CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

No.: 500-06-000523-106

COLETTE JOLY GOULET, [redacted];

Petitioner

vs

NOVARTIS PHARMA CANADA INC., [redacted];

and

NOVARTIS PHARMACEUTICALS CORP., [redacted];

and

NOVARTIS INTERNATIONAL AG, [redacted];

and

PROCTER & GAMBLE PHARMACEUTICALS CANADA INC., [redacted];

and

PROCTER & GAMBLE PHARMACEUTICALS INC., [redacted];

and

THE PROCTER & GAMBLE COMPANY, [redacted];

and

WARNER CHILCOTT CANADA CO., [redacted];

and

WARNER CHILCOTT PHARMACEUTICALS INC., [redacted];

and

WARNER CHILCOTT PLC, [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 QUÉBEC, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PETITIONER STATES THE FOLLOWING:

INTRODUCTION:

1. Petitioner wishes to institute a class action on behalf of the following Group:

SUB-GROUP A:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Bisphosphonate drugs, including but not limited to the brand name Actonel, manufactured, marketed or distributed by Respondents Procter & Gamble Pharmaceuticals Canada Inc., Procter & Gamble Pharmaceuticals Inc., The Procter & Gamble Company, Warner Chilcott Canada Co., Warner Chilcott Pharmaceuticals Inc. and Warner Chilcott PLC and/or any other related companies, or any other Group or Sub-Group to be determined by the Court;

SUB-GROUP B:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Bisphosphonate drugs, including but not limited to the brand name Aclasta, manufactured, marketed or distributed by Respondents Novartis Pharma Canada Inc., Novartis Pharmaceuticals Corp., Novartis International AG and/or any other related companies, 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", the "Group", "Consumers" or "Users");

2. Respondents, Novartis Pharma Canada Inc., Novartis Pharmaceuticals Corp., Novartis International AG, Procter & Gamble Pharmaceuticals Canada Inc., Procter & Gamble Pharmaceuticals Inc., The Procter & Gamble Company, Warner Chilcott Canada Co., Warner Chilcott Pharmaceuticals Inc. and Warner Chilcott PLC are hereinafter collectively referred to as the "**Respondents**";

3. Respondents are research-based pharmaceutical companies. They research, develop, design, test, manufacture, distribute, label, package, supply, market, sell, advertise, and distribute various pharmaceutical products including Bisphosphonate drugs in Canada;

4. Respondents placed various Bisphosphonate drugs distributed under various brand names including but not limited to the Actonel and Aclasta brands, (or any other drug of this type) (hereinafter referred to collectively as the "**Bisphosphonate drugs**"), in the streams of commerce, for the purpose of treating or relieving osteoporosis;

5. Respondents, Procter & Gamble Pharmaceuticals Canada Inc., Procter & Gamble Pharmaceuticals Inc., The Procter & Gamble Company, introduced their first Bisphosphonate drug under the brand name Didronel® (Etidronate Disodium) into the United States market on September 1, 1977;

6. The Respondent, Novartis Pharma Canada Inc., started marketing its Bisphosphonate drugs in Canada on June 30, 2005, under the brand name of Aclasta®, whose active ingredient is Zoledronic Acid;

7. The Respondent, Procter & Gamble Pharmaceuticals Canada Inc., started marketing its Bisphosphonate drug in Canada on August 18, 1999, under the brand name of Actonel®, whose active ingredient is Risedronate Sodium;

8. The Respondent Warner Chilcott PLC acquired The Procter & Gamble Company's global branded pharmaceuticals business on October 30, 2009, which transformed Warner Chilcott PLC into a global pharmaceuticals company with operations in 12 countries including Canada and Western Europe;

9. The Respondent, Warner Chilcott Canada Co., started marketing its Bisphosphonate drugs in Canada on February 18, 2010, under the brand name of Actonel®, whose active ingredient is Risedronate Sodium;

10. Respondents, together with or through their parent companies or partners, who have operations in many countries worldwide, marketed, advertised, distributed and sold the Bisphosphonate drugs to hundreds of thousands of Consumers across Canada;

11. The Respondents offer their products in Québec and throughout Canada and derive revenue as a result of Users located in Québec and throughout Canada;

12. Bisphosphonate drugs can cause increased negative health effects including but not limited to bone fractures, and/or other risks or side effects;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

13. Over five (5) years ago the Petitioner, **Colette Joly Goulet**, was prescribed and started using the Bisphosphonate drug "Actonel";

14. On August 8, 2010, Petitioner fractured her left shoulder and was transported by ambulance to a hospital;

15. On August 13, 2010, Petitioner was operated and a prosthesis was installed in her left shoulder;

16. Petitioner was hospitalized from August 13 to August 15, 2010 inclusively as a result of the operation to her fractured left shoulder;

17. Since her operation, Petitioner has had several physiotherapy sessions and will have to have many more in the next few months in order to recover;

18. Respondents failed to warn Petitioner and other Class Members, prior to their purchase and consumption, of the health risks posed by the Bisphosphonate drugs. Had the Respondents warned Consumers, the Petitioner and other Class Members would not have purchased or used the Bisphosphonate drugs;

19. The Class Members have incurred injuries and losses from the purchase, consumption, and use of the Bisphosphonate drugs, including expenses relating to medical treatment sought and received, physical injuries, the cost of the product, opportunity costs incurred as a result of illness or visits to medical facilities, loss of employment income, loss of enjoyment of life, pain and suffering, and anticipated future medical and health costs;

20. The Class Members have suffered and will continue to suffer physical injuries and other losses, or damages due to the use and consumption of the Bisphosphonate drugs, and claim damages as a result;

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

RISKS OF BISPHOSPHONATE DRUGS

21. Ingestion of Bisphosphonate drugs materially contributes to the risk of bone fractures, including but not limited to femoral fractures, shoulder fractures, or other bone fractures, or other risks or side effects;

RESPONDENTS' CONDUCT

22. Respondents researched, designed, tested, manufactured, marketed, labeled, distributed, promoted, and sold Bisphosphonate drugs in many countries including Canada;

23. Before and after Bisphosphonate drugs were put on the Canadian and Québec market, there had or have been numerous articles in leading medical journals published in many countries, that revealed that Bisphosphonate drugs are associated with an increased risk of inhibiting bone formation that lead to bone fractures, the titles of which are too numerous and unnecessarily prolix to be included herein, but which include the *Bone*, the *Bone Mineral*, the *Injury*, the *Journal of Bone and Join Surgery*, the *Journal of Bone and Mineral Research*, the *Journal of Orthopaedic Research*, the *Journal of Rheumatology*, the *Osteoporos*, the *Osteoporosis International*, etc;

24. At all material times, Respondents have marketed that Bisphosphonate drugs are safe and beneficial for long-term use, which is not true;

25. In 1989 Hodsman reported in *Bone Mineral* that long-term use of Didronel does not improve bone formation. Similar findings have been reported by other researchers since then;

26. In May of 1997, Homik et al published their study in the *Journal of Rheumatology*, titled "A metaanalysis on the use of bisphosphonates in corticosteroid induced osteoporosis", indicating that the efficacy of Bisphosphonates regarding fracture prevention cannot be concluded;

27. The recent study published by Shane et al in the *Journal of Bone and Mineral Research,* titled "Atypical Subtrochanteric and Diaphyseal Femoral Fractures: Report of a Task Force of the American Society for Bone and Mineral Research",

indicated that long-term use (usually for more than three years) of Bisphosphonate drugs may cause or increase the risk of femoral fractures;

28. Fractures are associated with an increased rate of death, substantial morbidity, significant costs, and devastating effects on independence and quality of life;

29. Had the Respondents done appropriate scientific research and testing, as well as carried out reviews of related medical journals, they should have known that Bisphosphonate drugs materially contribute to the risk of serious adverse medical events as described above and should have fully informed the medical professionals and patients/consumers, including the Petitioner and putative Class Members, of such risks in a timely manner;

30. Respondents knew or should have known of the risks of long-term use of Bisphosphonate drugs but portray Bisphosphonate drugs as a safe and effective solution to relieving various bone related disorders;

31. Had the true facts been disclosed that Bisphosphonate drugs are associated with devastating side effects that significantly lower their quality of life and may lead to death, consumers would not have used Bisphosphonate drugs;

32. Respondents misled or deceived Class Members by representing in written labeling, written marketing materials, and advertising that Bisphosphonate drugs do not pose the aforesaid risks to them during normal use for bone related disorders;

33. Respondents warranted that Bisphosphonate drugs were safe and fit for their intended and foreseeable purpose. However, Bisphosphonate drugs were not, and are not, safe for their intended use in that they pose an undue risk of harm to the Members of the Class;

34. At all material times, Respondents failed to provide the medical community and

the general public with a clear, complete, and current warning of the risks associated with Bisphosphonate drugs use, or failed to provide such warning in a timely manner, and Respondents were negligent in that regard;

35. Further, or in the alterative, Respondents did inferior research, design, and tests on Bisphosphonate drugs and made a defective drug product;

36. Had the true facts been disclosed that the Bisphosphonate drugs were associated with increased risks of bone fractures, or other risks or side effects as stated above, the use of said Bisphosphonate drugs on an objective Class wide basis would not have occurred and the Class Members would not have experienced the aforementioned injuries or health risks;

RESPONDENTS' LIABILITY

37. Consumers reasonably relied and rely upon the Respondents to ensure that the Bisphosphonate drugs are safe for human consumption and contain warnings about potential health risks, such as bone fractures, or other risks and side effects;

38. Respondents are liable for the damages suffered by the Petitioner and the Class Members in that Respondents failed to use sufficient quality control, to conduct adequate testing, and to perform proper manufacturing, production, or processing, or failed to take sufficient measures to prevent harmful Bisphosphonate drugs from being offered for sale, sold or used by Consumers, when they knew or ought to have known about the serious health risks but still sold and distributed their Bisphosphonate drugs in Canada;

39. As a direct and proximate result of the Respondents' negligence, the Class Members suffered pain, damages, injuries and risks for which the Respondents are solely liable;

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

41. Furthermore, and as a result of the Respondents' negligence and faults described herein, Class Members have suffered and claim damages for the following:

a) personal injuries suffered;

b) economic and financial losses (i.e. loss of income and earning capacity);

c) pain and suffering;

d) loss of amenities and enjoyment of life;

e) costs of past and future care and related expenses;

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

42. Moreover, the Respondents' conduct, through actions, omissions, wrongdoings, and their awareness of the serious hazards of said drugs, and their failure to fully, clearly, and in a timely way disclose and publicize the serious health effects resulting from the use of the Bisphosphonate drugs, subject the Respondents to punitive and exemplary damages;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

43. 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 Respondents 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;

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

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

b) As a result of negative health effects, were the Bisphosphonate drugs unsafe, or unfit for the purpose for which they were intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce in Canada by the Respondents?

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

d) Did Respondents fail to inform the Class Members of the health risks associated with the use of Bisphosphonate drugs?

e) Are Respondents liable to pay damages to the Group Members as a result of their negligence, or misrepresentations made to them in manufacturing, marketing, distributing or selling of the Bisphosphonate drugs, or as a result of the use of Bisphosphonate drugs?

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

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

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

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

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

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

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

GRANT Petitioner's action against Defendants;

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

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

CONDEMN Defendants to pay an amount in punitive and/or exemplary damages to the 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.

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

a) Respondents sell the Bisphosphonate drugs in the District of Montréal;

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

c) Respondent Novartis Pharma Canada Inc. has an establishment in the District of Montréal;

d) Respondents Warner Chilcott Canada Co. and Procter & Gamble Pharmaceuticals Canada Inc. both have a *fondé de pouvoir* in the District of Montréal;

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

50. 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 Bisphosphonate drugs for over five (5) years, without being made aware of the health risks associated with the use of said drugs;

b) suffered damages and injuries from using Bisphosphonate drugs, as detailed above;

c) 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;

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

e) 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;

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

g) 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;

h) 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;

51. 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, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Bisphosphonate drugs, including but not limited to the brand name Actonel, manufactured, marketed or distributed by Respondents Procter & Gamble Pharmaceuticals Canada Inc., Procter & Gamble Pharmaceuticals Inc., The Procter & Gamble Company, Warner Chilcott Canada Co., Warner Chilcott Pharmaceuticals Inc. and Warner Chilcott PLC and/or any other related companies, or any other Group or Sub-Group to be determined by the Court;

SUB-GROUP B:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Bisphosphonate drugs, including but not limited to the brand name Aclasta, manufactured, marketed or distributed by Respondents Novartis Pharma Canada Inc., Novartis Pharmaceuticals Corp., Novartis International AG and/or any other related companies, 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 the Bisphosphonate drugs cause an increase in negative health effects, and to what extent?

b) As a result of negative health effects, were the Bisphosphonate drugs unsafe, or unfit for the purpose for which they were intended as designed,

developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce in Canada by the Respondents?

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

d) Did Respondents fail to inform the Class Members of the health risks associated with the use of Bisphosphonate drugs?

e) Are Respondents liable to pay damages to the Group Members as a result of their negligence, or misrepresentations made to them in manufacturing, marketing, distributing or selling of the Bisphosphonate drugs, or as a result of the use of Bisphosphonate drugs?

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

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

h) Are 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 Petitioner's action against Defendants;

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

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

CONDEMN Defendants to pay an amount in punitive and/or exemplary

damages to the 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. and **ORDER** Respondents to pay for said publication costs;

THE WHOLE with costs to follow.

MONTRÉAL, September 29, 2010

MERCHANT LAW GROUP LLP
Attorneys for Petitioner