Form 4.02A

2009

Hfx. No. 315567

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

ALBERT CARL SWEETLAND and BARBARA FONTAINE

Plaintiffs

- and -

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Defendants

THIRD FRESH AS AMENDED NOTICE OF ACTION

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

To: GLAXOSMITHKLINE INC.

To: GLAXOSMITHKLINE LLC

Action has been started against you
The plaintiffs take action against you.

The plaintiffs started the action by filing this notice with the court on the date certified by the prothonotary. The plaintiffs claim the relief described in the attached statement of claim. The claim is based on the grounds stated in the statement of claim.

Deadline for defending the action
To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

- 15 days if delivery is made in Nova Scotia
- 30 days if delivery is made elsewhere in Canada
- 45 days if delivery is made anywhere else.

Judgment against you if you do not defend

The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

You may demand notice of steps in the action

If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

If you file a demand for notice, the plaintiffs must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

Rule 57 - Action for Damages Under $100,000

Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the plaintiffs state the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the plaintiffs.

This action is *not within* Rule 57. [State "within" if the action is for an order for judgment under $100,000, no other order (eg. injunction, declaration) is claimed, and the claim is based on debt, injury to property, injury to a person, supply of goods or services, breach of contract, breach of trust, or dismissal from employment.]

Filing and delivering documents

Any documents you file with the court must be filed at the office of the Prothonotary, 1815 Upper Water Street, Halifax, Nova Scotia (telephone # 424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

Contact information

The plaintiffs designate the following address:

Raymond F. Wagner, Q.C.
Wagners
1869 Upper Water Street
Halifax NS B3J 1S9

Documents delivered to this address are considered received by the plaintiffs on delivery.

Further contact information is available from the prothonotary.

Proposed place of trial
The plaintiffs propose that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Signature
Signed November 2, 2018.

Raymond F. Wagner, Q.C.
Solicitor for the Plaintiffs

Prothonotary's certificate

I certify that this notice of action, including the attached statement of claim, was filed with the court on November 2, 2018.

Prothonotary

ERIKA SCHMIDT
Deputy Prothonotary

FORM 4.02B

THIRD FRESH AS AMENDED STATEMENT OF CLAIM

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

I. OVERVIEW

1. The Defendants, GlaxoSmithKline Inc. and GlaxoSmithKline LLC, (collectively referred to as "GSK") form a global healthcare group engaged in the creation, discovery, development, manufacture and marketing of pharmaceutical and consumer health-related products. These two entities are affiliated companies in that they are wholly owned subsidiaries of a parent GlaxoSmithKline company.

2. GSK designed, researched, developed, tested, manufactured, marketed, packaged, promoted, distributed, licensed and sold the drug AVANDIA throughout the world, including Nova Scotia and the rest of Canada. The Plaintiffs allege that this was done in a tortious manner, resulting in class-wide harms.

3. Living Class Members have all been prescribed AVANDIA. Deceased individuals through Class Members who are lawfully entitled claimants under the *Fatal Injuries Act*, R.S.N.S. 1989, c. 163 in this proceeding had purchased and/or ingested AVANDIA.

4. Living Class Members have been continuously harmed by their use of the medication AVANDIA as hereinafter described. Deceased individuals had been harmed by the use of AVANDIA that caused or materially contributed to their death.

5. In this action, the Plaintiffs seek, on their own behalf and on behalf of the Class:

    (a) compensation for the personal injuries and other costs they have incurred as a result of having taken AVANDIA and/or;

    (b) disgorgement of the benefits that accrued to the Defendants as a result of their wrongful acts; and

(c) damages in the form of total funds required to establish a medical monitoring process for the benefit of the Class Members.

6. The Plaintiffs seek to certify this action as a class proceeding and plead the *Class Proceedings Act*, S.N.S 2007, c. 28, as providing the basis for such certification. The Plaintiffs, as the Representative Plaintiffs, do not have any interest adverse to any of the members of the proposed Class. The Plaintiffs states that there is an identifiable class that would be fairly and adequately represented by the Plaintiffs; that the Plaintiffs' claims raise common issues which predominate over issues affecting only individual members; and that a class proceeding would be the preferable procedure for the resolution of such common issues.

7. The Plaintiffs propose to bring an opt-out common law class proceeding on behalf of themselves and a Class of other individuals resident in Canada, who purchased and ingested AVANDIA. The proposed Class, which will include Primary Class Members and Family Class Members, will be further defined in the Motion for Certification.

II. REPRESENTATIVE PLAINTIFFS AND CLASS

8. The Plaintiff, **Albert Carl Sweetland**, resides on Medowlark Crescent in Halifax, Nova Scotia.

9. Albert Carl Sweetland was initially prescribed AVANDIA on December 14, 2001.

10. As a result of taking AVANDIA, Albert Carl Sweetland suffered significant myocardial dysfunction and sustained congestive heart failure in January of 2007.

11. The Plaintiff, **Barbara Fontaine**, resides in Thunder Bay, Ontario and is the wife and estate trustee of Mr. Richard Fontaine, deceased.

12. Mr. Richard Fontaine was originally prescribed AVANDIA on or about April 17, 2004.

13. On or about June 26, 2005, Mr. Fontaine was diagnosed as having suffered a heart attack.

14. On or about February 16, 2006, Mr. Fontaine discontinued his use of AVANDIA.

15. Mr. Fontaine died in April 2018.

16. The Plaintiff, **Barbara Fontaine,** brings this action as the wife and estate trustee of Mr. Fontaine as a result of the damages she has sustained including costs to treat Mr. Fontaine's injury and related travel expenses, and the loss of guidance, care and companionship from Mr. Fontaine.

17. The Plaintiffs seek certification of the following classes:

    (a) All persons in Canada, including their estates, who purchased and ingested the drug AVANDIA ("the Primary Class"); and

    (b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents, brothers and/or sisters of deceased members of the primary class ("the Family Class").

III. DEFENDANTS

18. The Defendant, GlaxoSmithKline Inc., is a corporation incorporated pursuant to the laws of Canada, with its head office situated in Mississauga, Ontario and a corporate office located in Halifax, Nova Scotia. It is, and has always been, the entity that conducts the manufacturing, promoting, labeling, marketing and selling of AVANDIA in Canada.

19. The Defendant, GlaxoSmithKline LLC, resulted from the merger of a number of previous companies; it is a corporation incorporated pursuant to the laws of the United States, with offices situated in Philadelphia, Pennsylvania, United States of America. It is the entity that conducts the manufacturing, promoting, labeling, marketing and selling of AVANDIA in the United States. It works in close partnership, and directs, the Defendant, GlaxoSmithKline Inc., in regards to the manufacturing, promoting, labeling, marketing and selling of AVANDIA in Canada. GlaxoSmithKline LLC also directs GlaxoSmithKline Inc. in all of the latter's interactions with the Canadian health regulator,

Health Canada. GlaxoSmithKline LLC or one of its predecessors is also one of the GlaxoSmithKline group of companies that developed Avandia. It is also responsible for overseeing and coordinating pharmacovigilance of Avandia on a worldwide basis; pharmacovigilance is the monitoring of a drug's side effects ("adverse events") after it has been introduced into the market. As the company that oversees and coordinates pharmacovigilance, GlaxoSmithKline LLC is in the sole possession of all of Avandia's global adverse event information.

20. The Defendants, GlaxoSmithKline Inc. and GlaxoSmithKline LLC are collectively referred to as "GSK"; and hereinafter references to GSK are intended to include the above mentioned corporations, their officers, employees, representatives, agents, and associates acting on behalf of GSK.

21. GlaxoSmithKline Inc. and GlaxoSmithKline LLC are wholly responsible for all the acts and omissions of their subsidiary companies by virtue of having succeeded or acquired those companies and by virtue of having assumed the obligations of those companies.

22. Further, and in the alternative, the Plaintiffs plead that, by virtue of the acts described herein, each of the companies comprising GSK, as set out above, is vicariously liable for the act and omissions of the others for the following reasons:

(a) Each was the agent of the other;

(b) Each Defendant's business was operated so that it was inextricably interwoven with the business of the other;

(c) Each Defendant entered into a common advertising and business plan with the other to distribute and sell AVANDIA;

(d) Each Defendant operated pursuant to a common business plan to distribute and sell AVANDIA;

(e) Each Defendant intended that the businesses be run as one business organization; and,

(f) The Defendant are related, associated or affiliated.

23. At all material times, GSK designed, researched, developed, tested, manufactured, marketed, packaged, promoted, distributed, licensed, and sold a drug having the active ingredient rosiglitazone maleate ("rosiglitazone") for the use by patients throughout the world, including Nova Scotia and the rest of Canada. At all material times, GSK designed, researched, developed, tested, manufactured, marketed, packaged, promoted, distributed, licensed and sold the rosiglitazone products throughout Nova Scotia and Canada under the brand names AVANDIA, AVANDAMET and AVANDARYL. The said rosiglitazone products are hereinafter collectively referred to as "AVANDIA".

IV. AVANDIA

24. AVANDIA is a brand-name anti-diabetic prescription drug used in the treatment of type II diabetes mellitus. The drug was approved by Health Canada on March 21, 2000 for the treatment of type II diabetes mellitus. The drug is one of a class of drugs known as thiazolidinediones (TZDs) and is a peroxisome proliferator-activated receptor agonist. It represents the most potent of the TZD group of drugs.

25. The sales for AVANDIA peaked in 2006 at approximately three billion dollars. At this time, AVANDIA sales were over $150 million in Canada. Approximately 7% of GSK's revenue was accrued from the sale of AVANDlA. AVANDIA was GSK's second best selling drug and the top-selling diabetes treatment.

26. Before AVANDIA was approved for sale in Canada, legitimate safety concerns were publically expressed to the U.S. Food and Drug Administration ("FDA") concerning the drug. Since then, numerous meta-analysis studies have been conducted on the effect of AVANDIA on the risk of heart related health problems. These studies, including GSK's own study and post-market reports, have shown that there is a significant increase in the risk of heart attack, heart failure and strokes in patients taking AVANDIA.

27. GSK's own studies into the safety of AVANDIA, including comparisons of AVANDIA with Actos (pioglitazone, a comparable drug manufactured by GSK's competitor) and with glyburide (an older, more studied and cheaper alternative to AVANDIA) indicate that AVANDIA was more dangerous than Actos and glyburide. GSK did not release

the results of these studies. Rather, it downplayed any cardiovascular risk and promoted AVANDIA as being as safe and effective as its competitors' product.

28. By June of 2007, the FDA announced that AVANDIA would be the subject of a "Black Box Warning", the highest level of warning label provided for by the FDA, in order to warn the public of the increased risk of heart attacks in those patients taking AVANDIA.

V. NATURE OF THE ACTION

29. The Plaintiffs and Class Members allege that the Defendants engaged in tortious conduct in the designing, researching, developing, testing, packaging, licensing, manufacturing, marketing, promotion, distributing and selling of AVANDIA in complete disregard for the health and safety of the Plaintiffs and Class Members.

30. The Plaintiffs and Class Members further allege that the Defendants were wholly and grossly negligent.

31. The Plaintiffs and Class Members further allege that the Defendants failed to warn the Plaintiffs and Class Members of the serious complications and problems that would ensue with the use of AVANDIA. These individuals were not given warning or, in the alternative, clear, complete and current warning of the health risks associated with the ingestion of AVANDIA.

32. The Plaintiffs and Class Members further allege that the Defendants expressly and impliedly breached warranties.

33. The Plaintiffs and Class Members further allege that they and thousands of other Canadians have sustained physical, mental, and economic harm through the use of AVANDIA as a result of the wholly and grossly negligent actions of the Defendants.

34. The Plaintiffs and Class Members further allege that the Defendants failed and/or chose not to adequately inform both users of AVANDIA and the doctors who prescribed the medication of the very serious risks associated with AVANDIA.

35. AVANDIA has caused damage to the physical and mental health of the Plaintiffs and Class Members.

36. The Plaintiffs allege on behalf of Class Members that the continued use of AVANDIA by Class Members creates ongoing risks to the health of the Class Members.

37. During the applicable times within the Class Period of May 1999 to the present when the Defendants were involved with the manufacture and distribution of AVANDIA, they knew or ought to have known of the potential safety risks with the drug.

38. None of the Defendants took any steps to prevent harm to the Plaintiffs and the Class Members or to protect the health and safety of the Plaintiffs and Class Members.

VI. CAUSES OF ACTION

(a) Conspiracy

39. During the class period the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking bona fides, conspired and agreed together, the one with the other and with persons unknown, as hereinafter set out.

40. The Plaintiffs plead that the Defendants' conspiracy involved both lawful and unlawful means with the predominant purpose of causing the Plaintiffs and the other Primary Class Members to acquire and ingest AVANDIA when they knew or should have known that such use would cause harm to the Primary Class Members and the Family Class Members.

41. The Defendants conspired with each other to unlawfully market, distribute, advertise and sell AVANDIA, intending that their conduct be directed towards the Primary Class Members, when they knew or should have known that in the circumstances,

injury and damage to the Primary Class Members and the Family Class Members was likely to result. They derived substantial compensation and revenues from the conspiracy.

42. As a result of the conspiracy, the Plaintiffs and the other Primary Class Members have suffered damage and loss, including other side effects as a result of the use of AVANDIA.

43. As a further result of the conspiracy, Family Class Members have suffered damages and loss, and continue to suffer damages and loss, including actual expenses reasonably incurred for the benefit of the Primary Class Member, a reasonable allowance for loss of income or the value of services provided to the Primary Class Member and an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Primary Class Member.

44. Some, but not all, of the Defendants' concerns, motivations and intentions in engaging in the conspiracy were to:

(a) increase the sales of AVANDIA and their profits;

(b) increase or hold their market share;

(c) avoid adverse publicity;

(d) place their profits above the safety of Primary Class Members and others;

(e) maintain brand trust and corporate image;

(f) avoid alerting the Primary Class Members, Health Canada, the FDA, health practitioners, the public and their competitors to the dangerous properties and effects of AVANDIA; and

(g) cause the Primary Class Members to ingest and continue to ingest AVANDIA and thereby suffer harm.

45. In furtherance of the conspiracy, the following are some, but not all, of the acts carried out by the Defendants or one or some of them:

(a) they submitted false, inaccurate and misleading information to Health Canada for the purpose of obtaining approval to market AVANDIA in Canada;

(b) they concealed and disguised information about the dangerous properties and effect of AVANDIA from Health Canada and other regulators, from health practitioners and from Primary Class Members;

(c) they misled Class Members, health practitioners and others about the efficacy, safety and effect of AVANDIA;

(d) they refused to issue correcting information or to stop selling AVANDIA even after its harmful effects and addictive properties became manifest;

(e) they decided not to warn Class Members and others in Canada of the dangers of taking AVANDIA;

(f) they developed and used marketing and promotional strategies that covered up the truth about AVANDIA's dangerous properties and effect. By way of examples, they promoted the results of their own, flawed studies in an effort to distract from and refute the conclusions regarding AVANDIA's harm that were published in the NEJM Article; they engaged in a "ghostwriting campaign" with respect to AVANDIA.

(b) Negligent design, development and testing:

46. The Defendants owed the Plaintiffs and Class Members a duty of care as follows:

(a) to ensure that AVANDIA was thoroughly and appropriately tested so as to determine if there were any potentially adverse side effects in consuming the drug;

(b) to ensure that AVANDIA was fit for its intended or reasonably foreseeable use;

(c) to design, develop and test AVANDIA using methods and processes that conform to industry standards and regulations; and

(d) to conduct appropriate follow-up studies on the efficacy and safety of

AVANDIA.

47. The Defendants were negligent in the design, development and testing of AVANDIA. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

(a) inappropriately tested AVANDIA to determine the magnitude of the risks associated with its use, including but not limited to the risk of serious heart problems;

(b) conducted inadequately powered studies and testing to determine the effects of AVANDIA on microvascular or macrovascular complications of diabetes, including cardiovascular morbidity and mortality;

(c) designed and developed AVANDIA in a manner that caused an increase in low-density lipoprotein cholesterol when they knew, or should have known, that this significantly increases the risk of adverse cardiovascular outcomes;

(d) inadequately tested the effects of AVANDIA on a user's serum lipids;

(e) designed and developed AVANDIA in a manner that caused a reduction in hemoglobin levels, when they knew or ought to have known that a reduced hemoglobin level may result in an increased risk of adverse cardiovascular outcomes;

(f) conducted inadequate or no follow-up studies on the efficacy and safety of AVANDIA;

(g) chose not to conform to industry standards, practices and regulations in the design, development and testing of AVANDIA;

(h) chose not to conform with applicable disclosure and reporting obligation;

(i) inappropriately monitored the post-market effects of AVANDIA;

(j) conducted no or inappropriate follow-up studies when the risks of AVANDIA became known to them;

(k) disregarded reports of symptoms of adverse events among patients who

participated in clinical trials of AVANDIA;

(l) instructed their employees to improperly monitor and record complaints of adverse health effects of AVANDIA;

(m) hired incompetent personnel and failed to adequately supervise the personnel conducting the design, development and testing of AVANDIA; and,

(n) took unreasonable steps to ensure that AVANDIA was fit for its intended or reasonably foreseeable use.

48. There existed alternative designs, for example, pioglitazone, which were safer and economically feasible to manufacture.

49. The negligence of the Defendants in the design, development and testing of AVANDIA created a substantial likelihood of harm for users of AVANDIA. The Plaintiffs and Class Members have suffered harm and damages as a result of the Defendant's negligence.

(c) Negligent Manufacturing

50. The Defendants owed the Plaintiffs and Class Members a duty of care as follows:

(a) to conform to industry standards, practices and regulations in the manufacturing of AVANDIA;

(b) to conduct adequate and routine inspections of the plants manufacturing AVANDIA; and,

(c) to have adequate and appropriate quality control methods in place at the plants manufacturing AVANDIA.

51. The Defendants were negligent in the manufacturing of AVANDIA. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

(a) did not meet industry standards, practices and regulations in the manufacturing of AVANDIA on a routine bases;

(b) inadequately inspected the plants manufacturing AVANDIA;

(c) manufactured AVANDIA without having in place adequate quality control protocols, or in disregard of those protocols;

(d) manufactured AVANDIA in plants where conditions resulted in cross-contamination between AVANDIA and other drugs and where conditions resulted in the inclusion of varying doses of AVANDIA in the same bottle;

(e) hired incompetent personnel and failed to adequately supervise the personnel manufacturing AVANDIA; and,

(f) continued to manufacture AVANDIA when they knew or ought to have known that this drug caused or could cause serious health problems and death.

52. The Plaintiffs and Class Members have suffered harm and damages as a result of the Defendants' negligence in the manufacturing of AVANDIA.

(d) Negligent distribution, marketing and sale

53. The Defendants owed the Plaintiffs and Class Members a duty of care as follows:

(a) to warn the Plaintiffs and Class Members that ingestion of AVANDIA carried a significant risk of adverse cardiovascular events;

(b) to take reasonably necessary and appropriate steps to ensure that prescribing physicians were appraised and fully and regularly informed of all the health risks associated with ingesting AVANDIA; and

(c) to inform Health Canada and other regulating agencies fully, properly, and in a timely manner of the cardiovascular health risks and complaints associated with the ingestion of AVANDIA.

54. The Defendants were negligent in the distribution, marketing and sale of AVANDIA. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

(a) misinformed Health Canada by providing it with incomplete and inaccurate

information concerning AVANDIA;

(b) concealed or mislead the Plaintiffs, Class Members and their physicians concerning the risks associated with ingesting AVANDIA;

(c) provided the Plaintiffs, Class Members and their physicians with inadequate and inappropriate warnings concerning the cardiovascular risks associated with the use of AVANDIA;

(d) provided the Plaintiffs, Class Members and their physicians with inadequate and incomplete updates and current information on the risks and efficacy of AVANDIA as such information became available from time to time;

(e) provided inappropriate warnings of the cardiovascular risks associated with the use of AVANDIA on package labels, product monograph or customer information pamphlets in Canada;

(f) provided no or inadequate warnings to the Plaintiffs and Class Members and their physicians and health regulators about the need for comprehensive regular medical monitoring necessary to assist in the early discovery of cardiovascular problems associated with the use of AVANDIA;

(g) after receiving actual and constructive notice of the cardiovascular risks associated with AVANDIA, failed to issue adequate warnings, recall the drug in a timely manner, publicize the risks and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiffs and Class Members and their physicians and health regulators of the drug's inherent risks;

(h) engaged in a system of improper and inadequate direction to their sales representatives and prescribing physicians respecting the correct usage of AVANDIA and the cardiovascular risks associated with the drug;

(i) represented that AVANDIA was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(j) misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of AVANDIA and its associated cardiovascular risks;

(k) continued to manufacture, market and promote the selling and/or distribution of, AVANDIA when they knew or ought to have known that this drug caused or could cause serious cardiovascular problems; and,

(l) actively encouraged aggressive dispensation of AVANDIA while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the increased cardiovascular risks associated with AVANDIA, when they knew or ought to have known about these increased risks.

55. The Plaintiffs and Class Members have suffered harm and damages as a result of the Defendants' negligence in the distribution, marketing and sale of AVANDIA.

(e) Breach of Warranty

56. The Defendants warranted to the Plaintiffs and the Class Members that AVANDIA was of merchantable quality and fit for use and safe for human consumption. The Defendants breached the warranty to the Plaintiffs and the Class Members by designing, testing, researching, formulating, developing, manufacturing, producing, labeling, advertising, promoting, distributing and/or selling AVANDIA which was inherently dangerous to users and which the Defendants knew or ought to have known would lead to serious complications.

(f) Waiver of Tort

57. As a result of the Defendants' conduct described herein, the Plaintiffs and Class Members reserve the right to elect at the trial of the common issues to waive the torts and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, or the net income received by the Defendants or a percent of the proceeds from the sale of AVANDIA.

58. The Plaintiffs and Class Members claim that such an election is appropriate for the following reasons, among others:

(a) revenue was acquired in a manner in which the Defendants cannot in good

conscience retain it;

(b) the integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;

(c) absent the Defendants' tortious conduct AVANDIA could not have been marketed nor would the Defendants have received any revenue from its sale in Canada;

(d) the Defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the potential to cause serious risk of injury; and

(e) the Defendants would be unjustly enriched if they were permitted to retain revenues realized from the sale of AVANDIA.

(g) Breach of Section 52 of the *Competition Act,* R.S. 1985, c. C-34

59. The Plaintiffs rely on, and plead a breach of the *Competition Act*, R.S. 1985, c. C-34. GSK's claims regarding AVANDIA's safety, effectiveness, and effectiveness compared with other comparable drugs, were representations made for the purpose of promoting the business interests of GSK and promoting AVANDIA. These representations were made to the public, including the Plaintiffs and other Class Members. They were false and misleading in a material respect, they were made by GSK knowingly or recklessly.

60. Accordingly, GSK has breached s.52 of the *Competition Act*, in knowingly or recklessly making false and/or misleading representations to the public. By reason of such breach, GSK is liable under s.36 of the *Competition Act* in damages, and for the costs of investigating and pursuing this action.

(h) Breach of the *Food and Drugs Act,* R.S. 1985, c. F-27

61. GSK engaged in unfair trade practices and specifically declared unlawful under ss. 3 and 9 of the *Food and Drug Act*, R.S. 1985, c. F-27. Such practices included making false or misleading representations or advertisements, knowingly or with reason to know, as to the characteristics of AVANDIA. Contrary to sections 8 and 11 of the *Food and Drugs*

Act, GSK sold to the Plaintiffs and Class Members' batches of AVANDIA that were, or included ingredients that were, manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

62. Such batches of AVANDIA originated in GSK's manufacturing plants, including its manufacturing plant in Cidra, Puerto Rico, where conditions resulted in cross-contamination between AVANDIA and other drugs and the inclusion of varying doses of AVANDIA in the same bottles.

(i) Breach of the *Consumer Protection Act* R.S.C. 92, s. 1

63. The Plaintiffs plead and rely upon the *Consumer Protection Act*, R.S.C. 92, s. 1 and equivalent legislation in other provinces. The companies that constitute GSK are "sellers" within the meaning of s.2 of the *CPA*. The Plaintiffs and Primary Class Members are "purchasers" within the meaning of s.26(2) of the *CPA*. In selling AVANDIA to the Plaintiff and Primary Class Members, GSK breached the conditions or warranties implied by s.26(3)(d), (e), (f) and (h) of the *CPA*.

(j) Breach of the *Sale of Goods Act*, R.S.C. 408, s.1

64. The Plaintiffs plead and rely upon the *Sale of Goods Act*, R.S. c. 408, s. 1 and equivalent legislation in other provinces. AVANDIA was purchased by the Plaintiffs and Class Members pursuant to consumer agreements within the meaning of the *Sale of Goods Act*. GSK represented that AVANDIA was safe, an effective diabetes treatment, and a more effective diabetes treatment than other similar drugs manufactured by GSK's competitors. These representations were in fact false, misleading or deceptive.

65. The Plaintiffs plead that AVANDIA was neither fit for its intended purpose nor of merchantable quality as an effective treatment for type II diabetes mellitus, or as a more effective treatment for type II diabetes mellitus than other comparable drugs. In making contrary representations, GSK acted in breach of section 17 of the *Sale of Goods Act*.

(k) Unjust enrichment

66. GSK voluntarily accepted and retained profits and benefits, derived from the Plaintiffs and Class Members, with full knowledge and awareness that, as a result of its conscious and intentional wrongdoings, Plaintiffs and Class Members did not receive a product of the quality, nature or fitness that had been represented by GSK or that Plaintiffs and Class Members, as a reasonable consumer, expected.

67. By virtue of the conscious wrongdoings alleged, GSK has been unjustly enriched at the expense of the Plaintiffs and Class Members. There is no juristic reason for GSK's enrichment.

VII. DAMAGES

68. The Plaintiffs' and Class Members' injuries and damages were caused by the Defendants, their servants and agents.

69. The Defendants have caused injury to the Plaintiffs and to the Class Members including:

(a) personal injury;

(b) out-of-pocket expenses including, but not limited to, those connected with medical care and treatment, medications and the cost of AVANDIA paid for directly by Class Members;

(c) cost of past and future medical and other care and services;

(d) past and future loss of income; and

(e) a loss of support, guidance, care and companionship.

70. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiffs and Class Members have been placed in a position where they have sustained or will sustain serious personal injuries and damages.

71. As a result of the conduct of the Defendants, the Plaintiffs and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

72. Some of the expenses related to the medical treatment that the Plaintiffs and Class Members have undergone, and will continue to undergo have been borne by provincial health insurers including the Nova Scotia Medical Services Insurance Plan. As a result of the negligence of the Defendants, the provincial health insurers have suffered and will continue to suffer damages.

73. The subrogated interests of the Provincial and Territorial health insurers includes the cost of all past and future insured services for the benefit of the Plaintiffs and Class Members on account of their consumption of AVANDIA.

74. Class Members who paid for their own AVANDIA seek a full refund of the purchase price. The Class Members are entitled to recover from GSK as special damages the cost of purchasing AVANDIA.

(a) Manifest Harm and Injuries:

75. In addition, the past and ongoing use of AVANDIA has resulted in the Plaintiffs and Class Members' physical and mental health injuries pleaded above, and have further led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, and out of pocket expenses.

76. The Plaintiffs and Class Members assert a claim for each of the types of damages listed above.

(b) Medical Monitoring: Responding to Material Risk of Illness

77. Further, the past and ongoing use of AVANDIA have also caused or materially contributed to increased health risks to the Plaintiffs and other Class Members. As a

result of the use, the Plaintiffs and Class Members have already and will continue to experience illness, anxiety, loss of amenities and enjoyment of life.

78. There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will detect at an early stage the serious problems which may result from the use of AVANDIA by the Class Members. However, not all of these tests are generally available or being administered to the Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm and risk of death therefrom.

79. The Class Members seek to recover damages in the form of the total funds required to establish a 'medical monitoring' process to be made available to the Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Class Members.

80. The damages referred to above may have been incurred directly by the Plaintiffs and Class Members, or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.

81. The Plaintiffs further allege that the establishment of a medical monitoring process is a necessary and appropriate step for all of the Defendants to take in the course of fulfilling their obligation to minimize the damages suffered by Class Members.

(c) Aggravated, Punitive and Exemplary Damages

82. The Defendants manufactured, marketed, promoted and sold AVANDIA with full knowledge of the fact that they were adversely impacting the physical and psychological health of the Plaintiffs and the Class Members. Knowledge of the risks associated with the use of AVANDIA was not released to the Plaintiffs and Class Members. Despite having specific information that the Plaintiffs and Class Members were at risk of serious problems associated with the use of AVANDIA, the Defendants continued or permitted the continuation of the manufacturing, marketing, promoting and selling of AVANDIA without any or reasonable controls.

83. These activities were carried out with reckless, callous and wanton disregard for the health, safety and pecuniary interests of the Plaintiffs and other Class Members. The Defendants knowingly compromised the interests of the Plaintiffs and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that AVANDIA posed to the Plaintiffs and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.

84. The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety or welfare of the Plaintiffs and Class Members**.**

85. Consequently, the Plaintiffs and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.

86. The Plaintiffs and Class Members plead that, by virtue of the acts described herein, the Defendants are liable to them in damages. Each of the Defendants is vicariously liable for the acts and omissions of the others for the following reasons:

(a) each was the agent of the other;

(b) each Defendants' business was operated so that it was inextricably interwoven with the business of the other;

(c) each Defendant entered into a common advertising and business plan with the other to distribute and sell AVANDIA;

(d) each Defendant owed a duty to the other and to the Plaintiffs and Class Member by virtue of the common business plan to distribute and sell AVANDIA; and

(e) each Defendant intended that the businesses be run as one global business organization.

VIII. GENERAL PROVISIONS

87. The Plaintiffs state that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiffs and other Class Members.

88. The Plaintiffs plead the doctrine of respondeat superior and state that the Defendants are vicariously liable to the Plaintiffs and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.

IX. STATUTES

89. The Plaintiffs plead and rely, inter alia, upon the following legislation:

Newfoundland

- *Consumer Protection Act, R.S.N.L. 1990 c. C-31*
- *Fatal Accidents Act, R.S.N.L. 1990, c. F-6*
- *Hospital lnsurance Agreement Act*, R.S.N.L. 1990, c. H-7
- *Medical Care Insurance Act*, 1999 S.N. 1999, c. 5.1
- *Sale of Goods Act*, R.S.N.L. 1990, c.S-6
- Current to Gazette Vol. 81:46 (November 17, 2006)

Nova Scotia

- *Consumer Protection Act, R.S., c.92*
- *Fatal Injuries Act, R.S.N.S. 1989, c. 163, amended 2000, c. 29, ss 9-12*
- *Health Services and Insurance Act, R.S.N.S. 1989, c. 197*
- *Sale of Goods Act, R.S., c.408*
- *Current to Gazette Vol. 30:21 (November 10, 2006)*

Prince Edward Island

- *Consumer Protection Act, R.S.P.E.I. 1988, c. C-19*
- *Fatal Accidents Act, R.S.P.E.I. 1988, c. F-5, as amended*

- *Hospital and Diagnostic Services Insurance Act, R.S.P.E.I. 1988, c H-8*
- *Sale of Goods Act, R.S.P.E.I. 1988, c. S-1*
- *Current to Gazette Vol. 132:47 (November 25, 2006)*

New Brunswick

- *Consumer Product Warranty and Liability Act,* Chap. C-18.1
- *Fatal Accidents Act,* R.S.N.B. 1973, c. F-7
- *Hospital Services Act,* R.S.N.B. 1973, c. H-9
- *Sale of Goods Act,* R.S.N.B. 1973, c.S-1
- Current to Gazette Vol. 164:1901 (November 29, 2009)

Quebec

- *Civil Code of Quebec* Book 5
- *Consumer Protection Act,* R.S.Q. chapter P-40.1

Ontario

- *Class Proceedings Act,* R.S.O. 1992, S.O. 1992, c.6;
- *Consumer Protection Act,* 2002 S.O. 2002, c.30, Sched. A;
- *Courts of Justice Act,* R.S.O. 1990, c.43;
- *Family Law Act,* R.S.O. 1990, C. F.3;
- *Health Insurance Act,* R.S.0. 1990, c. 11.6;
- *Negligence Act,* R.S.O. 1990, c. N.1;
- *Sale of Goods Act,* R.S.0. 1990, c. S.1;
- *Trustee Act,* R.S.O. 1990, c. T.23

Manitoba

- *Fatal Accidents Act,* C.C.S.M. c. F50, as amended
- *Manitoba Public Insurance Corporation Act,* C.C.S.M. c. P215
- *Sale of Goods Act,* C.C.S.M. c. 51O
- *The Consumer Protection Act,* C.C.S.M. c. C200

- *The Health Services Insurance Act*, R.S.M. 1987, c. H35
- *Trustee Act*, C.C.S.M. c.T160
- Current to Gazette Vol. 135:44 (November 4, 2006)

Saskatchewan

- *Department of Health Act*, R.S.S. 1978, c. D-17
- *Fatal Accidents Act*, R.S.S. 1978, c. F-11 as amended
- *The Consumer Protection Act*, 1996, c. C-30.1
- *The Sale of Goods Act*, R.S.S. 1978, c. S-1
- Current to Gazette Vol. 102:44 (November 3, 2006)

Alberta

- *Alberta Health Care Insurance Act*, R.S.A., 2000, C.A-20
- *Domestic Relations Act*, R.S.A. 2000, c. D10.5, was repealed by R.S.A. 2003, c. F-4.5 *[Family Law* Act]
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8
- *Hospital's Act*, R.S.A. 2000, c. H-12
- *Sale of Goods Act*, S-2 R.S.A 2000
- *Tort Feasors Act*, R.S.A. 2000, c. T-5

British Columbia

- *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2
- *Hospital's Insurance Act*, R.S.B.C. 1996, c. 204 [en. 1994, c. 37, s. 4; am. 1996, c. 24, s. 1(3)]
- *Sale of Goods Act*, R.S.B.C. 1996, c.410
- Current to Gazette Vol. 49:19 (October 20, 2006)

Nunavut

- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- Current to Gazette Vol. 8: 10 (October 31, 2006)

Northwest Territories

- *Consumer Protection Act,* R.S.N.W.T. 1988, c. C-17
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- *Sale of Goods Act*, R.S.N.W.T. 1988, c. S-2
- *Trustee Act,* R.S.N.W.T. 1988, C.S-2
- Current to Gazette Vol. XXVll:10 (October 31, 2006)

Yukon

- *Consumers Protection Act*, R.S.Y. 2002, c. 40
- *Hospital Insurance Services Act*, R.S.Y. 2002, c. 112
- *Sale of Goods Act*, R.S.Y. 2002, c. 198
- Current to Gazette Vol. 25:10 (October 15, 2006)

Canada

- *Food and Drugs Act*, (R.S., 1985, c. F-27)

and all relevant amendments thereto.

X RELIEF SOUGHT

90. The Plaintiffs repeats the foregoing paragraphs and states that the Defendants are jointly and severally liable for the following:

(a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiffs as Representative Plaintiffs for the Class;

(b) general damages, including aggravated damages for personal injuries;

(c) special damages for medical expenses and other expenses related to the use of AVANDIA;

(d) aggravated, punitive and exemplary damages;

(e) further or alternatively the Plaintiffs claim, on their own behalf and on behalf of the Class Members:

(i) a declaration that the benefits which accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;

(ii) an accounting of the benefits which accrued to the Defendants as a result of their wrongful acts;

(iii) a declaration that the Defendants hold in trust for the Class the benefits which accrued to the Defendants as a result of their wrongful acts;

(iv) disgorgement of the benefits which accrued to the Defendants as a result of their wrongful acts;

(f) damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Class Members, and to make recommendations about their treatment;

(g) subrogated claims on behalf of the Provincial providers of medical services;

(h) interest pursuant to the *Judicature Act*;

(i) costs; and

(j) such further and other relief as this Honourable Court deems just.

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Halifax, Nova Scotia this 18th day of August, A.D., 2009.

AMENDED at Halifax, Nova Scotia this 27th day of July, A.D., 2010.

SECOND AMENDED at Halifax, Nova Scotia this 5th day of June, A.D., 2015.

FRESH AS SECOND AMENDED at Halifax, Nova Scotia this 5th day of June, A.D., 2015.

THIRD AMENDED at Halifax, Nova Scotia this 2nd day of November, A.D., 2018.

Signature
Signed this day of , 2018.

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