Group Members?

d) Did the Respondent adequately advise and warn the Group Members of the negative health effects associated with the consumption of Accutane?

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

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

g) Is Respondent 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 Petitioner's action against Defendant;

CONDEMN Defendant 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 Defendant 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 Defendant 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;

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

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 provided for in the *Civil Code of Québec* and with full costs and expenses including expert's fees and publication fees to advise 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;

FIX the delay of exclusion at 30 days from the date of the publication of the notice to the Members;

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.

MONTREAL, July 15, 2010

Merchant Law Group LLP

MERCHANT LAW GROUP LLP
Attorneys for Petitioner

Nº.: 50 500 06-000512-109

SUPERIOR COURT

DISTRICT OF MONTREAL

YANN LEBRASSEUR

Petitioner

- vs -

HOFFMANN – LA ROCHE LIMITÉE

Respondent

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ORIGINAL

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