CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000545-109

(Class Action)
SUPERIOR COURT

J. ROSEN

Petitioner

-vs.-

PALADIN LABS INC., legal person duly constituted, having its head office at 6111, Royalmount Avenue, Suite 102, City of Montreal, Province of Quebec, H4P 2T4

Respondent

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

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER STATES AS FOLLOWS:

I. GENERAL PRESENTATION

A) The Action

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

    - all persons residing in Canada who have taken and/or purchased the drug DARVON-N (dextropropoxyphene) 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 have taken and/or purchased the drug DARVON-N (dextropropoxyphene) their successors,

assigns, family members, and dependants, or any other group to be determined by the Court.

B) The Respondent

2. Respondent Paladin Labs Inc. is a Canadian federal incorporation involved in the "development, production marketing of pharmaceuticals", the whole as appears more fully from a copy of the *Registre des entreprises* (CIDREQ) report, produced herein as **Exhibit R-1**;

3. Respondent has performed all of the commercial activities of designing, testing, manufacturing, labelling, packaging, assembling, advertising, marketing, promoting, branding, distributing, selling, and/or putting the drug Darvon-N onto the marketplace in Canada, including the province of Quebec;

4. The head office and manufacturing facility of the Respondent in all of Canada appears to be in the province of Quebec -- therefore, the drug Darvon-N is likely made there and shipped out from Quebec to the rest of Canada;

5. Unless the context indicates otherwise, the Respondent will be referred to as "Paladin" for the purposes hereof;

C) The Situation

6. The prescription drug Darvon-N (or Darvon as is referred to in the USA), a drug which contains the active ingredient dextropropoxyphene (also known as propoxyphene), was first approved for sale in the United States in 1957 by the US Food and Drug Administration (FDA). It has been approved for sale in Canada for an extended period of time as well;

7. Propoxyphene has been marketed in the USA since 1976 as either a single ingredient (e.g. "Darvon") or in combination with acetaminophen (e.g. "Darvocet") to treat mild to moderate pain, whether with or without a fever;

8. In Canada, propoxyphene belongs to the class of medications called narcotic analgesic (pain relievers) and is sold as a single ingredient only, as Darvon-N in 100 mg capsules;

9. As estimated 10 million people in the USA received prescriptions for Darvon and related drugs in 2009, according to the FDA;

10. In the year 2003, 119,584 prescriptions for Darvon-N were filled by Canadian retail drug stores and by the year 2008, that number had decreased to 28,473, according to the drug research firm IMS Health Canada;

11. The safety and efficacy of propoxyphene-containing drugs has been questioned since as early as 1974. More recently, in the year 2006, however, this issue came to the forefront when a Citizen Petition that was filed before the FDA requesting the removal of propoxyphene-containing products from the US marketplace due to safety concerns. A high level of cardiotoxicity was alleged, the whole as appears more fully from a copy of the FDA's Center for Drug Evaluation and Research Memorandum to the File, produced herein as **Exhibit R-2**;

12. On June 25th 2009, the European Medicines Agency (EMA) recommended that member states gradually withdraw propoxyphene products from their markets;

13. In July 2009, the FDA denied the 2006 Citizen Petition, but required the sponsor, Xanodyne Pharmaceuticals, Inc., to conduct a Thorough QT (TQT) study to evaluate the effects of propoxyphene on cardiac electrophysiology;

14. The sponsor submitted a preliminary report on August 26th 2010 of the study with a dosing of 600 mg daily of propoxyphene and a on October 10th 2010 submitted a preliminary report of the study with a dosing of 900 mg daily of propoxyphene;

15. The data in the Multiple Ascending Dose (MAD) study showed that when propoxyphene is taken at approved doses, there are significant changes to the electrical activity of the heart. These changes can increase the risk for serious abnormal heart rhythms;

16. Signs and symptoms of an abnormal heart rate or rhythm includes dizziness, light-headedness, fainting, and heart palpitations;

17. On November 19th 2010, the FDA requested that all makers of propoxyphene-containing products be removed from the market. Xanodyne Pharmaceuticals, Inc. who manufacture Darvon and Darvocet agreed to withdraw their products from the USA market, the whole as appears more fully from a copy of various FDA press releases, produced herein as **Exhibit R-3**;

18. On November 25th 2010, Health Canada informed the medical community that the Respondent , Paladin Labs Inc, had decided to voluntarily recall and withdraw the drug Darvon-N following the decision of the FDA, the whole as appears more fully from a copy of Health Canada's information to Health Care Professionals, produced herein as **Exhibit R-4**;

19. On December 1st 2010, Health Canada and the Respondent, Paladin Labs Inc., informed the public of the voluntary recall and withdrawal of the drug

Darvon-N, the whole as appears more fully from a copy of Health Canada's Public Communication and the Respondent's News Release, produced herein as **Exhibit R-5**;

20. On December 3rd 2010, a class action was filed in the United States District Court for the Eastern District of Louisiana against the company Xanodyne Pharmaceuticals, Inc. (the maker of Darvon and Darvocet in the USA) claiming bodily injury and lack of adequate warnings, the whole as appears more fully from a copy of said Class Action Complaint, produced herein as **Exhibit R-6**;

21. In view of the foregoing, the Respondent has:

    a) misrepresented information concerning both the safety and efficacy of the drug Darvon-N to the medical community and the public;

    b) failed to provide adequate warning to the medical community and the public about the drug Darvon-N's increased risk of serious heart rhythm abnormalities;

    c) placed the drug Darvon-N onto the marketplace that has only minimal effectiveness in the treatment of pain, but a significant and serious likelihood of injury;

II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

22. Petitioner was prescribed, purchased, and ingested the drug Darvon-N over a 3 week period during the summer of 2007;

23. He took the drug Darvon-N to alleviate pain that he was experiencing in his teeth and he understood that it was safe;

24. While Petitioner was using the drug Darvon-N, he experienced an episode of heart palpitations, chest pains, and dizziness -- in effect, the Petitioner felt like he was having a heart attack;

25. This event was quite traumatic to the Petitioner, however, he had ever never made the connection between this event and his ingestion of the drug Darvon-N until very recently;

26. Petitioner just recently found out that the FDA recommended that the makers of the drugs Darvon and Darvocet remove their products from the market in the USA;

27. Petitioner has also just recently found out that Health Canada has asked the makers of Darvon-N to do the same in Canada;

28. He now believes that his symptoms in the summer of 2007 were the direct result of his use of the drug Darvon-N;

29. Further, at no time was Petitioner made aware of the true risks associated with taking the drug Darvon-N, and more specifically, of the significant increase in the risk of serious heart rhythm abnormalities;

30. Petitioner would not have taken the drug Darvon-N if the Respondent had properly disclosed the true risks and benefits of taking this medication;

31. Petitioner is at risk of developing more pronounced health problems in the near future and will be followed by a physician;

32. Petitioner's modest pain relief by using the drug Darvon-N did not outweigh the injury that the Petitioner has suffered;

33. Petitioner's damages are a direct and proximate result of his use of the drug Darvon-N, Respondent's negligence and/or lack of adequate warnings, and Respondent's misrepresentations as to its efficacy;

34. In consequence of the foregoing, Petitioner is justified in claiming damages;

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

35. Every member of the class has either ingested and/or purchased the drug Darvon-N or is the successor, family member, assign, and/or dependant of a person who purchased and/or ingested the drug Darvon-N;

36. The class members' damages would not have occurred but for the acts and/or omissions of the Respondent in failing to ensure that the drug Darvon-N was safe for use, for failing to provide adequate warning of the risks associated with its use, and for over-promoting (and misrepresenting) their efficacy;

37. In consequence of the foregoing, each member of the class is justified in claiming at least one or more of the following as damages:

    a. physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, and increased risk of health problems;

b. out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of Darvon-N side effect services;

c. loss of income and loss of future income;

d. refund of the purchase price of the drug Darvon-N or alternately, the incremental costs of Darvon-N as paid for by class members and/or by the *Régie de l'assurance maladie du Québec*, the Ontario Health Insurance Plan, and other provincial health insurers;

e. disgorgement of all profits earned by the Respondent from the sale of the drug Darvon-N;

f. punitive damages;

38. As a direct result of the Respondent's conduct, the users' family members, and dependants have, had, and/or will suffer damages and loss, including:

a. out of pocket expenses, including paying or providing nursing, housekeeping and other services;

b. loss of income and loss of future income;

c. loss of support, guidance, care, consortium, and companionship that they might reasonably have expected to receive if the injuries had not occurred;

39. Some of the expenses related to the medical treatment that the class members have undergone or will undergo, will have been borne by the various provincial health insurers, including the *Régie de l'assurance maladie du Québec* and the Ontario Health Insurance Plan. As a result of the Respondent's conduct, these various provincial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect to all past and future insured services. These subrogated interests are asserted by the Petitioners and the class members;

40. All of these damages to the class members are a direct and proximate result their use of the drug Darvon-N, Respondent's negligence and/or lack of adequate warnings, and Respondent's misrepresentations as to its efficacy;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

A) The composition of the class renders the application of articles 59 or 67 C.C.P. difficult or impractical

41. Petitioner has reason to believe that there are approximately 119,584 persons who took and/or purchased the drug Darvon-N in the year 2003 and 28,473 persons in Canada who took and/or purchased the drug Darvon-N in the year 2008. However, Petitioner has no way of knowing the names and addresses of potential class members due to the confidential nature of medical and pharmacy records;

42. Class members are numerous and are scattered across the entire province and country;

43. 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 Respondent. Even if the class members themselves could afford such individual litigation, the court system could not as it would be overloaded. Further, 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;

44. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory judgements on questions of fact and law that are similar or related to all members of the class;

45. These facts demonstrate that it would be impractical, if not impossible, to contact each and every member of the class to obtain mandates and to join them in one action;

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

B) The questions of fact and law which are identical, similar, or related with respect to each of the class members with regard to the Respondent and that which the Petitioner wishes to have adjudicated upon by this class action

47. Individual questions, if any, pale by comparison to the numerous common questions that predominate;

48. The damages sustained by the class members flow, in each instance, from a common nucleus of operative facts, namely, Respondent's misconduct;

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

    a. Does Darvon-N cause, exacerbate, or contribute to the increased risk of serious heart rhythm abnormalities?

    b. Was the Respondent negligent and/or did they fail in their duty of safety, duty of care, and/or duty to inform imposed upon them as manufacturers, distributers and/or sellers of Darvon-N?

    c. Did the Respondent knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use of Darvon-N?

    d. Did the Respondent knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks and benefits from the use of Darvon-N?

    e. In the affirmative to any of the above questions, did Respondent conduct engage it's liability toward the members of the class?

    f. If the responsibility of the Respondent is established, what is the nature and the extent of damages and other remedies to which the members of the class can claim?

    g. Are members of the class entitled to bodily, moral, and material damages?

    h. Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking Darvon-N?

    i. Are the members of the class entitled to recover as damages an amount equal to the purchase price of Darvon-N or any part of the purchase price?

    j. Should Respondent be ordered to disgorge all or part of its ill-gotten profits received from the sale of Darvon-N?

    k. Are members of the class entitled to aggravated or punitive damages?

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

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

51. The action that Petitioner wishes to institute on behalf of the members of the class is an action in damages;

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

GRANT the class action of Petitioner and each of the members of the class;

DECLARE the Defendant liable for the damages suffered by the Petitioner and each of the members of the class;

CONDEMN the Defendant to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendant to reimburse to each of the members of the class, the purchase price of the product, and ORDER collective recovery of these sums;

CONDEMN the Defendant to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

RESERVE the right of each of the members of the class to claim future damages related to the use of Darvon-N;

CONDEMN the Defendant to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendant to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendant to an amount sufficient to compensate the various provincial health insurers for the medical treatments and expenses that the class members have undergone and will continue to undergo in the future, and ORDER the Defendant to deposit in the office of this court these sums so as to establish a fund to be administered as this Honourable Court deems fit;

CONDEMN the Defendant to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

A) <u>The Petitioner requests that he be attributed the status of representative of the Class</u>

53. Petitioner is a member of the class;

54. Petitioner is ready and available to manage and direct the present action in the interest of the members of the class that she wishes to represent and is determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the class, as well as, to dedicate the time necessary for the present action before the Courts of Quebec and the *Fonds d'aide aux recours collectifs*, as the case may be, and to collaborate with his attorneys;

55. Petitioner has the capacity and interest to fairly and adequately protect and represent the interest of the members of the class;

56. Petitioner has given the mandate to his attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

57. Petitioner, with the assistance of his attorneys, is ready and available to dedicate the time necessary for this action and to collaborate with other members of the class and to keep them informed;

58. Petitioner is in good faith and has instituted this action for the sole goal of having his rights, as well as the rights of other class members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Respondent's conduct;

59. Petitioner understands the nature of the action;

60. Petitioner's interests are not antagonistic to those of other members of the class;

B) <u>The Petitioner suggests that this class action be exercised before the Superior Court of justice in the district of Montreal</u>

61. A great number of the members of the class reside in the judicial district of Montreal and in the appeal district of Montreal;

62. Respondent has its head office and manufacturing facilities in the judicial district of Montreal;

63. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

64. 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 class herein described as:

- all persons residing in Canada who have taken and/or purchased the drug DARVON-N (dextropropoxyphene) 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 have taken and/or purchased the drug DARVON-N (dextropropoxyphene) their successors, assigns, family members, and dependants, or any other group to be determined by the Court.

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

a. Does Darvon-N cause, exacerbate, or contribute to the increased risk of serious heart rhythm abnormalities?

b. Was the Respondent negligent and/or did they fail in their duty of safety, duty of care, and/or duty to inform imposed upon them as manufacturers, distributers and/or sellers of Darvon-N?

c. Did the Respondent knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use of Darvon-N?

d. Did the Respondent knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks and benefits from the use of Darvon-N?

e. In the affirmative to any of the above questions, did Respondent conduct engage it's liability toward the members of the class?

f. If the responsibility of the Respondent is established, what is the nature and the extent of damages and other remedies to which the members of the class can claim?

g. Are members of the class entitled to bodily, moral, and material damages?

h. Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking Darvon-N?

i. Are the members of the class entitled to recover as damages an amount equal to the purchase price of Darvon-N or any part of the purchase price?

j. Should Respondent be ordered to disgorge all or part of its ill-gotten profits received from the sale of Darvon-N?

k. Are members of the class entitled to aggravated or punitive damages?

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

GRANT the class action of Petitioner and each of the members of the class;

DECLARE the Defendant liable for the damages suffered by the Petitioner and each of the members of the class;

CONDEMN the Defendant to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendant to reimburse to each of the members of the class, the purchase price of the product, and ORDER collective recovery of these sums;

CONDEMN the Defendant to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

RESERVE the right of each of the members of the class to claim future damages related to the use of Darvon-N;

CONDEMN the Defendant to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendant to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendant to an amount sufficient to compensate the various provincial health insurers for the medical treatments and expenses that the class members have undergone and will continue to undergo in the future, and ORDER the Defendant to deposit in the office of this court these sums so as to establish a fund to be administered as this Honourable Court deems fit;

CONDEMN the Defendant to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

DECLARE that all members of the class that have not requested their exclusion, be bound by any judgement to be rendered on the class action to be instituted in the manner provided for by law;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the members, date upon which the members of the class that have not exercised their means of exclusion will be bound by any judgement to be rendered herein;

ORDER the publication of a notice to the members of the group in accordance with article 1006 C.C.P. within sixty (60) days from the judgement to be rendered herein in LA PRESSE and the NATIONAL POST;

ORDER that said notice be available on the Respondent's website with a link stating "Notice to Darvon-N users";

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

THE WHOLE with costs including publications fees.

Montreal, December 13, 2010

(s) Jeff Orenstein

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CONSUMER LAW GROUP INC.
Per: Me Jeff Orenstein
Attorneys for the Petitioner