CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Action)

No: 500-06-000618-120

JIMMY WHYTE, residing and domiciled at Mohawk Beach Road, PO Box 94, Kahnawake, Québec, J0L 1B0

Petitioner

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, having its main place of business at 1-1 Doshomachi 4- chome, Chuoku, Osaka, Japan

and

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., having its main place of business at One Takeda Parkway Deerfield, IL 60015, U.S.A.

and

TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., having its main place of business at One Takeda Parkway, Deerfield, IL 60015, U.S.A.

and

TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., having its main place of business at One Takeda Parkway, Deerfield, IL 60015, U.S.A.

and

TAKEDA SAN DIEGO, INC., having its main place of business at 10410 Science Center Drive, San Diego, CA 92121, U.S.A.

and

ELI LILLY CANADA INC., having its main place of business at 3650 Danforth Ave., Toronto, ON M1N 2E8

and

TAKEDA CANADA, INC., having its main place of business at 6750 Century Ave., Suite 400, Mississauga, ON L5N 2V8

Respondents

MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE
(Article 1002 C.C.P.)

IN SUPPORT OF HIS MOTION, THE PETITIONER RESPECTFULLY SUBMITS AS FOLLOWS:

Introduction

1. This action relates to the pain and suffering and resulting damages suffered by the Petitioner and other Class Members hereinafter described as a result of the Respondents' negligent research and development, design, testing, manufacture, licensing, marketing, distribution and sale of pioglitazone hydrochloride under the brand name of ACTOS® ("ACTOS") in Canada.

2. The Petitioner alleges that ACTOS is defective and inherently dangerous in that it causes, materially contributes to, and materially increases the risks of bladder cancer and bone fractures.

3. The Petitioner further alleges that the Respondents have known about these defects but have failed to disclose these defects and the resulting risks to the health and life of the Petitioner, other Class Members, their treating physicians and regulatory authorities in Canada and have failed to recall ACTOS in Canada.

The Class

4. The Petitioner, Jimmy Whyte, intends to institute a class action on behalf of the persons forming part of the Class hereinafter described and of which the Petitioner is a member, namely:

> "All persons who reside or have resided in Québec who purchased and/or used the drug ACTOS® and the heirs, family members and dependents of said persons."

Petitioner's circumstances

5. The Petitioner's personal claim against the Respondents is based on the following facts:

6. The Petitioner was prescribed and began using 15 mg daily of ACTOS for the treatment of his Type-II diabetes in or about November, 2008.

7. In or about the late fall of 2011, the Petitioner began passing blood in his urine and medical investigations revealed the presence of polyps in his bladder.

8. In or about February of 2012, further follow up on the Petitioner's symptoms and medical condition revealed that he had developed bladder cancer.

9. In or about May 7, 2012, the Petitioner underwent surgery to remove his diseased bladder.

10. The Petitioner and his family, including his spouse and two daughters, have endured significant pain and suffering as a direct result of the Petitioner's use of ACTOS and the negligence of the Respondents described below;

11. The Petitioner was never warned of the risks associated with the use of ACTOS;

12. Had he been so advised he would have refused to use ACTOS and would have insisted on a safer alternative treatment;

13. But for the Respondents' negligence, he would not have suffered his injuries and incurred his damages;

14. The Petitioner's damages for personal injuries, pain, suffering, stress and inconvenience will be established at trial;

15. The Petitioner also claims punitive damages from the Respondents for their gross negligence and complete disregard for the health and lives of vulnerable patients, in an amount to be determined at trial;

16. In particular, the Respondents' conduct in continuing to market sell and distribute ACTOS when they knew or ought to have known of the serious health risks associated with the drug, including the risk of bone fractures and

of developing bladder cancer, showed complete indifference to or a conscious disregard for the life, health, safety and bodily integrity of the Petitioner and other Class Members, rights protected under art. 1 of the *Charter of Human Rights and Freedoms*, R.S.Q., c. C-12, justifying an award in punitive damages in such a sum that will serve to deter the Respondents from similar conduct in the future;

17. The Petitioner's spouse and two daughters have also suffered damages, including loss of income due to work absences required to attend to care for and provide services to the Petitioner, loss of care, guidance and companionship as well as expenses and special damages;

Respondents' liability

18. The Respondent, Takeda Pharmaceutical Company Limited ("Takeda Limited"), is a Japanese corporation with its headquarters in Osaka, Japan and at all times material to this action engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling ACTOS to Canadian consumers.

19. The Respondent, Takeda Pharmaceuticals North America, Inc. ("Takeda North America"), is a Delaware corporation, which has its principle place of business in Deerfield, Illinois and is a wholly owned subsidiary of Takeda Limited. At all times material to this action, Takeda North America was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labelling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

20. The Respondent, Takeda Pharmaceuticals International, Inc., ("Takeda International"), is an Illinois corporation which has its principle place of business in Deerfield, Illinois and is a wholly owned subsidiary of Takeda North America. At all times material to this action, Takeda International was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labelling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

21. The Respondent, Takeda Global Research & Development Center, Inc. ("Takeda Global"), is an Illinois corporation which has its principle place of business in Deerfield, Illinois and is a wholly owned subsidiary of Takeda North America. At all times material to this action, Takeda Global was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating,

compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labelling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

22. The Respondent, Takeda San Diego, Inc. ("Takeda San Diego"), is a California corporation which has its principle place of business in San Diego, California, and is a wholly owned subsidiary of Takeda North America. At all times material to this action, Takeda San Diego was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, libelling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

23. The Respondent, Takeda Canada, Inc. ("Takeda Canada"), is a Canadian corporation, incorporated pursuant to the laws of Ontario with its principal place of business in Mississauga, Ontario and is a wholly owned subsidiary of Takeda Limited. Subsequent to mid-June, 2009, Takeda Canada was engaged in the business of licensing, marketing, labelling, promoting, packaging, advertising and/or selling ACTOS to Canadian consumers. The above-referenced Respondents are referred to herein collectively as "the Takeda Respondents".

24. The Respondent, Eli Lilly Canada Inc. ("Lilly"), is a Canadian corporation, incorporated pursuant to the laws of Ontario with its principal place of business in Toronto, Ontario. In 1999, Takeda Limited licensed the Canadian commercial rights to ACTOS to Lilly. The original New Drug Submission ("NDS") for ACTOS was made by Lilly, which was granted a Notice of Compliance by Health Canada on August 17, 2000. Thereafter, Lilly was engaged in the licensing, marketing, labelling, promoting, packaging, advertising and/or selling of ACTOS in Canada, until mid-June, 2009, when such rights were acquired by Takeda Canada, Inc.

25. The business of each of the Respondents herein (collectively referred to herein as "the Respondents") is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the development, manufacture, marketing, sale and/or distribution of ACTOS in Canada, all of whom are or were subsidiaries and/or affiliates of, and/or in commercial licensing relationships with, Takeda Limited.

26. At all material times, the Respondents each participated in and/or shared the common purpose of one of more of the following: designing, developing, manufacturing, testing, inspecting, marketing, supplying, exporting, importing, and selling ACTOS in Canada for profit. The Respondents also shared the common purpose of concealing the defects in ACTOS from the Petitioner and Class Members.

27. At all relevant times, each of the Respondents acted on behalf of each other and Takeda Limited exercised control over its subsidiaries, corporate divisions and licensees because, among other things:

a) it operated itself and the other Respondents as a single global entity;

b) it controlled the day-to-day operations of its subsidiaries through its consolidated management structure;

c) it prepared its financial statements on a consolidated basis; and

d) it conspired with the other Respondents to manufacture, market, sell, and distribute the defective ACTOS.

28. At all material times, each Respondent was the agent of the other and as such, each Respondent is individually, as well as solidarily, liable to the Petitioner and other Class Members for their injuries, losses and damages because:

a) each company's business, insofar as it related to the manufacture, marketing and sale of ACTOS in Canada, was operated so that it was inextricably interwoven with the business of the other;

b) each company entered into a common business plan and shared the common purpose of developing, manufacturing and selling ACTOS in Canada for profit;

c) each company owed a duty to the other and to each Class Member and Family Class Member by virtue of the common business plan to manufacture and sell ACTOS in Canada; and

d) each company intended that its business, insofar as it related to the manufacture, marketing and sale of ACTOS in Canada, be run as one global business organization

History of ACTOS and mechanism of action

29. ACTOS (pioglitazone hydrochloride) was approved for sale in Canada in August, 2000 to control blood sugar levels in people with Type 2 (non insulin-dependant) diabetes, **Exhibit P-1**;

30. The active medicinal ingredient in ACTOS, pioglitazone hydrochloride, is in a class of drugs known as thiazolidinediones ("TZDs"), also known as glitazones, which act, in part, to decrease insulin resistance.

31. TZDs, including ACTOS, work by activating receptor molecules inside the cell nucleus, specifically peroxisome proliferator-activated receptor-gamma (PPARγ) which, once activated, modulate the expression of genes involved in lipid and glucose metabolism, insulin signal transduction and adipocyte and other tissue differentiation.

Respondents' knowledge of risks of bladder cancer with ACTOS

32. TZD PPARγ ligands, such as pioglitazone, have been shown to have significant effects on tumour cells, and to alter cell proliferation rates and differentiation in human cancer cell lines, including bladder cancer cells lines.

33. Indeed, prior to receiving approval to market ACTOS for sale in Canada, the Respondents were aware of pre-clinical data demonstrating that statistically significant rates of bladder tumours was observed in rats treated with the drug at levels equivalent to a human clinical dose.

34. In 2005, results of a randomized controlled trial assessing the potential protective effect of pioglitazone in preventing macrovascular events (known as the PROactive study) were published in the *Lancet*. Among the results was a significant excess in cases of bladder cancer reported in the pioglitazone treatment group, compared to the placebo-control group. Specifically, there were 14 cases of bladder cancer in the treatment group compared to only 6 cases in the placebo group, **Exhibit P-2**;

35. Prior to the publication of the PROactive results, in 2003, the FDA requested that the manufacturer of ACTOS conduct a safety study to assess whether therapy with the drug increased the risk of bladder cancer.

36. On September 17, 2010, the U.S. Food and Drug Administration ("FDA") issued a Safety Announcement which advised of this on-going ten-year epidemiological study designed to evaluate whether pioglitazone was associated with an increased risk of bladder cancer. It was further disclosed that an *interim analysis* of the study data revealed an increased risk of bladder cancer among patients with longer exposure to the drug and with those exposed to the highest dosage, **Exhibit P-3;**

37. These *interim results* were not published until April 2011 and they confirmed an increased risk of bladder cancer among patients with longer exposure. In particular, the risk for bladder cancer was found to be 30% higher among those whose duration of pioglitazone use was 12-24 months and 50% higher among those with greater than 24 months' exposure, **Exhibit P-4**;

38. Also noted in the September, 2010 FDA Safety Announcement was a three-year controlled clinical study on liver safety which also demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS versus a comparator. To date, the results of this study have not been published by the Respondents or otherwise.

39. In June of 2011, results were published of a study that reviewed adverse events reported to the FDA between 2004 and 2009 and which assessed the extent of association between pioglitazone use and bladder cancer. This study found a clear epidemiological signal for bladder cancer associated with pioglitazone; the reporting odds ratio (ROR) was indicative of a definite risk for pioglitazone (4.30 [95% CI 2.82-6.52 – where an odds ratio of greater than 1 implies a statistically significant result), **Exhibit P-5**;

40. On June 9, 2011, results were published from a broad retrospective cohort study conducted by the Caisse nationale de l'assurance maladie, involving almost 1.5 million French patients using pioglitazone between 2006-2009. The results of this analysis demonstrated a statistically significant correlation between exposure to pioglitazone and the occurrence of bladder cancer, and that the risk increased with exposure of longer than one year. As a result of these findings, the French regulator suspended sales of drugs containing pioglitazone on June 9, 2011, **Exhibit P-6; Exhibit P-7;**

41. On June 10, 2011, it was reported by Reuters that the German regulator had also suspended sales of the drug in Germany after that country's Federal Institute for Drugs and Medical Devices reviewed the results of the French epidemiological study.

42. On June 15, 2011, the FDA issued a further Safety Announcement related to ACTOS in which it advised that use of the drug for more than one year may be associated with an increased risk of bladder cancer and ordered that such risk was to be incorporated into the Warnings and Precautions section of the drug's label. The FDA reported that the risk of bladder cancer increased in a dose-dependant manner and was associated with the duration of use of ACTOS, **Exhibit P-8**;

43. The Safety Announcement also noted that exposure to ACTOS for greater than 12 months was associated with a 40% increase in risk and that use of ACTOS for more than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years' follow up.

44. On June 17, 2011, Health Canada issued a press release advising of the study results that demonstrated an increased risk of bladder cancer with the use of pioglitazone and announcing that it was undertaking a review of the drug's status, **Exhibit P-9**;

45. In October, 2011, a report was published in which the data from the PROactive study were reviewed and following a recalculation of the overall incidence of bladder cancer, the incidence in the pioglitazone treatment group was statistically greater than in the placebo group, **Exhibit P-10**;

46. Despite this ever growing body of knowledge which the Respondents were aware of or ought to have been aware of in relation to the increased risk for bladder cancer with ACTOS exposure, the Canadian product monograph did not include information about this side effect in the Warnings section and the Canadian patient information sheet contained no information whatsoever about an association with bladder cancer so as to allow Class Members to make an informed decision about using the drug, **Exhibit P-11**;

47. It was not until April 16, 2012, that the Respondents issued a Dear Healthcare Professional Letter, advising Canadian physicians about a "potential" association between ACTOS and the development of bladder cancer, and revised the product monograph for ACTOS, **Exhibit P-12**; **Exhibit P-13**;

48. In the interim, the evidence continues to accumulate supporting the clear existence of an association between the use of ACTOS and the development of bladder cancer, **Exhibit P-14; Exhibit P-15**; **Exhibit P-16**;

49. Thus, since before the inception of marketing of ACTOS in Canada, there has been concern for and evidence of an increased risk for bladder cancer with the use of this drug.

50. Further investigation and pooled analyses of the evidence continues to demonstrate a significantly increased risk of developing bladder cancer with ACTOS use, however, notwithstanding this robust body of scientific evidence demonstrating that the product is inherently dangerous and can cause, materially contribute to or materially increase the risk of bladder cancer, resulting in numerous cases of bladder cancer worldwide, the Respondents have failed to withdraw ACTOS from the Canadian stream of commerce and have continued to profit from the sale of ACTOS in Canada.

The Respondents' negligence

51. ACTOS was designed, developed, tested, manufactured, licensed, assembled, distributed, imported and/or exported, marketed, and/or sold by the Respondents. At all material times, the Respondents owed a duty of care to the Petitioner and to the Classes to provide a safely manufactured product. The Respondents breached the standard of care expected in the circumstances.

52. The Respondents also owed a duty to the Petitioner and other Class Members to initiate rigorous scientific studies to assess the possible association between ACTOS and the development of bladder cancer, to carefully monitor the safety and post-market performance of ACTOS and to warn the Petitioner and the other Class Members and their health care professionals and Canadian regulators of the defective nature of ACTOS and to recall it from the Québec market when it became obvious that the product could not be safely used, thereby causing risk of or actual serious personal injury and/or death.

53. The circumstances of the Respondents being in the business of designing, manufacturing and placing ACTOS into the Québec stream of commerce are such that the Respondents were in a position of legal proximity to the Class Members and therefore under an obligation to be fully aware of their safety when designing, manufacturing, assembling and marketing a product such as ACTOS.

54. It was reasonably foreseeable that a failure by the Respondents to design and manufacture a reasonably safe product, and thereafter to monitor its performance following market introduction (and to take corrective measures when required) would cause, materially contribute to, or materially increase the risk of harm to the Petitioner and the other Class Members.

55. The Respondents were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, importing and/or exporting, marketing and sale of ACTOS. Particulars of some, but not all, of the Respondents' acts of negligence follow:

a) they knew or should have known that ACTOS was unreasonably and dangerously defective and failed to warn the public, health care providers and the regulatory authorities in a timely manner;

b) they failed to adequately test the safety and efficacy of ACTOS before marketing and distributing it;

c) they failed to conduct any or adequate follow-up studies on the efficacy and safety of ACTOS;

d) they failed to adequately design, manufacture and/or test ACTOS to ensure that it was safe and free from defects prior to selling or distributing it;

e) they failed to assemble and manufacture ACTOS in such a manner that it would work safely and effectively without exposing the Respondents' consumers to injury or loss;

f) they knew or ought to have known that ACTOS was defective and that ACTOS would not properly perform the functions or purposes for which it was intended;

g) after receiving actual or constructive notice of problems with ACTOS, they failed to issue adequate or any warnings, withdraw or recall ACTOS, publicize the problem(s) and/or otherwise act properly and in a timely manner to alert the Petitioner and Class Members, the public and health care providers and regulators that ACTOS was defective;

h) they failed to provide clear instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damages from ACTOS;

i) they failed to monitor and follow up on reports of adverse reactions to ACTOS;

j) they failed to ensure that their employees complied with the appropriate quality system standards applicable to the manufacturing process;

k) they failed to properly supervise their employees, subsidiaries and licensees;

l) they failed to issue a safety notice or to recall ACTOS in a timely manner or at all; and

m) such further and other particulars of negligence within the knowledge of the Respondents.

56. At all times relevant to this action the Respondents knew, and had reason to know, that ACTOS was not safe for the patients for whom it was prescribed and the Respondents knew and had reason to know of the defects in ACTOS, but withheld this information and did not warn the Petitioner, the Class Members, physicians, or regulators, thereby preventing the Petitioner, the Class Members and their physicians, and the medical community, from making informed choices about the prescription and use of ACTOS.

Breach of contractual and legal Warranties

57. By marketing, advertising, distributing and selling ACTOS without adequate warnings as to its propensity to cause, materially contribute to, or materially increase the risk of serious adverse reactions, including the development of bladder cancer and the risk of fractures, and other known adverse health risks and while misrepresenting the safety of ACTOS to the Petitioner and other Class Members and their treating physicians, the Respondents created and breached both contractual and legal warranties that ACTOS were safe for its intended uses.

58. The Respondents warranted to the Petitioner and to other Class Members that ACTOS was of merchantable quality and fit for use. The Respondents breached this warranty to the Petitioner and other Class Members by manufacturing, marketing, distributing and selling ACTOS which was inherently dangerous to users.

59. In consenting to the use of ACTOS, the Petitioner and other Class Members and their physicians relied on the skill, judgment, representation and warranties of the Respondents. These warranties and representations were false in that ACTOS was not safe and was unfit for the uses for which it was intended. The defective condition of ACTOS existed at the time it left the Respondents' control.

60. As a result of these breaches, the Petitioner herein and other Class Members have suffered damages in an amount to be proven at the trial of this action.

The Situation of the Class Members

61. The facts giving rise to an individual action on behalf of each Class Member against the Respondents, other than the facts set out above with the necessary adaptations, are as follows:

62. Every Class Member purchased and/or used ACTOS in Québec;

63. A significant number of Class Members will have suffered health problems as a result of their use of ACTOS, in particular, the development and consequences of bladder cancer, which will have involved a variety of treatment modalities;

64. None of the Class Members were adequately warned about the risks associated with the use of ACTOS;

65. All Class Members are entitled to claim from the Respondents damages for personal injuries, pain and suffering;

66. All Class Members are entitled to claim from the Respondents damages for loss of employment income;

67. In addition, all Class Members are entitled to claim from the Respondents punitive damages in an amount to be determined by the Court for their gross negligence and complete disregard for the life, health, safety and bodily integrity of the Petitioner and other Class Members, rights protected under art. 1 of the *Charter of Human Rights and Freedoms*, R.S.Q., c. C-12, and Class Members;

68. The Respondents' conduct in continuing to market, sell and distribute ACTOS after obtaining knowledge of its association with the development of bladder cancer, showed complete indifference to or a conscious disregard for the safety of the Class Members, thereby justifying an award of punitive damages in such an amount as will serve to deter the Respondents from similar conduct in the future;

The Composition of the Classes makes the application of articles 59 and 67 C.C.P. difficult or impractical

69. ACTOS was approved for sale in Canada on or about August 17, 2000 and continues to be sold in Canada, including in Québec;

70. The Classes comprise numerous persons geographically dispersed throughout Québec;

71. Thus, it is impossible for the Petitioner to identify all such potential Class Members and/or obtain a mandate from each of them;

Identical, similar or related questions

72. The identical, similar or related questions of fact and law between each Class Member and the Respondents which the Petitioner wishes to have decided by the class action are as follows:

a) What are the health and safety risks associated with and/or caused by the use of ACTOS?

b) Can ACTOS cause and/or materially contribute to the development of bladder cancer?

c) Is ACTOS defective or unfit for the purpose for which it was intended (including usages that ought reasonably to have been foreseen by the Respondents) as designed, developed, fabricated, manufactured, sold,

imported, distributed, marketed or otherwise placed into the stream of commerce in Québec by one or all the Respondents?

d) Did the Respondents know or should they have known of the risks of harm associated with the use of ACTOS?

e) Did the Respondents fail to conduct adequate clinical trials prior to selling ACTOS in Québec?

f) Were the Respondents negligent and/or at fault in distributing or otherwise dealing with ACTOS in Québec?

g) Did the Respondents commit a fault calling into play their civil liability, pursuant to the applicable civil law rules in Québec?

h) Did the Respondents fail in their duty to adequately warn the Petitioner and the Class Members of the risks associated with the use of ACTOS and/or did they knowingly and recklessly misrepresent any risk of harm from ACTOS?

i) Are the Petitioner and Class Members entitled to claim compensatory damages from the Respondents?

j) Are the Petitioner and the Class Members entitled to claim punitive damages from the Respondents?

Individual question

73. The only question of fact and law which is specific to each Class Member is the quantum of each Class Member's damages.

The Nature of the recourse

74. The nature of the recourse which the Petitioner wishes to advance on behalf of the Class Members is a civil liability damages action;

The Conclusions

75. The conclusions sought by the Petitioner are:

GRANT the class action of the Petitioner and the Class Members against the Respondents;

CONDEMN the Respondents solidarily to pay to the Petitioner the total damages awarded by the court, for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs,

with interest at the legal rate and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents solidarily to pay to each Class Member an amount to be determined as compensation for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, to accrue from the date of service;

CONDEMN the Respondents solidarily to pay to the Petitioner punitive damages in an amount determined by the Court, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents solidarily to pay to each Class Member punitive damages in an amount determined by the Court, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents to reimburse the portion of the cost of ACTOS that is not covered by the public prescription drug insurance plan to the Petitioner and the Class Members;

ORDER the collective recovery of damages of Class Members;

CONDEMN the Respondents solidarily to pay such other amounts and grant Class Members such further relief as this Honourable Court may determine as being just and proper;

THE WHOLE with costs, including the costs of all exhibits, experts and publication notices;

Representative status

76. The Petitioner requests that he be ascribed the status of representative for the following reasons:

a) He is a Class Member;

b) He is well informed of the facts alleged in this motion;

c) He has all the required time, determination and energy to bring this matter to a conclusion and adequately represent the Class Members;

d) He cooperates with his attorneys and responds diligently and articulately to requests they make and he fully comprehends the nature of the class proceedings;

e) He is not aware of any conflict of interest with other Class Members;

77. Petitioner communicates herewith a draft notice to members (art. 1006 C.C.P.) complying with Form IV of the Rules of Practice of the Superior Court, as **Exhibit P-17**;

78. Petitioner communicates herewith copy of the Statement of Claim filed on December 21, 2011 in the Superior Court of Justice of Ontario in the matter of *Casseres v. Takeda Pharmaceutical Company Limited*, Court file no. CV-11-442584, which deals with the same subject matter, as **Exhibit P-18**;

79. Respondents Eli Lilly Canada Inc. and Takeda Canada, Inc. have an establishment or an agent in the District of Montreal according to CIDREQ, and the District of Montreal is a convenient judicial district for petitioner and his counsel;

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

WHEREFORE, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the institution of a class action as follows:

A civil liability action for damages;

GRANT the status of representative to Jimmy Whyte for bringing the said class action for the benefit of the Class described as follows, namely:

"All persons who reside or have resided in Québec who were prescribed and ingested the drug ACTOS® and the heirs, family members and dependents of said persons"

ORDER THAT the principal questions of fact and law to be determined collectively are as follows:

a) What are the health risks associated with and/or caused by the use of ACTOS?

b) Can ACTOS cause and/or materially contribute to the development of bladder cancer?

c) Is ACTOS defective or unfit for the purpose for which it was intended (including usages that ought reasonably to have been foreseen by the Respondents) as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Québec by one or all the Respondents?

d) Did the Respondents know or should they have known of the risks of harm associated with the use of ACTOS?

e) Did the Respondents fail to conduct adequate clinical trials prior to selling ACTOS in Québec?

f) Were the Respondents negligent and/or at fault in distributing or otherwise dealing with ACTOS in Québec?

g) Did the Respondents commit a fault calling into play their civil liability, pursuant to the applicable civil law rules in Québec?

h) Did the respondents fail in their duty to adequately warn the Petitioner and the Class Members of the risks associated with the use of ACTOS and/or did they knowingly and recklessly misrepresent any risk of harm from ACTOS?

i) Are the Petitioner and Class Members entitled to claim compensatory damages from the Respondents?

j) Are the Petitioner and the Class Members entitled to claim punitive damages from the Respondents?

ORDER THAT the conclusions sought with respect to such questions be identified as follows:

GRANT the class action of the Petitioner and the Class Members against the Respondents;

CONDEMN the Respondents solidarily to pay to the Petitioner the total damages awarded by the court, for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents solidarily to pay to each Class Member an amount to be determined as compensation for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, to accrue from the date of service;

CONDEMN the Respondents solidarily to pay to the Petitioner punitive damages in an amount determined by the Court, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents solidarily to pay to each Class Member punitive damages in an amount determined by the Court, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents to reimburse the portion of the cost of ACTOS that is not covered by the public prescription drug insurance plan to the Petitioner and the Class Members;

ORDER the collective recovery of damages of Class Members;

CONDEMN the Respondents solidarily to pay such other amounts and grant Class Members such further relief as this Honourable Court may determine as being just and proper;

THE WHOLE with costs, including the costs of all exhibits, experts and publication notices;

DECLARE THAT any Class Member who has not opted out of the Class be bound by any judgment to be rendered on the class action in accordance with the *Code of Civil Procedure;*

ORDER THAT the deadline for opting out be fixed at sixty (60) days from notice to Class Members and that at the expiry of the deadline, any Class Member who has not opted out be bound by any such judgment;

ORDER THAT a notice to the Class Members be published, in the form substantially similar to the draft notice to members communicated herewith as **Exhibit P-17**, to be published once in the daily newspapers *La Presse*, *The Gazette* and any other newspaper as ordered by the Court;

ORDER THAT the Respondents and counsel for the Petitioner publish the notice to the Class Members, in French and in English on a website to be determined;

ORDER THAT the Respondents be ordered to pay the translation and publication costs of the Notice to Class Members;

ORDER THAT the deadline for publishing the notice to Class Members be thirty (30) days from the date of final judgment on the present motion;

ORDER THAT the record be referred to the Chief Justice so that he may fix the district wherein the class action is to be brought and the judge before whom it will be heard;

ORDER TH AT the clerk of this Court, upon receiving the decision of the Chief Justice, in the event that the class action be brought in another district, transmit the present record to the clerk of the designated district;

THE WHOLE with costs, including the costs of notice and experts.

Montréal, July 30, 2012

Woods LLP

WOODS LLP
Counsel for the Petitioner

NOTICE OF PRESENTATION

To:

TAKEDA PHARMACEUTICAL COMPANY LIMITED
1-1 Doshomachi 4- chome,
Chuoku, Osaka, Japan

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,
One Takeda Parkway
Deerfield, IL 60015, U.S.A.

TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.
One Takeda Parkway
Deerfield, IL 60015, U.S.A.

TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC. One Takeda Parkway
Deerfield, IL 60015, U.S.A.

TAKEDA SAN DIEGO, INC.
10410 Science Center Drive
San Diego, CA 92121, U.S.A.

ELI LILLY CANADA INC.
3650 Danforth Ave.
Toronto, ON M1N 2E8

TAKEDA CANADA, INC.
6750 Century Ave., Suite 400
Mississauga, ON L5N 2V8

PLEASE BE ADVISED that the foregoing *Motion to institute a class action and to obtain the status of representative* will be presented *pro forma* to a judge of the Superior Court of Québec, sitting in practice division in and for the District of Montreal, at 9h00 on **September 18, 2012** in Room 2.16 of the Court House, 1 rue Notre-Dame East, Montréal, Québec, H2Y 1B6, Canada.

DO GOVERN YOURSELVES ACCORDINGLY.

Montréal, July 30, 2012

Woods LLP

WOODS LLP
Counsel for the Petitioner

C A N A D A
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Action)

NO:

JIMMY WHYTE

Petitioner

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

and

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.

and

TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.

and

TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.

and

TAKEDA SAN DIEGO, INC.

and

ELI LILLY CANADA INC.

and

TAKEDA CANADA, INC.

Respondents

LIST OF EXHIBITS

P-1 *Notice of Compliance* issued by Health Canada for ACTOS, dated August 17, 2000;

P-2 Copy of an article entitled "Secondary prevention of macrovascular events in patients with type 2 diabetes in the PROactive Study (PROspective pioglitazone Clinical Trial in macrovascular Events): a randomised controlled trial," dated October 8, 2005 and published by *The Lancet*;

P-3 Copy of a Drug Safety Communication issued by the FDA on September 17, 2010;

P-4 Copy of an article entitled "Risk of bladder cancer among diabetic patients treated with pioglitazone," dated April 2011 and published by *Diabetes Care*;

P-5 Copy of an article entitled "Assessing the association of pioglitazone use and bladder cancer through drug adverse event reporting," dated Jun 2011 and published by *Diabetes Care*;

P-6 Copy of a press release issued by the afssaps dated Jun 9, 2011;

P-7 Copy of an article entitled "Pioglitazone and risk of bladder cancer among diabetic patients in France: a population-based cohort study," dated March 31, 2012 and published by *Diabetologia*;

P-8 Copy of a Drug Safety Communication on ACTOS issued by the FDA on June 15, 2011;

P-9 Copy of *Information Update* issued by Health Canada on June 17, 2011;

P-10 Copy of a letter to the editor entitled "Pioglitazone and bladder cancer," dated October 29, 2011 and published by *The Lancet*;

P-11 Copy of the *Canadian Product Monograph* for ACTOS, current as at March, 2011;

P-12 Copy of a *Dear Healthcare Professional* letter dated April 16, 2012;

P-13 Copy of the revised *Canadian Product Monograph* for ACTOS;

P-14 Copy of an article entitled "The use of pioglitazone and the risk of bladder cancer in people with type 2 diabetes: nested case-control study," dated May 31, 2012 and published by the *British Medical Journal*;

P-15 Copy of an article entitled "Increased risk of bladder cancer with pioglitazone therapy in patients with diabetes: A meta-analysis," article in press as 2012.05.006 and published by *Diabetes Research and Clinical Practice*;

P-16 Copy of an article entitled "Use of thiazolidinediones and the risk of bladder cancer among people with type 2 diabetes: a meta analysis," dated July 3, 2012 and published by the *Canadian Medical Association Journal*;

P-17 Draft notice to members (art. 1006 C.C.P.) complying with Form IV of the Rules of Practice of the Superior Court;

P-18 Copy of the Statement of Claim filed on December 21, 2011 in the Superior Court of Justice of Ontario in the matter of *Casseres v. Takeda Pharmaceutical Company Limited*, Court file no. CV-11-442584.

Montréal, July 30, 2012

Woods LLP

WOODS LLP
Counsel for the Petitioner

500-06-000618-120

No. :

SUPERIOR COURT (Class Action)
DISTRICT OF MONTREAL
PROVINCE OF QUÉBEC

JIMMY WHYTE

Petitioner

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED,
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,
TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.,
TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.,
TAKEDA SAN DIEGO, INC.,
ELI LILLY CANADA INC.,
TAKEDA CANADA, INC.

Respondents

MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE (Article 1002 C.C.P.)

ORIGINAL

Mtre. Christopher L. Richter
File no.: 5415-1

Woods LLP
Barristers & Solicitors
2000 McGill College Ave., Suite 1700
Montreal, Quebec H3A 3H3
T 514 982-4545 F 514 284-2046
www.litigationboutique.com

Woods

161957

AUTO 1198

3607123