Court File No. CV-11-442584 OOCP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

GERALDINE CASSERES, Deceased, by her Estate Representative JOANN CASSERES, JOANN CASSERES, and RUSSEL CHAUVIN

Plaintiffs

-and-

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. and TAKEDA CANADA, INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

FRESH AS AMENDED STATEMENT OF CLAIM

AMENDED THIS June 7, 2017 PURSUANT TO RULE 26.02 (a) / MODIFIÉ CE ___ CONFORMÉMENT À LA RÈGLE ___
☐ THE ORDER OF ___ / L'ORDONNANCE DU ___
DATED / FAIT LE ___
REGISTRAR / GREFFIER
SUPERIOR COURT OF JUSTICE / COUR SUPÉRIEURE DE JUSTICE

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the *Rules of Civil Procedure*, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the *Rules of Civil Procedure*. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date: December 21, 2011

Issued by: "F. Yossef"
Local Registrar

Address of court office:

393 University Avenue
10th Floor
Toronto, Ontario
M5G 1E6

CLAIM

1. The plaintiff, Geraldine Casseres ("Geraldine"), by her estate representative Joann Casseres ("Joann"), Joann Casseres personally, and Russel Chauvin ("Russel") on their own behalf and on behalf of all members of the classes of persons described in paragraphs 20 and 21 ("the Class" or "Class Members" and "the Family Class" or "Family Class Members") *infra* seek an order:

a) certifying this action as a class proceeding and appointing Joann, as the representative of Geraldine's estate, and Russel as the representative plaintiffs of the Class and Joann as the representative plaintiff of the Family Class, all pursuant to the *Class Proceedings Act, 1992* ("CPA");

b) that the Defendants engaged in spoliation of evidence thus warranting: an adverse inference against the Defendants that the files and documents that were destroyed would have been unfavourable to the Defendants and would have been beneficial to the Plaintiffs in determining liability and damages. Such conduct warrants the exclusion of evidence of the Defendants on issues relating to liability and damages, special costs and punitive damages;

c) that the defendants owed a duty of care to the Class Members;

d) that the defendants were negligent in the development, testing, design, manufacturing, licensing, distribution, marketing and sale of ACTOS and are liable to the Classes for resulting damages;

e) that the defendants breached their duty to warn the plaintiffs and other Class Members of the risk of developing bladder cancer associated with ACTOS;

f) for general damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

g) for special damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

h) for punitive damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

i) for the costs of notice and administering the plan of distribution of the recovery in this action plus applicable taxes pursuant to s.26(9) of the CPA;

j) directing a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

k) for pre-judgment and post-judgment interest pursuant to sections 128 and 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

l) for the costs of this action on a substantial indemnity basis, together with all applicable taxes thereon; and

m) for such further and other relief as this Honourable Court deems just.

NATURE OF THE ACTION

2. This action relates to the pain and suffering and resulting damages suffered by the plaintiffs herein and other members of the Classes as a result of the defendants' negligent research and development, design, testing, manufacture, licensing, marketing, distribution and sale of pioglitazone hydrochloride under the brand name of ACTOS® ("ACTOS") in Canada.

3. Geraldine and Russel were prescribed ACTOS for the treatment of their diabetes and used the drug in accordance with the prescribing information provided by the defendants and in accordance with their treating physicians' instructions.

4. Geraldine, and Russel were both diagnosed with bladder cancer. It claimed Geraldine's life on April 12, 2011.

5. The plaintiffs allege 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. The plaintiffs further allege that the defendants have known about these defects but have failed to disclose these defects and the resulting risks to the health and

life of the plaintiffs, Class Members, their treating physicians and regulatory authorities in Canada and have failed to recall ACTOS in Canada.

THE PARTIES

6. Geraldine was 71 years old and resided in Toronto, in the province of Ontario, prior to her death from bladder cancer, on April 12, 2011. Her estate is represented herein by her daughter, Joann Casseres.

7. Joann is 44 years old and resides in Toronto, in the province of Ontario.

8. Russel is 79 years and resides in Cambellton, in the province of New Brunswick.

9. The defendant, 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.

10. The defendant, 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, labeling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

11. The defendant, 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, labeling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

12. The defendant, 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, labeling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

13. The defendant, 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, labeling, promoting, packaging, advertising, and/or selling ACTOS to Canadian consumers.

14. The defendant, 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, labeling, promoting, packaging, advertising and/or selling ACTOS to Canadian consumers. The above-referenced defendants are referred to herein collectively as "the Takeda defendants".

15. The defendant, 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, which was thereafter involved in the licensing, marketing, labeling, promoting, packaging, advertising and/or selling of ACTOS in Canada, until mid-June, 2009, when such rights were acquired by Takeda Canada, Inc.

16. The business of each of the defendants herein 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.

17. At all material times, the defendants 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 defendants also shared the common purpose of concealing the defects in ACTOS from the plaintiffs and Class Members.

18. At all relevant times, each of the defendants 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 defendants 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 defendants to manufacture, market, sell, and distribute the defective ACTOS.

19. At all material times, each defendant was the agent of the other and as such, each defendant is individually, as well as jointly and severally, liable to the plaintiffs 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 Class Members and Family Class Members 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.

THE CLASSES

20. Joann, as the representative of Geraldine's Estate and Russel bring this action on behalf of the members of the Class defined as follows:

> "All persons resident in Canada, excluding residents of Québec, who purchased and/or used ACTOS and their estates, administrators or other legal representatives, heirs or beneficiaries ("the Class" or "Class Members")"

21. Joann brings this action on her own behalf and on behalf of the members of the Family Class defined as follows:

> "All persons who on account of a personal relationship to a Class Member are entitled to assert a derivative claims for damages pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c.F.3, as amended and comparable provincial and territorial legislation ("the Family Class" or "Family Class Members")"

PLAINTIFFS' CIRCUMSTANCES

Geraldine's Circumstances

22. Beginning on or about February 13, 2002, Geraldine was prescribed ACTOS for the management of her non-insulin dependant Type-II diabetes, specifically for management of her blood-glucose levels. Geraldine took the medication as advised by her family doctor and in accordance with the dosing information provided by the defendants.

23. In or about April of 2008, after having been taking ACTOS for over six years, Geraldine suffered a shoulder fracture which required a partial replacement and in June of 2009, Geraldine suffered a fractured left hip which required surgical repair with internal fixation, followed by in-patient care at a rehabilitation hospital.

24. In or about September, 2008, Geraldine developed what was believed to be a bladder infection and underwent related investigations at North York General Hospital and Sunnybrook Hospital. As a result of these investigations, on or about December 2008, she was diagnosed with urachal carcinoma, a rare and inoperable form of bladder cancer.

25. By the time of her diagnosis, the cancer had already metastasized. Geraldine was required to undergo a 6-week course of aggressive chemotherapy, which began in the mid-January 2009, ultimately developed acute onset renal failure and congestive heart failure.

26. Notwithstanding the various medical interventions introduced to treat her cancer, Geraldine ultimately succumbed to the disease on April 12, 2011 at the age of 71.

27. Joann and the rest of Geraldine's family have, and will continue to suffer emotional anguish resulting from Geraldine's extreme pain, suffering and ultimate death from bladder cancer.

Russel's Circumstances

28. Russel was a practicing physician for approximately 41 years, including 21 years of general surgery (5 of which included family practice), and 20 years of family practice. He

retired from my family practice in 2007 and subsequently worked for 2 years (for approximately 30 days a year) at walk-in clinics until fully retiring in 2009.

29. He was diagnosed with non-insulin dependent Type-II diabetes in or around 2000 and he first began taking ACTOS in or around December 2006, using free samples which he had been provided by a pharmaceutical sales representative. He later obtained a further six months' supply from his daughter who is a practicing family physician in Battle Creek, Michigan. After using these free samples of ACTOS for approximately 10 months, he was formally prescribed ACTOS in or around October 2007. His last dispensed prescription on January 10, 2008 was for 100 pills of 30 mg (approximately 3 months' worth of pills).

30. In or around March 2008, Russel developed hematuria. Subsequent medical investigation revealed that he had a relatively large tumor in his bladder and on or about April 24, 2008, he was diagnosed with transitional cell carcinoma of the bladder.

31. Russel underwent surgery for removal of the tumor and one day of chemotherapy. As a result of the various medical interventions, his bladder cancer has been in remission.

FACTS

History of ACTOS and Mechanism of Action

32. 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. 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. Lilly

had acquired the Canadian commercial rights to ACTOS from Takeda Limited as part of a worldwide agreement in 1999.

33. 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.

34. 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.

Defendants' Knowledge of Risks of Bladder Cancer with ACTOS

35. 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.

36. Prior to ACTOS being approved for sale anywhere in the world, Takeda was also aware of pre-clinical data demonstrating significant safety concerns as compared with the anticipated efficacy of the drug. Takeda was working to develop the drug with the former North American pharmaceutical company, The Upjohn Company ("Upjohn"), up until September 1993, when Upjohn formally advised Takeda that it was withdrawing its participation in the development of ACTOS due to concerns with the drug's margin of safety. Takeda subsequently sought to have Upjohn attribute its withdrawal to financial and business reasons.

37. In addition, and also prior to receiving approval to market ACTOS for sale in Canada, as early as 1996, the defendants were aware of pre-clinical data demonstrating that statistically significant rates of bladder tumours were observed in rats treated with the drug at levels equivalent to a human clinical dose. By February of 1996, Takeda was aware of the results from two-year carcinogenicity studies on rats and mice which reflected a treatment-related increase in the incidence of hyperplasias and transitional cell tumors in the bladders of rats and in mice together with a kidney tumor in rats. This study had been conducted by a testing organization called MPI Research Labs ("MPI").

38. In response, Takeda retained Dr. Samuel Cohen in March 1996 to develop a hypothesis to explain these findings of bladder tumor-formation. This hypothesis posited that the bladder tumors resulted from the development of bladder calculi in the rats, a process that was unlikely to be replicated in humans. The hypothesis did not address the kidney tumor in rats nor the tumors in the mice.

39. Further, MPI, which had done the study, did not agree with Dr. Cohen's hypothesis in terms of the suggested strength of the correlation between bladder calculi and tumor-formation, which was the basis for believing that the development of the tumors was species-specific to rats. Indeed, MPI recommended 2-stage carcinogenesis and cell proliferation studies to understand the mechanistic basis for this outcome; a recommendation that Takeda did not follow.

40. In or about 1999, near the time of regulatory approval for ACTOS, Takeda was negotiating a co-promotion agreement for ACTOS with Lilly. Numerous issues required consideration, including the sharing of information relating to product liability exposure.

As part of a due diligence process associated with the negotiation of the co-promotion agreement, Takeda shared safety information with Lilly. This information revealed that Takeda had knowledge of bladder cancer being observed in pre-clinical studies in rats prior to July 1999.

41. Following regulatory approval for ACTOS, as evidence by the Notice of Compliance dated August 17, 2000, the Defendants received additional evidence of the association between ACTOS and bladder cancer in humans. In July of 2002, a Danish pharmaceutical company, which had been developing ragaglitazar, a diabetes drug in the same class as ACTOS, publicly announced that it was suspending its clinical development of ragaglitazar due to results from a two-year pre-clinical rat study. The study investigated both ragaglitazar and ACTOS and the results demonstrated the development of transitional cell bladder tumors with both drugs at the same rate. Ragaglitazar never came to the market as a result of these findings.

42. 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 increase 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 ACTOS treatment group compared to only 6 cases in the placebo group. The data from this study became available to the Defendants in early 2004 and reflected an almost three times (2.83) greater incidence of bladder cancer in the ACTOS-treated group, compared to placebo.

43. However, when the study was published in 2005, the Defendants manipulated the data such that one of the bladder cancers found in that data was reclassified, thereby reducing the risk ratio to a non-statistically significant finding.

44. The Defendants also conducted a disproportionality adverse event analysis on ACTOS, relating to cases of bladder cancer. This reflected that, up to March of 2005 alone, there was a statistically significant 190% excess in the number of cases of bladder cancer adverse event reports with ACTOS, compared to all other drugs on the market. This significant finding was never reported to the regulatory authorities and, instead, methodologically unsound alternative analyses were provided.

45. The Defendants thus had early and extensive knowledge of the risk of bladder cancer associated with the use of PIO from its pre-clinical development stages. They concealed that risk from regulatory authorities, prescribing physicians and the vulnerable population of diabetic patients. The Defendants also manipulated data in an attempt to conceal evidence of association between the ingestion of ACTOS and bladder cancer.

Regulatory action

46. 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.

47. 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.

48. 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.

49. 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 defendants or otherwise.

50. In June of 2011, results were published of a study that reviewed adverse events reported to the FDA between 2004-2009 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).

51. On June 9, 2011, results were published from a broad retrospective cohort study conducted by the Caisse national 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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. Although a robust body of scientific evidence demonstrates that the product is inherently

dangerous and has indicated that ACTOS can cause, materially contribute to or materially increase the risk of bladder cancer and had result in numerous cases of bladder cancer worldwide, the defendants have failed to withdraw ACTOS from the Canadian stream of commerce and have continued to profit from the sale of ACTOS in Canada.

57. Further, despite this ever growing body of knowledge which the defendants 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 has never included information about this side effect in the Warnings section.

58. Indeed, the Canadian patient information sheet current to March, 2011 contains no information whatsoever about an association with bladder cancer so as to allow Class Members to make an informed decision about using the drug.

Spoliation of Evidence

59. In decisions rendered by the trial Judge Rebecca F. Doherty in In Re: ACTOS (Pioglitazone) Products Liability Litigation, MDL No. 6:11-md-2299, Judge Doherty found that it was undisputed that Takeda had destroyed evidence in bad faith and intentionally at a time when Takeda was under a duty to retain all information, files and documents related to ACTOS.

60. Takeda has destroyed liability-related files belonging to at least 46 custodians intentionally and in bad faith. These 46 custodians had been employed by Takeda in Japan, United States, and Europe. Each of these Takada custodians had left Takeda in 2011 or earlier and had critical information regarding the development and marketing of

ACTOS. The 46 custodians included company presidents and key officers who were privy to critical information because they were intimately involved in the marketing and development of ACTOS during pivotal periods.

61. The files which were destroyed contained electronically generated and electronically stored documents, in addition to hard copy documents. These documents were destroyed and cannot be reproduced or fully reconstituted. The files were destroyed at a time when Takeda was under a duty to retain all information, files and documents related to ACTOS.

62. The deleted and destroyed files and documents were relevant to issues relating to liability, harm and damages, and the destruction of these documents and data is highly prejudicial to the Plaintiffs. The conduct of the Defendants warrants an adverse inference against the Defendants in that the files and documents destroyed would have been unfavourable to the Defendants and favourable to the Plaintiffs' in determining liability and damages. The conduct of the Defendants further warrants an order excluding all evidence of the Defendants on issues relating to liability and damages in addition to an award of punitive damages and special costs.

CAUSES OF ACTION

Negligence

63. ACTOS was designed, developed, tested, manufactured, licensed, assembled, distributed, imported and/or exported, marketed, and/or sold by the defendants. At all material times, the defendants owed a duty of care to the plaintiffs and to the Classes to

provide a safely manufactured product. The defendants breached the standard of care expected in the circumstances.

64. The defendants also owed a duty to Geraldine, Russel, 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 Geraldine, Russel, 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 Canadian 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.

65. The circumstances of the defendants being in the business of designing, manufacturing and placing ACTOS into the Canadian stream of commerce are such that the defendants 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.

66. It was reasonably foreseeable that a failure by the defendants 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 plaintiffs and the other members of the Classes.

67. The defendants 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 defendants' 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 defendants' 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 plaintiffs 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 concealed the fact that ACTOS were defective from the public, health care providers and the regulatory authorities, including the FDA and Health Canada;

j) they concealed adverse information regarding the testing and safety of ACTOS from the public, health care providers and regulatory authorities, including the FDA and Health Canada;

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

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

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

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

o) such further and other particulars of negligence within the knowledge of the defendants.

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

DAMAGES

69. As a result of the negligence of the defendants, the plaintiffs and Classes have suffered the following damages:

a) serious injury and, in some cases, death;

b) emotional and psychological trauma;

c) special damages for out of pocket expenses;

d) cost of future care and services;

e) loss of income; and,

f) such further and other damages the particulars of which will be provided prior to trial.

70. As a result of the defendants' negligence, Joann and other members of the Family Class have suffered the following damages:

a) actual expenses reasonably incurred for the benefit of a Class Member;

b) a reasonable allowance for travel expenses actually incurred in visiting the Class Member during his or her treatment or recovery;

c) where, as a result of the injury, nursing, housekeeping or other services have been provided for a Class Member, a reasonable allowance for loss of income or the value of the services; and

d) an amount to compensate for the loss of guidance, care and companionship that the Family Class Member might reasonably have expected to receive from a related Class Member if the injury or death had not occurred.

71. The plaintiffs and the other Class Members are also entitled to recover, as damages or costs in accordance with the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, the costs of administering the plan to distribute the recovery of this action.

PUNITIVE DAMAGES

72. The plaintiffs plead that the defendants have acted in such a high-handed, wanton and reckless manner, without regard to public safety, as to warrant a claim for punitive damages. In particular, Takeda has destroyed files belonging to at least 46 custodians intentionally and in bad faith. The deleted and destroyed files and documents were relevant to the issues of liability and damages and the destruction of these documents is prejudicial to the Plaintiffs. In addition, the defendants' conduct in the design, development, testing, manufacture, licensing, assembly, distribution, marketing, and sale of ACTOS, the failure to recall all ACTOS sooner or at all, and the facts pleaded above were entirely without care, deliberate, callous, disgraceful, wilful, and an intentional disregard of the Class Members' rights and safety, indifferent to the consequences, and motivated by economic considerations such as maintaining revenue and market.

PROVINCIAL HEALTH INSURERS

73. The provincial and territorial health insurers in Canada have incurred various expenses with respect to the medical treatment of Geraldine, Russel, and other Class Members as a result of the defendants' negligence. As a result, they have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their subrogated and direct rights of action in respect of all past and future insured services. This action is maintained on behalf of all such provincial and territorial health insurers, with the exception of the Régie de l'assurance maladie du Québec (RAMQ).

LEGISLATION

74. The plaintiffs plead and rely upon, *inter alia*, the following statutes and the regulations made thereunder (all as amended):

a) *Alberta Health Care Insurance Act*, R.S.A. 2000, c. A-20;

b) *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;

c) *Courts of Justice Act,* R.S.O. 1990, c.43;

d) *Family Law Act*, R.S.O. 1990, c. F.3;

e) *Fatal Accident Act,* R.S.N.I. 1990, c. F.6;

f) *Fatal Accidents Act*, C.C.S.M. c.F.50;

g) *Fatal Accidents Act,* R.S.A. 2000, c. F-8;

h) *Fatal Accidents Act,* R.S.N.B. 1973, c.F-7;

i) *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3;

j) *Fatal Accidents Act,* R.S.P.E.T. 1988, c. F-5;

k) *Fatal Accidents Act*, R.S.S. 1978, c.F-11, s.3;

l) *Fatal Accidents Act*, R.S.Y. 2002, c.86;

m) *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;

n) *Health Insurance Act,* R.S.O. 1990, c. 11.6;

o) *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;

p) *Health Services Insurance Act,* C.C.S.M., C.1135;

q) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;

r) *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7;

s) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3;

t) *Hospital Insurance Services Act*, R.SY. 2002, c. 112;

u) *Hospital Services Act,* R.S.N.B. 1973, c. 11-9;

v) *Hospitals Act*, R.S.A. 2000, c. 11-12;

w) *Negligence Act*, R.S.O. 1990, c. N.1;

x) *Trustee Act*, C.C.S.M. c. T160;

y) *Trustee Act,* R.S.N.W.T. 1988, c. T-8; and

z) *Trustee Act*, R.S.O. 1990, c. T.23.

REAL AND SUBSTANTIAL CONNECTION

75. There is a real and substantial connection between the subject matter of this action and the Province of Ontario for the following reasons:

a) the defendants have registered places of business in Ontario and manufacture, distribute, market, promote and/or sell ACTOS in Ontario and derive substantial revenue from such sales;

b) Geraldine, Russel, and other members of the Class were prescribed and used ACTOS in Ontario;

c) Geraldine, Joann and other members of the Classes resident in Ontario sustained their damages in Ontario; and

d) approval for the sale of ACTOS in Canada was granted in Ottawa, Ontario.

SERVICE OUTSIDE OF ONTARIO

76. This statement of claim may be served without court order outside Ontario because the claim is:

a) in respect of a tort committed in Ontario (rule 17.02(g));

b) in respect of damages sustained in Ontario arising from a tort or breach of contract however committed (rule 17.02(h));

c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and

d) against a person carrying on business in Ontario (rule 17.02(p

PLACE OF TRIAL

77. The plaintiffs propose that this action be tried in Toronto.

Date: June 6, 2017

ROCHON GENOVA LLP
Barristers & Solicitors
121 Richmond Street West
Suite 900
Toronto, Ontario
M5H 2K1

Joel P. Rochon (LSUC#: 28222Q)
Annelis Thorsen-Cavers (LSUC#: 28222Q)
Lisa M. Fenech (LSUC#:66276W)

Tel: (416) 363-1867
Fax: (416) 363-0263

KIM ORR BARRISTERS P.C.
19 Mercer Street
Toronto, ON M5V 1H2

Won J. Kim (LSUC #332918H)
Megan B. McPhee (LSUC #48351G)

Tel.: (416) 596-1414
Fax: (416) 598-0601

Lawyers for the Plaintiffs

GERALDINE CASSERES, Deceased, by her Estate Representative JOANN CASSERES et al.
Plaintiffs

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED et al.
Defendants

Court File No.: CV-11-442584 00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED AT
TORONTO

FRESH AS AMENDED STATEMENT OF CLAIM

ROCHON GENOVA LLP
Barristers and Avocats
121 Richmond Street West
Suite 900
Toronto, Ontario
M5H 2K1

Joel P. Rochon (LSUC#: 28222Q)
Annelis K. Thorsen (LSUC#: 42150K)
Lisa M. Fenech (LSUC#:66276W)

Tel: (416) 363-1867
Fax: (416) 363-0263

Lawyers for the Plaintiffs