Form 39.08

2009

Hfx. No. 315567

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

ALBERT CARL SWEETLAND and BARBARA FONTAINE

Plaintiffs

- and -

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Defendants

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

Affidavit of Madeleine Carter
Affirmed December 14, 2018
(Settlement Approval)

I, Madeleine Carter, of the City of Halifax, in the Province of Nova Scotia, AFFIRM AND SAY:

1. I am an associate with the law firm of Wagners, which together with Siskinds LLP (Ontario) is Class Counsel in this proceeding. As such, I have knowledge of the matters to which I hereinafter depose. Where I make statements that are not within my personal knowledge, I have stated the source of the information and believe that information to be true.

2. At times in this affidavit, I have referred to the collective views or conclusions of the team involved in the advancement of this proceeding. Where I use the terms "we", "us" or "our" or their derivatives, I am referring to lawyers and staff at Wagners and Siskinds LLP, unless otherwise noted or required by context. Defined terms used in this affidavit have the meanings given to them in the Settlement Agreement, unless otherwise noted.

I. RELEVANT PROCEDURAL BACKGROUND

(a) *The Sweetland Action*

3. A proposed class action was commenced in this Honourable Court on August 18, 2009, on behalf of a class of individuals resident in Canada who were prescribed and ingested Avandia (the Primary Class), and a family class of their relatives entitled to make a claim under the *Fatal Injuries Act*, R.S.N.S. 1989, c. 163. The pleadings were subject to three subsequent amendments: an Amended Statement of Claim was filed on July 27, 2010, a Fresh as Second Amended Statement of Claim was filed on June 5, 2015, and a Third Fresh as Amended Statement of Claim was filed on November 2, 2018. This final amendment was to reflect the substitution of Barbara Fontaine as the new representative plaintiff of the certified Family Class.

4. The allegations in this action are that Avandia, a pharmaceutical used to treat type II diabetes, increases the risk of cardiovascular events, including heart attacks (myocardial infarction) and congestive heart failure, and that adequate warnings were not given by the Defendants. The term Avandia refers to three drugs: Avandia, Avandamet and Avandaryl. They all contain the ingredient rosiglitazone.

5. On December 7, 2016, this Honourable Court issued an order certifying the within action as a class proceeding (the "Certification Order"). This is the only Canadian Avandia-related class action that has been certified.

6. On December 22, 2016, the Defendants filed a Notice of Application for Leave to Appeal and Notice of Appeal (Interlocutory) with the Nova Scotia Court of Appeal seeking to reverse the Certification Order, copies of which are attached hereto as **Exhibit "A"**.

7. On January 27, 2017, the Nova Scotia Court of Appeal issued an order, consented to by the Plaintiffs/Respondents, granting leave to appeal to the Defendants, a copy of which is attached hereto and marked as **Exhibit "B"**.

8. On March 13, 2017 the Defendants filed their Statement of Defence with this Honourable Court.

9. On June 2, 2017 the Defendants/Appellants filed their factum in support of their appeal, a copy of which is attached hereto as **Exhibit "C"**.

10. On August 1, 2017 the Plaintiffs/Respondents filed their factum in response to the appeal, a copy of which is attached hereto as **Exhibit "D"**.

11. The hearing of the Defendants' appeal has been placed in abeyance until March 29, 2019 to allow the parties to engage in exploratory settlement discussions, such that if the

proceeding has not been resolved by March 29, 2019, the parties are to seek the direction of the Nova Scotia Court of Appeal.

12. On October 23, 2018, this Court issued a Consent Order to amend the Second Amended Notice of Action and Statement of Claim, and an Amended Certification Order, both orders to reflect the substitution of a new representative plaintiff of the Family Class.

13. A copy of the Settlement Agreement executed October 11, 2018 is attached hereto as **Exhibit "E"**.

(b) ***Other Proposed Avandia Class Actions***

14. Other legal proceedings relating to Avandia have been commenced across Canada. A list of 16 of these proceedings and their respective statuses as of July 9, 2018 is attached hereto as **Exhibit "F"**. The source of the information contained in **Exhibit "F"** is counsel for the Defendants and I believe the information to be true. There is another list of these proceedings (without their respective statuses) attached as Exhibit "B" to the Settlement Agreement; it lists 18 proceedings. **Exhibit "F"** to this affidavit is missing reference to the action filed in Alberta by Docken & Company: *Ralito Bernales v. GlaxoSmithKline Consumer Healthcare Inc, et al*, Court File Nos. 1001-14991 and 1301-05007, and the action filed in Nova Scotia by Merchant Law Group, *Ronald Finck v. Glaxosmithkline Inc. et al*., Court File No. SH-300379.

15. I am informed by Madeline McKinnon, a lawyer with Siskinds LLP, and do verily believe, that on April 30, 2012, August 1, 2014 and September 18, 2014, Siskinds LLP filed three individual actions relating to Avandia in Ontario. These actions allege negligence in design and warnings, which caused or materially contributed to each of the plaintiffs suffering cardiovascular harm. Copies of these three claims are attached hereto as **Exhibits "G"**,

"H" and **"I"**. The background to the decision by Siskinds to file these individual actions is provided in paragraph 31, below.

16. Kim Orr Barristers P.C. ("Kim Orr") is counsel in *Lloyd et al. v. GlaxoSmithKline Inc. et al*, Court File No. CV-11-434420-00CP, commenced in 2007 by the Merchant Law Group. The source of this information is the decision of Justice Belobaba in *Waheed v. GlaxoSmithKline Inc*., 2013 ONSC 5792 (the "Waheed Decision"), a copy of which is attached to this affidavit as **Exhibit "J"**. In 2010, Kim Orr and Merchant Law Group agreed that Kim Orr would be the lead counsel and the two firms would work together. The source of this information is the Waheed Decision.

17. McPhadden Samac Tuovi ("MCST") is counsel for the plaintiffs in *Waheed v. GlaxoSmithKline Inc. et al*, Court File No. CV-09-385922CP, an overlapping proposed Avandia class action filed in Ontario in 2009.

18. In November, 2010, carriage motions brought by Kim Orr and MCST were heard by Justice Strathy of the Ontario Superior Court of Justice. After the hearing but before the release of the Court's decision, the parties agreed to settle the carriage motion on the basis that Kim Orr would be appointed counsel for the plaintiffs in the *Lloyd* class action, and the *Waheed* action would be effectively stayed. The parties agreed that the MCST consortium would be permitted to participate in the class action but only at Kim Orr's discretion and that no steps could be taken without Kim Orr's approval. This agreement resulted in a consent carriage order dated November 19, 2010. The source of this information is the Waheed Decision.

19. In 2012, MCST brought a motion to transfer carriage to it, arguing that despite three years passing, Kim Orr had still not brought a motion for certification. MCST said that it had

prepared a certification record and asked that it be granted carriage of the proposed class action. Justice Belobaba denied this request, for the reasons set out in the Waheed Decision.

20. The certification hearing in the *Lloyd* action began in December 2014. The certification motion was then adjourned to allow the plaintiffs to file better evidence. The motion has not resumed.

21. Meanwhile the within action proceeded to certification, with the cooperation of Related Counsel Firms: McPhadden Samac Tuovi LLP, Consumer Law Group (formerly Orenstein & Associates), Ches Crosbie (formerly of Russell Accident Law) and Clint Docken. Ches Crosbie is counsel in the action *Clyde Wiseman v. GlaxoSmithKline Inc. et al*, Court File No. 2582 CP, filed in Newfoundland and Labrador. Clint Docken is counsel in the action *Ralito Bernales v. GlaxoSmithKline Consumer Healthcare Inc, et al*, Court File Nos. 1001-14991 and 1301-05007, filed in Alberta. Consumer Law Group is counsel in the QC action of *Donna Woods v. GlaxoSmithKline Inc. et al*, Court File No. 500-06-000409-074. Consumer Law Group agreed to a temporary stay of the *Woods* action in February, 2017 in light of, and to support, the advancement of the *Sweetland* action.

II. THE SETTLEMENT

(a) ***Settlement Discussions & Role of Siskinds***

22. I am informed by Charles Wright, a lawyer at Siskinds LLP, and verily believe, that Siskinds began investigating Avandia-related claims in or around early 2007. While Siskinds did not commence a class proceeding, Siskinds took a number of steps to advance the Canadian Avandia litigation.

23. I am informed by Mr. Wright, and verily believe, that in or around early 2010, after monitoring Avandia litigation and noting regulatory steps taken by Health Canada, Siskinds began to be retained by individuals with potentially strong claims.

24. I am informed by Mr. Wright, and verily believe, that as no significant progress was being made at the time in the proposed Avandia class proceeding in Ontario, Siskinds began reviewing and preparing its individual Avandia cases for potential litigation.

25. I am informed by Mr. Wright, and verily believe, that Siskinds obtained and reviewed their clients' medical and pharmacy records (where available) and engaged in discussions with an expert in the field of cardiology to assist in evaluating these individual claims.

26. I am informed by Mr. Wright, and verily believe, that on April 30, 2012, Siskinds filed the first of three individual actions, *Vinerskis v GlaxoSmithKline Inc*. (the "Vinerskis Action").

27. I am informed by Mr. Wright, and verily believe, that the parties to the Vinerskis Action engaged in protracted negotiations aimed at agreeing upon a Discovery Plan, including documentary production. As a result, the parties attended multiple Status Hearings and motions to extend the court-ordered timelines.

28. I am informed by Mr. Wright, and verily believe, that in tandem with the pursuit of the Vinerskis Action, in June 2012 Siskinds commenced preliminary resolution discussions with Canadian and US defence counsel regarding Siskinds' individual claims.

29. I am informed by Mr. Wright, and verily believe, that in or about November 2013, Siskinds provided US defence counsel with medical briefs for 150 of its individual cases for the purpose of engaging in settlement discussions. I am informed by Mr. Wright, and verily believe, that these discussions failed to result in an agreement.

30. I am informed by Mr. Wright, and verily believe, that after communications with US defence counsel failed to result in an agreement, Siskinds filed two additional individual actions in Ontario. *Fontaine v GlaxoSmithKline Inc*. was commenced by Statement of Claim dated August 1, 2014, and *Ravindrakumar v GlaxoSmithKline Inc*. was commenced by Statement of Claim dated September 18, 2014.

31. I am informed by Mr. Wright, and verily believe, that Siskinds pursued individual litigation through these three "test cases", asserting different cardiovascular injuries, with knowledge that the filed class actions suspended applicable limitation periods, and that recommendations to clients relating to opting out of any certified class actions were never required as no opt out deadline ever arose.

32. I am informed by Mr. Wright, and verily believe, that in or about November 2014, Siskinds approached Motley Rice LLC in an effort to re-engage in settlement discussions with US defence counsel.

33. I am informed by Mr. Wright, and verily believe, that Motley Rice LLC is a national plaintiffs' litigation firm in the US. I am informed by Mr. Wright, and verily believe, that counsel from Motley Rice LLC sat on the Plaintiff Steering Committee for the Avandia Multi District Litigation ("MDL") before Judge Rufe in the Eastern District of Pennsylvania. I am informed by Mr. Wright, and verily believe, that Motley Rice settled a number of individual cases filed in the MDL, which included negotiating an Avandia Master Settlement Agreement.

34. I am informed by Mr. Wright, and verily believe, that Siskinds engaged in discussions concerning resolution of the Siskinds' case inventory at various points in time, including with the Defendants' US settlement counsel, and at times through Motley Rice.

35. I am informed by Mr. Wright, and verily believe, that in late 2015, Siskinds, working with Motley Rice LLC, re-engaged in negotiations with US defence counsel. I am informed by Mr. Wright, and verily believe, that the parties were able to reach an agreement in principle regarding which claims would be eligible for compensation.[1] However, no damages values were discussed.

36. I am informed by Mr. Wright, and verily believe, that around the same time, Siskinds and Canadian defence counsel reached an agreement for the Discovery Plan with respect to the three individual actions filed in Ontario by Siskinds.

37. I am informed by Mr. Wright, and verily believe, that in February 2016, US defence counsel expressed interest to Siskinds in resolving all Canadian Avandia claims on a national basis.

38. I am informed by Mr. Wright, and verily believe, that Siskinds agreed to pause the individual actions in Ontario and to work collaboratively with Wagners to negotiate a Canada-wide settlement. By this time, the certification hearing with respect to the within action had been heard (September 15-18, 2015), and the Court had issued a January 15, 2016 decision inviting the Plaintiffs to submit further evidence on certain aspects of the certification test. On February 26, 2016, the Plaintiffs filed their supplemental evidence (and the Certification Order was later issued, on December 7, 2016).

39. On or about March 28, 2016, Siskinds and Wagners met with US and Canadian defence counsel in Philadelphia and began negotiating a national resolution to include the certified

[1] Such claims are part of the Pre-Approved Claimants, listed in the confidential schedule to the Settlement Agreement, who are deemed to be Approved Claimants under the Settlement Agreement.

national class and the individual claims represented by Siskinds.

40. This meeting did not result in a resolution, and there were no material resolution discussions subsequent to this, until after the within class action was certified.

41. After the Certification Order was issued on December 7, 2016, and following the issuance by the Court of Appeal of a consent order granting the Defendants leave to appeal the Certification Order, the parties (Wagners, Siskinds and US and Canadian defence counsel) engaged in a series of meetings and conference calls over the course of approximately eleven (11) months to explore a potential settlement, reaching an agreement in principle in October, 2017. The settlement was reached on the basis of a hybrid settlement structure, consisting of both a fixed payment (i.e. the Minimum Settlement Amount) and an additional, claims-made component (i.e. additional payment up to the Maximum Settlement Amount, based upon the number of Approved Claims). The Defendants were therefore interested in restricting compensable conditions and making payments as modest as possible. Extensive negotiations occurred relating to structure, compensable conditions, eligibility criteria, and amount to be paid per claim. The nature of the compensable injury, causation, warnings and other matters were all debated at length.

42. The final Settlement Agreement was executed on October 11, 2018.

(b) ***Litigation Risks***

43. The developments over time in scientific research and regulatory action relating to the causal link between Avandia and cardiovascular harm greatly informed the litigation risks considered by Class Counsel, their settlement strategy, and the distribution scheme outlined in the Settlement Agreement. These developments are canvassed in detail in the expert

affidavits forming part of the certification record and are referenced in the Plaintiffs' brief in support of this motion.

44. Class Counsel is of the belief that the defences raised by the Defendants to certification and to the merits of the action, as outlined in their Statement of Defence, warrant consideration when assessing the advantage of continuing litigation versus attaining an out of court resolution, and when negotiating a fair and reasonable settlement in the best interests of the Class. The absolute value of the settlement recognizes that there is controversy in the literature relating to the causal link between Avandia and cardiovascular harm, including myocardial infarction.

45. Class Counsel is of the belief that due to the risks associated with continuing litigation through an appeal of certification, a common issues trial and the individual assessment stage, it is in the interest of Class Members to resolve the litigation on the terms contained in the Settlement Agreement.

46. Class Counsel is of the belief that any additional value to individual awards of damages that may result from a trial on the merits would be speculative and uncertain in light of the litigation risks identified by the Defendants, and would come with added delay.

47. Class Counsel recommended to the Representative Plaintiffs and to the representatives of the Provincial Health Insurers ("PHIs") (all provincial and territorial Ministries of Health or equivalents, who fund medical services in Canada) acceptance of the final settlement.

(c) ***Negotiations Relating to Eligibility Criteria***

48. It is the belief of Class Counsel that the limitation of compensation under the Settlement Agreement to the four cardiovascular harms compensable thereunder, the temporal requirement connecting Avandia use to the compensable harm (no more than one year after

ceasing use, and use before December 2010), and the allocation of points to Approved Claimants all reflect the challenges Class Members would confront if they were, in continued litigation, required to establish that their particular cardiovascular harm was caused by the Defendants' failure to provide adequate warnings.

i. Eligible Cardiovascular Harm

49. The parties agreed upon four types of eligible cardiovascular harm under the Settlement Agreement: myocardial infarction ("MI"), coronary artery bypass grafting surgery ("CABG"), percutaneous coronary intervention with stent placement ("Stenting"), and congestive heart failure ("CHF"). The differences between these eligible harms are described in the Plaintiffs' brief in support of this motion.

50. As myocardial infarction is the most severe harm of these four, Class Counsel assigned it the greatest allocation of base points in the Compensation Protocol. Based on the reports of experts filed in this action, the signal in the scientific literature is strongest for myocardial infarctions. Of the two preventative medical interventions, CABG and Stenting, CABG is more invasive and therefore Class Counsel assigned it a higher allocation of base points than Stenting. Accordingly, CABG claims are assigned more base points than Stenting claims.

51. The results of the long-term trial of Avandia as combination therapy, Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycemia in Diabetes (the "RECORD Study"), were re-adjudicated in 2013. This is described in the certification record and briefs of the parties. In particular, there is a memorandum dated November 19, 2013 documenting the position of the Office of New Drugs, a branch of the United States Food and Drug Administration, with regard to the "continuing marketing of rosiglitazone-containing

products (…) after careful consideration of the re-adjudication of the RECORD trial." This memorandum is attached as Exhibit "B" to the affidavit of Roslyn Theodore-McIntosh sworn March 26, 2015 and relied upon by the Defendants at certification. The memorandum states on page 1 of 28 that "In RECORD, the rate of myocardial infarction was not significantly increased relative to comparators (metformin and sulfonylureas). Although the point estimate for myocardial infarction in RECORD trends adversely (i.e., point estimate suggesting a -14-17% increase relative to comparators), the magnitude of the risk increase is much smaller than reported in the meta-analyses and is not reconcilable with the point estimate of another cardiovascular outcome (i.e., stroke) which trends favorably (i.e., 20-30% decrease) [underline added]." In other words, the re-adjudication of RECORD indicated that "stroke estimates all favored rosiglitazone (not statistically significant)", rather than favoring a comparator, as summarized at page 11 of 28 of the memorandum. On the basis of these results of the re-adjudication of the RECORD Study, the parties determined that stroke would not be a compensable injury under the Settlement Agreement.

ii. Eligibility criterion: use no later than December 2010

52. During negotiations with counsel for the Defendants, Class Counsel's position was that the Avandia use cut-off date should be as late as December 2010. Class Counsel argued that Class Members who took Avandia before the most stringent regulatory action was taken by Health Canada should be eligible for compensation.

53. Although it was argued by counsel for the Defendants that the cut-off should be 2007, because Class Members (and prescribing physicians) ought to have been aware by this time of any purported risk, ultimately the parties agreed on the cut off date of December 2010.

iii. Eligibility criterion: no fewer than 30 days of continuous Avandia use

54. With respect to the eligibility criterion concerning the length of time that Avandia must have been ingested in order for a Class Member to qualify, this was a matter of negotiation between the parties.

55. Counsel for the Defendants argued that the criterion should be 60 or more days of continuous use, as any causal link between Avandia and the qualifying cardiac event was weak if Avandia had been taken for fewer than 60 days. However, ultimately the parties agreed on the eligibility criterion of a minimum of 30 days of use.

(d) ***Estimated Number of Eligible Class Members***

56. The following provides the best available information at this time.

(i) Class Counsel (Wagners and Siskinds LLP)

(A) Wagners

57. To date there are 85 individuals who have contacted Wagners with respect to this litigation and have identified themselves as Class Members.

58. I am informed by Victor Lewin, a paralegal at Wagners, and verily believe, that based upon a review of medical records in Wagners' possession, 16 contacts appear to have eligible MI claims, 1 contact appears to have an eligible CABG claim and 5 contacts appear to have eligible CHF claims.

59. I am informed by Mr. Lewin, and verily believe, that based upon a review of medical records in Wagners' possession, 37 contacts appear to be ineligible to receive compensation under the Settlement Agreement.

60. I am informed by Mr. Lewin, and verily believe, that for the following contacts some required documentation is currently unavailable, preventing a determination of whether they may be eligible or ineligible to receive compensation under the Settlement Agreement:

- 8 MI claims
- 1 stent claim
- 16 CHF claims

61. I am informed by Mr. Lewin, and verily believe, that one contact has provided no information (including about his injury) to assess eligibility.

(B) Siskinds LLP

62. I am informed by Ms. McKinnon and verily believe that there are the following number of Pre-Approved Claimants (listed in the confidential Schedule to the Settlement Agreement and who the parties agree are deemed to be Approved Claimants):

- 142 MI/CABG/Stent claims (one Pre-Approved Claimant overlaps with Wagners' database)
- 34 CHF claims

63. I am informed by Ms. McKinnon, and verily believe, that the eligibility criteria applied to the Pre-Approved Claimants were the same as the eligibility criteria applicable under the Settlement Agreement.

64. I am informed by Ms. McKinnon, and verily believe, that there are currently 917 contacts in Siskinds' database including the above 176 Pre-Approved Claimants. I am informed by Ms. McKinnon, and verily believe, that this group includes anyone who had contacted Siskinds about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members, and further may be ineligible for compensation under the Settlement Agreement.

65. I am informed by Ms. McKinnon, and verily believe, that of these 917 contacts, there are 312 contacts who have never responded to Siskinds' requests for information after initial contact was made. With respect to this group of 312 contacts, it is possible some of them may be eligible Class Members, and may submit a claim, but there has been no reply to Siskinds' attempts at contact.

66. I am informed by Ms. McKinnon, and verily believe, that of these 917 contacts, there are 202 contacts who have been determined to be ineligible, categorized as follows:

(a) Contacts deemed ineligible by GSK during the pre-approval process: 32. In the process of determining eligibility of Pre-Approved Claimants, Siskinds sent medical records of 32 contacts to counsel for GSK. GSK determined these individuals to be ineligible under the agreed-upon eligibility criteria.

(b) Claims that were not submitted to GSK during the pre-approval process because Siskinds determined they did not satisfy eligibility requirements (e.g. no cardiac injury, did not take Avandia, or claims outside of timeline): 144

(c) Stroke cases: 26. Stroke is not a compensable injury under the Settlement Agreement.

67. I am informed by Ms. McKinnon, and verily believe, that of these 917 contacts, there are 51 contacts for whom some required documentation is currently unavailable, preventing Siskinds from determining whether they may be eligible or ineligible to receive compensation under the Settlement Agreement.

68. I am informed by Ms. McKinnon, and verily believe, that of these 917 contacts, there are 128 contacts who, despite initially contacting Siskinds, later informed Siskinds they had

retained another law firm or had no continuing interest in the Avandia litigation. It is presumed these 128 contacts are either counted among the Class Members contacts of other counsel, or are not Class Members.

69. I am informed by Ms. McKinnon, and verily believe, that of these 917 contacts, there are 48 contacts for whom the requisite medical records appear to be permanently unavailable. I am informed by Ms. McKinnon, and verily believe, that employees of Siskinds have attempted to obtain the requisite records from hospitals, physicians, and pharmacies, as applicable, but have been informed the records no longer exist.

(ii) Related Counsel Firms

(A) Guardian Law (Calgary, AB)

70. I am informed by Mr. Clint Docken of Guardian Law, and verily believe, that there are 28 contacts in Guardian Law's Avandia database. I am informed by Mr. Docken, and verily believe, that this group includes anyone who had contacted Mr. Docken (at Guardian Law, or his predecessor law firms of Higgerty Law and Docken & Company) about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members and further may be ineligible for compensation under the Settlement Agreement.

71. I am informed by Mr. Docken, and verily believe, that of these 28 contacts, there are 5 contacts who appear to have eligible MI claims based on medical records in possession of Guardian Law.

72. I am informed by Mr. Docken, and verily believe, that of these 28 contacts, 2 contacts may have eligible CHF claims, but that this cannot be verified one way or another until they have received further medical records.

73. I am informed by Mr. Docken, and verily believe, that of these 28 contacts, there are 21 contacts for whom the required documentation has not been received by Guardian Law to allow them to determine whether these contacts are Class Members, and further, whether they may be eligible under the Settlement Agreement.

(B) Patient Injury Law (Ches Crosbie) (St. John's, NL)

74. I am informed by Mr. Crosbie, and verily believe, that the *Wiseman* action in NL was not materially advanced, and that he has no information on potential Class Members in NL, other than the named proposed representative plaintiff in that action, Mr. Clyde Wiseman. Mr. Wiseman may have an eligible myocardial infarction claim, although as of today's date I do not have confirmation that he does.

(C) Consumer Law Group (Montreal, QC)

75. I am informed by Andrew Garonce, manager of class action communications at Consumer Law Group, and verily believe, that there are 514 contacts in Consumer Law Group's database. I am informed by Mr. Garonce, and verily believe, that this group includes anyone who had contacted Consumer Law Group about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members and further may be ineligible for compensation under the Settlement Agreement.

76. I am informed by Mr. Garonce, and verily believe, that of these 514 contacts, there are 6 contacts who appear to have eligible MI claims, 2 contacts who appear to have eligible CABG claims, 1 contact who appears to have an eligible stent claim, and 4 contacts who appear to have eligible CHF claims, based on medical records in possession of Consumer Law Group.

77. I am informed by Mr. Garonce, and verily believe, that of these 514 contacts, there are an additional 21 contacts who may have eligible claims, based on partial medical records and information provided by these contacts – 18 claims in the MI/CABG/Stent categories, and 3 CHF claims - but that this cannot be verified one way or another until they have received further medical records.

78. I am informed by Mr. Garonce, and verily believe, that apart from the 34 contacts described above, the required documentation for the remainder of the contacts has not been received by Consumer Law Group to allow them to determine whether these contacts are Class Members, and further, whether they may be eligible under the Settlement Agreement.

(D) McPhadden Samac Tuovi LLP (Toronto, ON)

79. I am informed by Mr. McPhadden, a lawyer at McPhadden Samac Tuovi LLP, and verily believe, that there are a total of 10 contacts in the Avandia database of McPhadden Samac Tuovi LLP. I am informed by Mr. McPhadden, and verily believe, that this group includes anyone who had contacted McPhadden Samac Tuovi LLP about Avandia litigation for any reason, with the result that some of these contacts may not be Class Members and further may be ineligible for compensation under the Settlement Agreement.

80. I am informed by Mr. McPhadden, and verily believe, that of these 10 contacts, 1 appears to have an eligible MI claim, and 1 appears to have an eligible stent claim. The remaining 8 contacts either appear to be ineligible based on documentation in their possession, or they do not currently have enough information to make that determination.

(iii) Number of Contacts of Other Avandia Class Action Firms

81. Merchant Law Group filed proposed class actions in five jurisdictions: BC, AB, SK, MB and NL.

82. Other than the SK action, which was stayed on consent pending resolution of the *Lloyd* action in Ontario, no materials steps have been taken in these actions subsequent to filing.

83. I am informed by Mr. Merchant that there are approximately 1200 contacts in Merchant Law Group's database. My belief is that this group includes anyone who had contacted Merchant Law Group about Avandia litigation, with the result that some of these contacts may not be Class Members and further may be ineligible for compensation under the Settlement Agreement.

84. I currently have no knowledge of the percentage of these contacts who may be eligible under the Settlement Agreement.

85. Based on the above available information, it is reasonable to anticipate that, if the Settlement Agreement is approved, the awards to Approved Claimants will not be subject to *pro rata* reductions: the Minimum Settlement Amount includes compensation for up to 200 Settling Claimants meeting the criteria for MI/CABG/Stenting claims, and compensation for up to 60 Settling Claimants meeting the criteria for CHF claims, as outlined in s. 5.1(a) of the Settlement Agreement. There is further payment by the Defendants for up to an additional 100 MI/CABG/Stenting claims (at $18,333.33 per claim), and up to 240 additional CHF claims (at $3,333.33 per claim), with any unused portion of the aggregate capped total of $1,000,000 available for CHF claims to be used for MI/CABG/Stenting claims in excess of the aggregate capped total of $5,500,000 for such claims, as outlined in s. 5.1(b) and (c) of the Settlement Agreement. Therefore only if there are more than 300 CHF claims will CHF awards be subject to a *pro rata* reduction, and only if there are more than 300 MI/CABG/Stenting claims (with no unused portion of the aggregate capped total of $1,000,000 available for CHF awards to be used for

MI/CABG/Stenting claims in excess of 300) will MI/CABG/Stenting awards be subject to a *pro rata* reduction.

86. Based on the current available information from Class Counsel and Related Counsel, and other Avandia class action firms outlined above, Class Counsel anticipates that the maximum number of claims contemplated by the Maximum Settlement Amount will not be reached (and thus no *pro rata* reductions) as the total number of Settling Claimants is estimated to be at or below 300 for each of the MI/CABG/Stenting category and the CHF category.

(e) ***Estimated Net Recovery for Approved Claimants***

87. With respect to the costs of claims administration, as it is unknown how many claims will ultimately be submitted, RicePoint Administration Inc.'s ("RicePoint") cost proposal consists of a fixed fee component of $55,000 and a per claim rate for each claim received by RicePoint.

88. I am informed by David Weir, Senior VP Business Development of RicePoint, and verily believe, that the fixed fee of $55,000 includes case set up, escrow account activities, distribution of payments to Settling Claimants and to PHIs, post-distribution activities (including attending to questions following distribution) and reporting to counsel for the parties after the Claim Deadline.

89. I am informed by Mr. Weir, and verily believe, that the cost of processing individual claims is $75.00 per claim, plus $35.00 per Risk Factor Adjustment review, if a Risk Factor Declaration is submitted by a claimant (it is optional). Out of pocket costs (e.g. scanning, support centre emails and calls, bank fees) are additional, as are applicable taxes.

90. Class Counsel estimates the maximum cost of claims administration as follows. Assuming the maximum contemplated number of MI/CABG/Stenting claims and CHF claims are submitted (i.e. 600 total), and assuming that each submitted claim includes an optional Risk Factor Declaration (to be reviewed for $35.00), the total per claim administration cost (excluding out of pocket costs and taxes) will be $66,000.[2] To this there must be added the fixed fee of $55,000, for a total estimated cost of claims administration of $139,150, excluding additional out of pocket costs.[3]

91. With respect to the costs of providing Hearing Notice and Settlement Approval Notice, I am informed by Mr. Weir, and verily believe, that the estimated cost of implementing the Hearing Notice Plan and the Settlement Approval Notice Plan will be $41,245, inclusive of tax, representing equal costs of $20,622.50 for each stage.

92. The total cost of notice and estimated cost of claims administration (assuming 600 total claims submitted, each with a Risk Factor Declaration, but excluding out of pocket expenses) is $180,395.

93. From the Settlement Payment, $250,000 has been agreed to be paid as a contribution to the costs of administration and disbursements.

94. Disbursements for which Court approval will be sought will not exceed $400,000. The combined total of maximum disbursements and estimated total costs of notice and claims administration is $580,395 [$400,000 (maximum disbursements) + $180,395 (estimated

[2] $75 to process claim + $35 to review Risk Factor Adjustment = $110 per claim x 600 claims [300 MI/CABG/Stenting claims + 300 CHF claims]
[3] Calculated as $55,000 + $66,000 = $121,000 plus 15% tax of $18,150.

total costs of notice and claims administration, assuming 600 claims submitted each with a Risk Factor Declaration) = $580,395].

95. After allocation of $250,000 from the Settlement Amount to pay a contribution to costs of administration and disbursements, a balance of $330,395 remains left to be paid from the Settlement Payment, in accordance with section 6.1 of the Settlement Agreement.

96. If there are 300 approved MI/CABG/Stenting claims and 300 approved CHF claims, the Maximum Settlement Amount of $6,750,000 will be paid by the Defendants.

97. Class Counsel has calculated the estimated average net amount (i.e. without accounting for points adjustments) to be received by Approved Claimants to be as follows, recognizing that due to the unknown number of eligible and ultimately approved claims, some assumptions must be made:

> Maximum Settlement Amount: $6,750,000
>
> Deduct legal fees of 25% plus tax: $1,940,625 [legal fees of $1,687,500 plus 15% tax ($253,125)] [disbursements accounted for below]
>
> Deduct $250,000 [Defendants' contribution to administration expenses/disbursements]
>
> Deduct $330,395 [estimated remaining balance of administration expenses and disbursements, per calculations in paragraph 95, above]
>
> = $4,228,980 to be distributed to Approved Claimants (inclusive of a 10% allocation to PHIs for their subrogated claims)

98. CHF claims are valued at approximately 18% of an MI claim ($3,333.33/$18,333,33 = 18.18%). Therefore, again assuming the Maximum Settlement Amount is paid (due to there being an estimated maximum of 300 Approved Claimants in each category), of $4,228,980

to be distributed to Approved Claimants, $768,828 will be used to pay CHF claims, and $3,460,152 will be used to pay MI/CABG/Stenting claims.

99. Assuming there are 300 approved MI/CABG/Stenting claims and 300 approved CHF claims, an approved MI/CABG/Stent claimant will receive a net average amount of $11,533.84 (of which 10% will be paid to the applicable PHI) and an approved CHF claimant will receive a net average amount of $2,562.76 (of which 10% will be paid to the applicable PHI).

III. RESOLUTION OF PHI CLAIMS

100. During the process of finalizing the terms of the proposed Settlement, Class Counsel (members of Siskinds LLP and/or Wagners) communicated by way of written letters and telephone calls with representatives of the PHIs.

101. In addition to those phone calls and written correspondence I was directly involved in, I am informed by Jill McCartney (a lawyer at Siskinds) and Ms. McKinnon, and verily believe, that they each had additional communications with representatives of the PHIs.

102. After being informed of the particulars of the action, the identified litigation risks and rationale for recommending the Defendants' offer, and upon negotiation of the terms of settlement, the PHIs provided their instructions to Class Counsel that confirmed their approval of the Settlement Agreement and that they would accept 10% of the allocation made by the Claims Administrator for each Settling Claimant in satisfaction of all statutory authority for the recovery of costs of insured health or medical services they may have with respect to the Settling Claimant's use of Avandia, and they agreed they would sign a release (Exhibit "F" to the Settlement Agreement) in return for such payment.

103. I am informed by Ms. McCartney, and verily believe, that written confirmation of acceptance of the terms of the Settlement Agreement has been received from each jurisdiction.

IV. CLASS ACTION EXPERIENCE OF CLASS COUNSEL

104. Raymond F. Wagner, Q.C. is the principal of Wagners. Mr. Wagner informs me and I do verily believe that he has a degree in law from Dalhousie Law School and was called to the bar of Nova Scotia in 1980.

105. Mr. Wagner informs me, and I do verily believe, that since 2004 Wagners has been involved in class action litigation across Canada and on a national basis. Mr. Wagner is an experienced trial lawyer repeatedly recognized by the peer review publications Lexpert and Best Lawyers. Mr. Wagner has appeared at numerous conferences and has given presentations to members of the CBA, APTLA, OTLA, AAJ and other associations.

106. Wagners has been class counsel in a number of settled class actions, including: *Elwin et al. v. Nova Scotia Home for Colored Children et al.*, Hfx No. 343536, a class action concerning historic institutional abuse; *Hemeon et al v. South West Nova District Health Authority*, Hfx No. 398067, a class action concerning a hospital privacy breach; *Schinold v. Capital District Health Authority et al.*, Hfx No. 390420, a class action concerning a hospital privacy breach; *Little v. Regional Health Authority B*, NB No. N/C/93/2013, a class action arising from allegedly contaminated cervical biopsy instruments; *Card vs. Merck Frosst Canada Ltd. et al*., Hfx No. 236090, a class action concerning the pharmaceutical Vioxx; *Thompson v. Cadbury Adams Canada et al.*, Hfx No. 292103, a class action concerning confectionary price-fixing; *Doucette v. Menu Foods et al*., Hfx No.

283226, a class action concerning tainted pet food; and *Tobin v. Dollar Financial Group Inc. et al.*, Hfx No. 218391, a class action concerning illegal interest rates.

107. Wagners is class counsel in a number of ongoing class actions, including the following: *Taylor v. Wright Medical et al.*, Hfx No. 355381, a certified class action concerning allegedly defective hip products; *Perrier & Martell v. Attorney General of Nova Scotia et al.*, Hfx No. 447198, a class action concerning alleged institutional abuse; *Downton v. Organigram Holdings Inc. et al.*, Hfx No. 460984, a class action concerning recalled medical marijuana; *Bellefontaine et al. v. Purdue Pharma et al.*, Hfx No. 285995, a class action concerning OxyContin and OxyNEO; *Gay et al. v. Regional Health Authority 7 et al.*, NB No. N/C/41/08, a certified class action concerning pathology errors; and *Morrison et al. v. Attorney General of Nova Scotia et al.*, Hfx No. 230887, a certified class action concerning residents of long-term care facilities, among other actions.

108. I am informed by Ms. McKinnon, and verily believe, that Siskinds has been counsel to plaintiffs in approximately 180 class proceedings and has successfully resolved more than 85 such proceedings. Siskinds currently has over 100 active class actions. Siskinds has particular expertise in prosecuting product liability cases, having been involved with over 30 product liability cases. Siskinds has been ranked as a Band 1 firm by Chambers & Partners. Charles Wright, a lead counsel appointed to this action, has repeatedly been recognized as one of Canada's leading class action lawyers, including being named by Lexpert/American Lawyer Guide as one of the Leading 500 Lawyers in Canada, by Chambers & Partners as a class actions leading practitioner, by Benchmark Canada as a litigation star, and as a recipient of the 2014 Lexpert Zenith Award. Mr. Wright is a co-author of Class Actions Law and Practice (Butterworths 1999), and he speaks frequently at public and legal forums on class action litigation.

V. NOTICE TO THE CLASS, OPT OUTS, OBJECTIONS

(a) Hearing Notice

109. Class Counsel cooperated with RicePoint in implementing the Hearing Notice Plan approved by this Honourable Court by way of the Hearing Notice Approval Order issued on November 5, 2018.

(b) Settlement Approval Notice

110. If the proposed settlement is approved, the Settlement Approval Notice will be disseminated to the Class according to the methods described in the Settlement Approval Notice Plan (both attached to the draft Settlement Approval Order).

111. Class Counsel will cooperate with RicePoint to implement the Settlement Approval Notice Plan.

(c) Opt Outs

112. To date, Class Counsel has received one Opt Out Form from a Class Member intending to opt out of the action.

(d) Objections to Settlement Agreement

113. To date, Class Counsel have received no written objections to the Settlement Agreement.

VI. APPROVAL OF CLAIMS ADMINISTRATOR

114. Attached as **Exhibit "K"** is an outline of the relevant experience of RicePoint, which was provided to me by David Weir, Senior VP Business Development of RicePoint.

AFFIRMED BEFORE ME at the City of Halifax, in the Province of Nova Scotia on December 14, 2018

Commissioner for Taking Affidavits

M. Carter
Madeleine Carter

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

INDEX OF EXHIBITS

Form 39.09

2009 Hfx No. 315567

This is Exhibit "A" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

Form 90.08

2016 C.A. No.

NOVA SCOTIA COURT OF APPEAL

Between:

GLAXOSMITHKLINE INC. and **GLAXOSMITHKLINE LLC**

Appellants

- and -

ALBERT CARL SWEETLAND and **MARY PATRICIA ADDICOTT-ANDREWS**

Respondents

NOTICE OF APPLICATION FOR LEAVE TO APPEAL AND NOTICE OF APPEAL (INTERLOCUTORY)

To: The Respondents
c/o Raymond F. Wagner, Q.C.
Wagners
3rd Floor - 1869 Upper Water Street
Halifax, NS B3J 2V2

Appellants appeal

The Appellants apply for leave to appeal and, if granted, will appeal from the Certification Order dated December 7, 2016 in the proceedings in the Supreme Court of Nova Scotia showing court number Hfx No. 315567 and granted by the Honourable Justice Michael J. Wood.

Order or decision appealed from

The Order was made on December 7, 2016. It was made at Halifax, Nova Scotia.

Grounds of appeal

The grounds of appeal are:

1. GlaxoSmithKline Inc. and GlaxoSmithKline LLC are defendants in a class proceeding certified by the Honourable Justice Wood with respect to the pharmaceutical product, Avandia, a drug used in the treatment of diabetes. Having diabetes increases a person's risk of heart disease and stroke.

2. In order for a case to be certified as a class proceeding, the judge determining the motion must find that the statutory criteria for certification are met. In the circumstances of a class action based in negligence, there must be a rational relationship among the essential elements of harm and causation, class definition and the common issues proposed. There must be an objectively identifiable class of two or more persons with common complaints, as well as a rational connection between a proper class definition and the proposed common issues.

3. In the case at bar, the requisite threshold for certification is not met. As detailed below, the Learned Chambers Judge committed reviewable errors in certifying a class proceeding pursuant to section 7(1) of the *Class Proceedings Act*, SNS 2007, c. 28 (the "***Act***").

Identifiable Class

4. In the case at bar, the Learned Chambers Judge certified identifiable classes, pursuant to section 7(1)(b) of the *Act*, as follows:

   (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and

   (b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

5. The Learned Chambers Judge erred in certifying classes that include persons with no claim in negligence against the defendants. The Primary Class definition includes those who were helped, not harmed, by taking Avandia and who therefore can have no cause of action against the defendants as well as those who developed heart disease and stroke as a result of the expected progression of the disease.

6. The proposed Primary Class and its related Family Class are impermissibly broad. The requirement for an objectively established connection between the class and the alleged claims is not met when the class contains those who have benefitted from taking the drug. Moreover, the class definition fails to meet the requirement of the Supreme Court of Canada in *Sun-Rype Products Ltd. v Archer Daniels Midland Company*, 2013 SCC 58 of an objective means of self-determination of membership in the class.

Common Issues (Negligence)

7. The Learned Chambers Judge certified common issues for determination in this class proceeding, the resolution of which will bind the Class Members, as follows:

   1. (a) Can AVANDIA cause or contribute to heart failure? If so, what is the magnitude of this increased risk?

      (b) Can AVANDIA cause or contribute to heart attacks? If so, what is the magnitude of this increased risk?

      (c) Can AVANDIA cause or contribute to strokes? If so, what is the magnitude of this increased risk?

   2. (a) If the answer to (1)(a) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart failure? If so, when?

      (b) If the answer to (1)(b) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart attack? If so, when?

      (c) If the answer to (1)(c) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of stroke? If so, when?

   3. (a) If the answer to (1)(a) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart failure?

      (b) If the answer to (1)(b) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart attack?

      (c) If the answer to (1)(c) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of stroke?

8. The Learned Chambers Judge committed reviewable errors by linking the proposed common issues to specific harm-based findings (heart failure, heart attack and stroke) without enunciating how the answer to these common issues could be applied to the Primary Class comprised of "all persons . . . who were prescribed and ingested Avandia".

9. The Learned Chambers Judge committed further reviewable errors by failing to require that the plaintiffs demonstrate the existence of a "credible or plausible" methodology for proving causation on a class-wide basis as discussed by the Supreme Court of Canada in *Pro-Sys Consultants v Microsoft Corporation,* 2013 SCC 57.

10. The Learned Chambers Judge compounded this error by failing to address that the question of causation for the class was incapable of resolution and that, while causation may ground an action in negligence, a mere association between two events cannot.

11. The Learned Chambers Judge thereby erred by certifying individual issues as common issues and by certifying common issues not supported by the minimum threshold of evidence required by section 7(1)(c) of the *Act* and the Supreme Court of Canada.

12. The cumulative effect of these errors was to certify an overly broad class that contains members, who:

   (a) have no cause of action against the defendants;

   (b) have failed to establish an evidentiary basis for their interest in resolution of the common issues; and

   (c) have failed to produce the requisite "credible or plausible methodology" for proving causation in this litigation.

Common Issues (Enterprise Liability)

13. The Learned Chambers Judge also certified "enterprise liability" as common issue 4, as below. In so doing, he committed a reviewable error.

   4. Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?

14. The Learned Chambers Judge permitted the plaintiffs to "lump together" the defendants as one entity. In endorsing this as a common issue, the Learned Chambers Judge committed a reviewable error. He failed to hold the plaintiffs to the required evidentiary threshold: the requirement to lead evidence that the defendants were either a shield or an alter ego of one another for a fraudulent or improper purpose. In so doing, he failed to apply the requirement that the plaintiffs show "some basis in fact" in seeking certification of this common issue.

Common Issues (Unjust Enrichment/Waiver of Tort)

15. Lastly, the Learned Chambers Judge certified "unjust enrichment and/or waiver of tort" as common issue 5, as below. In so doing, he committed a reviewable error.

   5. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:

      (a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,

      (b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?

16. The Learned Chambers Judge erred in certifying Common Issue 5 insofar as the appropriateness and availability of restitutionary relief should have been addressed at the certification stage. It was in the interests of the judiciary and all parties that the matter be ruled on directly at the early stage of the litigation.

Preferable Procedure

17. Having regard for the above-described required relationship among the cause of action in negligence, the class definition and the common issues certified, the Learned Chambers Judge committed reviewable errors in concluding that a class proceeding would be the preferable procedure for the fair and efficient resolution of the dispute, as required by section 7(1)(d) of the *Act*. The individual elements of causation necessary to the resolution of each class member's claim will dominate the litigation.

18. Section 7(2) of the *Act* describes the considerations that the Court must weigh when addressing whether a class proceeding is the preferable procedure in any particular case. This includes whether "the questions of fact or law common to the class members predominate over any questions affecting only individual members". By failing to provide necessary analysis of how this criteria was applied to the gap between the Primary Class, as defined, and the Common Issues in negligence, the Learned Chambers Judge erred in his interpretation of mandatory criteria, creating a reversible error.

Representative Plaintiffs

19. The Learned Chambers Judge committed reviewable errors in finding that the putative representative plaintiffs could fairly and adequately represent the interests of the class.

20. At first instance, the representative plaintiff failed to provide evidence of "two or more" members of the identifiable class. This failure showed deficiency at a fundamental level with respect to the adequacy of the representative plaintiffs.

21. By bifurcating the hearing, allowing the filing of additional evidence for which no "testing" was permitted and then, by providing further Reasons on the criteria of identifiable class, the Learned Chambers Judge committed further reviewable error.

22. The Learned Chambers Judge erred by directing how that fundamental flaw should be remedied rather than by finding that, six years after the litigation had been commenced in Nova Scotia, the representative plaintiffs had failed to put forward "some basis in fact" of an identifiable class. Rather than examining how this omission reflected on the adequacy of the representative plaintiffs in acting in the interests of the class, the Learned Chambers Judge reset the evidence. Without the opportunity to test this evidence through cross-examination, the adequacy of the representative plaintiffs on the point in issue was left unexplored.

23. The combination of these events has led to reviewable errors on the part of the Learned Chambers Judge.

24. Such further and other grounds as counsel may advise and this Honourable Court may permit.

Authority for appeal

1. Section 7(1) and (2) of the *Class Proceedings Act*.
2. Section 39 of the *Class Proceedings Act*.
3. Sections 38 – 40 of the *Judicature Act*, RSNS 1989, c. 240, as am.
4. Rule 90 of the *Nova Scotia Civil Procedure Rules*.
5. *Sun-Rype Products Ltd. v Archer Daniels Midland Company*, 2013 SCC 58
6. *Pro-Sys Consultants v Microsoft Corporation*, 2013 SCC 57

Order Requested

The Appellants say that the Court of Appeal should allow the appeal and that the Certification Order appealed from should be reversed so to: (a) dismiss the Respondents' motion for certification of this action as a class proceeding; and (b) grant the Appellants their costs on the motion below. The Appellants also seek an award of costs on the appeal.

Motion for Date and Directions

The application for leave to appeal (and if leave is granted, the appeal itself) will be heard on a date to be set by a judge. The Appellants will ask a judge of the Court of Appeal to set the date and give directions for hearing of the application for leave to appeal on Thursday, January 19, 2017 at 10:00 a.m. at The Law Courts, 1815 Upper Water Street, Halifax, Nova Scotia. You have the right to be present or represented by counsel. If you are not present or represented, the judge may proceed without you.

Contact information

The Appellants designate the following address:

Stewart McKelvey
Barristers & Solicitors
Suite 900 - Purdy's Wharf Tower One
1959 Upper Water Street
Halifax, NS B3J 3N2

Documents delivered to this address will be considered received by the Appellants on delivery.

Further contact information is available to each party through the Prothonotary.

Signature

Signed Dec 22, 2016

GOWLING WLG (Canada) LLP
Barristers & Solicitors
1 First Canadian Place
100 King Street West, Suite 1600
Toronto, ON M5X 1G5

Mary M. Thomson (LSUC #23275L)
Telephone: 416.862.4644
Facsimile: 416.862.7661

Counsel for the Appellants

STEWART McKELVEY
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Suite 900 - Purdy's Wharf Tower One
1959 Upper Water Street
Halifax, NS B3J 3N2

Scott R. Campbell
Telephone: 902.420.3383
Facsimile: 902.420.1417

Counsel for the Appellants

JENNIFER L. TAYLOR
A Barrister of the Supreme Court of Nova Scotia

Registrar's Certificate

I certify that this Notice of Application for Leave to Appeal and Notice of Appeal (Interlocutory) was filed with the Court on December 22nd, 2016

Court Administration
DEC 07 2016
Halifax, N.S.

Form 78.05

2009

Hfx. No. 315567

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

ALBERT CARL SWEETLAND and MARY PATRICIA ADDICOTT-ANDREWS

Plaintiffs

- and -

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Defendants

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

Order for Certification

sgd MJW J.

BEFORE THE HONOURABLE JUSTICE MICHAEL J. WOOD

THIS MOTION was made by the Plaintiffs for an Order for certification of the action as a class proceeding. The motion was heard on September 15-18, 2015. A written decision was released on January 15, 2016, by which the Court granted leave to the Plaintiffs to provide additional evidence and submissions on the section 7(1)(b) criterion that there be an identifiable class of two or more persons, as well as to provide redrafted common issues. The Defendants were also invited to make submissions on these issues. A supplemental written decision was released on June 1, 2016, by which the action was certified as a class proceeding.

UPON READING the Notice of Motion, the evidence filed by the parties, the Litigation Plan and the submissions of counsel;

AND UPON IT APPEARING that it is appropriate to certify the proceeding as a class proceeding in that:

(a) the pleadings disclose a cause of action;
(b) there is an identifiable class of two or more persons;
(c) the claims raise common issues;
(d) a class proceeding is the preferable procedure; and
(e) there are Representative Plaintiffs who would fairly represent the Classes, have produced a workable Litigation Plan and have no interests in conflict with the interests of other Class Members.

NOW UPON MOTION, IT IS HEREBY ORDERED:

1. That the action be and is hereby certified as a class proceeding pursuant to sections 4(3) and 7 of the *Class Proceedings Act*.

2. That the Classes be defined as:

   (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and

   (b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

3. That Albert Carl Sweetland and Mary Patricia Addicott-Andrews, c/o Wagners Law Firm, 1869 Upper Water Street, Suite PH301, Pontac House, Halifax, NS B3J 1S9, be appointed as the Representative Plaintiffs of the Primary Class and the Family Class, respectively.

4. That the claims to be determined and the relief sought are as alleged in the Fresh as Second Amended Notice of Action and Statement of Claim issued on June 5, 2015.

5. That the common issues for determination in this class proceeding, the resolution of which will bind the Class Members, are as follows:

1. (a) Can AVANDIA cause or contribute to heart failure? If so, what is the magnitude of this increased risk?

(b) Can AVANDIA cause or contribute to heart attacks? If so, what is the magnitude of this increased risk?

(c) Can AVANDIA cause or contribute to strokes? If so, what is the magnitude of this increased risk?

2. (a) If the answer to (1)(a) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart failure? If so, when?

(b) If the answer to (1)(b) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart attack? If so, when?

(c) If the answer to (1)(c) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of stroke? If so, when?

3. (a) If the answer to (1)(a) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or

otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart failure?

(b) If the answer to (1)(b) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart attack?

(c) If the answer to (1)(c) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of stroke?

4. Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?

5. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:

(a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,

(b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?

6. That the Class Members shall be given notice of the certification of this action as a class proceeding, in accordance with the form of the Notice of Certification, attached as Schedule "A" hereto, and in the manner as provided in the Litigation Plan.

7. That the Notice of Certification and its distribution satisfy the requirements of s. 22(6) of the *Class Proceedings Act*.

8. That the cost of providing the Notice of Certification to the Class Members will be borne by the Plaintiffs, subject to same being awarded to the Plaintiffs as disbursements at the conclusion of the common issues trial if the common issues are established against the Defendants.

9. That the Litigation Plan produced by the Plaintiffs is a workable method of advancing the proceeding subject to clarification and amendment if required.

10. That a Class Member may opt-out of the class action by sending a completed and signed Opt-Out Form, a copy of which is attached hereto as Schedule "B", to counsel for the Plaintiffs on or before the date to be determined by agreement of counsel and approved by the Court or (in the absence of any agreement of counsel) as directed by the Court.

11. That the parties adopt the following schedule for the remaining steps in the action:

(a) Sixty (60) days from the date the Certification Order has been issued by the Court, the Defendants shall deliver their Statements of Defence;

(b) Six (6) months following the delivery of the Statements of Defence and/or Reply, the parties will exchange their Affidavits of Documents;

(c) Eight (8) months following the exchange of the Affidavits of Documents, the parties will complete their examinations for discovery;

(d) Six (6) months after all undertakings arising out of the examinations for discovery have been concluded, the Plaintiffs will deliver any expert report(s);

(e) Three (3) months after receiving the Plaintiffs' expert report(s), the Defendants will deliver any responding expert report(s); and

(f) The parties will request a Case Management Conference for the purpose of scheduling the common issues trial.

12. That the costs of this certification motion be paid forthwith by the Defendants in an amount agreed to by the parties or, in the absence of any such agreement, in an amount determined by the Court.

Issued December 7, 2016.

Prothonotary

SARAH DRYSDALE
Deputy Prothonotary

Consented to as to form:

Raymond F. Wagner, Q.C.
Solicitor for the Plaintiffs
Wagners
1869 Upper Water Street
Suite PH301, Pontac House
Halifax, NS B3J 1S9

Mary M. Thomson
Solicitor for the Defendants
Gowling WLG (Canada) LLP
1 First Canadian Place
100 King Street West
Suite 1600
Toronto, Ontario M5X 1G5

IN THE SUPREME COURT
COUNTY OF HALIFAX, N.S.
I hereby certify that the foregoing document, identified by the seal of the court, is a true copy of the original document on the file herein.
DEC 07 2016
Deputy Prothonotary

SARAH DRYSDALE
Deputy Prothonotary

SCHEDULE "A"

NOTICE OF CERTIFICATION OF THE AVANDIA CLASS ACTION

To: Users of AVANDIA Diabetes Medication

Notice Of Certification:

Class Members be advised of a certification of a class action lawsuit regarding the alleged harm caused by the diabetes medication AVANDIA. It is alleged that AVANDIA increases the risk of heart failure, heart attack and/or stroke.

Who is included?

There are two classes (collectively "Class Members"):

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

b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

If you are a Class Member you do not need to do anything at this point to get the benefit of any ruling on the common issues. A judgment on the common issues will bind all Class Members who do not opt-out, whether favourable or adverse to the class.

What is the nature of the claims?

Compensation and/or damages for negligent design, development and testing of AVANDIA, negligent distribution and marketing of AVANDIA, and waiver of tort.

What options do Class Members have?

Class Members may opt-out of the class action by sending an "Opt-Out Form," signed by the Class Member, to class counsel on or before the deadline stipulated in the Opt-Out Form.

Class Counsel Compensation:

The Representative Plaintiffs have entered into a Contingency Fee Agreement with class counsel. Class counsel will apply to the Court at the conclusion of the case to have their legal fees approved. Class counsel will pay for all case expenses incurred in prosecuting the case and if the case is successful, class counsel will apply to the court to be reimbursed for these case expenses. If the case is not successfully settled or tried, class counsel will not be paid or be reimbursed for any expenses.

Where can Class Members get more information? You may contact class counsel for more information.

If you do not want to participate, you must opt out on or before the deadline stipulated in the opt out form. If you opt out you will not be entitled to share in any recovery.

For more information, or to access opt-out forms, visit

http://www.wagners.co

or contact class counsel at the address below:

Wagners
1869 Upper Water Street
Suite PH 301, Pontac House
Historic Properties
Halifax NS B3J 1S9
Office: 902-425-7330
Toll Free: 1-800-465-8794
Fax: 902-422-1233
Email: seriousinjury@wagners.co

Representatives of the Class:

Albert Carl Sweetland
Mary Patricia Addicott-Andrews

c/o Wagners
1869 Upper Water Street
Suite PH 301, Pontac House
Historic Properties
Halifax NS B3J 1S9

This summary notice has been approved by the Supreme Court of Nova Scotia. Do not Contact the Court about this Certification.

SCHEDULE "B"

2009 Hfx. No. 315567

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

ALBERT CARL SWEETLAND and MARY PATRICIA ADDICOTT-ANDREWS

Plaintiffs

- and –

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Defendants

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

OPT-OUT FORM
DEADLINE – 2017

I, _____ , opt out of the class action against the above-named Defendants with respect to the diabetes medication Avandia.

I understand that by opting out of the class action, I will not be entitled to share in any recovery or take any benefit of any ruling in this case, but I will be free to bring my own claim if I wish. I understand that if I opt out of the class action and wish to bring my own claim, my own claim may be subject to a limitation period. I understand this Opt Out Form must be received by Wagners by _____.

My information is as follows:

Print Name of Class Member: _____ Date of birth: _____

Email address: Telephone:

Address: _____ Address2: _____

City, Prov.: _____ Postal Code: _____

Date: Signature:

_____

SUPREME COURT OF NOVA SCOTIA
Citation: *Sweetland v. GlaxoSmithKline*, 2016 NSSC 18

Date: 20160115
Docket: *Hfx* No. 315567
Registry: Halifax

Between:

Albert Carl Sweetland and Mary Patricia Addicott-Andrews

Plaintiffs

v.

GlaxoSmithKline Inc. and GlaxoSmithKline LLC

Defendants

Judge: The Honourable Justice Michael J. Wood

Heard: September 15, 2015 in Halifax, Nova Scotia

Counsel: Raymond Wagner, Q.C. and Michael Dull, for the Plaintiffs
Scott R. Campbell, Mary Thomson and Josh Hanet, for the Defendants

By the Court:

[1] AVANDIA is a medication which was developed and marketed for the treatment of Type 2 diabetes. It is the trade name for a product known as Rosiglitazone.

[2] The product monograph for AVANDIA includes cautions that it may cause fluid retention and congestive heart failure.

[3] The plaintiffs in this litigation allege the defendants were negligent in the design, manufacture and marketing of AVANDIA in Canada. They wish to have this matter certified as a Class Proceeding under the *Class Proceedings Act*, S.N.S. 2007, c. 28 (the "*Act*"). The defendants oppose the certification request.

[4] Section 7(1) of the *Act* sets out the criteria to be applied by the court on a certification motion. It reads as follows:

> 7 (1) The court shall certify a proceeding as a class proceeding on an application under Section 4, 5 or 6 if, in the opinion of the court,
>
> (a) the pleadings disclose or the notice of application discloses a cause of action;
>
> (b) there is an identifiable class of two or more persons that would be represented by a representative party;
>
> (c) the claims of the class members raise a common issue, whether or not the common issue predominates over issues affecting only individual members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the dispute; and
>
> (e) there is a representative party who
>
> (i) would fairly and adequately represent the interests of the class,

> (ii) has produced a plan for the class proceeding that sets out a workable method of advancing the class proceeding on behalf of the class and of notifying class members of the class proceeding, and
>
> (iii) does not have, with respect to the common issues, an interest that is in conflict with the interests of other class members.

[5] The certification motion is procedural in nature. It is not the time for assessing the substantive merits of the plaintiffs' allegations except to the extent that they may impact on the certification criteria. At this stage the court performs a gatekeeping function directed to ensuring that the claims being advanced in the litigation lend themselves to resolution through the mechanism of a class proceeding.

[6] Since the motion is procedural, the rules with respect to the admission of evidence are somewhat more relaxed. For example, hearsay is admissible (*Civil Procedure Rule* 22.15; *Elwin v. Nova Scotia Home for Coloured Children*, 2013 NSSC 196). The party seeking certification must satisfy the court that the requirements in s.7(1) of the *Act* have been met. With the exception of s.7(1)(a) the applicant must provide sufficient evidence to show there is some basis in fact for concluding that each of the criteria have been met. It is important to remember that this does not involve any threshold assessment of the relative strength or weakness of the allegations being made.

Evidence on the Certification Motion

Plaintiffs' Affidavits

[7] Albert Carl Sweetland is one of the plaintiffs. He was prescribed and took AVANDIA between December 2001 and January 2006. He was diagnosed with congestive heart failure in January 2007 and subsequently received treatment for that condition. He confirms his willingness to accept the responsibility of acting as a representative plaintiff should certification be granted.

[8] Patricia Addicott-Andrews is the other plaintiff. Her mother, Mary Agnes Addicott, died in August 2006 and she is the executrix of her estate. Her mother took AVANDIA between April 2004 and November 2004. She suffered an acute myocardial infarction in April 2004. Ms. Addicott-Andrews confirms her willingness to accept the responsibility of being a representative plaintiff should certification be granted.

[9] Michael Dull is one of the lawyers acting for the plaintiffs. His affidavit attaches various documents related to AVANDIA including product monographs, correspondence from the defendants and documents issued by Health Canada. He also provides details of the experience of the law firms who will act as class counsel should certification be granted. He confirms that his firm has been contacted by approximately 64 potential class members as of November 2014.

[10] Dr. Robert Myers is a cardiologist practicing in Ontario. In his affidavit Dr. Myers summarizes the human cardiovascular system and discusses the nature of various types of heart disease. He also describes AVANDIA and his understanding of the mechanism by which it assists in the treatment of Type 2 diabetes. Dr. Myers' affidavit summarizes his opinion at paragraph 63 which reads:

> 63. In my opinion, there exist a number of mechanisms that provide a plausible biological explanation for the occurrence of adverse cardiac events in some Avandia users:
>
> a. Avandia causes an increase in the volume of water in the blood, which damages arteries;
>
> b. Avandia damages cardiac muscles, either by increasing the volume of water in the blood or through direct action;
>
> c. Avandia activates genes other than its intended target, which genes influence the heart's function.

[11] Dr. Lorraine Lipscombe is a physician licensed to practice in Ontario with a specialist certificate in endocrinology. She has particular expertise in the treatment of diabetes. In her affidavit Dr. Lipscombe discusses Type 2 diabetes and its complications. She also describes AVANDIA and the mechanism by which it regulates the amount of glucose in a patient's blood. She outlines the risks associated with the use of AVANDIA in the treatment of diabetes, particularly those associated with the cardiovascular system. She expresses the opinion that the 2001 product monograph did not adequately or accurately warn of the cardiovascular risks associated with AVANDIA. Dr. Lipscombe reviews various studies and articles concerning AVANDIA and opines that the risks associated

with AVANDIA outweigh its benefits. She concludes that the defendants failed to provide proper warnings about the possibility that AVANDIA could cause adverse cardiovascular events thereby placing more patients with Type 2 diabetes at increased risk of cardiovascular disease and mortality.

Defendants' Affidavits

[12] Dr. Brian W. Gilbert is a cardiologist practising in Ontario. He expresses the opinion that in order to determine the probable cause of an individual's heart attack or heart failure, it is necessary to evaluate and consider their medical and family histories as well as their cardiovascular risk profile. He provides a list of 16 different cardiovascular risk factors that should be taken into account. Diabetes is one of them.

[13] Dr. Gilbert reviewed the available medical records for Albert Sweetland and Mary Addicott. In Mr. Sweetland's case he identified six cardiovascular risk factors which could have caused or significantly contributed to his reported congestive heart failure. With respect to Ms. Addicott he concluded she was at extremely high risk for having a cardiovascular ischemic event. He found she had multiple long-standing risk factors for cardiovascular disease. He noted that she suffered heart failure and had a heart attack before she took AVANDIA and her fatal heart attack was more than 18 months after her last reported use of that medication.

[14] A summary of Dr. Gilbert's opinion is found in the following paragraphs from his affidavit:

> 67. In order to determine what may have caused an individual's cardiovascular event such as a heart attack or heart failure, an expert would need to review and consider the individual patient's medical records, family history and the relevant cardiovascular risk factors described above. An opinion on probable cause can only be done on a case-by-case basis because each individual's presentation will differ, not only with respect to the presence of specific risk factors, but also with respect to the duration of the specific risk factors and the degree to which each was controlled or uncontrolled.
>
> 68. The above review of the medical records of Mr. Sweetland and Mrs. Addicott shows the individual nature of their medical and family histories, their individual cardiovascular risk profiles and their individual cardiovascular complications. The variances between them is illustrative of the variances among all patients who suffer adverse cardiovascular events. No two patients are identical. All patients must be considered individually.

> 69. Diabetes and cardiovascular disease are multi-factorial. Each case is affected by a patient's medical history including hypertension, diabetes, dyslipidemia including high LDL and triglycerides and low HDL levels as well as their age, gender, heredity, obesity, a lack of exercise and history of smoking, among other factors. In any given individual, a unique combination of risk factors determines the propensity for developing cardiovascular disease. It is an individual case-by-case analysis.
>
> 70. For the purposes of this Affidavit, the most common cardiovascular risk factors have been noted. Other risk factors with less frequent occurrence may present in a particular patient, again emphasizing that each patient's course is unique and individual.

[15] Dr. Tina Kader is an endocrinologist practising in Quebec. She indicates that she has treated thousands of diabetic patients over the course of her career. She describes the progressive nature of Type 2 diabetes and the complicated and individualized aspects of medical care for diabetes patients and, in particular, the evaluation of potential risks and benefits of any particular medication. She indicates that diabetes is a significant risk factor for cardiovascular disease and notes there are other patient circumstances which may contribute to cardiovascular complications.

[16] Dr. Kader says that diabetes is a complex and multifactorial disease with treatment options varying between patients. In addition treatment for any particular person will evolve as the disease progresses. When considering any proposed therapy the treating physician must undertake an informed analysis of the risk and benefit to the patient. This requires an individualized approach taking into account any risk factors which might exist.

[17] Roslyn Theodore-McIntosh is an employee of the defendants' law firm. She attached various documents from the U.S. Food and Drug Administration website as well as copies of pleadings in other law suits brought in Ontario relating to AVANDIA.

[18] Drs. Lipscombe, Myers, Gilbert and Kader were cross-examined out of court and the transcripts of those examinations were filed as part of the motion record.

Certification Criteria

[19] The certification criteria are set out in s.7(1) of the *Act*. The party seeking certification, in this case the plaintiffs, have the onus of satisfying the court that

each of the criteria are established. Other than the requirement that the pleadings disclose a cause of action, there is an evidentiary burden to show that all of the criteria have been satisfied. This burden is not a high one and simply requires there to be some basis in fact to conclude that the criteria are met.

[20] The goals of class proceedings legislation are to facilitate access to justice, modify harmful behaviour and conserve judicial resources. These overriding principles must be kept in mind when determining if certification is appropriate. The certification hearing focuses on whether a class proceeding is the proper mechanism for resolving the issues raised in the litigation.

[21] The parties have provided me with dozens of certification decisions from across the country. It is apparent from reviewing these that each is based upon the particular evidence and submissions which were presented. These cases illustrate how general principles may be applied but are no substitute for a careful analysis of the circumstances found in the motion record before me.

Cause of Action

[22] Section 7(1)(a) of the *Act* requires that the pleadings disclose a cause of action. The test to be applied is the same as for summary judgment on pleadings: assuming all facts pleaded to be true is it plain and obvious that the plaintiffs' action cannot succeed?

[23] In this case the plaintiffs have amended the Statement of Claim twice. At the hearing counsel indicated they wish to do so a third time. Mr. Wagner says this amendment would remove a number of causes of action and leave the plaintiffs to rely only on the following:

1. Negligent design, development and testing;
2. Negligent distribution and marketing;
3. Waiver of tort.

[24] The defendants agree, for purposes of certification, that the two negligence allegations are properly pleaded but disagree that waiver of tort should be certified as a cause of action. In addition, the Statement of Claim alleges that the two GlaxoSmithKline corporate defendants are liable for the actions of each other on the basis of agency and vicarious liability. The defendants dispute that this allegation is properly pleaded.

[25] There has been considerable debate about whether waiver of tort is a stand-alone cause of action or simply an alternative remedy once a tort has been proven. In *Arora v. Whirlpool Canada LP*, 2013 ONCA 657, the court upheld a decision to refuse certification on the basis that the Statement of Claim did not disclose a cause of action. The motions judge had decided that waiver of tort required some form of actionable wrongdoing and since the Statement of Claim did not plead any other cause of action, a claim based on waiver of tort was untenable.

[26] In *Heward v. Eli Lilly & Co.*, [2007] O.J. No. 404 ("*Heward*"), Justice Cullity discussed the issue of waiver of tort in the context of a certification hearing. With respect to whether it was a cause of action for certification purposes he commented:

> 31 In considering the adequacy of the pleading of waiver of tort, I am no longer satisfied that it is helpful - or even meaningful - to ask simply whether the concept is, or is not, a cause of action. A question framed in this manner may obscure the essential nature of the inquiry under section 5(1)(a) - namely whether the material facts that would, or could, entitle the plaintiffs to a disgorgement remedy have been pleaded. I believe it is likely to be even more confusing to ask whether waiver of tort is a cause of action or only a remedy. Different remedies - such as an equitable accounting or a constructive trust - may be available. To ask whether it is a cause of action also tends to confuse the issue with the more narrow question whether the availability of the remedy is dependent or "parasitic" on proof of all of the constituent elements of an actionable tort including, specifically, damages. This is the first of the issues I have referred to as not finally settled in the authorities. However, proof that an actionable tort was committed would not, in itself, satisfy the requirements of pleading waiver of tort. The cause of action in tort is not identical to the cause of action that must be disclosed for the purposes of section 5(1)(a). The latter requires proof of a causal connection between the tort and the defendants' enrichment. The existence of this connection has been pleaded in this case.

[27] In light of the limited jurisprudence defining the nature and scope of the doctrine Justice Cullity was reluctant to resolve the issue on the basis of the pleadings alone. His concerns are found in the following passage from his decision:

> 47 On the basis of the facts pleaded in this case, it would be open to a trial judge to find (a) that the defendants breached a duty of care by deliberately concealing, or withholding, information about harmful side-effects of Zyprexa for the purpose of gaining the approval of Health Canada, (b) that they intended to,

> and did, profit thereby and (c) that, but for the breach of duty, such profits would not have been obtained. In connection with the third of these possible findings, I note that it is explicit in the pleading that none of the primary plaintiffs would have taken the drug if they had been informed of its alleged side-effects. In this sense, the enrichment was caused by the defendants' wrongdoing and, in these circumstances, I am not prepared to conclude that the plaintiff's claim to a disgorgement remedy based on waiver of tort is bound to fail. Nor do I believe that it is sufficiently clear that a deliberate breach of a duty of care must be regarded as a precondition for such a remedy.
>
> 48 As was recognised at first instance, and in the Divisional Court, in Serhan there may well be important issues of policy to be considered when drawing the line between cases where a disgorgement remedy should be granted and those in which it should be denied. These are questions that must surely be confronted on the basis of a full factual record, and not on a procedural motion such as this. As Epstein J. stated in Serhan (at para 68):
>
> ... the resolution of the questions the defendants raised about the consequences of identifying waiver of tort as an independent cause of action in circumstances such as exist here, involves matters of policy that should not be determined at the pleading stage.
>
> 49 Finally, I note that, whereas it has been frequently emphasised in cases in this jurisdiction that in situations where the law is unsettled, or in a state of development, the court should be slow to deal with unresolved legal issues simply on the basis of the pleadings, a less restrictive approach to the plain and obvious test may be accepted in British Columbia: see, for example, Pearson v. Boliden, [2002] B.C.J. 2593 (B.C.C.A.), para 39.

[28] I agree with this approach and I am not prepared to dismiss the possibility of compensation based upon waiver of tort at this stage. Nor am I foreclosing the defendants from arguing that it is not a stand-alone cause of action and is only remedial in nature. Even if waiver of tort remains as an issue following certification, the question of entitlement should be separated from the quantification of compensation (see *Goodridge v. Pfizer Canada Inc.*, 2010 ONSC 1095 ("*Goodridge*"), and *Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681 ("*Parker*")). I will discuss this further when I consider the proposed common issue dealing with waiver of tort.

[29] The defendants say that the "enterprise liability" pleading alleging the corporate defendants are agents and vicariously liable for the actions of each other

is deficient. They rely on *Durling v. Sunrise Propane Energy Group Inc.*, 2012 ONSC 4196, where the court struck out a claim based on agency with leave to amend to correct the deficiencies. I have reviewed that decision and conclude that the Statement of Claim in this case includes more detail in support of the allegations of enterprise liability. The defendants' submissions have not satisfied me that this portion of the pleading should be struck out because the plaintiffs' claims cannot succeed.

[30] For the reasons above I have concluded that the plaintiffs have met the criteria of a pleading that discloses a cause of action.

Identifiable Class of Two or More Persons

[31] Section 7(1)(b) requires an identifiable class of two or more persons. The plaintiffs seek certification of two classes and these are described as follows:

1. All persons in Canada including their estates who purchased and ingested the drug AVANDIA ("the primary class"); and
2. 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").

[32] Mr. Sweetland is proposed as a representative of the primary class and Ms. Addicott-Andrews on behalf of the family class.

[33] The class definition criterion is important because it identifies the persons who have a potential claim, defines who is entitled to receive notice, and determines those who will be bound by the result. As with the remaining criteria, the plaintiff must show some basis in fact for the class definition which is proposed.

[34] The characteristics which will bring someone within the scope of the class must be objective. The reason for this is to ensure those who are entitled to be given notice, and will be bound by the results, can be readily identified.

[35] The defendants argue the proposed class definition is too broad and it should be limited to those persons who suffer a specified adverse consequence from taking AVANDIA. I do not accept that proposition. According to the expert evidence there are a range of cardiovascular complications which may arise in patients with diabetes and which might be caused or contributed to by AVANDIA.

Some appear to be progressive in nature and become increasingly more problematic over time. The medical histories of the two representative plaintiffs are illustrative of that point.

[36] Mr. Wagner, on behalf of the plaintiffs, argues that some patients may not know they have suffered an adverse cardiovascular event without further diagnostic steps being taken.

[37] The weakness with the defendants' position is that it would make it difficult to determine who should receive notice. Similarly, if the matter proceeds to a conclusion, will the outcome be binding on people who took AVANDIA and suffer from an undiagnosed cardiac problem? These individuals would never know they were part of the plaintiff class in this proceeding if membership was defined by medical condition.

[38] This is no requirement that all members of the proposed class ultimately have a claim against the defendant.

[39] I am satisfied the definitions proposed by the plaintiffs are objective and reasonable. It will allow the parties, as well as potential class members, to determine who falls within the scope of the litigation. These are the people who will be entitled to receive notice and be bound by the outcome. In my view it is not necessary to further restrict the scope of the class by adding a diagnostic component to the definition.

[40] As part of this criterion the plaintiffs must show some basis in fact for the assertion that there are two or more class members. In this case they propose two classes and therefore must demonstrate two or more members of each class.

[41] The only evidence related to this issue is found in the affidavits of Mr. Dull and Ms. Theodore-McIntosh. In paragraph 8, Mr. Dull says his firm has been contacted by "approximately 64 potential class members and their representatives". Ms. Theodore-McIntosh attaches pleadings from three individual actions commenced in Ontario alleging negligence in the manufacture and marketing of AVANDIA.

[42] In *Martin v. AstraZeneca Pharmaceuticals PLC*, 2012 ONSC 2744 ("*Martin*"), the plaintiffs filed an affidavit of counsel indicating the firm had been in contact with more than 30 potential class members. The court found this was not sufficient evidence of two or more persons for purposes of class certification.

The rationale for this conclusion is found in the following passage from the decision:

> **203** In my view, the plaintiffs have not provided a sufficient evidentiary basis to establish that a class of two or more persons exists. While I appreciate that the burden on the plaintiff to satisfy the s. 5 criteria is low, the evidence that has been provided is insufficient. I agree with the observations of Winkler, J. in *Lau v. Bayview Landmark Inc.*, [1999] O.J. No. 4060 (S.C.J.) at para. 23:
>
> > o [A] class proceeding cannot be created by simply shrouding an individual action with a proposed class. That is to say, it is not sufficient to make a bald assertion that a class exists. The record before the court must contain a sufficient evidentiary basis to establish the existence of the class.
>
> **204** As Nordheimer, J. stated in *Bellaire v. Independent Order of Foresters*, [2004] O.J. No. 2242 (S.C.J.) at para. 33 ("*Bellaire*"):
>
> > o In my view, before the extensive process of a class proceeding is engaged, it ought to be clear to the court that there is a real and subsisting group of persons who are desirous of having their common complaint (assuming there to be a common complaint) determined through that process. The scale and complexity of the class action process ought not to be invoked at the behest, and for the benefit, of a single complainant. [Emphasis added.]
>
> **205** Other decisions have expressed the same points. For example in *Chartrand v. General Motors Corp.*, 2008 BCSC 1781, Martinson J. described the identifiable class requirement as an "air of reality test," testing the reality of the linkage between the plaintiff's claim and the proposed class. This requires not simply that there be a theoretical link between the claim, the class and the common issues, but that there be a demonstrated link in fact to two or more bona fide claimants.
>
> **206** It is not enough to say that more than thirty potential class members, who consumed Seroquel for both on and off-label uses, have been in contact with class counsel. There is no evidence about the nature of the contact. More importantly, there is no evidence to show that any of these people are desirous of having their common complaint (assuming there to be a common complaint) determined through the class action process. This cannot be assumed from the mere fact that a person contacted counsel.

[43] A similar conclusion was reached in *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42 (see paragraphs 128-136) ("*Singer*").

[44] The necessity of having two or more persons who fall within the scope of the class and also wish to advance their claim through a class proceeding was accepted by A.C.J. Rooke in dismissing the certification application in *Buelow v. Morrissey*, 2013 ABQB 277 (see paragraphs 34-39).

[45] In *Wakelam v. Johnson & Johnson*, 2011 BCSC 1765, the plaintiff did not file any evidence to support the existence of other individuals who shared her complaint and wanted to have it litigated through a class proceeding. There was evidence to establish the defendants' medication was widely marketed and they had received reports of adverse effects from that product. The court held this was not sufficient to establish the requirement for two or more identifiable class members. The court gave leave for the plaintiffs to filed additional affidavit evidence identifying individuals who fell within the class definition and supported a class proceeding. Relying on this additional evidence, the court concluded that the certification criterion had been met. The British Columbia Court of Appeal reversed the certification decision but found no error in the trial judge's approach to the requirement for two or more class members (see 2014 BCCA 36, at paras. 101 to 105).

[46] Although I am satisfied that the proposed classes are appropriate I do not believe the plaintiffs have provided the necessary evidence for me to conclude there are two or more members of each class interested in pursuing their claims through a class proceeding. Mr. Dull's affidavit simply notes they have been contacted by potential class members but provides no further information. The fact that others have started individual actions in Ontario suggests those people are not interested in a class proceeding in Nova Scotia. As a result, I conclude the certification criterion in s.7(1)(b) has not been met.

Common Issues

[47] The existence of common issues is fundamental to a class proceeding. Without the element of commonality the issues of judicial economy and access to justice disappear. This criterion is where most of the disputes on certification arise.

[48] One of the frequently cited summaries of the general principles to be applied to the common issue analysis is found in the decision of Strathy J. in *Singer*, at para. 140:

> 140 The following general propositions, which are by no means exhaustive, are supported by the authorities:
>
> A: The underlying foundation of a common issue is whether its resolution will avoid duplication of fact-finding or legal analysis: Western Canadian Shopping Centres Inc. v. Dutton, above, at para. 39.

> B: The common issue criterion is not a high legal hurdle, and an issue can be a common issue even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution: Cloud v. Canada (Attorney General), above, at para. 53.
>
> C: There must be a basis in the evidence before the court to establish the existence of common issues: Dumoulin v. Ontario, [2005] O.J. No. 3961 (S.C.J.) at para. 25; Fresco v. Canadian Imperial Bank of Commerce, above, at para. 21. As Cullity J. stated in Dumoulin v. Ontario, at para. 27, the plaintiff is required to establish "a sufficient evidential basis for the existence of the common issues" in the sense that there is some factual basis for the claims made by the plaintiff and to which the common issues relate.
>
> D: In considering whether there are common issues, the court must have in mind the proposed identifiable class. There must be a rational relationship between the class identified by the Plaintiff and the proposed common issues: Cloud v. Canada (Attorney General), above at para. 48.
>
> E: The proposed common issue must be a substantial ingredient of each class member's claim and its resolution must be necessary to the resolution of that claim: Hollick v. Toronto (City), above, at para. 18.
>
> F: A common issue need not dispose of the litigation; it is sufficient if it is an issue of fact or law common to all claims and its resolution will advance the litigation for (or against) the class: Harrington v. Dow Corning Corp., [1996] B.C.J. No. 734, 48 C.P.C. (3d) 28 (S.C.), aff'd 2000 BCCA 605, [2000] B.C.J. No. 2237, leave to appeal to S.C.C. ref'd [2001] S.C.C.A. No. 21.
>
> G: With regard to the common issues, "success for one member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent." That is, the answer to a question raised by a common issue for the plaintiff must be capable of extrapolation, in the same manner, to each member of the class: Western Canadian Shopping Centres Inc. v. Dutton, above, at para. 40, Ernewein v. General Motors of Canada Ltd., above, at para. 32; Merck Frosst Canada Ltd. v. Wuttunee, 2009 SKCA 43, [2009] S.J. No. 179 (C.A.), at paras. 145-146 and 160.
>
> H: A common issue cannot be dependent upon individual findings of fact that have to be made with respect to each individual claimant: Williams v. Mutual Life Assurance Co. of Canada (2000), 51 O.R. (3d) 54, [2000] O.J. No. 3821 (S.C.J.) at para. 39, aff'd [2001] O.J. No. 4952, 17 C.P.C. (5th) 103 (Div. Ct.), aff'd [2003] O.J. No. 1160 and 1161 (C.A.); Fehringer v. Sun Media Corp., [2002] O.J. No. 4110, 27 C.P.C. (5th) 155, (S.C.J.), aff'd [2003] O.J. No. 3918, 39 C.P.C. (5th) 151 (Div. Ct.).
>
> I: Where questions relating to causation or damages are proposed as common issues, the plaintiff must demonstrate (with supporting evidence) that there is a workable methodology for determining such issues on a class-wide basis: Chadha

> v. Bayer Inc., [2003] O.J. No. 27, 2003 CanLII 35843 (C.A.) at para. 52, leave to appeal dismissed [2003] S.C.C.A. No. 106, and Pro-Sys Consultants Ltd. v. Infineon Technologies AG, 2008 BCSC 575, [2008] B.C.J. No. 831 (S.C.) at para. 139.
>
> J: Common issues should not be framed in overly broad terms: "It would not serve the ends of either fairness or efficiency to certify an action on the basis of issues that are common only when stated in the most general terms. Inevitably such an action would ultimately break down into individual proceedings. That the suit had initially been certified as a class action could only make the proceeding less fair and less efficient": Rumley v. British Columbia, [2001] 3 S.C.R. 184, [2001] S.C.J. No. 39 at para. 29.

[49] This statement of principles was adopted with approval by the Nova Scotia Court of Appeal in *Canada (Attorney General) v. MacQueen*, 2013 NSCA 143, at para. 123.

[50] It is incumbent on the party seeking certification to identify and draft the common issues which they believe should be certified. These issues represent the questions that the court will be asked to decide at the common issues trial. The judge hearing the certification motion has jurisdiction to amend or modify the common issues however they should rarely do so. It is for the party seeking certification to define the case which they believe meets the necessary criteria and not for the court to anticipate how the matter should be framed to better accord with the *Act*. In my view it would be analogous to the court amending pleadings on its own motion in order to better set out a cause of action or defence.

[51] If I conclude that any of the plaintiffs' suggested common issues should not be certified I will not offer specific suggestions about how those deficiencies might be corrected unless the amendment is minimal and does not change the essential character of the proposed common issue.

[52] The thrust of the defendants' opposition to certification arises most clearly when one considers the common issues. The causes of action advanced by the plaintiffs (other than waiver of tort if it is considered a cause of action) are based in negligence which requires proof that the plaintiffs suffered damage caused by the defendants. The nature of the alleged damage resulting from ingesting AVANDIA is congestive heart failure, heart attack or stroke. The defendants argue that no member of either class can recover damages without proof they suffered from one of these events and that it was caused by the medication.

[53] AVANDIA is prescribed for Type 2 diabetes and the medical evidence on certification is clear that people with that disease are at a higher risk of suffering heart failure, heart attack or stroke. The defendants say there is no way to determine whether a particular cardiovascular event was caused by a patient's underlying medical condition or AVANDIA. In addition, they argue that any consideration of individual causation requires a detailed assessment of the patient and all of their risk factors. For these reasons the defendants argue the proposed common issues are not, in fact, common to the class and will not significantly advance the claims in negligence.

[54] The plaintiffs prepared several versions of their proposed common issues at various stages of the litigation. The final document presented at the certification hearing reads as follows:

1. Can AVANDIA cause, or contribute to, adverse cardiovascular events including heart failure, heart attacks, and strokes? If so, what is the magnitude of this increased risk?
2. If the answer to (1) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA? If so, when?
3. Was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants? If so, in what way or ways was AVANDIA defective or unfit?
4. Did the Defendants breach a duty of care owed to class members by designing, developing, fabricating, manufacturing, selling, importing, distributing, marketing or otherwise placing AVANDIA into the stream of commerce in Canada?
5. Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?
6. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:

(a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of

AVANDIA? If so, in what amount and for whose benefit is such accounting to be made? Or, in the alternative,

(b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims, and, if so, in what amount, and for whom are such proceeds held?

7. Are Class Members entitled to recover the medical costs incurred in the screening, diagnosis and treatment of adverse cardiovascular events caused by taking AVANDIA?

8. Are Class Members entitled to recover as damages an amount equal to the purchase price of AVANDIA, or part of the purchase price of AVANDIA? If so, why and in what amount?

9. Can damages of Class Members be determined, in whole or in part, on an aggregate basis? If so, who should pay what amount, to whom and why?

10. Should one or more of the Defendants pay punitive damages? Should punitive damages be assessed in the aggregate? If so, in what amount and how should punitive damages be distributed?

11. Should the Defendants, or any of them, pay prejudgment and post-judgment interest, at what annual interest rate, and should the interest be compound interest?

12. Should the Defendants, or any of them, pay the cost of administering and distributing any monetary judgment and/or the cost of determining eligibility and/or the individual issues? If so, who should pay what cost, why, in what amount and to what extent?

[55] I will review each of the proposed common issues and determine whether the plaintiffs have established that it is appropriate for certification.

Common Issue #1 - Can AVANDIA cause, or contribute to, adverse cardiovascular events including heart failure, heart attacks, and strokes? If so, what is the magnitude of this increased risk?

[56] The plaintiffs describe this as a question of general causation the answer to which will assist in proving causation of damages for class members in the individualized assessment process which may follow the common issues trial. The

plaintiffs say that general causation has been certified as a common issue in a number of class proceedings involving product liability claims. For example, in *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260, the common issue was whether there existed a causal connection between the use of hormone therapies and breast cancer. The court upheld the certification of this common issue for the following reasons:

> 52 Wyeth disputes that there exists in this case a "propensity to injure" or, as referred to in Harrington, "general causation". As noted, Wyeth's central submission is that the plaintiff did not provide evidence as to how the "causal connection" between hormone therapy and breast cancer might be proven given the numerous other risk factors. Wyeth argues that, at most, the evidence only shows an "association" between hormone therapy and breast cancer, which Wyeth submits does not equate to a causal connection. Accordingly, Wyeth contends there was no evidence to support the certification of the common question of a "causal connection."

> 53 As the Court observed in Harrington, the division between general and specific causation affects certification. This division is examined in an article by Patrick Hayes entitled Exploring the Viability of Class Actions Arising from Environmental Toxic Torts: Overcoming Barriers to Certification, 19 J. Env. L. & Prac. 190 at 195:
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> Proving causation in the context of toxic substances, however, puts the added burden on plaintiffs to establish two types of causation, both general and specific. This is because, unlike the causal connection between being hit by a car and suffering a broken bone, for instance, the causal connection between a toxic substance and a disease is not as easy to decipher. Thus, a plaintiff must first prove "general" or "generic" causation -- that a particular substance is capable of causing a particular illness. The issue must be addressed, whether explicitly or implicitly, in toxic torts litigation, since it is axiomatic that "an agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general." Next, a plaintiff must prove "specific" or "individual" causation -- that exposure to a particular toxic substance did, in fact, cause the plaintiff's illness.

> 54 I recognize that these comments were made in the context of toxic tort class actions, where it may be said the proof of legal causation is particularly challenging. However, as can be seen from Wyeth's submissions, it is the appellants' fundamental contention that individual class members will be unable to prove legal causation. The underlying, unspoken assertion is that "if the action is doomed to fail there is little point in certifying the class proceeding": L.(T.) v.

> Alberta (Director of Child Welfare), 2006 ABQB 104 at para. 36, 58 Alta. L.R. (4th) 23.

> 55 However, as has been stated many times, on a certification hearing, the court is not to weigh the competing evidence. Here there is evidence that, if accepted at the trial of the common issues, may answer the general causation question as to whether there is a causal connection between hormone therapy and breast cancer. A positive answer would obviously move the litigation forward, although individual class members may face formidable challenges in establishing causation specific to themselves.

> 56 In saying this, I have not overlooked Wyeth's argument that, at best, the plaintiff's evidence -- that uses the phrase "causal association" -- merely established an "association" between hormone therapy and breast cancer and not actual causation, or the "causal connection" certified as a common issue. In my opinion, this argument amounts to semantics not substance. The word "association" is synonymous with the "connection" the plaintiff seeks to establish, and these two words should not be interpreted in isolation. Their meaning is dependent on the modifying adjective, which, in both cases, is "causal". Thus, in my view, both expressions clearly refer to general causation. The fact that Dr. Kirsh chose "association" to describe the potential link does not render the common question unsupported by evidence.

> 57 Moreover, this initial link, if established, is clearly a substantial element of each class member's claim in negligence. A finding of general causation will obviously influence specific causation depending on the strength of the evidence supporting general causation. For example, if it were found that hormone therapy doubles the risk of developing breast cancer, the individual class members, depending on their individual circumstances, may more readily prove specific causation. Wyeth's awareness of the link is also relevant to the standard of care. Moreover, it is doubtful that an individual litigant could marshall the medical and epidemiological evidence necessary to establish the connection. On the other hand, if the link is not established, the class proceeding will come to an end.

> 58 Furthermore, I am not persuaded the plaintiff had to establish, at this stage of the proceedings, the methodology by which the court can determine that hormone therapy causes breast cancer. That determination will necessarily be informed by the expert evidence at trial; if no methodology is available, it is difficult to see how general causation will be established. However, there is in my view sufficient evidence to support the general causation issue posed, which deserves to be tried.

[57] Similarly in *Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681, the court certified a common issue about whether the subject medication increased the risk of patients experiencing certain specific psychiatric symptoms. The basis for certification was described by Perell J. as follows:

> 83 As explained by the British Columbia Court of Appeal in Harrington v. Dow Corning Corp., supra, at paras. 42 to 45, typically the first two steps in a products liability action are: (1) determining whether the product is defective or whether although non-defective, the product has a propensity to injure; and (2) determining what the manufacturer knew about the dangerousness of its product. The first step, known as the general causation step, determines whether the product is capable of causing harm. The second step is part of determining whether the manufacturer had a duty of care not to sell the product or to sell it only with an appropriate warning.

> 84 Amended question 1 is a general causation question. As noted earlier in this judgment, in my opinion, there is some basis in fact for the general causation common issue. It is also a very productive common issue that does not depend upon the individual experiences or individual claims of class members.

> 85 Visualize, if the common issues trial determines that CHAMPIX (R) does not increase the risk of suicide or attempts to commit suicide, this determination would bind Mr. Parker, Mr. Dunn, and Ms. Clow and their claims would fail as would the claims of any Class member with a claim based on suicide or attempted suicide. Conversely, if the common issues trial established that using CHAMPIX (R) does increase thoughts about suicide or dying, or attempts to commit suicide, then individual Class members who experienced these symptoms will have advanced their claims of a failure to warn.

[58] Since certification is based upon the particular evidence and circumstances of each case it should not be surprising to find that general causation questions are not always certified as common issues. For example, in *Martin* the court refused to certify a common issue asking whether the medication in question caused "weight gain, diabetes and/or related metabolic disturbances". The court's first concern was that the phrase "metabolic disturbances" was unclear and not consistently used by the experts. The court also concluded that the general causation question lacked commonality for the following reasons:

232 Common issue 1 is a general causation question. This means that if it was accepted as a common issue, an individual trial would be required to determine if Seroquel caused each class member to gain weight and/or develop diabetes. This common issue alone would not determine liability.

233 The plaintiffs have offered no evidence to show that this issue is capable of being assessed in common. It is not susceptible to a single answer at this abstract level. Asking in the abstract if Seroquel can cause weight gain and diabetes is only the beginning of the inquiry. There is a problem with a general causation question when there is no evidence that "compelling epidemiological or statistical evidence might be sufficient to establish individual causation or go a long way to doing so": *Merck Frosst Canada Ltd. v. Wuttunee*, [2009] S.J. No. 179 at para 144 (Sask. C.A.), leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 512 ("*Wuttunee*").

234 Adding to the difficulty is the fact that this is not a case where the drug is alleged to have caused a unique harm. In contrast, Seroquel is alleged to cause weight gain and diabetes. These are two conditions that are ubiquitous in society. The evidence that has been provided shows that this general causation question is just the beginning of the inquiry and that its resolution is dependent upon individual findings of fact with respect to each claimant.

235 The plaintiffs' expert, Dr. Wirshing, states that there is "great variability in the degree to which different populations of patients are affected by the metabolic toxicity of Seroquel." When Dr. Wirshing was cross-examined he provided further evidence that there would be considerable difficulty managing this issue in common. He agreed that the population data shows that some patients taking Seroquel will gain weight, some will lose weight and others will experience no weight change. As a result, the population data will not assist in determining causation for the class and an individual inquiry is required.

236 In Dr. Barrett's report he also explains the inability to answer this common issue by relying on the population data. It is clear from the following evidence that this common issue cannot be assessed in common. He states as follows in section 5 of his report:

- Population data is useful in providing an understanding for the risk factors that lead to diabetes and the relative magnitude of each risk factor. However, in determining whether or not Seroquel caused weight gain or DM in an individual patient it is not sufficient to simply examine population data. Population data cannot be translated to the issue of causation in the individual patient. This is underscored by the fact that diabetes and obesity are both common disorders in the Canadian population in the absence of Seroquel administration.
- In order to determine individual causation the court does need to appreciate as necessary background and context the population risk factors described in the section on general causation. It is then necessary to identify all of the diabetes risk factors the individual has and consider the strength of each individual risk factor possessed by the individual in order to appreciate the overall diabetes risk for that individual. Only then can one address whether Seroquel as a possible single risk factor can reasonably be considered as causative in that individual. This process requires analysis of the medical records,

psychiatric records, history of pharmaceutical use and life changes that are occurring in each individual.

237 The individuality of this issue is also apparent from the evidence of Dr. Chue. He states at page 31 of his report as follows:

- In order to determine whether a drug such as Seroquel caused a specific "Heath Risk" to occur in a particular individual, an understanding is required of the prevalence, nature, etiology, and known or associated risk factors in the general population for each of the specific "Heath Risks".
- With this understanding, one would then need to consider the individual's unique circumstances including their risk factors for that specific "Heath Risk". This will require a comprehensive analysis by specialists qualified in the medical fields applicable to the particular "Health Risk". This will entail a review for each individual of their full medical history including complete medication exposure history, family history and psychiatric history, and other relevant factors including age, ethnicity, lifestyle, and gender. This information would be obtained from medical and psychiatric records, and pharmacy records. Where there is incomplete information, further investigations and/or physical examination may be required.
- Taking weight gain as an example, there is an epidemic of obesity in Canada with weight gain being an increasing problem in all strata of the general population. The population with mental illness is at greater risk of weight gain and obesity than the general population. Thus, a recorded weight change in an individual patient treated with Seroquel must be analyzed carefully taking into account the individual's specific risk factors and medical history in the context of the background population risk.

238 When the evidence dealing with diabetes is considered the individuality of the issue remains and we are led to the same conclusion: there is no evidence that this issue can be managed in common.

[59] This passage refers to the Saskatchewan Court of Appeal decision in *Merck Frosst Canada Ltd. v. Wuttunee*, 2009 SKCA 43 ("*Wuttunee*"), where the court refused to certify the question as to whether medication could cause or exacerbate "cardiovascular or gastrointestinal conditions". The concern was that because of the broad nature of the question a large number of conditions might be included. As a result the answer to the question would not assist any particular class member in establishing their claim. The court rejected the idea that the problem could be alleviated by establishing a number of subclasses. The court's analysis was as follows:

142 Further still, it is argued, the issue is also not susceptible to a single answer at a more abstract level, for it must be separately asked and answered across the broad array of cardiovascular and gastrointestinal effects alleged by the plaintiffs. Clearly, the question of whether Vioxx "can" cause adverse cardiovascular conditions is distinct from the question of whether it "can" cause adverse gastrointestinal effects. Whether it can cause high blood pressure is different from whether it can cause blood clotting.

143 Finally, the appellants argue that the resolution of the question could not, in any case, contribute substantially to any class member's claim of injury because the question of individual causation would turn on many factors other than the inherent properties of Vioxx. The appellants argue that "a class-wide" determination of whether Vioxx "can" cause or exacerbate "cardiovascular conditions" in the abstract would not alleviate in any significant respect a particular class member's obligation to prove that Vioxx caused his or her particular cardiovascular conditions.

144 While Klebuc C.J. was faced with some of these same arguments, he relied on the fact that similar arguments had been raised and rejected in other class actions involving pharmaceutical drugs. To the argument that a general answer to the question of whether Vioxx poses an increased risk of, for example, heart attack or stroke does not go far in "proving" that an individual's heart attack or stroke was caused by his having taken Vioxx, other judges have pointed out that legal proof need only be on the balance of probabilities and that the certainty of scientific proof is not required. Thus, compelling epidemiological or statistical evidence might be sufficient to establish individual causation, or go a long way to doing so. Moreover, it is not appropriate at the certification stage to try to anticipate the extent to which the plaintiffs will succeed in relation to the common issues.

145 However, the wide diversity of complaints to which this issue is addressed was not considered below. In my respectful view, this diversity is fatal to consideration of this issue as a "common" issue. Clearly it is not susceptible to a single answer that would apply to the claims of all members of the class. Thus, while it is conceivable that proof that Vioxx significantly increased the risk of, for example, high blood pressure, might support the claims of the induced or purchaser subclasses (and I am by no means certain that it would), it would be irrelevant to those who claim other unrelated adverse conditions or injuries.

146 While, in theory, this lack of commonality across the class could be addressed by reference to subclasses (more refined and detailed, to be sure, than

those identified in the certification order), it is significant that no attempt was made at the certification stage to do so, even though the class was divided into subclasses at that stage. In fact, any realistic attempt to break the question down into an array of distinct questions in a way that would apply to every claim asserted shows how very complex the question is. The appellants do not exaggerate, in my view, when they assert that this issue would require the court to determine and evaluate all of the effects that Vioxx may have on all of the gastrointestinal and cardiovascular body systems. The answers would almost necessarily vary from one sub-subclass complaint to another. This is a far cry, in my respectful view, from the "limited differentiation amongst class members" envisaged in the suggestion, in Rumley, of the possibility of a "nuanced" answer, where there might be variations in the answer to a common issue among class members.

[60] In my view the plaintiffs' use of the phrase "adverse cardiovascular events" is problematic. That term is not defined and not consistently used by the plaintiffs' expert witnesses. Dr. Lipscombe uses a variety of terms, some of which appear to overlap in meaning or are interchangeable. These include cardiovascular "events", "outcomes" and "disease". She also refers to "cardiac events", "cardiac ischemia" and "myocardial ischemic events". Dr. Myers discusses cardiovascular "injuries". "side effects" and "harm". He uses the terms "heart problems" and "heart disease" to describe conditions such as heart failure, angina, myocardial infarction and fluid retention alleged to be caused by AVANDIA. His concluding opinion speaks to adverse "cardiac" rather than "cardiovascular" events.

[61] The word "event" connotes something that happens at a particular point in time such as a heart attack or stroke. Congestive heart failure develops gradually and could hardly be categorized as an event. Drs. Lipscombe and Myers refer to a range of problems including high blood pressure, angina and other types of heart disease in their discussion of the human cardiovascular system. Approving a common issue that is based on adverse cardiovascular events leaves too much uncertainty about what might be included. The range of potential problems the plaintiffs might try to prove at the common trial is broad and not necessarily limited to those identified by their expert witnesses to date.

[62] I agree with the analyses in the *Martin* and *Wuttunee* decisions and would not certify a common issue including the phrase "adverse cardiovascular events". By removing those words and limiting the issue to heart failure, heart attack and stroke, my concerns with respect to clarity and the lack of commonality would be addressed.

[63] It is clear from the expert evidence that heart failure, heart attack and stroke raise different issues in relation to AVANDIA. Dr. Lipscombe describes heart attack and stroke as ischemic events and discusses the risks associated with them separately from non-ischemic risks such as congestive heart failure. Since 2001, the product monograph for AVANDIA has included a discussion of risks related to congestive heart failure however, there was no mention of heart attack until 2012 and stroke was never included. In my view common issue #1 should be divided into three separate questions related to each of heart failure, heart attack and stroke.

[64] Subject to the above comments I would certify this common issue with the modifications I have noted.

Common Issue #2 - If the answer to (1) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA? If so, when?

[65] In light of my direction that common issue #1 should be split into three questions for each of the conditions identified, common issue #2 should be similarly separated. The issues with respect to the duty to warn are distinct for each ailment. For example, congestive heart failure, heart attack and stroke have been treated quite differently in AVANDIA product monographs over the years.

[66] Although all of the monographs since 2001 have referred to heart failure as a risk, Dr. Lipscombe says that none of them contain adequate disclosure of the problem.

[67] The product monographs have never specifically identified stroke as a risk with AVANDIA, although Dr. Lipscombe is of the opinion the defendants should have identified this at least ten years ago. Heart attack was described as a risk in 2012 but not in 2001. Dr. Lipscombe expresses the opinion the heart attack risk was disclosed too late.

[68] In *Martin* the court concluded that the duty to warn could not proceed as a common issue. The reason was because it could not be expressed as a single question for the entire class. As the state of knowledge evolved, the duty to warn evolved as well. There were different health risks identified, each of which would have their own potential warning. Similar concerns led the Saskatchewan Court of Appeal to refuse to certify the duty to warn as a common issue in the *Wuttunee* case.

[69] In this case there are three cardiovascular conditions which are alleged to be exacerbated by AVANDIA. There was an evolving state of knowledge on the part of the defendants and different warnings given at various points in time. Despite this, I believe the duty to warn should be certified as a common issue. I would adopt the reasoning of Cullity J. in *Heward* where he states:

> 90 A second objection that the first issue fails to take into account the evolution of representations made by the defendants during the class period is not, in my judgment, fatal. The position of the plaintiffs - supported by the evidence of Dr Chue - is that none of the representations adequately warned class members of the risks of which they had knowledge, or reasonably ought to have been aware. If a court at trial found that later, but not earlier, warnings were adequate, a nuanced response such as that referred to by McLachlin C.J. in Rumley, at para 32, would be possible.

[70] A similar view was expressed by the British Columbia Court of Appeal in *Bartram v. GlaxoSmithKline Inc.*, 2013 BCCA 462 (see paras. 32-35).

[71] I am satisfied this common issue should be certified with the modification that it separately address each of the three cardiovascular conditions in question.

Common Issue #3 – Was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants? If so, in what way or ways was AVANDIA defective or unfit?

[72] In his submissions counsel for the plaintiffs said this common issue is too broadly stated and should be redrafted so it is limited to the particular cardiovascular conditions which AVANDIA is alleged to cause. I agree, however I am not prepared to rewrite the proposed issue as I believe that is the responsibility of plaintiffs' counsel.

[73] Counsel for the defendants argues an assessment of fitness cannot be done outside of the context of an individual class member's claim. Ms. Thompson says that in answering this question it will be necessary to consider the alleged risks as

well as the benefits of AVANDIA in the circumstances of a particular patient's needs and susceptibilities.

[74] At the certification stage the burden on the plaintiff is to show that a proposed common issue can be answered on a class-wide basis and that the result will advance the individual claims of class members. In my view the intended purpose of AVANDIA can be discerned from the product monograph as interpreted by expert opinion. This is what Dr. Lipscombe does in her affidavit. She also provides her opinion with respect to the cardiovascular risks of the medication and the potential benefits. She comes to the conclusion the benefits do not outweigh the risks and for this reason she no longer prescribes it for her patients. In my view this evidence of Dr. Lipscombe is sufficient to establish some basis in fact for the plaintiff's position that the question of AVANDIA's fitness for use in treatment of Class 2 diabetes can be answered on a class-wide basis. Certifying a common issue such as this does not mean the defendants lose the opportunity to argue at the common issues trial that a class-wide answer is not possible. That hearing will involve significantly more evidence than is necessary for certification.

[75] In principle, I am prepared to certify a common issue on the question of AVANDIA's fitness for purpose, however not on the terms proposed. The current version of this common issue is too broadly stated and must be redrafted by counsel for the plaintiffs.

Common Issue #4 – Did the Defendants breach a duty of care owed to class members by designing, developing, fabricating, manufacturing, selling, importing, distributing, marketing or otherwise placing AVANDIA into the stream of commerce in Canada?

[76] This proposed common issue is extremely broad and could apply to any potential duty of care. It provides no guidance as to the evidence to be called or the question which needs to be answered at the common issues trial. In any negligence action, whether a defendant breached a duty of care is a crucial issue to be decided. In a class proceeding, if breach of duty is to be a common issue, there must be evidence to permit the certification judge to assess whether the question of breach can be answered on a class-wide basis and will advance the individual claims of class members.

[77] The evidence filed by the plaintiffs on this certification motion identifies an issue with respect to the alleged increased risks of heart failure, heart attack and stroke resulting from the use of AVANDIA. The evidence also raises a question about whether the defendants adequately disclosed the nature and extent of those risks. The plaintiffs have shown the basis for a common issue which examines whether the product is unfit due to the potential risks outweighing the benefits. There is no evidence of any other potential breach of a duty of care which could, or should, be considered at the common issues trial.

[78] I am satisfied the alleged breaches of duty raised by the plaintiffs' certification evidence are adequately covered in the first three common issues and there is no purpose to certifying this general question.

[79] Common issues should not be so broadly stated that they provide no direction or limitation and permit the plaintiffs to redefine the common trial under the umbrella of a widely stated issue. The proper procedural route for a plaintiff who identifies a new common issue during the course of the litigation is to make a motion for leave to amend the certification order to add the new issue based upon a proper evidentiary record.

[80] For the above reasons I am not prepared to certify this common issue as proposed by plaintiffs' counsel.

Common Issue #5 – Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?

[81] The question of whether the defendants are liable for the actions of each other, and if so on what basis, does not require any consideration of the circumstances of individual class members. It can readily be decided on a class-wide basis. The answer will assist the individual class members because it will determine whether either or both of the defendants are responsible for any damages which might be awarded. I will certify this common issue as proposed by the plaintiffs.

Common Issue #6 – By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis: (a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? If so, in what amount and for whose benefit is

such accounting to be made? Or, in the alternative, (b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims, and, if so, in what amount, and for whom are such proceeds held?

[82] This proposed common issue seeks a remedy in restitution. There is considerable judicial debate as to whether waiver of tort requires proof of wrongdoing before compensation can be awarded. A useful discussion of this issue is found in the Supreme Court of Canada decision in *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57, at paras. 93-97.

[83] Claims for restitutionary remedies based upon unjust enrichment require a determination of whether the defendants were enriched to the deprivation of the plaintiffs, and if so, to what extent. In the circumstances of this class proceeding the calculation of enrichment and deprivation would be a massive undertaking. It would necessitate disclosure of financial records over a period in excess of fifteen years which would have to be interpreted by expert witnesses. It is obvious to me that the availability of a restitutionary remedy such as proposed by this common issue is very much a live question. Rather than burden the common issues trial with the additional complexities arising out of the quantification issues I believe the most efficient approach is to ask the general question as to whether relief based on unjust enrichment or waiver of tort is even available to class members.

[84] In my view, this common issue should be amended to remove any reference to quantification. This is consistent with the approach in the *Goodridge* and *Parker* cases as well as the Ontario Divisional Court in *Peter v. Medtronic, Inc.; Robinson v. Medtronic, Inc.*, 2010 ONSC 3777 ("*Medtronic*"). In that case the court upheld a decision to bifurcate the issues of entitlement and quantification for the waiver of tort claim for the following reasons:

> 27 In exercising his discretion pursuant to s. 12 of the CPA, the motion judge is required to keep in mind the underlying policy objectives of that Act, including expeditious access to justice and judicial efficiency. Here, the motion judge noted that class proceedings are inherently bifurcated and concluded that it would be more efficient, expeditious and less costly to bifurcate the liability and quantification issues relating to waiver of tort.
>
> 28 In coming to his decision, he applied the factors from Westjet, supra. He concluded that entitlement to elect waiver of tort is independent and severable

> from the amount of an accounting or disgorgement arising from the waiver of tort claim. In my view, he correctly concluded there is a key threshold issue to be determined in relation to waiver of tort - namely, when is it that there has been a breach of a legal obligation giving rise to a claim to compensation in waiver of tort.
>
> 29 There is no merit to the appellants' argument that bifurcation will deprive the court of the full factual record needed to determine the waiver of tort claim. Given the facts of this case and the pleading, there is no need for extensive disclosure of the financial information sought at this stage of the proceeding.
>
> 30 The motion judge also concluded that the appellants would be unable to make an informed decision whether to elect a disgorgement remedy without the ability to compare the value of compensatory damages. Such damages can only be determined in this case after individual trials on causation and liability.
>
> 31 The appellants have made arguments that the time frame for the proceeding will be lengthened, and emphasized the vulnerability of class members because of their age and state of health. However, the motion judge concluded that bifurcation will advance the trial process while the discovery relating to quantification would delay the process. In effect, the appellants ask this court to weigh the factors in favour of and against bifurcation and substitute our decision. That is not our task on this appeal.
>
> 32 The decision of the motion judge was a reasonable one, based on a consideration of the factors in Westjet, as applied to the facts and pleadings in this case. Moreover, the motion judge made a finding that there would be serious prejudice to the respondents if discovery were not divided, given the potential impact on the respondents' competitive position. The appellants have not established any palpable and overriding error in the finding made by the motion judge.

[85] If the common issues trial decides that a restitutionary remedy is available to the plaintiffs the quantification may raise a number of questions requiring individual consideration. These include whether there must be an election to take restitution in lieu of compensatory damages. Depending on their different circumstances some plaintiffs may be entitled to restitution and others not. These issues may lend themselves to determination in individual assessments or as further common issues across the main class or new subclasses. The resolution of all of

these matters can be addressed within the broad authority of the trial judge following the initial decision on this common issue.

[86] With the necessary redrafting to remove reference to quantification of any restitutionary remedy I will certify this common issue.

Common Issue #7 – Are Class Members entitled to recover the medical costs incurred in the screening, diagnosis and treatment of adverse cardiovascular events caused by taking AVANDIA?

Common Issue #8 – Are Class Members entitled to recover as damages an amount equal to the purchase price of AVANDIA, or part of the purchase price of AVANDIA? If so, why and in what amount?

[87] In my view, these common issues raise questions of individual damages. The plaintiffs have provided no evidence to show these questions can be decided on a class-wide basis.

[88] It is a pre-condition to recovery of damages that a plaintiff prove that AVANDIA has caused them to suffer congestive heart failure, heart attack or stroke. That is so whether the claim is for pain and suffering or the costs described in these proposed common issues.

[89] As with the restitutionary claims, the common issues judge has the ability to craft appropriate procedures for individual damage assessment if the plaintiffs succeed at the first stage. If any damage issues lend themselves to resolution on a common basis across a class or subclass the judge could make the determination at that time.

Common Issue #9- Can damages of Class Members be determined, in whole or in part, on an aggregate basis? If so, who should pay what amount, to whom and why?

[90] Aggregate monetary awards are dealt with in s. 32 of the *Act* which reads as follows:

> 32 (1) Once a defendant has been found liable, the court may make an order for an aggregate monetary award in respect of all or any part of a defendant's liability to class or subclass members and may give judgment accordingly if

> (a) monetary relief is claimed on behalf of some or all class or subclass members;
>
> (b) no questions of fact or law other than those relating to the assessment of monetary relief remain to be determined in order to establish the amount of the defendant's monetary liability; and
>
> (c) the aggregate or a part of the defendant's liability to some or all class or subclass members can, in the opinion of the court, reasonably be determined without proof by individual class or subclass members.
>
> (2) Before making an order under subsection (1), the court shall provide the defendant with an opportunity to make submissions to the court in respect of any matter relating to the proposed order including, without limiting the generality of the foregoing,
>
> (a) submissions that contest the merits or amount of an award under that subsection; and
>
> (b) submissions that individual proof of monetary relief is required due to the individual nature of the relief.
>
> (3) Before making an order under subsection (1), the court may permit the admission of additional evidence that, in the opinion of the court, is relevant in the circumstances.

[91] This section makes it clear that the question of aggregate damages can only be made following a finding of liability and after hearing further submissions from the defendant. The court may also decide to permit the admission of additional evidence. In my view, it is premature to consider certifying aggregate damages as a common issue at this stage. The question of an aggregate award may be raised following a finding of liability whether or not it is included in the initial certification order.

[92] I will not certify this common issue as proposed by the plaintiffs.

Common Issue #10 – Should one or more of the Defendants pay punitive damages? Should punitive damages be assessed in the aggregate? If so, in what amount and how should punitive damages be distributed?

[93] Punitive damages are awarded to reflect misconduct on the part of a defendant. In order to make such an award the court must first find the defendant liable to the plaintiff on the basis of a cause of action asserted in the statement of claim. The quantification of punitive damages cannot be done without knowing what compensatory damages have been awarded and to whom.

[94] Punitive damages have been certified as a common issue in class proceedings, however each case is decided on its own facts. Here the defendants will not be liable to the plaintiffs until proof of individual loss following the common issues trial. The trial judge will not have the necessary evidence to decide either liability or quantum of punitive damages. I endorse the following comments from the divisional court in *Medtronic*, upholding the trial judge's refusal to certify punitive damages as a common issue:

> 37 The motion judge reasonably held that a trial judge would be unable to rationally and appropriately consider punitive damages without knowing the amount of compensatory damages as well as the degree of misconduct, the harm caused, and the availability of other remedies. This is consistent with what the Supreme Court said above at para. 94 of its reasons, as well as at para. 123. In this class proceeding, causation, liability and the quantum of compensatory damages will not be determined at the common issues trial. Therefore, the motion judge correctly concluded that entitlement to punitive damages cannot be determined at the common issues trial.
>
> 38 Counsel for the appellants asserts that the present decision departs from a large number of cases in which entitlement to punitive damages has been included in the common issues, arguing that this case is having a "profound impact" on class proceedings. However, it is apparent that each case turns on its own facts. In McKenna v. Gammon Gold Inc., [2010] O.J. No. 1057, 2010 CarswellOnt 1460 (S.C.J.), the issue of punitive damages was held to be a common issue, while in Ramdath v. George Brown College of Applied Arts & Technology, [2010] O.J. No. 1411 (S.C.J.), entitlement to punitive damages was not a common issue. In contrast, in Anderson v. St. Jude Medical Inc., [2010] O.J. No. 8 (S.C.J.), the trial judge ordered bifurcation of the issues of liability for and quantification of punitive damages. However, the following common issue is to be determined in the common issues trial: "Does the defendants' conduct merit an award of punitive damages?"

> 39 I note that Chief Justice McLachlin in Rumley v. British Columbia, [2001] 3 S.C.R. 184 observed that "the appropriateness and amount of punitive damages will not always be amenable to determination as a common issue" (at para. 34). In that case, liability was based on allegations of systemic negligence. Therefore, the issue of punitive damages was appropriately a common issue.
>
> 40 In the present case, liability to class members in negligence or conspiracy will not be determined until the trials to determine the individual issues. The motion judge correctly applied the principles from Whiten when he concluded that entitlement to punitive damages could not be determined until after the individual trials to determine causation and the quantum of compensatory damages. Therefore, he made no error in principle in rejecting punitive damages as a common issue.

[95] The *Whiten* principles referred to in this passage were recently applied by the Nova Scotia Court of Appeal in *Industrial Alliance Insurance and Financial Services Inc. v. Brine*, 2015 NSCA 104. This decision confirms my conclusion that neither entitlement to nor quantification of punitive damages can be determined until after a finding of liability and assessment of individual harm.

[96] I will not certify punitive damages as a common issue in this case.

Common Issue #11 – Should the Defendants, or any of them, pay prejudgment and post-judgment interest, at what annual interest rate, and should the interest be compound interest?

Common Issue #12 – Should the Defendants, or any of them, pay the cost of administering and distributing any monetary judgment and/or the cost of determining eligibility and/or the individual issues? If so, who should pay what cost, why, in what amount and to what extent?

[97] These two common issues represent matters which can only be decided once it has been determined whether there will be a monetary award, on what basis, and to whom. This will be decided once individual class members have proven their damages. For this reason these proposed common issues should not be certified for determination at the common issues trial.

Preferable Procedure

[98] Section 7(1)(d) of the *Act* requires the plaintiffs to satisfy the court that a class proceeding would be the preferable procedure for the fair and efficient resolution of the dispute. Section 7(2) sets out certain mandatory considerations. It reads as follows:

> (2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the dispute, the court shall consider
>
> (a) whether questions of fact or law common to the class members predominate over any questions affecting only individual members;
>
> (b) whether a significant number of the class members have a valid interest in individually controlling the prosecution of separate proceedings;
>
> (c) whether the class proceeding would involve claims or defences that are or have been the subject of any other proceedings;
>
> (d) whether other means of resolving the claims are less practical or less efficient;
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means; and
>
> (f) any other matter the court considers relevant.

[99] The analysis with respect to the preferable procedure must take place through the lens of the three primary objectives of class proceedings, namely, judicial economy, access to justice and behaviour modification.

[100] In assessing the issues of fairness and efficiency it is necessary to consider how the claims of class members will be advanced. In cases where there are too many issues which are not common to the entire class the proceeding becomes unmanageable and the preferability criteria is not met. This was the situation in *Martin* and *Wuttunee*.

[101] I am satisfied the revised common issues can be managed and decided in a common issues trial. Based upon the certification record and the defendants' response, it appears the questions with respect to the alleged risks associated with AVANDIA can be addressed through expert testimony. The issue of what risks should have been disclosed and when will also involve expert evidence and inquiry into the defendants' state of knowledge during the period when the medication was marketed and distributed in Canada. These issues, as well, lend themselves to resolution in a common trial.

[102] The defendants' opposition to certification is premised on the argument that the determination of cardiovascular risk will not significantly advance the claims of class members because individual proof of causation is needed. They also argue that such proof is virtually impossible to obtain because AVANDIA recipients are at inherently higher risk of cardiovascular compromise. The cross-examinations of the plaintiffs' experts include comments suggesting that individual causation may be very difficult to prove. Problems with causation will exist whether class members pursue individual law suits or a class proceeding. As a result, it should not be a basis on which certification is refused. Even if the common issue trial is relatively short and the individual proof of damage extensive, that does not mean there is no efficiency to be gained by an answer in common to the questions of risk, breach of duty, joint liability and restitution.

[103] The advantage to a class proceeding is the ability of the court to craft an effective process for resolution of individual claims (if needed) once the common issues are determined. It allows the parties and the court to be creative in maximizing efficiency without compromising the ultimate legal requirements for proof of liability and damages.

[104] I am satisfied the class proceeding proposed in this case represents a fair, efficient and manageable method for advancing the claims of class members. Despite reaching this conclusion, I should still consider whether there are any other alternatives which would be preferable. The defendants suggest case-managed individual actions with common discovery and coordinated trials. In my view this suggestion does not come close to overriding the preferability of a class proceeding.

[105] With case-managed individual actions all claimants would have to start litigation and make disclosure including individual medical records. Unless orders were issued severing liability from damages, the plaintiffs would have to prove all

aspects of their damages including individual causation and quantification as well as the basis for a punitive award. With a class proceeding, this would only be necessary if the matter continued to individual damage assessments following success by the plaintiffs at the common issues trial.

[106] With individual actions there would be claims in various jurisdictions which would be subject to different rules of court. There could not be a common case management judge, nor could any portion of the trials realistically involve common testimony. Although I have no information concerning the number of potential plaintiffs it is easy to envision that it could be many dozens of people. There is a cost to the parties and the court in administering that number of separate proceedings.

[107] I am satisfied the plaintiffs have established the preferability criterion for certification.

Appropriate Representative Party and Litigation Plan

[108] Section 7(1)(e) requires a representative party who would fairly and adequately represent the interests of the class, does not have a conflicting interest and presents a workable litigation plan.

[109] Here there are two proposed classes and therefore two representatives. Each has filed an affidavit providing information about their personal circumstances which would bring them within the scope of the class definition. They agree to act as representative plaintiffs and acknowledge the responsibilities which they have accepted. They confirm retention of experienced counsel and that they have no conflict of interest. These affidavits satisfy the basic requirements of the *Act*.

[110] The litigation plan provided as part of the motion record is very general in nature. In some respects it will have to be amended in light of my decision with respect to the common issues. It was not addressed to any extent in counsels' submissions at the certification hearing. If certification is granted I would expect to receive a revised litigation plan and hear further submissions from counsel before finalizing that document.

Conclusion

[111] As is apparent from this decision I will not grant the certification order based upon the motion record before me. The plaintiffs may be able to remedy the

problems which I have identified and, in the interests of fairness, I have concluded that I should give them an opportunity to do so. I will permit them to supplement the evidence related to the criterion of two or more class members required by s. 7(1)(b) of the *Act* and to file a revised list of common issues.

[112] The plaintiffs will also be permitted to file further written submissions limited to the new evidence and revised common issues. Once they have done so, the defendants may file evidence and submissions in response. I will give my final decision on the certification motion based upon the written materials, without a further hearing.

[113] The plaintiffs' additional materials must be filed within 45 calendar days of the date of this decision and the defendants' response within a further 20 days thereafter.

Wood, J.

SUPREME COURT OF NOVA SCOTIA
Citation: *Sweetland v. GlaxoSmithKline Inc.*, 2016 NSSC 139

Date: 20160601
Docket: Hfx No. 315567
Registry: Halifax

Between:

Albert Carl Sweetland and Mary Patricia Addicott-Andrews

Plaintiffs

v.

GlaxoSmithKline Inc. and GlaxoSmithKline LLC

Defendants

SUPPLEMENTAL CERTIFICATION DECISION

Judge:	The Honourable Justice Michael J. Wood
Heard:	September 15-18, 2015, in Halifax, Nova Scotia
Final Written Submissions:	May 13, 2016
Counsel:	Raymond F. Wagner, Q.C., Michael Dull, and Madeline Carter for the Plaintiffs Scott R. Campbell, Mary M. Thomson, and Josh Hanet for the Defendants

By the Court:

[1] On January 15, 2016, I issued my decision on the certification motion in this proceeding (2016 NSSC 18). In it I noted certain deficiencies in the plaintiffs' evidence with respect to the certification criteria requiring an identifiable class of two or more persons. Rather than dismiss the motion I granted the plaintiffs leave to file supplemental evidence on this issue.

[2] In my January decision I also invited the plaintiffs to redraft their list of common issues to reflect my concerns with respect to what had been initially proposed.

[3] Counsel for the plaintiffs filed a revised list of common issues as well as five affidavits. There were two affidavits from individuals who were prescribed Avandia and wished to pursue their claims against the defendants in this proposed class proceeding. There were two additional affidavits from spouses of deceased individuals who had been prescribed Avandia and wished to have their claims against the defendants litigated in this proceeding. All four of the affidavits included statements that the individuals who were prescribed and took Avandia were diagnosed with congestive heart failure, heart attack, or stroke.

[4] The fifth affidavit filed by counsel for the plaintiffs was from Richard Crossman, a paralegal employed with the plaintiffs' law firm. It indicated that Mr. Crossman had provided questionnaires to potential class members who had expressed an interest in pursuing the class action and that 71 completed forms were received.

[5] The defendants objected to all of the affidavits. The complaint about the four potential class members was the reference to suffering congestive heart failure, heart attack, or stroke, which evidence was said to be irrelevant and prejudicial. I agree with the defendants. The proposed classes are limited to persons who purchased and ingested the drug Avandia and families of deceased class members. The class definition makes no reference to suffering heart failure, heart attack, or stroke and, therefore, such allegations are irrelevant to the question of certification. I ignored this evidence for purposes of this supplemental decision. I do not think it is necessary to formally strike out the portions of the affidavits containing the offending comments.

[6] The objection to Mr. Crossman's affidavit is that it does not address the question of whether there are two or more members of each class who wish to have their claims resolved through the mechanism of a class proceeding. Once again, I agree with the defendants and have ignored Mr. Crossman's affidavit in its entirety.

[7] The only remaining objection by the defendants is that none of the four affidavits say that the individuals actually purchased Avandia, which is how the proposed class is defined. In each case, the affidavit states that Avandia was prescribed and taken. The defendants go on to suggest that the class should be redefined to refer to persons who have "been prescribed and ingested Avandia". This was not part of the defendants' submissions on the original certification motion and I will not entertain this new argument at this stage.

[8] I am satisfied that the evidence provided by the plaintiffs remedies the deficiencies noted in the initial certification decision and they have provided some evidence to establish the existence of two or more members of each class. I will leave it to counsel to discuss whether to adopt the proposed change in definition suggested by defence counsel as part of the process of finalizing the form of order.

[9] The defendants requested an order that the deponents produce medical histories in support of the allegations that they have suffered cardiovascular problems. No formal motion was made and, as I have already indicated, this evidence is irrelevant with respect to certification and so there is no reason to order its production.

[10] As part of their submissions the plaintiffs provided a revised common issues list addressing comments made in my initial certification decision. The only objection from the defendants was with respect to the new common issue five which reads as follows:

> 5. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:
>
> (a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,
>
> (b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?

[11] I had concluded that entitlement and quantification of these claims should be dealt with separately and only entitlement should be considered as a common issue. The defendants' complaint is that the reformatted common issue does not go far enough because it continues to raise matters of quantification as well as specific remedies for class members. They argue that the common issue should read as follows:

> Are the class members entitled to relief based on unjust enrichment or wavier of tort in the circumstances of this case?

[12] In my view the plaintiffs' revised common issue does not raise any issue of quantification and addresses my concerns with respect to the complexities of that question. Their proposal addresses two potential remedies and therefor is more focused than the general question suggested by the defendants. In my view it is the preferable approach to the issue.

[13] Having considered the supplemental evidence and submissions of both parties I am prepared to certify this proceeding as a class proceeding based upon the plaintiffs' revised list of common issues. As indicated in paragraph 110 in my initial certification decision, I expect to receive a revised litigation plan from the plaintiffs and will accept further submissions from counsel if there is any dispute with respect to that document.

Wood, J.

Form 59.09

2009 Hfx No. 315567

This is Exhibit "H" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

4823-1860-7833, v. 15

2016 C.A. No. 458702

NOVA SCOTIA COURT OF APPEAL

Between

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Appellants

- and -

ALBERT CARL SWEETLAND and MARY PATRICIA ADDICOTT-ANDREWS

Respondents

NOVA SCOTIA COURT OF APPEAL

CONSENT ORDER

BEFORE THE HONOURABLE JUSTICE DAVID P.S. FARRAR IN CHAMBERS

WHEREAS the Appellants filed a Notice of Application for Leave to Appeal and Notice of Appeal (Interlocutory) on December 22, 2016, a true copy of which is attached hereto as Schedule "A";

AND WHEREAS pursuant to section 39 of the *Class Proceedings Act*, SNS 2007, c. 28, a single judge of the Court of Appeal must grant leave to appeal;

AND WHEREAS the parties consent to leave to appeal being granted, as evidenced by the signatures of their counsel below;

On the motion of the Appellants, the following is therefore and hereby ORDERED:

1. Leave to appeal is granted, pursuant to section 39 of the *Class Proceedings Act*. The appeal will proceed on the grounds of appeal as set out in Schedule "A" to this Consent Order.

Issued January 27, 2017

REGISTRAR

Caroline McInnes
Registrar

CONSENTED TO:

Mary M. Thomson
Co-counsel for the Appellants

Scott R. Campbell
Co-counsel for the Appellants

M. Carter (Maddy Carter)
Per: Raymond F. Wagner, Q.C.
Counsel for the Respondents

IN THE NOVA SCOTIA COURT
I hereby certify that the foregoing is a true copy of the original order in the
Dated at Halifax, this 27th day of January
A.D., 2017

Caroline McInnes
Registrar

SCHEDULE "A"

REGISTRAR
Nova Scotia Court of Appeal
DEC 22 2016
HALIFAX, N.S.

Form 90.09

2016 C.A. No. 458702

NOVA SCOTIA COURT OF APPEAL

Between:

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

Appellants

- and -

ALBERT CARL SWEETLAND and MARY PATRICIA ADDICOTT-ANDREWS

Respondents

NOTICE OF APPLICATION FOR LEAVE TO APPEAL AND NOTICE OF APPEAL (INTERLOCUTORY)

To: The Respondents
c/o Raymond F. Wagner, Q.C.
Wagners
3rd Floor - 1869 Upper Water Street
Halifax, NS B3J 2V2

Appellants appeal

The Appellants apply for leave to appeal and, if granted, will appeal from the Certification Order dated December 7, 2016 in the proceedings in the Supreme Court of Nova Scotia showing court number Hfx No. 315567 and granted by the Honourable Justice Michael J. Wood.

Order or decision appealed from

The Order was made on December 7, 2016. It was made at Halifax, Nova Scotia.

Grounds of appeal

The grounds of appeal are:

1. GlaxoSmithKline Inc. and GlaxoSmithKline LLC are defendants in a class proceeding certified by the Honourable Justice Wood with respect to the pharmaceutical product, Avandia, a drug used in the treatment of diabetes. Having diabetes increases a person's risk of heart disease and stroke.

2. In order for a case to be certified as a class proceeding, the judge determining the motion must find that the statutory criteria for certification are met. In the circumstances of a class action based in negligence, there must be a rational relationship among the essential elements of harm and causation, class definition and the common issues proposed. There must be an objectively identifiable class of two or more persons with common complaints, as well as a rational connection between a proper class definition and the proposed common issues.

3. In the case at bar, the requisite threshold for certification is not met. As detailed below, the Learned Chambers Judge committed reviewable errors in certifying a class proceeding pursuant to section 7(1) of the *Class Proceedings Act*, SNS 2007, c. 28 (the "***Act***").

Identifiable Class

4. In the case at bar, the Learned Chambers Judge certified identifiable classes, pursuant to section 7(1)(b) of the *Act*, as follows:

   (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and

   (b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

5. The Learned Chambers Judge erred in certifying classes that include persons with no claim in negligence against the defendants. The Primary Class definition includes those who were helped, not harmed, by taking Avandia and who therefore can have no cause of action against the defendants as well as those who developed heart disease and stroke as a result of the expected progression of the disease.

6. The proposed Primary Class and its related Family Class are impermissibly broad. The requirement for an objectively established connection between the class and the alleged claims is not met when the class contains those who have benefitted from taking the drug. Moreover, the class definition fails to meet the requirement of the Supreme Court of Canada in *Sun-Rype Products Ltd. v Archer Daniels Midland Company*, 2013 SCC 58 of an objective means of self-determination of membership in the class.

Common Issues (Negligence)

7. The Learned Chambers Judge certified common issues for determination in this class proceeding, the resolution of which will bind the Class Members, as follows:

   1. (a) Can AVANDIA cause or contribute to heart failure? If so, what is the magnitude of this increased risk?

      (b) Can AVANDIA cause or contribute to heart attacks? If so, what is the magnitude of this increased risk?

      (c) Can AVANDIA cause or contribute to strokes? If so, what is the magnitude of this increased risk?

   2. (a) If the answer to (1)(a) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart failure? If so, when?

      (b) If the answer to (1)(b) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of heart attack? If so, when?

      (c) If the answer to (1)(c) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA about the risk of stroke? If so, when?

   3. (a) If the answer to (1)(a) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart failure?

      (b) If the answer to (1)(b) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of heart attack?

      (c) If the answer to (1)(c) is yes, was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, due to the risk of stroke?

8. The Learned Chambers Judge committed reviewable errors by linking the proposed common issues to specific harm-based findings (heart failure, heart attack and stroke) without enunciating how the answer to these common issues could be applied to the Primary Class comprised of "all persons . . . who were prescribed and ingested Avandia".

9. The Learned Chambers Judge committed further reviewable errors by failing to require that the plaintiffs demonstrate the existence of a "credible or plausible" methodology for proving causation on a class-wide basis as discussed by the Supreme Court of Canada in *Pro-Sys Consultants v Microsoft Corporation*, 2013 SCC 57.

10. The Learned Chambers Judge compounded this error by failing to address that the question of causation for the class was incapable of resolution and that, while causation may ground an action in negligence, a mere association between two events cannot.

11. The Learned Chambers Judge thereby erred by certifying individual issues as common issues and by certifying common issues not supported by the minimum threshold of evidence required by section 7(1)(c) of the *Act* and the Supreme Court of Canada.

12. The cumulative effect of these errors was to certify an overly broad class that contains members, who:

    (a) have no cause of action against the defendants;

    (b) have failed to establish an evidentiary basis for their interest in resolution of the common issues; and

    (c) have failed to produce the requisite "credible or plausible methodology" for proving causation in this litigation.

Common Issues (Enterprise Liability)

13. The Learned Chambers Judge also certified "enterprise liability" as common issue 4, as below. In so doing, he committed a reviewable error.

    4. Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?

14. The Learned Chambers Judge permitted the plaintiffs to "lump together" the defendants as one entity. In endorsing this as a common issue, the Learned Chambers Judge committed a reviewable error. He failed to hold the plaintiffs to the required evidentiary threshold: the requirement to lead evidence that the defendants were either a shield or an alter ego of one another for a fraudulent or improper purpose. In so doing, he failed to apply the requirement that the plaintiffs show "some basis in fact" in seeking certification of this common issue.

Common Issues (Unjust Enrichment/Waiver of Tort)

15. Lastly, the Learned Chambers Judge certified "unjust enrichment and/or waiver of tort" as common issue 5, as below. In so doing, he committed a reviewable error.

    5. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:

       (a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,

       (b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?

16. The Learned Chambers Judge erred in certifying Common Issue 5 insofar as the appropriateness and availability of restitutionary relief should have been addressed at the certification stage. It was in the interests of the judiciary and all parties that the matter be ruled on directly at the early stage of the litigation.

Preferable Procedure

17. Having regard for the above-described required relationship among the cause of action in negligence, the class definition and the common issues certified, the Learned Chambers Judge committed reviewable errors in concluding that a class proceeding would be the preferable procedure for the fair and efficient resolution of the dispute, as required by section 7(1)(d) of the *Act*. The individual elements of causation necessary to the resolution of each class member's claim will dominate the litigation.

18. Section 7(2) of the *Act* describes the considerations that the Court must weigh when addressing whether a class proceeding is the preferable procedure in any particular case. This includes whether "the questions of fact or law common to the class members predominate over any questions affecting only individual members". By failing to provide necessary analysis of how this criteria was applied to the gap between the Primary Class, as defined, and the Common Issues in negligence, the Learned Chambers Judge erred in his interpretation of mandatory criteria, creating a reversible error.

Representative Plaintiffs

19. The Learned Chambers Judge committed reviewable errors in finding that the putative representative plaintiffs could fairly and adequately represent the interests of the class.

20. At first instance, the representative plaintiff failed to provide evidence of "two or more" members of the identifiable class. This failure showed deficiency at a fundamental level with respect to the adequacy of the representative plaintiffs.

21. By bifurcating the hearing, allowing the filing of additional evidence for which no "testing" was permitted and then, by providing further Reasons on the criteria of identifiable class, the Learned Chambers Judge committed further reviewable error.

22. The Learned Chambers Judge erred by directing how that fundamental flaw should be remedied rather than by finding that, six years after the litigation had been commenced in Nova Scotia, the representative plaintiffs had failed to put forward "some basis in fact" of an identifiable class. Rather than examining how this omission reflected on the adequacy of the representative plaintiffs in acting in the interests of the class, the Learned Chambers Judge reset the evidence. Without the opportunity to test this evidence through cross-examination, the adequacy of the representative plaintiffs on the point in issue was left unexplored.

23. The combination of these events has led to reviewable errors on the part of the Learned Chambers Judge.

24. Such further and other grounds as counsel may advise and this Honourable Court may permit.

Authority for appeal

1. Section 7(1) and (2) of the *Class Proceedings Act*.
2. Section 39 of the *Class Proceedings Act*.
3. Sections 38 – 40 of the *Judicature Act*, RSNS 1989, c. 240, as am.
4. Rule 90 of the *Nova Scotia Civil Procedure Rules*.
5. *Sun-Rype Products Ltd. v Archer Daniels Midland Company*, 2013 SCC 58
6. *Pro-Sys Consultants v Microsoft Corporation*, 2013 SCC 57

Order Requested

The Appellants say that the Court of Appeal should allow the appeal and that the Certification Order appealed from should be reversed so to: (a) dismiss the Respondents' motion for certification of this action as a class proceeding; and (b) grant the Appellants their costs on the motion below. The Appellants also seek an award of costs on the appeal.

Motion for Date and Directions

The application for leave to appeal (and if leave is granted, the appeal itself) will be heard on a date to be set by a judge. The Appellants will ask a judge of the Court of Appeal to set the date and give directions for hearing of the application for leave to appeal on Thursday, January 12, 2017 at 10:00 a.m. at The Law Courts, 1815 Upper Water Street, Halifax, Nova Scotia. You have the right to be present or represented by counsel. If you are not present or represented, the judge may proceed without you.

Contact information

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Signed Dec. 22, 2016

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Registrar's Certificate

I certify that this Notice of Application for Leave to Appeal and Notice of Appeal (Interlocutory) was filed with the Court on December 22nd, 2016

A.E. ANSELM
Deputy Registrar

Form 31.05

2009 Hfx No. 315567

This is Exhibit "C" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme Court of Nova Scotia

4813-1686-7855, v. 15

2016 C.A. No. 458702

NOVA SCOTIA COURT OF APPEAL

Between:

GLAXOSMITHKLINE INC. and **GLAXOSMITHKLINE LLC**

Appellants

- and -

ALBERT CARL SWEETLAND and **MARY PATRICIA ADDICOTT-ANDREWS**

Respondents

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PART 1 – CONCISE OVERVIEW OF APPEAL

1. GlaxoSmithKline ("GSK") makes and distributes a drug used in the treatment of diabetes, "Avandia". The vast majority of patients using Avandia received long-term benefits from the drug.

2. A motion for certification of a class of "all persons . . . who were prescribed and ingested Avandia" was initially refused pending delivery of further and better evidence relating to the proposed "identifiable class" and revised common issues.

3. In a decision subsequent to the filing of additional evidence, the Chambers Judge certified the action as a class proceeding pursuant to the Nova Scotia *Class Proceedings Act*.[1] This is an appeal from the resulting Certification Order.

4. The Appellants submit that the Chambers Judge erred in certifying this action as a class proceeding for four principal reasons:

   (a) By certifying a primary class of "all users", the Chambers Judge failed to ensure that a "rational relationship" existed between the essential elements of the cause of action, the class definition, and approved common issues proposed. An "all users" class of Avandia would be comprised almost entirely of persons who have suffered no harm and for whom there can be no cause of action. The Chambers Judge compounded his error by incongruously specifying harm-based common issues regarding heart failure, heart attack, and stroke.

   (b) The Chambers Judge failed to require the Plaintiffs to demonstrate a "credible or plausible" methodology for proving general causation questions on a class-wide

[1] *Class Proceedings Act*, SNS 2007, c. 28.

   (ii) The question of whether Avandia "can contribute to" heart failure, heart attack, or stroke is not a relevant legal issue in this case because of the "but for" standard mandated by the Supreme Court of Canada, particularly in circumstances where the very disease itself for which Avandia was prescribed causes heart failure, heart attack, and stroke. There is no evidence on the motion record of a methodology to tease out whether an individual patient's heart failure, heart attack, or stroke was caused by Avandia or by their underlying disease.

   (d) The Chambers Judge, some six years after the action was initially brought and after a three and a half day hearing on certification, called on the Plaintiffs to file additional evidence to establish an identifiable class: (i) without allowing that evidence to be tested by the Appellants; (ii) without commenting on the previous (in)adequacy of the proposed Representative Plaintiffs; and (iii) without addressing the fundamental flaw that the Plaintiffs had not met the burden of "some basis in fact" regarding four of the criteria for class certification.

5. Finally, the Chambers Judge committed reviewable errors: (i) in certifying certain other common issues; (ii) in finding that a class proceeding is the preferable procedure for resolution of this dispute, particularly given the lack of any meaningful advance of the case arising from the questions of general causation as certified; and (iii) in concluding that the Representative Plaintiffs can properly represent the interests of the class.

6. Alone, and in combination, these errors require the review and intervention by this Honourable Court.

7. The Appellants therefore seek an order allowing the appeal, reversing the Certification Order, and dismissing the Plaintiffs' motion for certification. The Appellants also seek their costs on this appeal, and on the motion below.

PART 2 – CONCISE STATEMENT OF FACTS

(A) Facts

8. This litigation involves allegations of heart failure, heart attack, and stroke related to three related drugs used in the treatment of Type 2 diabetes: Avandia, Avandamet, and Avandaryl. In this Factum, all three of these drugs will be referred to as "**Avandia**." The Plaintiffs' expert agreed that Avandia is a "very effective" drug for controlling patients' blood sugar.[3]

9. The Plaintiffs allege that Avandia causes or increases the risk of heart failure, heart attack, or stroke. They bring this case by way of personal injury claims against the Appellants, alleging negligent design, development and testing of Avandia as well as negligent distribution of the drug. Lastly, they allege that there were inadequate warnings about the potential side effects of Avandia.

10. Diabetes, on its own, is a significant risk factor for adverse cardiovascular events. People with Type 2 diabetes are at a very high risk for heart disease, with 80% of diabetics having a cardiovascular complication. Indeed, Type 2 diabetes is a cardiovascular risk equivalent, meaning that the risk of having a heart attack in a patient with diabetes is the same risk as in someone who has already had a heart attack.[4]

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[3] Transcript of Cross-Examination of Dr. Lipscombe at pages 94-95 [Appeal Book, Volume 2, Tab 18].
[4] Affidavit of Dr. Tina Kader at para 23 [Appeal Book, Volume 3, Tab 26].

11. Notably, there are a variety of other risk factors, including hypertension, smoking, obesity, physical inactivity, diet, sleep apnea, alcohol consumption, age, and family history that can contribute to an individual suffering a cardiovascular event. Each patient presents a unique medical profile, often with multiple overlapping cardiovascular risk factors. Therefore, determining the cause of a cardiovascular event in an individual patient will be unique to that specific patient and will always require individual enquiry.

12. Any treatment decision including the prescribing of Avandia is a unique one made between the patient and his or her physician. All drugs carry risks and potential adverse effects. Physicians act as "learned intermediaries", reviewing information about the benefits and potential risks of medications. Physicians relay pertinent information regarding medications to patients and together, the physician and patient choose the right treatment plan specific to that patient.

13. Avandia was approved by Health Canada on March 21, 2000 (approval for Avandamet was received on February 13, 2003 and Avandaryl on October 21, 2004). The product monograph for Avandia has been revised from time to time to reflect new scientific data about the drugs, including changes in the Appellants' knowledge of the product's risks and benefits.

14. In 2007, an alleged "signal" of increased risk of heart attack with Avandia was raised in the medical literature. A researcher reviewed and reported on a number of mostly short-term trials not designed to assess the risk of heart attack. After publication of his study, litigation and regulatory review began. Further study was recommended and completed. It concluded that there is no elevated risk of heart attack or other major adverse

cardiovascular events in patients treated with Avandia when compared to standard-of-care drugs.[5]

15. The claims of the Representative Plaintiffs for the "primary" class and the "family" class are based on the alleged experiences of two individuals who were prescribed Avandia, neither of who suffered a cardiovascular event while taking Avandia.

(a) Albert Sweetland (representative plaintiff for the "primary" class) never suffered a heart attack. His alleged injury is an episode of congestive heart failure, which occurred 9 months after he last took Avandia. Medical records show that his congestive heart failure was caused by constrictive pericarditis, an unrelated illness.[6] In any event, the product monograph warned that congestive heart failure was a potential adverse effect of taking Avandia.

(b) Mary Agnes Addicott (mother of Mary Patricia Addicott-Andrews, representative plaintiff for the "family class") had a heart attack before she took Avandia and another heart attack at the age of 74, two years after she stopped taking Avandia. Mrs. Addicott's diabetes was poorly controlled. She had suffered from multiple diseases and complications for years.[7]

(B) The Motion and Decisions Below

The January 15, 2016 Decision

16. The motion for certification of this action came before the Chambers Judge twice.

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[5] Exhibits "C" & "D" to the Affidavit of Roslyn Theodore-McIntosh [Appeal Book, Volume 3, Tab 28].
[6] Affidavit of Dr. Brian Gilbert at paras 56-58 [Appeal Book, Volume 3, Tab 24].
[7] Affidavit of Dr. Brian Gilbert at paras 60-66 [Appeal Book, Volume 3, Tab 24].

17. In the first instance, the Chambers Judge reviewed the evidence and found, as follows, with respect to the criteria for certification found in s. 7(1) of the *Class Proceedings Act*.

18. **Cause of action**: Prior to the motion for certification, the Appellants conceded that the pleadings disclosed causes of action in negligent design, development and testing, and negligent distribution and marketing.

(a) Regarding the pleading of "waiver of tort", the Chambers Judge agreed with the approach taken in *Heward v Eli Lilly & Co*,[8] and permitted waiver of tort to proceed as a cause of action. He concluded: "I am not prepared to dismiss the possibility of compensation based upon waiver of tort at this stage. Nor am I foreclosing the defendants from arguing that it is not a stand-alone cause of action and is only remedial in nature."[9]

(b) With respect to the "enterprise liability" of the Appellants, the Chambers Judge referred to *Durling v Sunrise Propane Energy Group*,[10] in which the court struck out a claim based on agency. He concluded that "the Statement of Claim in this case includes more detail [than in *Durling*] in support of the allegations of enterprise liability. The [Appellants'] submissions have not satisfied me that this portion of the pleading should be struck out because the plaintiffs' claims cannot succeed."[11]

19. **Identifiable Class of Two or More Persons:** The Chambers Judge identified the "primary" and "family" classes as proposed by the Plaintiffs. He rejected the Appellants'

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[8] *Heward v Eli Lilly & Co*, [2007] OJ No 404 (Ont Sup Ct) [Tab 11 of the Appellants' Authorities].
[9] Certification Decision, para 29 [Appeal Book, Volume 1, Tab 4].
[10] *Durling v Sunrise Propane Energy Group Inc*, 2012 ONSC 4196 [Tab 9 of the Appellants' Authorities].
[11] Certification Decision, para 29 [Appeal Book, Volume 1, Tab 4].

argument that the proposed definitions were overly broad and should be limited to those persons who allege harm while taking Avandia.[12] The Chambers Judge observed:

> The [Appellants] argue the proposed class definition is too broad and it should be limited to those persons who suffer a specified adverse consequence from taking AVANDIA. I do not accept [the Appellants'] proposition. According to the expert evidence there are a range of cardiovascular complications which may arise in patients with diabetes and which might be caused or contributed to by AVANDIA. Some appear to be progressive in nature and become increasingly more problematic over time. The medical histories of the two representative plaintiffs are illustrative of that point.
>
> ...
>
> This is no requirement that all members of the proposed class ultimately have a claim against the defendant.[13]

20. The Chambers Judge nonetheless went on to find that the Plaintiffs had failed to establish "some basis in fact" that there were two or more members of each class interested in pursuing their claims as a class proceeding. Accordingly, he concluded that the certification requirement in s. 7(1)(b) had not been met.[14]

21. **Common Issues:** The Chambers Judge set out the principles of law applicable to the definition of common issues and observed:

> It is incumbent on the party seeking certification to identify and draft the common issues which they believe should be certified. These issues represent the questions that the court will be asked to decide at the common issues trial. The judge hearing the certification motion has jurisdiction to amend or modify the common issues however they should rarely do so. It is for the party seeking

[12] The Appellants argue that the class definition should be limited to those who suffered an adverse event "while" taking Avandia, not who suffered "from" taking Avandia. The class definition posited by the Appellants do not seek to determine causality as part of the definition (which would include a prohibited "claims limiter") but rather sought to focus the class definition of those who had an adverse cardiovascular event while taking Avandia, causality to be addressed at a later date on an individual basis. Avandia, as noted, provided benefit to the vast majority of users and remains available to prescribing physicians today. Notably, the Family Class is derivative of the Primary Class and will therefore fail if the Primary Class fails.

[13] Certification Decision, paras 35 and 38 [Appeal Book, Volume 1, Tab 4].

[14] Certification Decision, para 46 [Appeal Book, Volume 1, Tab 4].

> certification to define the case which they believe meets the necessary criteria and not for the court to anticipate how the matter should be framed to better accord with the *Act*. In my view it would be analogous to the court amending pleadings on its own motion in order to better set out a cause of action or defence.
>
> If I conclude that any of the plaintiffs' suggested common issues should not be certified I will not offer specific suggestions about how those deficiencies might be corrected unless the amendment is minimal and does not change the essential character of the proposed common issue.[15]

22. The Chambers Judge then considered each of the common issues proposed by the Plaintiffs on the certification motion:

> 1. *Can AVANDIA cause, or contribute to, adverse cardiovascular events including heart failure, heart attacks, and strokes? If so, what is the magnitude of this increased risk?*

23. The Chambers Judge observed that proposed common issue 1 was presented as a general causation question, that "the plaintiff's use of the phrase 'adverse cardiovascular events' is problematic",[16] and that "[a]pproving a common issue that is based on adverse cardiovascular events leaves too much uncertainty about what might be included".[17] The Chambers Judge nonetheless indicated that he would certify this common issue if the phrase "adverse cardiovascular events" was excluded and the issue were divided into three separate questions relating specifically to heart failure, heart attack, and stroke.[18]

> 2. *If the answer to (1) is yes, did any of the Defendants breach a duty to warn the users of AVANDIA? If so, when?*

[15] Certification Decision, paras 50-51 [Appeal Book, Volume 1, Tab 4].

[16] Certification Decision, para 60 [Appeal Book, Volume 1, Tab 4].

[17] Certification Decision, para 61 [Appeal Book, Volume 1, Tab 4].

[18] Certification Decision, paras 61-63 [Appeal Book, Volume 1, Tab 4].

24. The Chambers Judge expressed concern, citing *Martin v Astrazeneca Pharmaceuticals PLC*,[19] that the duty to warn could not proceed as a common issue as it may not be possible to express it as a single question for the entire class. Nevertheless, he indicated that he would certify the issue if it were divided into three separate questions relating to heart failure, heart attack, and stroke as with proposed common issue 1.[20]

> 3. *Was AVANDIA defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Defendants? If so, in what way or ways was AVANDIA defective or unfit?*

25. With respect to proposed issue 3, the Chambers Judge noted that while a class-wide answer to the question might not be possible, he was prepared to certify a less broadly stated version of this proposed common issue.[21]

> 4. *Did the Defendants breach a duty of care owed to class members by designing, developing, fabricating, manufacturing, selling, importing, distributing, marketing or otherwise placing AVANDIA into the stream of commerce in Canada?*

26. The Chambers Judge indicated that proposed issue 4 was "extremely broad" and that he was not prepared to certify it as a common issue.[22]

> 5. *Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?*

[19] *Martin v AstraZeneca Pharmaceuticals PLC*, 2012 ONSC 2744, *aff'd* 2013 ONSC 1169 (Div Ct) [Tab 13 of the Appellants' Authorities].

[20] Certification Decision, para 71 [Appeal Book, Volume 1, Tab 4].

[21] Certification Decision, paras 74-75 [Appeal Book, Volume 1, Tab 4].

[22] Certification Decision, paras 76, 80 [Appeal Book, Volume 1, Tab 4].

27. The Chambers Judge indicated that proposed issue 5 "does not require any consideration of the circumstances of individual class members", that "[i]t can readily be decided on a class-wide basis", and that "[t]he answer will assist the individual class members because it will determine whether either or both of the defendants are responsible for any damages which might be awarded". This issue could be certified.[23]

> 6. *By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:*
>
> *(a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? If so, in what amount and for whose benefit is such accounting to be made? Or, in the alternative,*
>
> *(b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims, and, if so, in what amount, and for whom are such proceeds held?*

28. The Chambers Judge noted, "[t]here is considerable judicial debate as to whether waiver of tort requires proof of wrongdoing before compensation can be awarded", referring to *Pro-Sys Consultants Ltd v Microsoft Corporation*.[24] Noting the difficulty of answering this question in common, the Chambers Judge observed:

> Claims for restitutionary remedies based upon unjust enrichment require a determination of whether the defendants were enriched to the deprivation of the plaintiffs, and if so, to what extent. In the circumstances of this class proceeding the calculation of enrichment and deprivation would be a massive undertaking. It would necessitate disclosure of financial records over a period in excess of fifteen years which would have to be interpreted by expert witnesses. It is obvious to me that the availability of a restitutionary remedy such as proposed by this common issue is very much a live question. Rather than burden the common issues trial with the

[23] Certification Decision, para 81 [Appeal Book, Volume 1, Tab 4].

[24] Certification Decision, para 82 [Appeal Book, Volume 1, Tab 4]; *Pro-Sys*, *supra* at paras 93-97 [Tab 17 of the Appellants' Authorities].

> additional complexities arising out of the quantification issues I believe the most efficient approach is to ask the general question as to whether relief based on unjust enrichment or waiver of tort is even available to class members.
>
> In my view, this common issue should be amended to remove any reference to quantification....[25]

29. The Chambers Judge held that he would certify this issue following its redrafting to remove references to quantification of remedy, which might require individual assessments.[26]

> 7. *Are Class Members entitled to recover the medical costs incurred in the screening, diagnosis and treatment of adverse cardiovascular events caused by taking AVANDIA?*
>
> 8. *Are Class Members entitled to recover as damages an amount equal to the purchase price of AVANDIA, or part of the purchase price of AVANDIA? If so, why and in what amount?*

30. The Chambers Judge refused to certify proposed issues 7 and 8, observing that "these common issues raise questions of individual damages. The Plaintiffs have provided no evidence to show these questions can be decided on a class-wide basis."[27]

> 9. *Can damages of Class Members be determined, in whole or in part, on an aggregate basis? If so, who should pay what amount, to whom and why?*

31. The Chambers Judge refused to certify proposed issue 9, noting that s. 32 of the *Class Proceedings Act* "makes it clear that the question of aggregate damages can only be made following a finding of liability and after hearing further submissions from the defendant"; accordingly, "it is premature to consider certifying aggregate damages as a common issue at this stage".[28]

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[25] Certification Decision, paras 83-84 [Appeal Book, Volume 1, Tab 4].
[26] Certification Decision, paras 85-86 [Appeal Book, Volume 1, Tab 4].
[27] Certification Decision, para 87 [Appeal Book, Volume 1, Tab 4].
[28] Certification Decision, para 91 [Appeal Book, Volume 1, Tab 4].

> 10. *Should one or more of the Defendants pay punitive damages? Should punitive damages be assessed in the aggregate? If so, in what amount and how should punitive damages be distributed?*

32. The Chambers Judge refused to certify proposed issue 10, noting that "[i]n order to make such an award the court must first find the defendant liable to the plaintiff on the basis of a cause of action asserted in the statement of claim.... Here the defendants will not be liable to the plaintiffs until proof of individual loss following the common issues trial".[29]

> 11. *Should the Defendants, or any of them, pay prejudgment and post-judgment interest, at what annual interest rate, and should the interest be compound interest?*
>
> 12. *Should the Defendants, or any of them, pay the cost of administering and distributing any monetary judgment and/or the cost of determining eligibility and/or the individual issues? If so, who should pay what cost, why, in what amount and to what extent?*

33. The Chambers Judge refused to certify proposed issues 11 and 12, finding that they "represent matters which can only be decided once it has been determined whether there will be a monetary award, on what basis, and to whom. This will be decided once individual class members have proven their damages".[30]

34. **Preferable Procedure:** The Chambers Judge determined that a class action was the preferable procedure in this case, and rejected the Appellants' alternative suggestion of case-managed individual actions with common discovery and coordinated trials. He wrote:

> I am satisfied the revised common issues can be managed and decided in a common issues trial. Based upon the certification record and the defendants' response, it appears the questions with respect to the alleged risks associated with AVANDIA can be addressed through expert testimony. The issue of what risks should have been disclosed and when will also involve expert evidence and inquiry into the defendants' state of knowledge during

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[29] Certification Decision, paras 93-94 [Appeal Book, Volume 1, Tab 4].
[30] Certification Decision, para 97 [Appeal Book, Volume 1, Tab 4].

> the period when the medication was marketed and distributed in Canada. These issues, as well, lend themselves to resolution in a common trial.
>
> The defendants' opposition to certification is premised on the argument that the determination of cardiovascular risk will not significantly advance the claims of class members because individual proof of causation is needed. They also argue that such proof is virtually impossible to obtain because AVANDIA recipients are at inherently higher risk of cardiovascular compromise. The cross-examinations of the plaintiffs' experts include comments suggesting that individual causation may be very difficult to prove. Problems with causation will exist whether class members pursue individual law suits or a class proceeding. As a result, it should not be a basis on which certification is refused. Even if the common issue trial is relatively short and the individual proof of damage extensive, that does not mean there is no efficiency to be gained by an answer in common to the questions of risk, breach of duty, joint liability and restitution.[31]

35. **Appropriate Representative Party and Litigation Plan:** The Chambers Judge observed that the affidavits filed by each of the two proposed representative Plaintiffs "satisfy the basic requirements of the [*Class Proceedings*] *Act*".[32] The Chambers Judge further observed that the Litigation Plan as filed was "very general in nature", that it would have to be amended given his reasons, and that he would expect to receive a revised plan and further submissions from counsel.[33]

36. Given his initial reasons, the Chambers Judge concluded by refusing to certify the action as a class proceeding, however, he commented that "[t]he plaintiffs may be able to remedy the problems which I have identified and, in the interests of fairness, I have concluded that I should give them an opportunity to do so".[34]

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[31] Certification Decision, paras 101-02 [Appeal Book, Volume 1, Tab 4].
[32] Certification Decision, para 109 [Appeal Book, Volume 1, Tab 4].
[33] Certification Decision, para 110 [Appeal Book, Volume 1, Tab 4].
[34] Certification Decision, para 111 [Appeal Book, Volume 1, Tab 4].

37. The Chambers Judge then permitted the Plaintiffs to supplement their evidence relating to the "two or more class members" requirement, to file a revised list of common issues and to file further written submissions. He permitted the Appellants to file evidence and submissions in response.[35]

The June 1, 2016 Decision

38. The Plaintiffs subsequently filed five additional affidavits and a revised list of common issues. This ultimately led to certification by the Chambers Judge of this action as a class proceeding.[36] The Appellants filed supplemental responding submissions noting that the Plaintiffs' additional affidavits contained improper and unnecessary evidence, went beyond the direction of the Chambers Judge and were prejudicial to the Appellants. The Appellants asked that the affidavits be removed from the supplemental motion record or, in the alternative, that certain affiants be required to provide medical evidence in support of their allegations following which the Appellants, at their election, should be allowed to test the evidence through cross-examination.

39. The Chambers Judge informed counsel that he would ignore parts of four affidavits and completely disregard the fifth. He rejected the Appellants' request that the additional affiants produce medical histories in support of the allegations that they suffered cardiovascular problems.[37] He did not acknowledge or respond to the Appellants' corresponding request for cross-examination of the affiants.[38] He did not order that the additional affidavits be removed from the motion record.

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[35] Certification Decision, para 112 [Appeal Book, Volume 1, Tab 4].
[36] Supplemental Certification Decision, para 13 [Appeal Book, Volume 1, Tab 5].
[37] Supplemental Certification Decision, para 9 [Appeal Book, Volume 1, Tab 5].
[38] See Appeal Book, Volume 5, Tab 37, pages 2332-33.

40. The Chambers Judge concluded that "the evidence provided by the plaintiffs remedies the deficiencies noted in the initial certification decision and they have provided some evidence to establish the existence of two or more members of each class".[39] He also accepted that the action could be certified based on the Plaintiffs' revised list of common issues although he dealt specifically only with revised proposed issue 5, which read as follows:

> 5. *By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:*
>
> *(a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,*
>
> *(b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?*

41. In rejecting the Appellants' argument that the revised issue still raised quantification issues, the Chambers Judge held that "the plaintiffs' revised common issue does not raise any issue of quantification and addresses my concerns with respect to the complexities of that question. Their proposal addresses two potential remedies and therefore is more focused than the general question suggested by the defendants. In my view it is the preferable approach to the issue."[40]

[39] Supplemental Certification Decision, paras 5-6, 8 [Appeal Book, Volume 1, Tab 5].
[40] Supplemental Certification Decision, para 12 [Appeal Book, Volume 1, Tab 5].

The Litigation Plan and Certification Order

42. The parties subsequently submitted their respective positions on the terms of the Litigation Plan and certain other matters.[41] Following a Case Management Conference for directions held on November 24, 2016, the Chambers Judge issued an Order dated December 7, 2016, certifying this action as a class proceeding under the *Class Proceedings Act* (the "**Certification Order**").[42]

43. Leave to appeal was granted by Consent Order dated January 27, 2017 as required by s. 39(3)(a) of the *Class Proceedings Act*.[43]

PART 3 – LIST OF ISSUES

44. This appeal raises the following issues:

(a) Did the Chambers Judge err in certifying an impermissibly broad class that is comprised almost entirely of individuals with no claim in negligence?

(b) Did the Chambers Judge err in failing to require the Plaintiffs to demonstrate a "credible or plausible methodology" to prove the general causation question on a class-wide basis and did the Chambers Judge err in failing to hold the Plaintiffs to the requisite evidential threshold on general causation?

(c) Did the Chambers Judge err in certifying "enterprise liability" as a common issue?

[41] Appeal Book, Volume 5, Tabs 38 and 39.
[42] Appeal Book, Volume 1, Tab 3.
[43] Appeal Book, Volume 1, Tab 2.

(d) Did the Chambers Judge err in certifying "unjust enrichment and/or waiver of tort" as a common issue instead of addressing the appropriateness and availability of restitutionary relief at the certification stage?

(e) Did the Chambers Judge err in finding that a class action was the preferable procedure for the fair and efficient resolution of the dispute when individual issues would overwhelm any possible common issues and where case-management alternatives exist?

(f) Did the Chambers Judge err in finding that the putative representative Plaintiffs could fairly and adequately represent the interests of the class, where there is no evidence that Avandia caused harm to either of them?

PART 4 – STANDARD OF REVIEW FOR EACH ISSUE

45. The Supreme Court of Canada has determined that issues of law are reviewable on a standard of correctness whereas issues of mixed fact and law are only reviewable for correctness if the trial judge has committed an extricable error of law or principle; examples of extricable errors include "the application of an incorrect standard, a failure to consider a required element of a legal test, or similar error in principle".[44]

46. The governing standard of review for a certification motion in a class proceeding in Nova Scotia was clearly set out by this Court in *Canada (Attorney General) v MacQueen* as follows:

> [111] Whether a common issue exists and whether a class action is the preferable procedure for the fair and efficient resolution of the dispute are questions of mixed fact and law. **These questions are subject to a standard of review of palpable and overriding error unless the certification judge made some extricable error in principle with respect to the characterization of the standard or its application in which case it is an error of law reviewable on the standard of correctness.**[45] [emphasis added]

[44] *Housen v Nikolaisen*, 2002 SCC 33 at paras 8, 31, 33, 36.

PART 5 – ARGUMENT

(A) Issue One: Impermissibly Broad Classes

47. The Chambers Judge erred in certifying impermissibly broad classes; namely:

(a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "**Primary Class**"); and

(b) The spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "**Family Class**").

48. The Appellants submit that the Chambers Judge erred in certifying classes that include persons with no claim in negligence against the Appellants. Harm is an essential element of negligence. The Primary Class definition includes those who were helped, not harmed, by taking Avandia and those who therefore can have no cause of action against the Appellants. It also includes those who developed heart disease and stroke as a result of the expected progression of their diabetes.

49. By adopting a broad class definition encompassing "All persons in Canada ... who were prescribed and ingested Avandia", the Chambers Judge disregarded the requirement that

[45] *Canada (Attorney General) v MacQueen*, 2013 NSCA 143 [Tab 5 of the Appellants' Authorities]. See also: *Wright Medical Technology Canada v Taylor*, 2015 NSCA 68 at paras 30-32 [Tab 27 of the Appellants' Authorities]; and *Capital District Health Authority v Murray*, 2017 NSCA 28 at paras 26-27 [Tab 6 of the Appellants' Authorities].

a "rational relationship" be established among the required criteria for class certification.[46] The Chambers Judge's decision further disregarded the principle from *Hollick v Toronto (City)* that "[t]here must be some showing ... that the class is not unnecessarily broad – that is, that the class could not be defined more narrowly without arbitrarily excluding some people who share the same interest in the resolution of the common issue."[47]

50. The line of authority characterized by *Frohlinger v Nortel Networks Corp.* has similarly cautioned that a class definition cannot be assessed without considering how the requirements for class certification work together:

> Over-inclusive class definitions can be avoided ... by adherence to the concept that the core of a class proceeding is the element of commonality. **It is implicit in that concept that the cause of action, the scope of the class and the common issues are inextricably inter-related.** Indeed, the first three criteria for certification as a class proceeding ... may be stated in a single sentence as follows: There must be a cause of action, shared by an identifiable class, from which common issues arise.[48]

51. In *Martin v Astrazeneca Pharmaceuticals PLC*, the court added: "It is not enough for there to be a common defendant. Nor is it enough that class members assert a common type of harm. ... **There must be commonality in the actual wrong that is alleged against the defendant and some evidence to support this.**"[49] Put another way, "[t]here must be rational connection between the proposed class definition, the proposed causes of action,

[46] See *Western Canadian Shopping Centres Inc. v Dutton*, 2001 SCC 46 at para 38 [Tab 25 of the Appellants' Authorities] and its application in subsequent jurisprudence.
[47] *Hollick v Toronto (City)*, 2001 SCC 68 at para 21 [emphasis in original] [Tab 12 of the Appellants' Authorities].
[48] *Frohlinger v Nortel Networks Corp.* (2007), 40 CPC (6th) 62 (Ont SC) at para 25, *per* Winkler J. [emphasis added] [Tab 10 of the Appellants' Authorities].
[49] *Martin*, *supra* at para 95 [emphasis added] [Tab 13 of the Appellants' Authorities].

and the proposed common issues. This has often been interpreted to mean that all members of the proposed class must have at least a colourable claim."[50]

52. As Winkler J. (as he then was) observed in *Bywater v Toronto Transit Commission*, "for the mutual benefit of the plaintiff and the defendant, the class definition ought not to be unduly narrow nor unduly broad."[51] The important policy goal of access to justice is not served by certifying an overly broad class where the majority of the proposed class enjoys no cause of action against the defendant. Doing so squanders party and court resources on litigating claims with no chance of success.

53. This is the very reason why McLachlin C.J. observed in *Hollick*, "[w]here the class could be defined more narrowly, the court should either disallow certification or allow certification on condition that the definition of the class be amended".[52] Similarly, LeBel and Fish JJ. noted in *Robertson v Thomson Corp* that a class should not include members with no cause of action.[53]

54. The Primary Class and its related Family Class, as certified by the Chambers Judge, are impermissibly and unnecessarily broad. The requirement for an objectively established connection between the class and the alleged claims is not met when the class contains

[50] Warren K. Winkler *et al*, *The Law of Class Actions in Canada* (Toronto: Thomson Reuters Canada, 2014), at page 92 [Tab 28 of the Appellants' Authorities], citing *Toms Grain & Cattle Co. v Arcola Livestock Sales Ltd.*, 2006 SKCA 20 at para 28 [Tab 23 of the Appellants' Authorities]: "[T]he mere fact that a group of people is identifiable is not sufficient to render them a class for the purpose of a class action. In addition, there must be a rational connection between the proposed class definition, the proposed causes of action and the proposed common issues. In effect, the class description must describe persons who in fact have a claim asserted in the statement of claim. This has often been interpreted to mean that all members of the proposed class must have at least a colourable claim and that the class definition should not be over-inclusive or under-inclusive, sweeping in those who do not have a claim against the proposed defendants or arbitrarily excluding others who share the same cause of action".
[51] *Bywater v Toronto Transit Commission* (1998), 27 CPC (4th) 172, (Ont Gen Div) at para 10 [Tab 4 of the Appellants' Authorities].
[52] *Hollick*, *supra* at para 21 [Tab 12 of the Appellants' Authorities].
[53] *Robertson v Thomson Corp.*, 2006 SCC 43 at para 59 [Tab 19 of the Appellants' Authorities].

those who have benefitted from taking the drug. Plaintiffs' experts agreed that not all persons who took Avandia suffered harm. In fact, the vast majority who were prescribed and ingested Avandia benefited from the medication.

55. Moreover, it becomes impossible to link such an overly broad class with the common issues allowed by the Chambers Judge given that those common issues are anchored in a specific allegation of harm; namely, heart failure, heart attack, or stroke.

56. The class definition consequently fails to meet the requirement of the Supreme Court of Canada in *Sun-Rype Products Ltd. v Archer Daniels Midland Company* that a key purpose of the class definition is to "identify those persons who have a potential claim for relief against the defendants ..."[54] As defined, almost everyone captured by the class definition will *not* have a potential claim for relief against the Appellants.

(B) Issue Two: General Causation Issues

57. The Chambers Judge erred by failing to require that the Plaintiffs demonstrate the existence of a "credible or plausible" methodology for proving the common issues on a class-wide basis.

58. In *Pro-Sys*, the Supreme Court confirmed that a plaintiff must present a "credible or plausible" methodology that "offer[s] a realistic prospect of establishing loss on a class-wide basis".[55] This is particularly so when a broad class definition is applied.

[54] *Sun-Rype Products Ltd. v Archer Daniels Midland Company*, 2013 SCC 58 at para 57 [emphasis added] [Tab 21 of the Appellants' Authorities].
[55] *Pro-Sys*, *supra* at para 118 [Tab 17 of the Appellants' Authorities].

59. In *Andriuk v Merrill Lynch Canada Inc.*, the Court of Appeal of Alberta upheld a decision refusing certification where the plaintiffs "had failed to demonstrate a methodology to determine causation."[56]

60. *Andriuk* concerned claims against Merrill Lynch for conduct alleged to have depressed the price of a stock artificially. In denying certification, the motion judge observed that the plaintiffs had not met their burden to show the availability of a methodology to prove their loss:

> [T]he Plaintiffs are required to show that it is possible they can meet the burden they acknowledge, namely, to prove loss apart from other market forces and to link such loss with each of Merrill's impugned actions taken pursuant to the mandate. ... [E]ven ignoring what evidence Merrill has brought forward, it remains up to the Plaintiffs to show that the necessary calculations can actually be done on a class-wide basis. They have failed to meet their burden by referring only to [Merrill Lynch's expert's] comment in cross-examination that stock prices may decrease with increased sales. That is a very general observation and does not respond to the specifics of the case at bar which call for an attribution of any decreased market price to Merrill's three-pronged mandate. The question is whether this necessary calculation is even possible.
>
> **It is not clear why the Plaintiffs would wait until after discoveries have been completed to determine this threshold issue. On balance, it would simply not promote efficiency or judicial economy to permit certification when there is no basis in fact to show that the primary but novel form of class-wide loss asserted by the Plaintiffs could ever be established.**[57]

61. The Court of Appeal for British Columbia has also adopted this requirement, applying it beyond the indirect-purchaser context in *Charlton v Abbott Laboratories, Ltd.* and *Miller v Merck Frosst Canada Ltd.*, both product liability claims involving pharmaceutical companies.

[56] *Andriuk v Merrill Lynch Canada Inc.*, 2014 ABCA 177 at para 11 [Tab 3 of the Appellants' Authorities].
[57] *Andriuk v Merrill Lynch Canada Inc.*, 2013 ABQB 422 at paras 133-34 [emphasis added] [Tab 3 of the Appellants' Authorities].

62. In *Charlton*, the Court of Appeal overturned certification where the motion judge "erred by failing to consider whether the class had adduced some evidence of a method of proving the claim."[58] In that case, the plaintiffs alleged that the drug sibutramine caused or contributed to heart attack, stroke, and arrhythmia, and should not have been marketed. The Court observed that the motion judge had asked the wrong question when considering whether these issues should be certified:

> The question that ought to have been asked at the certification hearing in relation to both types of claims, is not whether the resolution of the general causation question will advance the class claims, but rather, whether there is a reasonable prospect of doing so.
>
> The evidence before the certification judge was that the question whether sibutramine causes or contributes to heart attacks, strokes, and arrhythmia on a class-wide basis is incapable of resolution. **There was no evidence of a methodology for establishing that the class as a whole, as opposed to those who were wrongly prescribed sibutramine despite a history of disease, was affected or put at risk by its use of sibutramine.**[59]

63. Courts in *Andriuk*, *Charlton*, and *Miller*[60] all recognized that the methodology requirement established by the Supreme Court in *Pro-Sys* is fundamentally procedural and a crucial consideration on certification that serves important policy goals. As the Court of Appeal noted in *Charlton*: "[s]eeking evidence of a methodology of addressing causation for the class serves the objective of class proceedings and the *Act* must be applied with a purposive approach."[61]

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58 *Charlton v Abbott Laboratories, Ltd.*, 2015 BCCA 26 at para 112 [Tab 7 of the Appellants' Authorities].
59 *Charlton, supra* at paras 111-12 [emphasis added] [Tab 7 of the Appellants' Authorities].
60 *Miller v Merck Frosst Canada Ltd.*, 2015 BCCA 353 at para 37 [Tab 15 of the Appellants' Authorities]: "[E]very case requires plaintiffs to show how general causation of the common issue could be established".
61 *Charlton, supra* at para 84 [Tab 7 of the Appellants' Authorities].

64. In the case before the Honourable Court below, the Chambers Judge certified general causation as a common issue despite the fact that the Plaintiffs had failed to advance any methodology, never mind a "credible and plausible" one, that would allow the Court to consider causation on a class-wide basis. Whether Avandia can cause congestive heart failure, heart attack, or stroke is an academic, scientific inquiry, the result of which cannot be applied to establish causation in the class as defined. Simply put, there is no methodology that would permit causation to be established on a class-wide basis.

65. Even if an answer to the scientific question of general causation could be found, this would only take place at the most general level of abstraction. For example, the evidence required to address this question for a putative class member who alleges congestive heart failure (about which warnings were contained in the product monograph since Avandia was marketed in Canada) will not resemble the evidence required from a putative class member who alleges having suffered a stroke as a result of taking Avandia in the same time period.

66. Moreover, individual inquiry would still be required in relation to the allegation of specific causation for each and every class member. This would require a detailed assessment of each class member's unique patient profile and risk factors and an appreciation of the reality that Type 2 diabetes is, itself, a significant risk factor for heart failure, heart attack, and stroke.

67. From a legal perspective, there is simply no meaningful advancement of the case by asking – academically or scientifically – whether Avandia <u>can</u> cause or contribute to a particular cardiovascular condition. All that matters is whether, in fact and in law, Avandia did or did not cause the harm that is alleged by each and every class member.

68. Moreover, the purely academic nature of this enquiry is further emphasized when one looks to and compares the differing evidence of the Representative Plaintiffs in this case. As noted at paragraph 15 of this Factum:

(a) Mr. Sweetland never suffered a heart attack. His alleged injury is an episode of congestive heart failure, which occurred 9 months after he last took Avandia. His congestive heart failure was caused by constrictive pericarditis, an unrelated illness. In any event, the product monograph warned of this potential adverse event.

(b) Ms. Addicott-Andrews represents the interests of her deceased mother, who had a heart attack before she took Avandia and another heart attack at the age of 74, two years after she stopped taking Avandia. Mrs. Addicott's diabetes was poorly controlled, and she had suffered from multiple diseases and complications for years.

69. Multiple and diverse alleged harms require a methodology for grouping them into one common issue, the need for which was seen with the allegations of multiple complications from vaginal mesh in *O'Brien v Bard Canada Inc.* As in *O'Brien*, the Plaintiffs in this case have "failed to propose any methodology to show that a finding of causation of the multitude of injuries ... can be extrapolated across the class."[62] Similarly, as the Saskatchewan Court of Appeal found in *Wuttunee*, which dealt with the alleged side effects of the drug, Vioxx, the diversity of claims alleged is fatal to consideration of the issue of general causation as a "common" issue.[63]

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62 *O'Brien v Bard Canada Inc.*, 2015 ONSC 2470 at para 204 [Tab 16 of the Appellants' Authorities].
63 *Merck Frosst Canada Ltd. v Wuttunee*, 2009 SKCA 43 at para 145 [Tab 14 of the Appellants' Authorities].

70. As noted, Avandia is prescribed to patients with Type 2 diabetes who already have a significantly increased risk for congestive heart failure, heart attack, and stroke in addition to small vessel disease involving peripheral blood vessels, the eyes, kidneys and/or nerves.[64] There is no signature "Avandia" heart failure, heart attack, or stroke.[65] The Plaintiffs proposed no methodology by which the question of whether Avandia caused these conditions in putative class members could be determined in common.

71. Indeed, the Plaintiffs' experts conceded that the issue of causation cannot be determined in common and that it will require an individual inquiry to determine whether Avandia caused the alleged harm.[66] The most that the Plaintiffs' experts were able to say was that Avandia may have "contributed" to cardiovascular disease in some patients yet none of the experts could explain how Avandia may have contributed to cardiovascular disease. This is far short of what is required for advancing general causation as a common issue.[67] In *Resurface Corp. v Hanke*,[68] the Supreme Court of Canada affirmed that the test for causation in negligence is the "but for" test.

72. More recently, in *Clements v Clements*, the law of "material contribution" was clarified. In restating the role of "material contribution" in the law of causation in Canada, the Chief Justice wrote:

> As a general rule, a plaintiff cannot succeed unless she shows as a matter of fact that she would not have suffered the loss "but for" the negligent act or acts of the defendant. A trial judge is to take a robust and pragmatic approach to determining if a plaintiff has established that the defendant's

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64 Affidavit of Dr. Tina Kader at para 24 [Appeal Book, Volume 3, Tab 26].
65 See Transcript of Cross-Examination of Dr. Myers at pages 91-92 [Appeal Book, Volume 2, Tab 16].
66 See Transcript of Cross-Examination of Dr. Lipscombe at page 123 [Appeal Book, Volume 2, Tab 18]; Transcript of Cross-Examination of Dr. Myers at page 92 [Appeal Book, Volume 2, Tab 16].
67 See *eg Singer v Schering-Plough Canada Inc.*, 2010 ONSC 42 at para 140 [Tab 20 of the Appellants' Authorities].
68 *Resurface Corp. v Hanke*, 2007 SCC 7 at para 22 [Tab 18 of the Appellants' Authorities].

> negligence caused her loss. Scientific proof of causation is not required.
>
> Exceptionally, a plaintiff may succeed by showing that the defendant's conduct materially contributed to risk of the plaintiffs injury, where (a) the plaintiff has established that her loss would not have occurred "but for" the negligence of two or more tortfeasors, each possibly in fact responsible for the loss; and (b) the plaintiff, through no fault of her own, is unable to show that anyone of the possible tortfeasors in fact was the necessary or "but for" cause of her injury, because each can point to one another as the possible "but for" cause of the injury, defeating a finding of causation on a balance of probabilities against anyone.[69]

73. "Material contribution" therefore should only be applied in cases of multiple concurrent tortfeasors, which is not the situation here. The Supreme Court in *Clements* clarified that material contribution is not a default position when scientific evidence of causation is lacking.[70] Cases determined on the basis of material contribution should be rare.[71]

74. The question of whether Avandia caused congestive heart failure, heart attack, or stroke cannot be determined on a class-wide basis. It is an individual issue that, at best, requires consideration of an individual's unique medical condition and risk factors. The Plaintiffs have done nothing to show a methodology that could assist the Court in determining causation in common.

75. Not only have Plaintiffs failed to establish a methodology for establishing causation on a class-wide basis, they also failed to present evidence before the Chambers Judge on the actual question of general causation (*e.g.* "can" Avandia cause or contribute to any of the specified medical conditions?).

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[69] *Clements v Clements*, 2012 SCC 32 at para 46 [Tab 8 of the Appellants' Authorities].
[70] *Clements*, *supra* at para 38 [Tab 8 of the Appellants' Authorities].
[71] The policy reason for material contribution remaining in Canadian jurisprudence is to prevent multiple tortfeasors from escaping liability by pointing to each other on the issue of causation, which is not a concern in this case.

76. The question of general causation is not supported in the evidence. At best, the Plaintiffs' experts could point only to a "signal" of association between Avandia and heart failure and heart attacks. There was no evidence of a "signal" of association between Avandia and stroke. At law and in medicine, "association" is not equivalent to "causation", particularly here where the evidence shows that: (i) there is no "signature" injury related to Avandia; and (ii) Type 2 diabetes, as a disease itself, increases the risk of heart failure, heart attack, and stroke. The evidence falls well short of meeting the Plaintiffs' legal requirement to show causation on the "but for" standard.[72]

77. As a matter of law, the inclusion by the Chambers Judge of "contribute to" in the certified question is irrelevant given the Supreme Court of Canada's mandate that "material contribution" is unavailable in the circumstances of this case. Put bluntly, the language of the certified question is doctrinally opposed to the dictates of the common law.

78. At best, the more general the language used in a certified common issue – namely, "Can AVANDIA cause or contribute to ..." the less it does to remediate the concern that class certification can advance the case in any meaningful way. As most recently highlighted by this Court:

> It is unnecessary that the common issue "predominates over issues affecting only individual members". But the common ingredient should be "substantial". **If the issues are common "only when stated in the most general terms"** and would "ultimately break down into individual proceedings", then duplication is not avoided, the underlying objective is frustrated, and **class certification is inappropriate**.[73] [emphasis added]

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[72] See *Wise v Abbott Laboratories, Limited*, 2016 ONSC 7275 [Tab 26 of the Appellants' Authorities].
[73] *Capital District Health Authority*, *supra* at para 67 [citations omitted] [Tab 6 of the Appellants' Authorities]. See also *Singer*, *supra* at para 140 [Tab 20 of the Appellants' Authorities].

(C) Issue Three: No Enterprise Liability

79. The Chambers Judge erred in certifying "enterprise liability" as a common issue, which was certified as follows:

> 4. *Is each of the Defendants responsible in law for the acts or omissions of either one or both of the other Defendants in respect of the design, development, fabrication, manufacture, sale, import, distribution, and/or marketing of AVANDIA in Canada?*

80. The allegations as pled treat the two Appellants together as if they were one corporation.[74] Corporations are however separate legal personalities, as confirmed by *Dunlop v Sunrise Propane Energy Group*, and can only be treated as one if one corporate entity uses the other as a shield or alter ego for a fraudulent or improper purpose,[75] or they are in an agency relationship.

81. The Fresh as Second Amended Statement of Claim takes an "enterprise liability" approach and "simply lumps" the Appellants "together as one" entity,[76] which they define as "GSK". As noted in both *Dunlop* and *Martin*,[77] this is impermissible. The Plaintiffs do not even plead that one of GSK Inc. or GSK LLC was the shield or alter ego of the other for a fraudulent or improper purpose.

82. Furthermore, while the Claim attempts to allege an agency relationship, it baldly states that "each was the agent for the other".[78] The Claim makes no assertion as to which company was principal and which was agent.

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[74] Para 20 of the Fresh as Second Amended Statement of Claim [Appeal Book, Volume One, Tab 10].
[75] *Dunlop*, *supra* at paras 110-12 [Tab 9 of the Appellants' Authorities].
[76] *Martin*, *supra* at paras 117-18, 120 [Tab 13 of the Appellants' Authorities].
[77] *Martin*, *supra* at paras 126-27 [Tab 13 of the Appellants' Authorities].
[78] Para 86(a) of the Fresh as Second Amended Statement of Claim [Appeal Book, Volume One, Tab 10].

83. In the Appellants' respectful submission, this improper pleading of enterprise liability taints the entire Claim such that a corresponding common issue cannot be certified. As noted in *Martin*, where the enterprise liability pleadings nearly mirror those contained in the Fresh as Second Amended Statement of Claim:

> Not only is the pleading inconsistent but it lacks clarity as to each defendant's role because the pleading simply lumps them together as one ...
>
> ... Instead, the plaintiffs attribute liability to the defendants en masse, asserting that "[t]he business of each ... is inextricably interwoven with that of the other and each is the agent of the other for the purposes of research, development, manufacture, marketing, sale and/or distribution of Seroquel in Canada." **This bald assertion of enterprise liability is deficient for three reasons**.
>
> First, as a matter of pleading, it is inappropriate to simply "lump together" the three defendants ...
>
> Second, as a matter of substantive law, a parent corporation is not interchangeable with its subsidiary ... Applying these principles, Ontario courts have frequently struck out allegations of enterprise liability where the plaintiff failed to plead material facts that would justify piercing the corporate veil ...
>
> Third, while the plaintiffs seek to justify enterprise liability on the basis that each defendant "is the agent of the other," this bald pleading, unsupported by any material facts, is insufficient to establish an agency relationship ...
>
> ... These are significant pleading deficiencies in the context of a products liability class action and prevent the statement of claim from satisfying s.5(1)(a).[79]

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[79] *Martin*, *supra* at paras 117-27 [Tab 13 of the Appellants' Authorities].

84. The Chambers Judge rejected the Appellants' arguments on "enterprise liability",[80] referring only to the factual differences in *Durling*. No mention is made of the Appellants' references to the above-quoted passages in *Martin*.[81]

85. Regardless of the technical pleadings issues, it is material that the Plaintiffs advanced no evidence on the motion for certification in support of their bald pleadings of enterprise liability. In particular, there was no evidence that the Appellants were either a shield or an alter ego of one another for a fraudulent or improper purpose, nor was there any evidence to suggest an agency relationship.

86. The Chambers Judge failed to hold the Plaintiffs to their evidentiary burden on certification and erred by certifying a common issue in the absence of the requisite "some basis in fact".

(D) Issue Four: No Unjust Enrichment / Waiver of Tort

87. The Chambers Judge certified "unjust enrichment and/or waiver of tort" as a common issue, albeit after requiring that the Plaintiffs revise its scope. In so doing, the Chambers Judge committed a reviewable error. His Lordship should have concluded that such restitutionary relief is unavailable in a negligence / personal injury case.

88. During the certification motion, and with reference to recent authorities on point, the Appellants' counsel made detailed submissions on the "vexing question of waiver of tort".[82]

89. The Appellants argued:

[80] Certification Decision, para 29 [Appeal Book, Volume 1, Tab 4].
[81] Transcript of Hearing on September 17, 2015 at pages 396-404, Appeal Book, Volume 4, Tab 31.
[82] Transcript of Hearing on September 17, 2015 at page 405 et seq, Appeal Book, Volume 4, Tab 31.

(a) No court has answered the question of whether "waiver of tort" can be relied upon as an independent cause of action. Likewise, no court has answered the question of whether it is available as restitutionary relief in a personal injury / negligence case.

(b) That said, and referring to the decision of Justice Lax in *Andersen v St. Jude Medical, Inc.*, there is no need for a full evidentiary record to answer these questions. To quote Justice Lax:

> [594] Given the philosophical and policy considerations mentioned above, it is my view that the fundamental question for a court to answer is whether the recognition (or not) of the waiver of tort doctrine is within the capacity of a court to resolve, or whether it has such far-reaching and complex effects that it is best left to consideration by the Legislature. On the basis of my experience, the answer to this and the other questions surrounding the waiver of tort doctrine is not dependent on a trial with a full factual record and may require no evidence at all.[83]

(c) As such, the availability of such restitutionary relief can and should be addressed at the certification stage.

(d) Such restitutionary relief is unavailable in the negligence / personal injury context. There is no "gap" for the law of restitution to fill, and it would fundamentally rewrite the law of negligence if damages can be awarded without any proof of causation and harm.[84]

[83] *Andersen v St. Jude Medical, Inc.*, 2012 ONSC 3660 [Tab 2 of the Appellants' Authorities]. See also *O'Brien*, supra at paras 157-65 [Tab 16 of the Appellants' Authorities].
[84] See *Andersen*, supra at para 593 [Tab 2 of the Appellants' Authorities]. The Chambers Judge was clearly alive to the consequence of such restitutionary relief in this case: see eg Transcript of Hearing on September 17, 2015 at page 416 [Appeal Book, Volume 4, Tab 31].

(e) For these reasons, such restitutionary relief should not and cannot form the basis of a certified common issue.

90. The Chambers Judge decided not to resolve the ongoing debate, concluding: "I am not prepared to dismiss the possibility compensation based upon waiver of tort at this stage."[85] However, having taken such a position, the Chambers Judge ought not to have certified the following as a common issue:

> 5. By virtue of unjust enrichment and/or waiver of tort, are the Defendants liable on a restitutionary basis:
>
> (a) to account to any of the Classes, including provincial insurers which have subrogated claims, for any part of the proceeds of the sale of AVANDIA? Or, in the alternative,
>
> (b) such that a constructive trust is to be imposed on any part of the gross revenue from the sale of AVANDIA for the benefit of the Classes, including the provincial insurers which have subrogated claims?

91. The Appellants' respectfully submit that the Chambers Judge erred by failing either to answer the "waiver of tort" debate or to decline "waiver of tort" as a common issue. Had he engaged with the "waiver of tort" debate, and for the reasons argued by the Appellants on the motion below, the Chambers Judge would have had to conclude that such restitutionary relief is unavailable in this case (and therefore cannot form the subject of a certified cause of action or common issue). It was in the interests of the judiciary and all parties that the question be ruled on at this at this early stage of the litigation.

(E) Issue Five: Not the Preferable Procedure

92. As in *Canada (Attorney General) v MacQueen*, this Court's consideration of the Chambers Judge's conclusion on "preferable procedure" will be dictated by its conclusion on the

[85] Certification Decision, para 28 [Appeal Book, Volume 1, Tab 4].

preceding issues. If this Court agrees that the Chambers Judge erred in the foregoing ways, he is not entitled to deference on issue of preferable procedure.

93. As this Court concluded in *MacQueen*:

> [184] The standard of review of the certification judge's conclusion that a class proceeding would be the preferable procedure for the fair and efficient resolution of the claim is the same as review of common issues. However, again as will be explained, **in light of the errors found on the part of the certification judge in certifying the causes of action and the common issues, it is necessary for us to look at the issue of preferability afresh without deference to the certification judge.**[86] [emphasis added]

94. Accordingly, the Appellants reiterate their position on the motion below[87] and seek a fresh consideration by this Court on preferable procedure.

95. The Appellants respectfully submit that the Chambers Judge committed reviewable errors in concluding that a class action would be the preferable procedure for adjudication of this dispute, as required by s. 7(1)(d) and s. 7(2) of the *Class Proceedings Act*. This includes whether "the questions of fact or law common to the class members predominate over any questions affecting only individual members".

96. The preferable procedure analysis, at its core, turns on whether the individual elements of causation necessary to the resolution of each class member's claim will "overwhelm" the litigation as a whole.

97. Caution against certifying a class proceeding where the common issues will be overwhelmed by the individual issues was most recently addressed by this Court in *Capital District Health Authority v Murray*. Quoting from the Winkler text on class actions, Justice

[86] *MacQueen*, supra at para 184 [Tab 5 of the Appellants' Authorities].
[87] See: Appeal Book, Volume 5, Tab 34, pages 2258-68; and Appeal Book, Volume 4, Tab 31, pages 2080-89.

Fichaud noted the concern that resolution of the common issues will "mark just the beginning of the process leading to a final disposition of the claims":

> [118] *Winkler, The Law of Class Actions in Canada*, pages 130-31, summarizes the governing proposition:
>
> The notion of individual issues "overwhelming" the common issues is often repeated in the case law. A class proceeding will not satisfy the requirement that it be the preferable procedure to resolve the common issues if the common issues are overwhelmed by the individual issues such that the resolution of the common issues will, in substance, mark just the beginning of the process leading to a final disposition of the claims of the class members. **If the resolution of the common issues would not put the class members in a better position than if they simply pursued individual claims, there is little, if any benefit to proceeding by way of a class action.** This would be the case where the resolution of the common issue would not materially advance each class member's claim for damages and where the questions affecting individual claims would inevitably break down into a long series of individual trials dealing with many complex issues. In such circumstances, any potential judicial efficiency would be lost, and there would be no advantage to a class proceeding that would justify its imposition on the absent class members, the defendant, or the court.[85] [emphasis added]

98. The "caution" noted by Justice Fichaud tracks what was expressed by this Court in *MacQueen*, particularly where liability would remain an issue for each and every claim following complete success on a common issues trial. In *MacQueen*, this Court wrote:

> [183] There would be no reductions in unnecessary duplication in the findings of facts that would result in significant judicial economy. Like *Hollick*, any common issue is negligible in relation to the individual issues. **In order to recover, each of the individual class members would have to establish material physical damage to their property or a substantial interference with the use and enjoyment of their property. Each class proceeding would break down into individual claims for each of the class members.**

[85] *Capital District Health Authority*, *supra* at paras 118-19 [Tab 6 of the Appellants' Authorities].

> [184] Turning now to access to justice, the respondents argue that the class members' claims, individually, are so small that it would not be worthwhile for them to pursue relief individually and their financial resources are such that they cannot afford to bring separate proceedings ... as we have explained, the determination of what constitutes a nuisance **is so individualized that it would still be necessary for the individual claimants to pursue their own claims**. Any costs they would incur in proving nuisance would not be significantly mitigated by certification of this proceeding. **The individual claims, here, are not simply an assessment of liability following a finding of liability. Rather, liability is an issue for each and every claim**.
>
> [185] Finally, we agree, as the certification judge noted, that behaviour modification has a broader focus than this case. It has minimal, if any, application to these appellants ... The courts' task is to determine whether a class action would be fair and efficient resolution of the dispute taking into account the factors in CPA's 7(2)(a) to (e) and "any other matter the court considers relevant". **In this case the individual issues overwhelm the only issue common to all class members and the resolution of that issue simply does not advance the litigation**.
>
> [186] Having examined the common and individual issues **and taking into account that which each class member must prove to demonstrate liability**, our conclusion is that a class action is not the preferable procedure for proceeding with these actions.[86] [emphasis added]

99. Likewise in this case, and even if the question of general causation conceptually could be adjudicated on a common basis, liability would remain an issue for each and every claim. Each of the individual class members would have to establish specific causation in relation to Avandia being the "but for" cause of their harm, ruling out all of the other risk factors (inclusive of Type 2 diabetes itself) for a cardiovascular event.

100. Put simply, each class member would still need to establish liability for the harm to them related to the circumstances of their use of the drug, including why Avandia was prescribed and in what dosage and for what duration, after what discussions with their prescribing

[86] *MacQueen*, *supra* at paras 183-86 [Tab 5 of the Appellants' Authorities].

physician they had on risks and benefits of the drug in the context of their specific risk factors, including other treatments tried and failed for their diabetes, and their personal and family cardiovascular history. As was recently stated by the British Columbia Court of Appeal, such a class action would "merely be a prelude to many individual trials."[90]

101. Accordingly, the Chambers Judge should have concluded that a class action is not the preferable procedure for resolution of the claims of Avanadia users. None of the three principal goals / advantages of class actions, either sufficiently or at all, is met in this case:

(a) Judicial economy is not fostered, because significant trials on liability and damages will still need to follow the common issues trial for each and every class member.

(b) Access to justice would not be furthered by certification. The nature of the injuries alleged by individual class members, if causation is proven, would result in significant damages. This is not a case where, by virtue of the quantum of a claim, it is unlikely that a plaintiff would or could commence an individual claim. In *AIC Limited v Fischer*, the Supreme Court of Canada concluded that "individual court actions [were] not a viable option" because of the "modest" size of the claims.[91] In the case at bar, and as mandated by *Fischer*,[92] the Appellants have laid out a workable method by which efficiencies can be obtained without the expense and delays associated with class proceeding.[93]

[90] *Vaugeois v Budget Rent-A-Car of B.C. Ltd.*, 2017 BCCA 111 at para 21 [Tab 24 of the Appellants' Authorities], citing *Thorburn v British Columbia (Public Safety and Solicitor General)*, 2013 BCCA 480 [Tab 22 of the Appellants' Authorities].

[91] *AIC Limited v Fischer*, 2013 SCC 69 at paras 19, 27 & 50 [Tab 1 of the Appellants' Authorities]. See also *Vaugeois*, *supra* at paras 17-25 [Tab 24 of the Appellants' Authorities].

[92] See also this Court's decision in *Capital District Health Authority*, *supra* at para 108 [Tab 6 of the Appellants' Authorities].

[93] Appeal Book, Volume 5, Tab 34, pages 2259-61.

(c) Behaviour modification is of limited concern. Because of the size of the individual claims, the Appellants would not be effectively "immunized" from litigation for reasons of economy.

(F) Issue Six: Inadequate Representative Plaintiffs

102. The Chambers Judge committed reviewable errors in finding that the putative Representative Plaintiffs could fairly and adequately represent the interests of the class.

103. At first instance, the Representative Plaintiffs failed to provide evidence of "two or more" members of the identifiable class. This was highlighted by the Chambers Judge in his initial decision.[94]

104. This deficiency discloses the inadequacy of the Representative Plaintiffs, however this was not addressed by the Chambers Judge during his assessment of s. 7(1)(e) of the *Class Proceedings Act*. Instead, the Chambers Judge allowed the Plaintiffs to file additional evidence to remedy the fact that they had failed on "some basis in fact" despite having had at least six years to prepare for the motion on certification.

105. Once the additional affidavits were filed, the Appellants were deprived of any opportunity to test the veracity of the evidence, a fundamental right.[95] According to the Chambers Judge, this is because any such testing would be irrelevant (as it would only go to the assessment of whether the additional affiants had suffered cardiovascular harm).[96] In

[94] Certification Decision at para 46 [Appeal Book, Volume 1, Tab 4].

[95] In their supplemental submissions, the Appellants made the following request: "In the alternative, the Plaintiffs should be ordered to produce all medical records that support the allegations made, following which the Defendants should be permitted at their election to conduct cross-examination on the supplementary evidence and/or to file further responding submissions. Regardless, the Plaintiffs should be required to produce all pharmacy records in support of the prescription and use of Avandia" [Appeal Book, Volume 5, Tab 37, page 2338].

[96] Supplemental Certification Decision, para 9 [Appeal Book, Volume 1, Tab 5].

other words, the Appellants suffered a further prejudice following the incorrect and overly broad definition of the classes.

106. In the Appellants' respectful submission, the compound effect of the above gives rise to a manifest injustice. Six years after the litigation had been commenced, the Representative Plaintiffs still failed to put forward "some basis in fact" of an identifiable class. Rather than examining how this omission reflected on the adequacy of the Representative Plaintiffs in acting in the interests of the class, the Chambers Judge reset the evidence and allowed an incorrect class definition to further prejudice the rights of the Appellants.

PART 6 – ORDER OR RELIEF SOUGHT

107. For all the foregoing reasons, the Appellants respectfully submit that this appeal should be allowed. As such, the Certification Order should be reversed so to:

(a) dismiss the Plaintiffs' motion for certification of this action as a class proceeding; and

(b) grant the Appellants their costs on the motion below.

108. The Appellants also respectfully request an award of costs on this appeal in the amount of $5000, plus disbursements.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

June 2, 2017

Mary M. Thomson

Scott R. Campbell

APPENDIX A – LIST OF CITATIONS

JURISPRUDENCE

1. *AIC Limited v Fischer*, 2013 SCC 69
2. *Andersen v St. Jude Medical Inc.*, 2012 ONSC 3660 [excerpt only]
3. *Andriuk v Merrill Lynch Canada Inc.*, 2013 ABQB 422, aff'd 2014 ABCA 177
4. *Bywater v Toronto Transit Commission* (1998), 27 CPC (4th) 172 (Ont Gen Div)
5. *Canada (Attorney General) v MacQueen*, 2013 NSCA 143
6. *Capital District Health Authority v Murray*, 2017 NSCA 28
7. *Charlton v Abbott Laboratories, Ltd.*, 2015 BCCA 26
8. *Clements v Clements*, 2012 SCC 32
9. *Durling v Sunrise Propane Energy Group Inc.*, 2012 ONSC 4196
10. *Frohlinger v Nortel Networks Corp.* (2007), 40 CPC (6th) 62 (Ont SC)
11. *Heward v Eli Lilly & Co*, [2007] OJ No 404
12. *Hollick v Toronto (City)*, 2001 SCC 68
13. *Housen v Nikolaisen*, 2002 SCC 33
14. *Martin v AstraZeneca Pharmaceuticals PLC*, 2012 ONSC 2744, aff'd 2013 ONSC 1169 (Div Ct)
15. *Merck Frosst Canada Ltd. v Wuttunee*, 2009 SKCA 43
16. *Miller v Merck Frosst Canada Ltd.*, 2015 BCCA 353
17. *O'Brien v Bard Canada Inc.*, 2015 ONSC 2470
18. *Pro-Sys Consultants v Microsoft Corp*, 2013 SCC 57

19. *Resurface Corp. v Hanke*, 2007 SCC 7
20. *Robertson v Thomson Corp.*, 2006 SCC 43
21. *Singer v Schering-Plough Canada Inc.*, 2010 ONSC 42
22. *Sun-Rype Products Ltd. v Archer Daniels Midland Company*, 2013 SCC 58
23. *Thorburn v British Columbia (Public Safety and Solicitor General)*, 2013 BCCA 480
24. *Toms Grain & Cattle Co v Arcola Livestock Sales Ltd.*, 2006 SKCA 20
25. *Vaugeois v Budget Rent-A-Car of B.C. Ltd.*, 2017 BCCA 111
26. *Western Canadian Shopping Centres Inc. v Dutton*, 2001 SCC 46
27. *Wise v Abbott Laboratories, Limited*, 2016 ONSC 7275
28. *Wright Medical Technology Canada v Taylor*, 2015 NSCA 68

COMMENTARY

29. Winkler, WK et al, *The Law of Class Actions in Canada* (Toronto: Thomson Reuters Canada, 2014) [excerpt]

APPENDIX B – STATUTES AND REGULATIONS

1. *Class Proceedings Act*, SNS 2007, c. 28

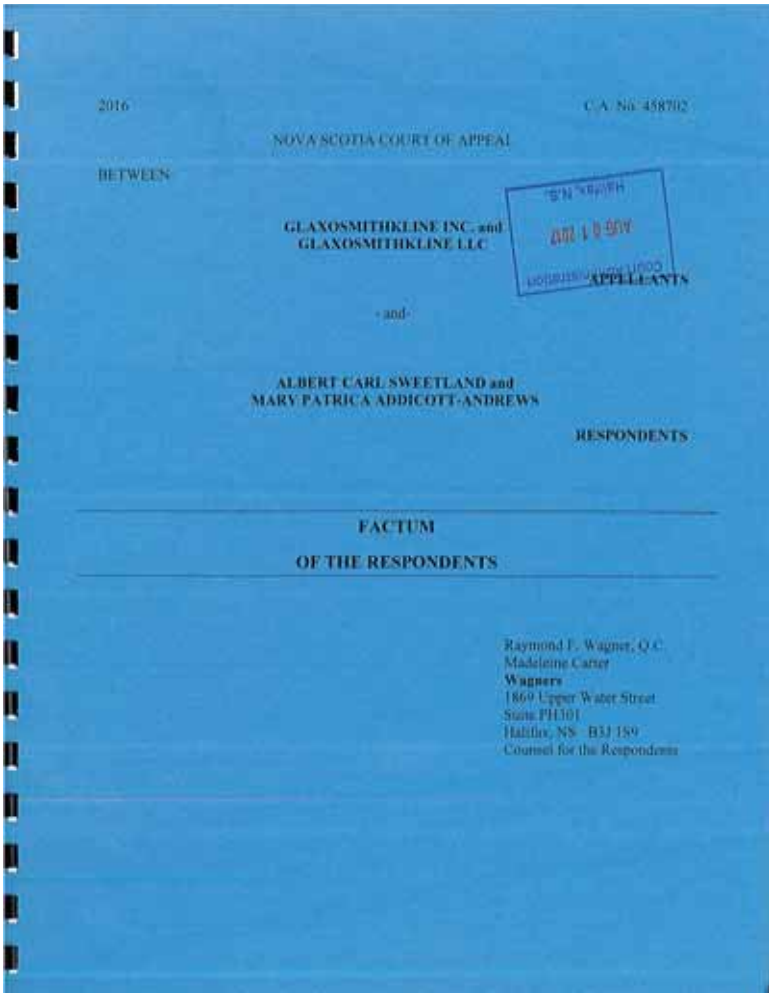
Form 33.09

2009 Hfx No. 315567

This is Exhibit "D" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme Court of Nova Scotia



2016 C.A. No. 458702

NOVA SCOTIA COURT OF APPEAL

BETWEEN

GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC

APPELLANTS

- and -

ALBERT CARL SWEETLAND and MARY PATRICA ADDICOTT-ANDREWS

RESPONDENTS

FACTUM

OF THE RESPONDENTS

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2016 C.A. No. 458702

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INDEX

PART I - CONCISE OVERVIEW OF APPEAL

1. The Appellants advance numerous and wide-ranging arguments on this appeal. They are a reiteration of the arguments they made on the motion for certification. After attentive consideration and analysis by the Chambers Judge, these arguments were properly rejected.

2. The Appellants have not demonstrated the ability of any one of these alleged errors – or of the totality of the alleged errors - to reach the high threshold necessary to warrant appellate intervention.

3. In certifying the action, the Chambers Judge applied well-established principles to the evidence before him, relying on the developed body of class action jurisprudence of this Court and courts across Canada, including the Supreme Court of Canada. The Chambers Judge took note of the "dozens of certification decisions from across the country" put forward by the Respondents in support of certification. At the same time, the Chambers Judge was expressly attuned to the need to carefully analyze the circumstances of the motion record before him.[1]

4. The Chambers Judge made no palpable and overriding errors in certifying this action. It follows that the Appellants' appeal must be dismissed.

[1] Certification Decision, para. 21 [Appeal Book, Volume 1, Tab 4].

PART II - CONCISE STATEMENT OF FACTS

i. Certification Motion and Order

5. On August 18, 2009, the Respondents commenced an action against the Appellants alleging that Avandia causes adverse cardiovascular events, and, in summary, that the Appellants negligently designed the drug and failed to warn that it caused adverse cardiovascular events. The claim was subsequently amended; the most recent version is the Fresh as Second Amended Statement of Claim, filed on June 5, 2015.

6. At paragraphs 6 through 43 of the Respondents' Certification Brief dated July 3, 2015,[2] the Respondents set out the factual background to their claim and a summary of the evidence contained in their certification record. This summary includes an overview of the scientific research supporting the claim and a summary of the regulatory steps taken by Health Canada and other regulators to caution physicians about Avandia. The Respondents respectfully refer the Court to this summary rather than repeat it in this factum.

7. In a judgement dated January 15, 2016 (the "Certification Decision"), the Chambers Judge correctly stated that it is not a high burden to show that all of the certification criteria have been met and simply requires there to be some basis in fact to conclude that the criteria are met.[3] The Chambers Judge granted the Respondents leave to file supplementary evidence relating to the section 7(1)(b) criterion of two or more class

[2] Appeal Book, Volume 5, Tab 33.
[3] Certification Decision, para. 19 [Appeal Book, Volume 1, Tab 4].

members, and to file a revised list of common issues, as he concluded that the other requirements for certification had been established. The Chambers Judge also invited both sides to provide further written submissions on the supplemental evidence and revised common issues.[4]

8. Subsequent to the completion of these steps, the Chambers Judge issued a Supplemental Certification Decision certifying the action on the basis of the revised common issues.[5]

9. On January 27, 2017, by consent, the Appellants were granted leave to appeal the Certification Order.[6]

PART III - LIST OF ISSUES

10. The Appellants advance six main issues on appeal. This Court must determine if the Chambers Judge committed any of the errors advanced by the Appellants, and if so, whether any such error warrants the intervention of this Court.

PART IV - STANDARD OF REVIEW

11. The Supreme Court of Canada and appellate courts across the country recognize that a certification decision is entitled to substantial deference.[7] The governing standard of

[4] Certification Decision, paras. 111-113 [Appeal Book, Volume 1, Tab 4].
[5] Supplemental Certification Decision [Appeal Book, Volume 1, Tab 5].
[6] Appeal Book, Volume 1, Tab 2.
[7] See e.g. *AIC Limited v. Fischer*, [2013] 3 S.C.R. 949 at para. 65 [*AIC Limited*] [Appellants' Authorities, Tab 1]; *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at paras. 111, 126 [*Pro-Sys*] [Appellants' Authorities, Tab 17]; *Capital District Health Authority v. Murray*, 2017 NSCA 28 at paras. 26-27 [*Murray*] [Appellants' Authorities, Tab 6]; *Wright Medical Technology Canada Ltd. v. Taylor*, 2015 NSCA 68 at paras. 30-31 [*Wright Medical*], leave to appeal to S.C.C. refused, [2015] S.C.C.A. No. 388 [Appellants' Authorities, Tab 27]; *Gay v. New Brunswick (Regional Health Authority 7)*, 2014 NBCA 10 at para. 48 [*Gay*] [Respondents' Authorities, Tab 9]; *Canada (Attorney General) v. Anderson*, 2011 NLCA 82 at paras. 38, 121 [*Anderson*] [Respondents' Authorities, Tab 6].

appellate review was recently affirmed by this Court in *Capital District Health Authority v. Murray*,[8] in turn citing Justice Saunders in *Wright Medical Technology Canada Ltd. v. Taylor*:[9]

> [30] The governing standard of appellate review for the determination of the questions of common issues, and preferable procedure under the *Act*, was described by this Court in *Canada (Attorney General) v. MacQueen*, 2013 NSCA 143 (N.S.C.A.) at para. 111, leave to appeal refused [2014] S.C.C.A. No. 51 (S.C.C.):
>
> > [111] Whether a common issue exists and whether a class action is the preferable procedure for the fair and efficient resolution of the dispute are questions of mixed fact and law. These questions are subject to a standard of review of palpable and overriding error unless the certification judge made some extricable error in principle with respect to the characterization of the standard of review or its application in which case it is an error of law reviewable on the standard of correctness (*Ring v. Canada (Attorney General)*, paras. 6-7).
>
> [31] The unique nature of certification proceedings attracts special considerations on appeal. Courts across the country have recognized that a decision to grant a certification order is entitled to substantial deference. While of course no deference arises in cases where the motions judge has erred in principle, considerable deference is given to conclusions based on the weighing and balancing of factors that arise in certification proceedings. Justice Cromwell makes this point in *AIC Limited v. Fischer*, 2013 SCC 69 at para. 65 [...]

12. Justice Fichaud, writing for the Court in *Murray*, *supra* further cites a text authored by two experienced class action jurists and a leading class action academic. The passage repeats the high threshold to warrant appellate intervention:

> [27] Warren K. Winkler, Paul M. Perell, Jasminka Kalajdzic and Alison Warner, *The Law of Class Actions in Canada* (Toronto: Thomson Rogers Canada Limited, 2014), pp. 362-63, comments on the standard of review for points that arise on this appeal:
>
> > … Errors in principle in the approach to the certification criteria will also provide the basis for [sic] appellate intervention; deference does not

[8] *Murray, supra* at paras. 26-27 [Appellants' Authorities, Tab 6].
[9] *Wright Medical, supra* at paras. 30-31 [Appellants' Authorities, Tab 27].

shield errors in principle.

…

… As for the common issues criterion, if the motion judge misconceives the action as being a collection of individual claims and thereby disregards evidence showing some basis in fact to support the existence of common issues, this error in principle will displace the substantial deference otherwise owed to certification judges when considering the common issues criterion and justifies appellate intervention.

A number of appellate courts have held that the decision of a class action judge on the criterion of "preferable procedure" is entitled to special deference, because the judge must weigh and balance a number of factors in assessing this criterion.

13. In *Murray*, the Court of Appeal stated that the objectives of class action legislation – to promote access to justice, judicial economy and behaviour modification – "should guide the judge's exercise of discretion on certification and the other procedural aspects of case management,"[10] citing the aforementioned text *The Law of Class Actions in Canada* and authorities cited therein.

14. Class proceedings legislation provides for "flexibility and adjustment at all stages of the proceeding," and is intended to facilitate access to justice, therefore any intervention by appellate courts at the certification stage "should be restricted to matters of general principle."[11]

15. Certification is intended to be a first step in the litigation. The *Class Proceedings Act*[12] provides that an order on a certification application is not an order determining the merits

[10] *Murray, supra* at para. 35 [Appellants' Authorities, Tab 6].
[11] *Anderson, supra* at para. 12 [Respondents' Authorities, Tab 6]. See also *Griffin v. Dell Canada Inc*., [2009] O.J. No. 3438 (Div. Ct.) at para. 34, ref'g leave to appeal [2009] O.J. No. 418, 72 C.P.C. (6th) 158 [Respondents' Authorities, Tabs 10 and 11]; *Cassano v. Toronto Dominion Bank*, 2007 ONCA 781 at para. 23 [Respondents' Authorities, Tab 7].
[12] *Class Proceedings Act,* S.N.S. 2007, c. 28 [*CPA*] [Respondents' Authorities, Tab 23].

of the proceeding.[13] This informs both the applicable evidentiary standard at first instance and the standard of review on appeal.

16. A plaintiff's evidentiary burden on a certification application is to show "some basis in fact" for each of the certification requirements other than the requirement that the pleadings disclose a cause of action. The plaintiff's evidentiary burden is thus modest, and does not relate to the merits of the lawsuit.

PART V - ARGUMENT

17. The Appellants' appeal of the Certification Order is rooted primarily in six untenable arguments.

Issue 1: The Chambers Judge erred in certifying a class definition that does not include a condition of membership that a user has suffered heart failure, a heart attack and/or stroke while taking Avandia.

18. The Appellants argued at certification that the proposed class definition was too broad. They said it should be limited to those persons who suffered a heart attack, stroke and/or congestive heart failure while taking Avandia.

19. The Chambers Judge rejected this proposition.

20. The Appellants' proposed condition of membership would contravene the principle that class membership must be determined by objective criteria, independent of the outcome or merits of the litigation.

[13] *CPA*, s. 8(2) [Respondents' Authorities, Tab 23].

21. The purposes of a clearly identifiable class definition are to: (a) identify persons with potential claims; (b) define those persons who will be bound by the result; and (c) describe those entitled to receive notice of certification.[14] Introducing merits issues into the class definition presents a number of challenges in achieving these purposes.

22. The Chambers Judge accepted the position of the Respondents that the expert evidence showed that cardiovascular harm is progressive in nature, and cardiovascular events may occur without an individual knowing about it or receiving a diagnosis, at least initially (for example, a "silent" heart attack that is identified after-the-fact by a healthcare professional). Therefore an individual may incorrectly believe him- or herself excluded from the class, should harm be a condition of membership. The Appellants' proposal would also exclude those unaware of precisely the type of cardiovascular event they suffered, and whether they suffered it while taking Avandia.

23. In addition, such a definition may lead class members to believe they must themselves determine whether their cardiovascular harm was causally connected to Avandia, or whether they have a "good claim" that Avandia caused their harm. Case law maintains that class members cannot be required to determine whether they will be successful against a defendant.[15]

[14] *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 (Gen. Div.) at para. 10 [*Bywater*] [Respondents' Authorities, Tab 4].
[15] *Boulanger v. Johnson & Johnson Corp.*, [2007] O.J. No. 179 (Sup. Ct.) at paras. 19-22 [Respondents' Authorities, Tab 3]; *Bywater, supra* at paras. 10-11 [Respondents' Authorities, Tab 4].

24. The Chambers Judge was provided with several examples of pharmaceutical class actions in which the use of the medication in question, without a merits-based "harm" component, was a sufficient definition.

25. The argument of the Appellants that a rational connection is missing between the alleged wrongdoing and class definition, should there be no harm qualification, was considered by the Chambers Judge and rejected. It was not, as the Appellants submit, disregarded. Rather, the Chambers Judge engaged with the Appellants' argument that a harm qualification was necessary, pointedly asking the Respondents:

> **THE COURT:** What about the principle that all members of the class should at least have a colourable claim and that it's really the position of the defendants that it's overbroad that we know today that there are people within the scope of it who have no claim.
>
> **MR. WAGNER:** Right.
>
> **THE COURT:** And so that we should -- I mean they're really arguing that it should be more narrowly -- if it is to be certified, more narrowly described because it's overbroad. And there are cases that will support their position. So why is it that you think it should be described this way as opposed to something more narrow? Such as, and I'm not suggesting that you do it, people who have suffered cardiovascular events, or heart attacks, or something like that.[16]

26. The Chambers Judge was provided with the Respondents' written submissions referring to the decision of Justice Cullity of the Ontario Superior Court in *Tiboni v. Merck Frosst*

[16] Transcript of Hearing on September 15, 2015, pages 74-75 [Appeal Book, Volume 4, Tab 29].

Canada Ltd.[17] Relevant portions of the *Tiboni* decision were also read by the Respondents' counsel in oral submissions as being directly applicable here.[18] In *Tiboni*, the defendant argued that a class definition which was not limited only to those class members who alleged to suffer harm was lacking a rational connection with the alleged wrongdoing, and was therefore over-inclusive. Justice Cullity rejected the defendant's argument, remarking:

> Whether or not a class accepted in this case is limited to those who claim to have suffered harm, only those who make such a claim will have any possibility of obtaining relief for Merck's negligence, and all persons who ingested Vioxx will be "bound" in the sense that they will be unable to relitigate an unfavourable decision on the common issues and obtain damages for negligence. […] For essentially the same reasons as those provided by Winkler J. in *Attis*, I cannot accept the submission of Merck's counsel that the plaintiffs have the burden of establishing by evidence that all members of the class are likely to have causes of action against the defendants, if this means that all will probably have suffered harm. In any class action involving claims in tort for personal injury, or economic loss, it is possible that the claims of some class members will be unsuccessful. This is virtually ordained by the authorities that preclude merits-based class definitions.[19]

27. The need for a "rational connection" between the proposed class definition, the alleged causes of action and the proposed common issues does not equate to a legal requirement that the proposed class be defined to include only those who claim to have suffered the alleged harm while ingesting a pharmaceutical. That would fly in the face of the long line of cases considered by the Chambers Judge, in which no harm component was contained in the class definition. The rationality of the connection persists in the absence of a harm qualification: the Primary Class is comprised of individuals who took one common medication, Avandia, and the common issues relate to Avandia and the alleged liability

[17] [2008] O.J. No. 2996 (Sup. Ct.) [*Tiboni*] [Respondents' Authorities, Tab 20].
[18] Transcript of Hearing on September 15, 2015, pages 71-74 [Appeal Book, Volume 4, Tab 29].
[19] *Tiboni, supra* at paras. 77-78 [Respondents' Authorities, Tab 20].

of the Defendants for the alleged harm caused by the common drug. Only those Primary Class Members who can establish individual liability and damages, after the common issues have been determined, will be eligible for an award of damages. Thus there is no genuine overbreadth concern.

28. The Chambers Judge accepted that there is no requirement that all members of a proposed class ultimately have a claim against the defendant.[20] The Chambers Judge also heard the submissions by the Respondents that there was no concern about having "too many people in the class" from the perspective of providing notice, given the broad, indirect notice program.[21]

29. To allow the parties and potential class members to have certainty about who falls within the definition, who is entitled to notice and who will be bound by the outcome, the appropriate and reasonable court-endorsed approach is to allow the common issues themselves to narrow the claims, as the Chambers Judge approved. This approach avoids the concerns noted by the Chambers Judge in paragraphs 35 through 37 of the Certification Decision.

30. With respect to the Appellants' assertion that that the Class, as certified by the Chambers Judge, would be "comprised almost entirely of individuals with no claim in negligence,"[22] they have provided no proof of this.[23] Nevertheless, if the suggestion is

[20] Certification Decision, para. 38 [Appeal Book, Volume 1, Tab 4].
[21] Transcript of Hearing on September 15, 2015, pages 78-79 [Appeal Book, Volume 4, Tab 29].
[22] Appellants' Factum, para. 44(a). See also paras. 4(a) and 56 of the Appellants' Factum.

that the number of individuals who ultimately seek to have their individual claims determined is small, relative to the certified Class, that is not a factor weighing against certification.

31. The Respondents submit that the Chambers Judge made no reviewable error in certifying the Primary Class as defined.

Issue 2: The Chambers Judge erred by not requiring the Plaintiffs demonstrate a credible or plausible methodology to prove general causation on a class-wide basis.

32. The Appellants' argument hinges on their position that because Avandia users are already at risk of heart failure, heart attack and stroke by virtue of their diabetes, general causation is too difficult to adjudicate. It is impossible to isolate whether the drug actually caused the alleged harm, they argue. For the reasons that follow, the Appellants' argument must be rejected.

[23] The Appellants further assert that the Class "includes those who developed heart disease and stroke as a result of the expected progression of their diabetes." This assertion is unfounded; individual claims have not been assessed and therefore this statement is premature and lacking evidentiary support.

i. What is the "Workable Methodology" Requirement?

33. Considerable attention has been given to the "workable methodology" requirement since it was considered by the Supreme Court of Canada in its 2013 trilogy.[24] Understanding its origins helps illuminate the purpose of the requirement.

34. The matter of leading sufficient evidence of a method to prove general causation originally arose in the context of economic loss cases, as in *Pro-Sys*. These cases involve a quest for evidence of models of calculation for losses that would not necessitate consideration of individual circumstances. The claim in *Pro-Sys* concerned alleged overcharges levied by the defendant against "indirect purchasers". The issue arose whether there was evidence of a methodology to establish that the overcharges had been passed on to the indirect-purchaser level in the distribution chain. Justice Rothstein's remarks on a "credible or plausible" methodology to establish loss on a class-wide basis are worthy of review, and are reproduced at some length here:

> [115] The role of the expert methodology is to establish that the overcharge was passed on to the indirect purchasers, making the issue common to the class as a whole (see *Chadha*, at para. 31). The requirement at the certification stage is not that the methodology quantify the damages in question; rather, the critical element that the methodology must establish is the ability to prove "common impact", as described in the U.S. antitrust case of *In Re: Linerboard Antitrust Litigation*, 305 F.3d 145 (3rd Cir. 2002). That is, plaintiffs must demonstrate that "sufficient proof [is] available, for use at trial, to prove antitrust impact common to all the members of the class" (*ibid.*, at p. 155). It is not necessary at the certification stage that the methodology establish the actual loss to the class, as long as the plaintiff has demonstrated that there is a methodology capable of doing so. In indirect purchaser actions, this means that

[24] *AIC Limited, supra* [Appellants' Authorities, Tab 1]; *Sun-Rype Products Ltd. v. Archer Daniels Midland Company*, 2013 SCC 58 [Appellants' Authorities, Tab 21]; and *Pro-Sys, supra* [Appellants' Authorities, Tab 17].

> the methodology must be able to establish that the overcharges have been passed on to the indirect-purchaser level in the distribution chain.
>
> [116] The most contentious question involving the use of expert evidence is how strong the evidence must be at the certification stage to satisfy the court that there is a method by which impact can be proved on a class-wide basis. The B.C.C.A. in *Infineon* called for the plaintiff to show "only a credible or plausible methodology" and held that "[i]t was common ground that statistical regression analysis is in theory capable of providing reasonable estimates of gain or aggregate harm and the extent of pass-through in price-fixing cases" (para. 68). This was the standard adopted by Myers J. in the present case. Under this standard, he found the plaintiffs' methodologies to be adequate to satisfy the commonality requirement.
>
> …
>
> [118] In my view, the expert methodology must be sufficiently credible or plausible to establish some basis in fact for the commonality requirement. This means that the methodology must offer a realistic prospect of establishing loss on a class-wide basis so that, if the overcharge is eventually established at the trial of the common issues, there is a means by which to demonstrate that it is common to the class (i.e. that passing on has occurred). The methodology cannot be purely theoretical or hypothetical, but must be grounded in the facts of the particular case in question. There must be some evidence of the availability of the data to which the methodology is to be applied.

35. Subsequent to the Supreme Court of Canada trilogy, the "workable methodology" requirement has received attention outside the economic loss line of cases, in the traditional tort/personal injury damages context.

36. For example, the British Columbia Court of Appeal, in *Charlton v. Abbott Laboratories Inc.*,[25] applied the requirement to a product liability claim in the pharmaceutical context.

37. At the hearing of the motion for certification of the present matter, a considerable amount of time was spent by counsel discussing *Charlton*. The *Charlton* decision was thoroughly

[25] 2015 BCCA 26 [Respondents' Authorities, Tab 8].

reviewed by both parties, both in written and oral submissions. All of the arguments advanced on this appeal were addressed before, and reviewed by, the Chambers Judge.

38. The statements of the Court in *Charlton* must be situated in the context of the unique facts of that case. In *Charlton*, the British Columbia Court of Appeal allowed the defendants' appeal from certification of a class action impugning a weight loss drug alleged to cause heart problems. The appeal was allowed on the basis of the complete absence of evidence of a method to answer the general causation question; on the unique facts of that case, there was no existing controlled study examining adverse cardiac events in the specific population for whom it was indicated and to whom it was marketed (i.e. those without cardiovascular disease). Also, critical to the Court's conclusion, the complete absence of evidence could not be prospectively rectified for the purposes of resolving the class action, because the drug had been taken off the market. Therefore studies in the target population were impossible.

39. The *Charlton* decision devotes several paragraphs to a careful statement of the difference between the case before it – which entirely lacked evidence of general causation – and those cases suitable for certification because there is some evidence of general causation, notwithstanding that it may be challenged by the defendant's competing expert.

40. The British Columbia Court of Appeal affirms two critical points:

> 1. Competing evidence is not to be weighed at certification;[26] and

[26] *Charlton*, *supra* at paras. 93-94 [Respondents' Authorities, Tab 8].

> 2. Where there is some evidence by which general causation may be proven (i.e. a pharmaceutical *can* lead to an adverse event), it will defeat a defendant's argument that establishing individual, or "specific" causation of a medical condition (i.e. was *this* plaintiff's heart condition caused by the pharmaceutical) will require careful consideration of the individual's medical history.[27]

41. The general causation issue is central to, and the answer to it can be extrapolated to, the claim of each class member. This centrality is illustrated by the British Columbia Supreme Court in *Bartram (Litigation guardian of) v. GlaxoSmithKline Inc.*[28] in relation to the antidepressant drug Paxil:

> If the plaintiffs fail to prove general causation, that will be the end of the matter. If they succeed, it will then be up to each individual plaintiff to show that the injury that occurred was of a kind that can be caused by Paxil and was in fact one that would likely not have occurred but for the use of Paxil.[29]

ii. Respondents Led Evidence of Methodology to Prove General Causation

42. The Respondents squarely acknowledged their onus of showing some basis in fact of a plausible methodology by which general causation could be proven at the common issues trial. The requirement to show "some basis in fact" of a methodology to prove general causation at trial was comprehensively addressed by the Respondents at paragraphs 98-108 of their Certification Brief[30] and paragraphs 30-39 of their Certification Reply

[27] *Charlton, supra* at paras. 94-97 [Respondents' Authorities, Tab 8].
[28] 2012 BCSC 1804 [*Bartram Sup. Ct.*], aff'd 2013 BCCA 462 [*Bartram C.A.*] [Respondents' Authorities, Tabs 1 and 2].
[29] *Bartram Sup. Ct.*, *ibid.* at para. 31 [Respondents' Authorities, Tab 1].
[30] Certification Brief [Appeal Book, Volume 5, Tab 33].

Brief.[31] In turn, the Appellants provided submissions on general causation, including the "workable methodology" requirement, at paragraphs 79-87 of their Certification Brief.[32]

43. The Appellants' submissions on this appeal with respect to the adequacy of the Respondents' evidence on general causation ignore the evidentiary record before the Chambers Judge. The Respondents led evidence of two experts in relation to the general causation issues, and circumstantial evidence arising from Health Canada's later regulatory action. The Respondents clearly drew the attention of the Chambers Judge to this evidence during the motion for certification.[33] Therefore the Chambers Judge did not overlook the Respondents' burden to show some evidence of a workable methodology to prove general causation. Rather, the Chambers Judge found that the Plaintiffs had demonstrated a workable methodology of proving general causation.

44. In support of the conclusion that the general causation issues can be answered at the common issues trial, the Respondents relied at certification on the affidavit and testimony of Dr. Lorraine Lipscombe, a physician, endocrinologist and epidemiologist who has extensively studied the impact of Avandia on cardiovascular health, and on the vast body of scientific literature she refers to in support of her opinion (some of which she herself conducted).[34] The Respondents rely on this expert evidence, and the scientific research underpinning it – contained in particular in the studies found as Exhibits "F", "I", "J",

[31] Certification Reply Brief [Appeal Book, Volume 5, Tab 35].
[32] Appeal Book, Volume 5, Tab 34.
[33] Transcript of Hearing on September 16, 2015, page 147 lines 12-21; pgs. 148-150 [Appeal Book, Volume 4, Tab 30].
[34] Affidavit of Dr. Lorraine Lipscombe sworn January 15, 2015 [Appeal Book, Volume 2, Tab 17]; Cross-Examination of Dr. Lipscombe held May 26, 2015 [Appeal Book, Volume 2, Tab 18].

"K" and "L" to Dr. Lipscombe's affidavit - as evidence of a methodology of proving causation of the alleged cardiovascular harm in a population of diabetic users, notwithstanding the "background risk" of cardiovascular problems.

45. As counsel for the Respondents submitted to the Chambers Judge, the conclusions and outcomes of the research referred to by Dr. Lipscombe were conclusive enough to cause regulatory bodies to act on them, and they provide meaningful information in answering the general causation issues.[35] Confirmed by the volume of scientific literature relied on by Dr. Lipscombe in her opinion, the causal link between Avandia and heart failure, stroke and heart attack can be studied in a population that is at a background risk of cardiovascular events, and indeed has been. There is no dearth of available evidence like there was in the unique case of *Charlton*. To the contrary, the issue has been studied.

46. This scientific evidence establishing a causal link between Avandia and cardiovascular harm was sufficient to cause stringent regulatory steps to be taken by Health Canada between 2007 and 2010, ultimately leading to changes in the monograph materials, albeit too late in the Respondents' submission.[36]

[35] Transcript of Hearing on September 16, 2015, page 158 lines 4-9 [Appeal Book, Volume 4, Tab 30].
[36] In 2007 Health Canada prompted GSK to prepare a public "Dear Healthcare Professional Letter" which was published by Health Canada on June 1, 2007 (the "2007 Dear Healthcare Professional Letter"). In it, the public was warned about the "cardiac safety of AVANDIA". Health Canada cautions of "an increased risk of myocardial infarction and cardiovascular death in patients with type 2 diabetes treated with Avandia". [Dull Affidavit Exhibit "G"; Appeal Book, Volume 2, Tab 14]. On November 1, 2007, Health Canada restricted the prescription of Avandia as a last option alternative: (i) it was no longer approved as monotherapy or with sulfonylurea, except when metformin was not tolerated/contraindicated; (ii) it was contraindicated with all stages of heart failure; and (iii) it was not to be used with insulin or as triple therapy. Health Canada advised patients to speak to their doctors to "revisit" their treatment through Avandia. [Dull Affidavit, Exhibit "H"; Appeal Book, Volume 2, Tab 14]. The Appellants' own expert at certification, Dr. Tina Kader, a physician, acknowledged that she stopped prescribing Avandia following the release of the Nissen article, and has not changed this practice. [Transcript of Cross-Examination of Dr. Kader, question 251, line 15; Appeal Book, Volume 3, Tab 27]. In 2010, Health Canada implemented the extraordinary "Patient Informed Consent Process" with respect to Avandia, which restricted prescription only to patients who acknowledge they have been informed of the heart-related risks of Avandia, and that they are aware of other diabetes treatment options. Health Canada ordered that Avandia only be prescribed after a patient has signed a consent form acknowledging the dangers of heart attack, angina and heart failure. [Lipscombe Affidavit Exhibit "N"; Lipscombe Affidavit para. 93; Appeal Book, Volume 2, Tab 17] In the US the FDA in 2007 directed GSK to issue a "black box" warning – the strongest health warning the FDA can direct - in the labeling for Avandia. The first black box warning was added in the US in May 2007, relating to heart failure. In November of 2007, in the US GSK was required to add a boxed warning of an increased risk of heart attack. [Lipscombe Affidavit, paras. 71-72; Appeal Book, Volume 2, Tab 17]. From September 2010 to June 2013, the FDA imposed a restricted prescription program in the US which required doctors and patients to enroll in order to prescribe and receive Avandia. American patients were required to provide informed, written consent in order to be eligible for the drug [Lipscombe Affidavit, para. 94; Appeal Book, Volume 2, Tab 17].

47. The Appellants paid lip service to the established principle that at a motion for certification the judge is not to weigh the conflicting expert evidence,[37] while inviting the Chambers Judge to discount the expert evidence of Dr. Lipscombe on general causation on the basis that she did not take into account the 2013 re-adjudication of the RECORD study. This is a GSK-funded study that, the Appellants argue, disproves the merits of the Respondents' allegations[38] (the limitations and criticisms of the 2013 research are nonetheless expressly acknowledged.)[39] The Chambers Judge appropriately declined to wade into the merits at certification,[40] consistent with the direction of the Supreme Court of Canada.

48. There is simply no merit to the Appellants' submission that the Respondents failed to advance any methodology of proving general causation, or that the Chambers Judge failed to hold the Respondents to their burden. The Respondents' expert evidence was considered and accepted by the Chambers Judge. The Chambers Judge cites at length analysis from the decision of Justice Strathy in *Singer v. Schering-Plough Canada Inc.*,

[37] Transcript of Hearing on September 16, 2015, pages 340-341 [Appeal Book, Volume 4, Tab 30].
[38] See for e.g. Transcript of Hearing on September 16, 2015, pages 340-346 [Appeal Book, Volume 4, Tab 30].
[39] Transcript of Hearing on September 17, 2015, pages 377-379 [Appeal Book, Volume 4, Tab 31].
[40] See for e.g. Transcript of Hearing on September 17, 2015, page 386 lines 8-21 [Appeal Book, Volume 4, Tab 31].

2010 ONSC 42 which at paragraph 140(I) states the need for a plaintiff who proposes questions relating to causation or damages as common issues to "demonstrate (with supporting evidence) that there is a workable methodology for determining such issues on a class-wide basis."[41]

iii. Resolving General Causation Issues Moves Litigation Forward

49. Remaining with the matter of general causation, the Appellants further dispute the utility of the general causation inquiries. At certification the Appellants argued at length that the utility of general causation issues are minimized due to the remaining need, if general causation is proven, to establish specific causation in relation to each Class Member.

50. At the motion for certification the Chambers Judge engaged with this argument, directing the following question to the Respondents:

> **THE COURT:** So why is it necessary to decide the increased risk question?
>
> **MR. WAGNER:** So on the increase side, what we're talking about is can Avandia increase the risk. Because if it doesn't increase the risk then there's no case that that individual has.
>
> **THE COURT:** But is it necessary -- if it does increase the risk does that take you any distance down the road? Because you still have to prove actual causation.[42]

51. The three general causation questions in this case – Can Avandia cause or contribute to heart failure? If so, what is the magnitude of this increased risk?; Can Avandia cause or

[41] Certification Decision, para. 48 [Appeal Book, Volume 1, Tab 4].
[42] Transcript of Hearing on September 15, 2015, page 104 [Appeal Book, Volume 4, Tab 29].

contribute to heart attacks? If so, what is the magnitude of this increased risk?; Can Avandia cause or contribute to strokes? If so, what is the magnitude of this increased risk? – are the threshold questions that must be resolved before it becomes logical to proceed to the subsequent common issues.

52. A general causation inquiry asks if a drug has the *potential* to cause harm (i.e. "can it cause") in relation to class members generally, whereas specific causation – an inquiry not part of the common issues trial - asks whether the potential for harm was *actualized* in relation to a particular class member (i.e. "did it cause?"). Because general causation is concerned with potentialities, rather than actualities, it is framed in terms of increased likelihood of causing harm. Whether a drug causes or increases the likelihood of certain side effects or medical conditions is an appropriate common issue.[43]

53. The general causation issue is meaningful because it is a requisite component of the claim of each Class Member. Establishing that a drug can cause the alleged harm resolves a fundamental aspect of the liability issue and advances the litigation for each class member.[44] If general causation cannot be proven, that's the end of the matter; if it is proven, it's then up to each Class Member to establish that his or her injury was of a kind that can be caused by Avandia, and would likely not have occurred but for the ingestion

[43] *Bartram C.A., supra* at para. 15 [Respondents' Authorities, Tab 2].
[44] See for e.g. *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260 at para. 55 [*Stanway*] [Respondents' Authorities, Tab 19].

of Avandia.[45] Establishing the link between Avandia and the alleged harm is an important step in the litigation.

54. Resolution of this issue permits class members, after the common issues trial, to present claims of *specific* causation of, and compensation for, harm they've experienced and that Avandia has been found to cause on a general basis. If the fundamental link between the drug and harm is not established on a general level then the litigation will fail for each class member.

55. In addition, the finding on general causation informs, or influences, just how readily specific causation may be proved, as the Respondents submitted at the hearing of the certification motion.[46] For example, if Avandia is found to double the risk of heart attack in its users at large, individual class members may more readily prove specific causation.[47]

56. Although the merits of the general causation question were not the proper focus of the certification motion, the Appellants led extensive evidence disputing the merits of the alleged causal link between Avandia and the alleged cardiovascular harm, relying primarily on the re-adjudication of the RECORD study. This is a relevant point to

[45] *Bartram Sup. Ct.*, *supra* at para. 31 [Respondents' Authorities, Tab 1].
[46] In *Stanway v. Wyeth Canada Inc., supra* the British Columbia Court of Appeal, at paragraph 57, discussed the significance of the general causation issue to the class members' claims of negligence: "Moreover, this initial link, if established, is clearly a substantial element of each class member's claim in negligence. A finding of general causation will obviously influence specific causation depending on the strength of the evidence supporting general causation. For example, if it were found that hormone therapy doubles the risk of developing breast cancer, the individual class members, depending on their individual circumstances, may more readily prove specific causation. Wyeth's awareness of the link is also relevant to the standard of care. Moreover, it is doubtful that an individual litigant could marshall the medical and epidemiological evidence necessary to establish the connection. On the other hand, if the link is not established, the class proceeding will come to an end."
[47] *Schwoob v. Bayer Inc.*, 2013 ONSC 2207 at para. 34 [Respondents' Authorities, Tab 18].

consider here, because if class members were deprived of a class action and left with the (unviable) alternative of individual actions, each individual would need to overcome that general causation challenge in their individual litigation. This consideration underscores the significance of the general causation common issues, and additionally emphasizes the preferability of a class action.

57. It is not a condition of certification that a common issue "predominate" over issues affecting only individual members in order to be common for purposes of certification. Nor is it a condition of certification that the resolution of the common issues be determinative of each class member's claim. As Justice Cullity explained in *Tiboni*:

> Unlike in the United States, the question is not whether common issues predominate over the individual issues. The test is not the same. It requires a consideration of the extent to which the resolution of the common issues will advance the three objectives of the CPA - access to justice; judicial economy; and behavioural modification.[48]

iv. General Causation Issues will be Resolved with Scientific Evidence

58. At paragraph 64 of their factum the Appellants assert that "Whether Avandia can cause congestive heart failure, heart attack, or stroke is an academic, scientific inquiry, the result of which cannot be applied to establish causation in the class as defined."

59. The fact that the general causation question is answered with the aid of "scientific inquiry" is not a deficiency of the case. Scientific study is precisely, and necessarily, what is going to inform the determination at trial of the general causation questions. The

[48] *Tiboni, supra* at para. 96 [Respondents' Authorities, Tab 20]. See also *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 39 [*Dutton*] [Appellants' Authorities, Tab 25].

key role of scientific evidence in these pharmaceutical cases is indeed confirmed by *Charlton* – scientific evidence was, critically, absent (recall that the Court of Appeal wanted to see evidence of a controlled study examining adverse cardiac events in the specific population for whom it was indicated and to whom it was marketed, but it could not because the drug was off the market and thus could not be studied).

v. One Product, One Type of Harm

60. The Appellants weave into their submissions on general causation issues the argument that the Chambers Judge erred in certifying a class action that seeks to resolve, in one common issues trial, claims relating to three types of alleged harms: heart failure, heart attack and stroke.

61. This case alleges harm to a singular biological system, the cardiovascular system. The case does not allege disparate and varied side effects more generally. The trial will focus on one pharmaceutical compound, containing the active ingredient rosiglitazone maleate. The case therefore involves one set of warnings. The case looks at the conduct and knowledge of the Appellants in relation to this one compound.

62. This class action is not on equal footing with *O'Brien v. Bard*[49] or *Merck Frosst Canada Ltd. v. Wuttunee*[50], both cases in which the diversity of the claims advanced were fatal to the common issues criterion.

[49] *O'Brien v. Bard*, 2015 ONSC 2470 [*O'Brien*] [Appellants' Authorities, Tab 16].
[50] 2009 SKCA 43 [*Wuttunee*] [Appellants' Authorities, Tab 14].

63. In *Wuttunee*, the general causation issue was framed as "Whether Vioxx can cause or exacerbate cardiovascular or gastrointestinal conditions".[51] The alleged harm was found to be vague and broad:

> Although Vioxx was recalled from the market because of its perceived tendency to increase the risk of thrombotic cardiovascular events, it is apparent from this synopsis, and from the subclass descriptions and common issues approved in the certification order, that the respondents intend, in this action, to allege that Vioxx caused or contributed to a wide variety of cardiovascular or gastrointestinal conditions or events suffered by members of two of the subclasses approved, by no means limited or related to thrombotic cardiovascular events. The factual and theoretical bases for these additional claims, however, are unclear.[52]

64. In *O'Brien v. Bard*, a total of 19 different vaginal mesh products were alleged to have caused personal injuries. Justice Perell declined to certify the general causation question because he concluded as follows:

> In its submissions that Ms. O'Brien's class action wants for commonality, Bard relies on numerous idiosyncratic factors about the Class Members and their physicians. By and large, those differences among the Class Members would not defect a finding of commonality. The commonality problem for Ms. O'Brien's class action is on the defendant's side of the forensic ledger, where a decision about one product, even about its use of surgical mesh, does not produce a class-wide decision because of <u>significant levels of difference among Bard's products.</u>[53] [underline added]

65. Clearly, for the reasons stated in paragraph 63 above, the obstacles presented in *Wuttunnee* and *O'Brien* do not arise in this case.

66. Moreover it is worth repeating that it is the evidence of the Respondents' expert, Dr. Robert Myers, that the interrelated cardiovascular events of stroke, heart attack and

[51] *Ibid.*
[52] *Wuttunne, supra* at para. 39 [Appellants' Authorities, Tab 14].
[53] *O'Brien, supra* at para. 131 [Appellants' Authorities, Tab 16].

congestive heart failure may commonly be attributable to increased fluid retention caused by Avandia.[54]

vi. General Causation Distinct from Specific Causation

67. The lines between general and specific causation must not be blurred when reviewing the Appellants' submissions. Specific causation is an individual inquiry. That is acknowledged by the Respondents. But the individual nature of specific causation does not diminish the appropriateness of this case as a class action. The individual nature of specific causation has no bearing on the evidentiary burden with respect to *general* causation. Therefore it is irrelevant that the Respondents' experts agreed, when pressed in cross-examination, that specific causation could only be determined upon examination of individual circumstances of Class Members.

68. Related to these statements by the Respondents' experts, it is critical not to impose or project on the Respondents' experts – both of whom are medical professionals – an understanding of legal terminology. The nature of the evidence they provide, and on which they rely in arriving at their opinions, is scientific. They are not qualified to make statements as to whether or not their findings, conclusions and opinions constitute legal causation. Therefore it is unreasonable to suggest that the Respondents will at trial fail to prove general causation on a balance of probabilities because the scientific terminology used by the Respondents' certification experts does not mirror or match the legal language, or legal burden.

[54] Affidavit of Dr. Robert Myers, sworn September 20, 2013 at para. 57 [Appeal Book, Volume 2, Tab 15].

vii. No Circumvention of "But For" Causation Test

69. The Respondents disagree with the Appellants that the Chambers Judge's inclusion of the phrase "contribute to" in the general causation issues is irrelevant (which would in any event not constitute a reviewable error). The phrase "contribute to" in the context of general causation does not constitute an end-run around the independent "but for" test of specific causation.

70. Establishing general causation means establishing a causal connection between a drug and harm in a particular population on a statistical or epidemiological level (a "general" level). If the general causation issue is resolved in the Respondents' favour, the "but for" test continues to apply in the specific, or individual, causation analysis.

71. Chief Justice McLachlin made an obiter comment in *Clements* that the application of the "material contribution" test may be expanded as new situations raise new considerations.[55] This comment made in *Clements* is not relied on by the Respondents to satisfy their burden at certification with respect to general causation. Rather, this comment may become relevant at the stage of individual assessments – a matter for another phase of the litigation.

72. The Respondents submit that the Chambers Judge made no reviewable error in certifying the three general causation issues.

Issue 3: That the Chambers Judge erred in certifying "enterprise liability" as a common issue.

[55] *Clements v. Clements,* 2012 SCC 32 at para. 44 [Appellants' Authorities, Tab 8].

73. The pleadings clearly identify the individual roles of the two Appellants and the foundation for their alleged agency relationship. The agency relationship forms the basis for the pleading of enterprise liability.

74. The pleading of enterprise liability is supported by the following materials facts: The Appellant GlaxoSmithKline Inc. is identified by the Respondents as the entity that conducts the manufacturing, promoting, labeling, marketing and sale of Avandia in Canada.[56] The pleadings identify the Appellant GlaxoSmithKline LLC as the entity that conducts the manufacturing, promoting, labelling, marketing and selling of Avandia in the United States, and one of the entities (or a successor entity thereof) that developed Avandia.[57] The pleadings also allege that GlaxoSmithKline LLC is responsible for monitoring the worldwide adverse events associated with Avandia, and that it works in close partnership with and directs GlaxoSmithKline Inc.'s manufacturing, promoting, labelling, marketing and sale of Avandia in Canada and the latter's interactions with Health Canada.[58]

75. The Chambers Judge took the correct approach to the pleading of agency. In the context of s. 7(1)(a) of the *CPA* – assessing whether the pleadings disclose a cause of action – the Chambers Judge concluded that the Appellants had not satisfied him that the pleading of enterprise liability should be struck because the claim could not succeed. The Chambers Judge properly applied the *Hunt v. Carey* test. No evidence is to be considered in assessing whether s. 7(1)(a) is satisfied. Only the pleadings, assumed to be true, are to be

[56] Fresh as Second Amended Statement of Claim, para. 18 [Appeal Book, Volume 1, Tab 10].
[57] *Ibid*. at para. 19 [Appeal Book, Volume 1, Tab 10].
[58] *Ibid*.

considered. The Chambers Judge's reasons at paragraphs 29 and 30 of the Certification Decision indicate that he was satisfied the pleadings contain material facts to support the pleading.[59]

76. The Chambers Judge also concluded that the pleadings in this case "includ[e] more detail in support of the allegations of enterprise liability" than in *Durling v. Sunrise Propane Energy Group Inc.*[60] It should be noted that in *Durling*, where the judge did conclude the pleadings were deficient, the plaintiff was given leave to amend the pleadings to correct the deficiency. Therefore if the Chambers Judge had made an error in certifying this common issue on the basis of the pleadings before him (which the Respondents submit he did not), it would not warrant overturning the decision to certify the issue, or the action more broadly.

77. The Appellants further submit that insufficient evidence was led by the Respondents to establish that the Appellants are, in fact, agents of one another. The Appellants submit that the Chambers Judge erred by failing to apply the requisite evidentiary burden at certification.

78. However, the Respondents' evidentiary burden to satisfy the common issues requirement in s. 7(1)(c) of the *CPA* is to show some basis in fact that the issue is a common one. Common issues are defined in s. 2(e) of the *CPA* as:

[59] In *Martin v. AstraZeneca Pharmaceuticals PLC*, 2012 ONSC 27 44, aff'd 2013 ONSC 1169 (Div. Ct.) [Appellants' Authorities, Tab 13], the judge concluded that there were no material facts supporting the pleading of an agency relationship. The Chambers Judge in the present case did not arrive at the same conclusion.
[60] 2012 ONSC 4196 [Appellants' Authorities, Tab 9].

(a) common but not necessarily identical issues of fact, or

(b) common but not necessarily identical issues of law that arise from common but not necessarily identical facts.

79. Certification is not a preliminary merits test. Related to this principle, the common issues criterion is not a high legal hurdle.[61] The relevant question is whether dealing with those questions as common issues will avoid duplication of fact finding or legal analysis.[62] This Court has explicitly stated that "whether there is an "arguable case with respect to the defendants' potential liability" is not the legal test for determining common issues."[63]

80. In the context of the requirement in section 7(1)(c) that the claimant lead some evidence – "some basis in fact" – that the proposed common issue is indeed a "common issue", the Chambers Judge correctly applied the legal test to the proposed common issue relating to enterprise liability. He directed himself to consider whether its resolution was independent of any individual findings of fact in relation to individual class members, and whether its resolution would advance each class member's claim.[64] The Chambers Judge remarked as follows at paragraph 81 of the Certification Decision:

> The question of whether the defendants are liable for the actions of each other, and if so on what basis, does not require any consideration of the circumstances of individual class members. It can readily be decided on a classwide basis. The answer will assist the individual class members because it will determine whether either or both of the defendants are

[61] *Ibid*.
[62] *Hollick v. Metropolitan Toronto (Municipality),* 2001 SCC 68 at para. 15 [*Hollick*] [Appellants' Authorities, Tab 12].
[63] *Canada (Attorney General) v. MacQueen,* 2013 NSCA 143 at para. 122 [emphasis added] [*MacQueen*] [Appellants' Authorities, Tab 5].
[64] See e.g. *Hollick, supra* at para. 18 [Appellants' Authorities, Tab 12].

> responsible for any damages which might be awarded. I will certify this common issue as proposed by the plaintiffs.

81. The Respondents submit that the Chambers Judge made no reviewable error in certifying the enterprise liability common issue.

Issue 4: That the Chambers Judge erred in certifying the unjust enrichment/waiver of tort common issue, because, the Appellants submit, restitutionary relief is unavailable in a negligence/personal injury case.

82. The Appellants contradict themselves by conceding that no court has yet answered the question of whether "waiver of tort" can be relied on as a form of restitutionary relief in a personal injury/negligence case. Indeed the Chambers Judge declined to resolve this issue at the procedural motion. The Chambers Judge also declined to resolve at the procedural motion the issue of whether waiver of tort is an independent cause of action or merely a remedy. As the Chambers Judge noted, there has been "considerable debate about whether waiver of tort is a stand alone cause of action or simply an alternative remedy once a tort has been proven."[65] The Chambers Judge is attuned to the debate.[66]

83. The Chambers Judge did not err in failing to resolve these issues on the procedural motion before him. The Chambers Judge agreed with the approach adopted by other motions judges that a procedural motion – such as a certification motion - is not the place to confront these questions.

[65] Certification Decision, para. 25 [Appeal Book, Volume 1, Tab 4].
[66] Transcript of Hearing on September 15, 2015, pages 59-61 [Appeal Book, Volume 4, Tab 29].

84. Moreover, as Justice Cullity noted in paragraph 49 of *Heward v. Eli Lilly & Co*.,[67] in cases where the law is unsettled or in a state of development, the court should be reluctant to deal with issues on the basis of the pleading alone. Relatedly, it is a fundamental principle of class action law that the novelty of a pleaded cause of action is no basis to deny certification.

85. The Appellants may advocate for a different outcome, as they did at the motion for certification, but nonetheless the Chambers Judge was bound to follow the reasoning of the Supreme Court of Canada in *Pro-Sys* that the pleadings stage is "not the proper place to resolve the details of the law of waiver of tort, nor the particular circumstances in which it can be pleaded".[68] The Chambers Judge committed no reviewable error in certifying this common issue.

Issue 5: That the Chambers Judge erred in concluding that a class action was the preferable procedure for resolving the claims.

86. The Appellants rely on *MacQueen* to say that, if the Chambers Judge is found to have made the preceding errors they advance on this appeal, the issue of preferability should be considered "afresh" without deference to the certification judge.

87. For all of the foregoing reasons, the Chambers Judge made no reviewable errors warranting intervention from this Court. In any event, it is wrong to assert that this

[67] [2007] O.J. No. 404 [*Heward*] [Appellants' Authorities, Tab 11].
[68] *Pro-Sys, supra* at para. 97 [Appellants' Authorities, Tab 17, citing Justice Epstein at paragraph 68 of *Serhan (Trustee of) v. Johnson & Johnson* (2006), 85 O.R. (3d) 665 (Div. Ct.). In the present case, the Chambers Judge, at paragraph 27 of the Certification Decision, cited Justice Cullity in *Heward, supra* who in turn relied on this same passage from *Serhan*.

passage in *MacQueen* should be followed by this Court if it did find that the Chambers Judge made any of the errors advanced by the Appellants.

88. In *Wright Medical*, this Court cautioned that it would be "misguided to mechanically transpose this Court's reasoning in *MacQueen*, to the features of this case."[69] The Court of Appeal said in *Wright Medical* that the facts, surrounding circumstances, evidence, pleadings and causes of action in *MacQueen* were all "so readily distinguishable from the much narrower issues" raised by that appeal. Referring to *MacQueen*, the Court in *Wright Medical* said the following:

> The failings which led to a setting aside of the certification order in *MacQueen* had to do with errors arising from the motion judge's failure to consider and apply correct legal principles, misstating the legal test for determining common issues, and failing to conduct a proper analysis of commonality. Respectfully, those shortcomings are not evidenced in this case.[70]

89. The same conclusion applies here. The Appellants have not established any errors that warrant a setting aside of the deference owed to the Chambers Judge. The deference owed to the Chambers Judge is substantial.[71] The assessment of preferability is discretionary in nature. This informs the standard of review on appeal. The Supreme Court of Canada has held:

> [A] decision by a certification judge is entitled to substantial deference: see e.g. *Pearson*, at para. 43; *Markson v. MBNA Canada Bank*, 2007 ONCA 334, 85 O.R. (3d) 321, at para. 33. Specifically, "[t]he decision as to preferable procedure is ...

[69] *Wright Medical*, *supra* at para. 36 [Appellants' Authorities, Tab 27].
[70] *Ibid.*
[71] *Wright Medical, supra* at para. 31 [Appellants' Authorities, Tab 27].

> entitled to special deference because it involves weighing and balancing a number of factors": *Pearson*, at para. 43.[72]

90. This Court, in *Wright Medical*, stated that the standard of review of a finding on preferable procedure is "palpable and overriding error".[73]

91. The Chambers Judge found that a class proceeding was the preferable procedure to resolve the class members' claims. This finding is owed considerable deference and must not be overturned absent a palpable and overriding error.

92. In 2013 the Supreme Court of Canada made it clear that the preferability analysis is a comparative one.[74] Would a class member be better off having the common issues resolved in a class action than if he or she pursued litigation in another form?

93. In this case, the Appellants proposed case-managed individual actions with common disclosure. At the hearing of the certification motion, the Chambers Judge pointedly asked counsel for the Respondents to address this proposed alternative to a class action in assessing preferability.[75]

94. Counsel for the Respondents submitted that the Appellants' proposal for case-managed actions overseen by a judge of the Supreme Court of Nova Scotia would not suit a national action, as it would require coordination across multiple jurisdictions and invite

[72] *AIC Limited*, *supra* at para. 65 [Appellants' Authorities, Tab 1], citing *Pearson v. Inco Ltd*. (2006), 78 O.R. (3d) 641 (C.A.) at para. 43. See also *Gay, supra* at para. 116 [Respondents' Authorities, Tab 9]; *Hoy v. Medtronic Inc*., 2003 BCCA 316 at para. 38 [Respondents' Authorities, Tab 13].
[73] *Wright Medical, supra* at para. 51 [Appellants' Authorities, Tab 27].
[74] *AIC Limited*, *supra* at paras. 26-38 [Appellants' Authorities, Tab 1].
[75] Transcript of Hearing on September 16, 2015, page 205 lines 7-11 [Appeal Book, Volume 4, Tab 30].

inconsistent results.[76] Further, it was submitted by counsel for the Respondents, any complexities associated with proving the remaining individual issues remain present in both types of litigation, whether in the context of a phase of a class action, or within case-managed individual actions; case-managed individual actions provide no preferable alternative in this respect.[77]

95. In addition, the special tools afforded to a case management judge overseeing a class action pursuant to the *Class Proceedings Act* – specifically by sections 15 and 30 – to enable individuals to come forward and resolve their claims in an efficient and productive manner would not be available outside a class action.[78]

96. These problems with case-managed individual actions were accepted by the Chambers Judge. In assessing preferability in the present case, the Chambers Judge correctly stated as follows:

> Problems with causation will exist whether class members pursue individual law suits or a class proceeding. As a result, it should not be a basis on which certification is refused. Even if the common issue trial is relatively short and the individual proof of damage extensive, that does not mean there is no efficiency to be gained by an answer in common to the questions of risk, breach of duty, joint liability and restitution. [79]

97. The Chambers Judge continued:

[76] Transcript of Hearing on September 16, 2015, pages 206-212 [Appeal Book, Volume 4, Tab 30].
[77] Transcript of Hearing on September 16, 2015, page 210 lines 17-21 [Appeal Book, Volume 4, Tab 30].
[78] Transcript of Hearing on September 16, 2015, pages 212-216 [Appeal Book, Volume 4, Tab 30].
[79] Certification Decision, para. 102 [Appeal Book, Volume 1, Tab 4].

> [A class proceeding] allows the parties and the court to be creative in maximizing efficiency without compromising the ultimate legal requirements for proof of liability and damages.[80]

98. The Chambers Judge's finding that one class proceeding is preferable to a multitude of individual actions – or case-managed individual actions, as proposed by the Appellants - does not amount to a palpable and overriding error warranting appellate intervention.

99. Individual litigation would see each claimant, independently and in a serial manner, establishing each of the issues presently certified as common issues *before* proceeding to move on to the remaining individual issues. Individual claimants would have to adduce evidence on each of these issues. As recognized by the Chambers Judge, in case-managed individual actions each claimant would have to start litigation and prove all aspects of their claim and damages, including the basis for punitive damages, while a class action would only necessitate proof of individual causation and damages if there was success at a common issues trial.[81]

100. Individual litigation of this nature is an expensive proposition; even if the damages awarded in a successful case are more than "modest" – as the Appellants assert - the costs of mounting complex litigation involving a pharmaceutical would be prohibitive in most cases. Only a class action will truly provide access to justice for these Class Members.

101. The preferability of a class action in the above respects is not eliminated simply because liability questions remain after the conclusion of the common issues trial. In the

[80] Certification Decision, para. 103 [Appeal Book, Volume 1, Tab 4].
[81] Certification Decision, para. 105 [Appeal Book, Volume 1, Tab 4].

Respondents' submission, this Court has not declared the preferability criterion to fail in such circumstances, contrary to the Appellants' interpretation of *Murray* and *MacQueen*.

102. In the Respondents' respectful view, if this Court had made such a blanket declaration, that declaration would be inconsistent with class action jurisprudence (common issues need not be determinative of liability[82]) and it would overlook the significant efficiencies gained by a complex, expensive common issues trial involving a pharmaceutical, such as this one. It would fail to appreciate the different types of class actions and common issues trials, and their varying demands. The more expensive and complex a claim, the greater the efficiencies realized by resolving those issues capable of common resolution in a common issues trial, and the less feasible it would be to individually litigate all of the issues.

103. It is preferable for a common issues trial to make possible an individual claims process - even if that individual claims process may resemble "individual trials" - rather than shut claimants out of the judicial system. The complexity of a claim is no reason to deny the preferability of a class action. Access to justice should not be denied on that basis.

104. The Chambers Judge concluded that a class action is the preferable procedure to resolve Class Members' claims, and this conclusion is owed substantial deference. The Chambers Judge made no error to warrant a setting aside of this conclusion.

Issue 6: Did the Chambers Judge err by finding that the Representative Plaintiffs could fairly and adequately represent the interests of the Class?

[82] See note 48.

105. The key considerations in assessing the adequacy of a representative plaintiff are: Does the proposed representative plaintiff have a common interest with other class members?[83] Would he or she vigorously prosecute the claim?[84] What is the motivation of the representative?[85] Is the representative's counsel competent?[86] Does the representative plaintiff have capacity to bear any costs that may be incurred by the representative?[87]

106. The proposed representative plaintiff need not be "typical" of the class nor the "best" possible representative.[88]

107. The Chambers Judge granted leave to file further evidence in support of the requirement in s. 7(1)(b) of the *CPA* that there be "two or more persons" in an identifiable class. In doing so, he relied on the same approach taken by the British Columbia Supreme Court in *Wakelam v. Johnson & Johnson*.[89] In particular, the Chambers Judge seemed to want to see further evidence that there were other individuals "interested in pursuing their claims through a class proceeding."[90]

108. In granting the Respondents leave to file supplemental evidence, the Chambers Judge was employing the procedural flexibility that is necessary to facilitate realization of the

[83] *Campbell v. Flexwatt Corp.,* [1997] B.C.J. No. 2477 (C.A.) at paras. 75-76 [Respondents' Authorities, Tab 5].
[84] *Ibid*.; *Dutton*, *supra* at para. 41 [Appellants' Authorities, Tab 25].
[85] *Dutton*, *ibid*.
[86] *Ibid*.
[87] *Ibid*.
[88] *Ibid*.
[89] 2011 BCSC 1765, rev'd 2014 BCCA 36 [Respondents' Authorities, Tabs 21 and 22]. As the Chambers Judge notes at paragraph 45 of the Certification Decision, although certification was reversed in that case, the Court of Appeal found no error in the trial judge's approach to the requirement for two or more class members, and confirmed that the certification judge did not err in concluding that the supplemental evidence demonstrated the existence of an identifiable class of two or more persons (see paras. 101-105 of the British Columbia Court of Appeal decision).
[90] Certification Decision, para. 46 [Appeal Book, Volume 1, Tab 4].

statutory purposes of the *CPA*.[91] The comments of experienced class action jurist Justice Belobaba, in *Keatley Surveying Ltd. v. Teranet Inc*.,[92] are particularly illuminating:

> In my view, there are two factors that set appeals of certification motions apart from other matters. One factor is the unique nature of a class action. As a procedural vehicle designed to promote judicial economy, access to justice, and behaviour modification, the class action demands a more flexible approach in which plaintiffs are not held strictly to their arguments as initially formulated: *Halvorson*, at para. 23. A strict approach could result in an action that is otherwise amenable to certification failing on appeal simply because it was not argued in an ideal manner at first instance. This could lead to multiple claims (thousands, in some cases) proceeding individually in a manner antithetical to judicial economy. Or, perhaps worse, access to justice and behaviour modification might be forgone entirely if class members are unable to bring claims that were not certified, because they are too expensive to bring individually.[93]

109. Counsel for the Representative Plaintiffs fulfilled the request of the Chambers Judge. They submitted several affidavits as additional evidence of two or more members of each of the Primary and Family Classes.[94] The Chambers Judge accepted the affidavits of Ms. Newhouse, Mr. White, Mr. Moulton and Ms. Walsh as satisfying the requirement to show two or more members of each Class.

[91] Comments confirming the flexibility of class actions often arise in the context of an appeal of a decision denying certification, at which point aspects of the class action, such as class definitions and/or common issues, may be reformulated: see for e.g. *Halvorson v. British Columbia (Medical Services Commission)*, 2010 BCCA 267 at para. 23, citing *Markson v. MBNA Canada Bank*, 2007 ONCA 34 at para. 39, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 346 [Respondents' Authorities, Tab 12.]
[92] 2014 ONSC 1677 (Div. Ct.), aff'd 2015 ONCA 248 [Respondents' Authorities, Tabs 15 and 16]. The motion for certification had previously been dismissed: 2012 ONSC 7120 (Sup. Ct.) [Respondents' Authorities, Tab 14]. At a later motion for summary judgment, brought by both sides, Justice Belobaba concluded that the determinative common issue was answered in favour of the defendant, and therefore granted its motion for summary judgment: 2016 ONSC 1717 (Sup. Ct.) [Respondents' Authorities, Tab 17].
[93] 2014 ONSC 1677 (Div. Ct.) at para. 35 [Respondents' Authorities, Tab 15].
[94] Affidavit of Richard Crossman sworn February 26, 2016 (the "Crossman Affidavit") [Appeal Book, Volume 2, Tab 23]; Affidavit of Kathryn Ann Newhouse sworn February 9, 2016 [Appeal Book, Volume 2, Tab 19]; Affidavit of David Edwin White sworn February 5, 2016 [Appeal Book, Volume 2, Tab 20]; Affidavit of Gilbert Everett Moulton sworn February 10, 2016 [Appeal Book, Volume 2, Tab 21]; Affidavit of Ann Walsh sworn February 24, 2016 [Appeal Book, Volume 2, Tab 22].

110. There was no prejudice to the Appellants from a lack of opportunity to respond: counsel for the Appellants had the opportunity to provide submissions on the supplemental evidence. These submissions were clearly reviewed and considered by the Chambers Judge. Indeed, the Chambers Judge accepted the position of the Appellants that evidence relating to suffering heart failure, heart attack and stroke was irrelevant to certification, in light of the class definition making no reference to these cardiovascular outcomes.[95] As a result, the Chambers Judge saw no need to require that the affiants produce medical histories in support of the allegations of these cardiovascular outcomes.[96] It would have been an inefficient and irrelevant exercise, to the prejudice of these affiants.

111. The Appellants challenge the adequacy of the Representative Plaintiffs on the basis that they somehow failed to meet the standard imposed on them, because they needed to file supplemental evidence of "two or more" members of the identifiable class.

112. It is an artifice to suggest that this in any way reflects on the adequacy of the Representative Plaintiffs in a manner relevant to s. 7(1)(e) of the *CPA*. It is counsel who determines the contents of the evidentiary record at certification, not the Representative Plaintiffs. There has been no failing, in any way relevant to the legal test under the *CPA*, on the part of the Representative Plaintiffs.

113. Nor, it is submitted, was this failing a consequential reflection on the competency of counsel for the Representative Plaintiffs. It should be noted that jurisprudence more recent than that relied on by the Chambers Judge calls into question the basis for the

[95] Supplemental Certification Decision, para. 5 [Appeal Book, Volume 1, Tab 5].
[96] Supplemental Certification Decision, para. 9 [Appeal Book, Volume 1, Tab 5].

Chambers Judge's request for further evidence of individuals desirous of advancing their claims through the vehicle of a class action.

114. *Keatley Surveying Ltd. v. Teranet Inc*.[97] is a copyright class action certified on appeal to the Divisional Court (Ontario). Certification was upheld by the Ontario Court of Appeal. In first instance, the motion judge had required that the plaintiff put forward evidence that there were two or more persons who wished to have their copyright infringement complaint determined in the class proceeding. However, at the Divisional Court, Justice Sachs, in certifying the action, found that this was an error:

> Neither the plain language of the *CPA* nor the recent jurisprudence from the Supreme Court of Canada (which was released after the motion judge rendered her decision) make any mention of such a requirement.[98]

PART VI - ORDER OR RELIEF SOUGHT

115. For the foregoing reasons, the Respondents respectfully submit that this appeal should be dismissed, with an award of costs on this appeal in the amount of $5000, plus disbursements.

All of which is respectfully submitted this 1st day of August, 2017.

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[97] See note 92.
[98] 2014 ONSC 1677 (Div. Ct.), *supra* note 92 at para. 9 [Respondents' Authorities, Tab 15].

Appendix A - List of Citations

JURISPRUDENCE

1. *Bartram (Litigation guardian of) v. GlaxoSmithKline Inc.*, 2012 BCSC 1804
2. *Bartram (Litigation guardian of) v. GlaxoSmithKline Inc.*, 2013 BCCA 462
3. *Boulanger v. Johnson & Johnson Corp.*, [2007] O.J. No. 179 (Sup. Ct.)
4. *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 (Gen. Div.)
5. *Campbell v. Flexwatt Corp.,* [1997] B.C.J. No. 2477 (C.A.)
6. *Canada (Attorney General) v. Anderson*, 2011 NLCA 82
7. *Cassano v. Toronto Dominion Bank*, 2007 ONCA 781
8. *Charlton v. Abbott Laboratories Inc.*, 2015 BCCA 26
9. *Gay v. New Brunswick (Regional Health Authority 7)*, 2014 NBCA 10
10. *Griffin v. Dell Canada Inc*., [2009] O.J. No. 3438 (Div. Ct.)
11. *Griffin v. Dell Canada Inc*., [2009] O.J. No. 418, 72 C.P.C. (6th) 158
12. *Halvorson v. British Columbia (Medical Services Commission)*, 2010 BCCA 267
13. *Hoy v. Medtronic Inc*., 2003 BCCA 316
14. *Keatley Surveying Ltd. v. Teranet Inc*., 2012 ONSC 7120 (Sup. Ct.)
15. *Keatley Surveying Ltd. v. Teranet Inc*., 2014 ONSC 1677 (Div. Ct.)
16. *Keatley Surveying Ltd. v. Teranet Inc*., 2015 ONCA 248
17. *Keatley Surveying Ltd. v. Teranet Inc*., 2016 ONSC 1717 (Sup. Ct.)
18. *Schwoob v. Bayer Inc.*, 2013 ONSC 2207
19. *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260
20. *Tiboni v. Merck Frosst Canada Ltd.,* [2008] O.J. No. 2996 (Sup. Ct.)
21. *Wakelam v. Johnson & Johnson,* 2011 BCSC 1765
22. *Wakelam v. Johnson & Johnson,* 2014 BCCA 36

Appendix B - Statutes and Regulations

LEGISLATION

23. *Class Proceedings Act,* S.N.S. 2007, c. 28

Form 39.01

2009 Hfx No. 315567

This is Exhibit "I:" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme Court of Nova Scotia

AVANDIA CLASS ACTION
NATIONAL SETTLEMENT AGREEMENT
Made as of October 11, 2018

Between

ALBERT CARL SWEETLAND AND MARY PATRICIA ADDICOTT-ANDREWS

and

GLAXOSMITHKLINE INC. AND GLAXOSMITHKLINE LLC

TABLE OF CONTENTS

AVANDIA NATIONAL SETTLEMENT AGREEMENT

1. PREAMBLE & RECITALS

The Parties hereby enter into this Settlement Agreement providing for the settlement of the Avandia class proceeding commenced in the Supreme Court of Nova Scotia under Halifax Court File No. 315567 (the "Nova Scotia Proceeding") pursuant to the terms and conditions set forth herein, subject to the approval by the Courts as set forth herein;

WHEREAS, the Nova Scotia Proceeding was certified as an "all users" national class action by the Supreme Court of Nova Scotia pursuant to an Order issued on December 7, 2016 (the "Certification Order");

WHEREAS, the Parties intend by this Settlement Agreement to resolve all claims for damages due in any way to the use of Avandia by (a) all persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and (b) the spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class") who do not Opt Out of the Nova Scotia Proceeding;

WHEREAS, Class Counsel shall bring a motion on consent for leave to amend the pleadings in the Nova Scotia Proceeding and, if deemed necessary by the Court, to formally amend the Certification Order issued December 7, 2016, to remove Mary Patricia Addicott Andrews as a representative plaintiff and substitute Barbara Fontaine as a representative plaintiff for the Family Class;

WHEREAS, individual actions have been commenced in Ontario by Siskinds LLP arising from the same subject matter as the Nova Scotia Proceeding;

WHEREAS, proposed class proceedings have been filed, but not certified, in other jurisdictions across Canada, arising from the same subject matter as the Nova Scotia Proceeding;

WHEREAS, counsel to the Parties have conducted settlement negotiations;

WHEREAS, the Defendants have denied and continue to deny any wrongdoing or liability of any kind;

WHEREAS, the Plaintiffs and Class Counsel have concluded that this Settlement Agreement provides substantial benefits to Class Members and is fair, reasonable and in the best interests of Class Members based on an analysis of the facts and applicable law, taking into account the extensive burdens and expense of litigation, including the risks and uncertainties associated with protracted trials and appeals, as well as the fair, cost-effective and assured method provided in this Settlement Agreement of resolving the claims of Class Members;

WHEREAS, the Defendants have similarly concluded that this Settlement Agreement is desirable in order to avoid the time, risk, uncertainty and expense of defending multiple and protracted litigation, and to resolve finally and completely the pending and potential claims of Class Members;

WHEREAS, Class Counsel have obtained approval of the settlement provided for in this Settlement Agreement from, and have the authority to sign this Settlement Agreement on behalf of the Related Counsel Firms;

WHEREAS, the Parties, in accordance with Protocols established for the management of multi-jurisdictional class actions, seek to conclude all outstanding Avandia litigation in Canada, including all putative class actions and representative actions;

WHEREAS, The Honourable Justice Michael J. Wood of the Supreme Court of Nova Scotia is the Designated Settlement Administrative Judge within the meaning of the Canadian Judicial Protocol for the Management of Multi-Jurisdictional Class Actions;

WHEREAS, the Parties shall seek the Settlement Approval Order;

WHEREAS, the Provincial and Territorial Health Insurers ("Provincial Health Insurers") have confirmed, or shall confirm, that they approve, and will not object to court approval of, the settlement provided for in this Settlement Agreement, they will accept ten percent (10%) of the allocation made by the Claims Administrator for each Settling Claimant in satisfaction of all Rights of Recovery that they may have, whether by subrogation or by independent right of action, respecting the Settling Claimant's use of Avandia, and they will execute and deliver to the Claims Administrator a Provincial Health Insurer Release in exchange for each payment;

WHEREAS, if the Settlement Approval Order is obtained, the Parties shall seek the Dismissal Orders;

NOW THEREFORE, subject to the issuance of the Settlement Approval Order and the Dismissal Orders, this Settlement Agreement embodies the terms of the resolution of claims of Class Members and of the Provincial Health Insurers.

2. DEFINITIONS

Unless a particular section of this Settlement Agreement explicitly provides for another interpretation, the following terms, as used in this Settlement Agreement and its exhibits, shall have the meanings set forth below. Terms used in the singular shall be deemed to include the plural, and vice versa, where appropriate. Feminine pronouns and female references shall be deemed to include the masculine, and vice versa, where appropriate.

(a) **"Administrative Account"** means the interest bearing trust account with one of the Canadian Schedule 1 banks under the control of the Claims Administrator.

(b) **"Approved Claimants"** shall mean Class Members who are approved by the Claims Administrator or are Pre-Approved Claimants, as defined herein, to receive compensation pursuant to this Settlement Agreement.

(c) **"Claim Deadline"** shall mean the date eight (8) months after the date on which the Settlement Approval Notice is first published, or such other date as may be approved by the Supreme Court of Nova Scotia.

(d) **"Claim Form"** shall mean the form developed by the Claims Administrator, in consultation with Class Counsel and Defendants' Counsel, which Class Members shall complete in order to file a claim under this Settlement Agreement.

(e) **"Claims Administration Costs"** shall mean all costs, other than Class Counsel Legal Fees, required to implement this Settlement Agreement, including without limitation, costs required to satisfy the notice provisions.

(f) **"Claims Administration Protocol"** shall mean Schedule A to the Compensation Protocol.

(g) **"Claims Administrator"** shall mean, subject to the approval of the Supreme Court of Nova Scotia, RicePoint Administration Inc.

(h) **"Class"** shall mean (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and (b) the spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

(i) **"Class Counsel"** shall mean the law firms of Wagners and Sekonds LLP.

(j) **"Class Counsel Legal Fees"** shall mean all legal fees, disbursements and applicable taxes in respect of all legal services provided by Class Counsel, Related Counsel Firms, or any other law firm for the benefit of the Class, as approved by the Supreme Court of Nova Scotia.

(k) **"Class Members"** shall mean members of the Primary Class and Family Class.

(l) **"Compensation Protocol"** shall mean the Court-approved plan, substantially in the form attached hereto as Exhibit "A", for administering this Settlement Agreement and distributing the Escrow Settlement Payment.

(m) **"Courts"** shall mean the Supreme Court of Nova Scotia, the Ontario Superior Court, the Court of Queen's Bench for Saskatchewan, Superior Court of Québec, the Supreme Court of British Columbia, the Court of Queen's Bench of Alberta, the Court of Queen's Bench of Manitoba, the Court of Queen's Bench of New Brunswick, the Supreme Court of Prince Edward Island, and the Supreme Court of Newfoundland and Labrador.

(n) **"Defendants"** shall mean those entities named as defendants in the Nova Scotia Proceeding.

(o) **"Defendants' Counsel"** shall mean the law firm of Gowling WLG (Canada) LLP.

(p) **"Dismissal Orders"** shall mean those orders that grant approval, recognition, dismissal and/or discontinuance of the cases listed in Exhibit "B", as may be necessary and appropriate, to conclude related litigation and give effect to this Settlement Agreement across Canada.

(q) **"Effective Date"** shall mean the date on which the Settlement Approval Order becomes a Final Order and all of the Dismissal Orders have been obtained and become Final Orders.

(r) **"Escrow Account"** means the interest bearing trust account with one of the Canadian Schedule 1 banks under the control of the Claims Administrator.

(s) **"Escrow Settlement Payment"** means the Settlement Payment plus any interest accruing thereon after payment of taxes and all Non-Refundable Expenses.

(t) **"Execution Date"** shall mean the date on which this Settlement Agreement has been signed by Class Counsel and Defendants' Counsel, collectively.

(u) **"Final Order"** means any order contemplated by this Settlement Agreement from which no appeal lies or in respect of which any right of appeal has expired without the initiation of proceedings in respect of that appeal, or proposed appeal such as the delivery of a notice of appeal or application for leave to appeal.

(v) **"Hearing Notice"** shall mean the notice approved by the Supreme Court of Nova Scotia, substantially in the full and abridged forms attached hereto as Exhibit "C", which advises Class Members of Certification and the hearing to approve the settlement provided for in this Settlement Agreement.

(w) **"Hearing Notice Date"** shall mean the date on which the Hearing Notice is first published, which date shall be agreed upon by the Parties, or such other date as may be approved by the Supreme Court of Nova Scotia.

(x) **"Hearing Notice Order"** shall mean the order of the Supreme Court of Nova Scotia that approves the Hearing Notice.

(y) **"Maximum Settlement Amount"** shall mean a fund of up to CAD$6,750,000.00.

(z) **"Minimum Settlement Amount"** shall mean a fund of CAD$4,116,666.67.

(aa) **"Non-Refundable Expenses"** shall mean the costs of publishing and distributing the Hearing Notice, including the associated professional fees, and any Claims Administration Costs incurred prior to payment of the Minimum Settlement Amount by the Defendants.

(bb) **"Notice"** means the Hearing Notice and the Settlement Approval Notice.

(cc) **"Notice Plan"** shall mean the method approved by the Supreme Court of Nova Scotia, substantially as described at Exhibit "D" hereto, by which the Hearing Notice and the Settlement Approval Notice are disseminated.

(dd) **"Opt Out"** shall mean a person who would have been a Class Member but for his or her timely and valid request for exclusion pursuant to the process set out in section 8.1 of this Settlement Agreement.

(ee) **"Opt Out Deadline"** shall mean the date sixty (60) days after the date of publication of the Hearing Notice, or such other date as may be approved by the Supreme Court of Nova Scotia.

(ff) **"Opt Out Form"** shall mean the form for requesting exclusion from the Class as defined in the Nova Scotia Proceeding, attached hereto as Exhibit "E".

(gg) **"Opt Out Threshold"** shall mean the number of Opt Outs required to trigger the Defendants' right to elect to terminate this Settlement Agreement as described in section 7.1(a) of this Settlement Agreement, fixed by way of a supplementary agreement and kept confidential subject to the direction of the Supreme Court of Nova Scotia.

(hh) **"Parties"** shall mean the Plaintiffs and the Defendants.

(ii) **"Plaintiffs"** shall mean the persons appointed by the Supreme Court of Nova Scotia as representative plaintiffs in the Nova Scotia Proceeding.

(jj) **"Pre-Approved Claimants"** shall mean the claimants listed in the confidential Schedule who the Parties agree are deemed to be Approved Claimants, who satisfy the criteria for a myocardial infarction ("MI"), coronary artery bypass grafting ("CABG"), and cardiac stenting procedures ("Stenting") claim, or congestive heart failure ("CHF") claim, as set out in the Compensation Protocol.

(kk) **"Provincial Health Insurers"** shall mean all provincial and territorial Ministries of Health or equivalents, provincial and territorial governments, and/or provincial and territorial plans funding medical services throughout Canada.

(ll) **"Provincial Health Insurer Release"** shall mean the form of Release, attached hereto as Exhibit "F", to be executed in exchange for any payment hereunder to a Provincial Health Insurer.

(mm) **"Provincial Health Insurer Rights of Recovery"** or "**Rights of Recovery**" shall mean the statutory authority for the recovery of costs of insured health or medical services, as defined in the empowering legislation of each jurisdiction, as set out in the attached Exhibit "G".

(nn) **"Related Counsel Firms"** shall mean Consumer Law Group (including Arias, Sanguinetti Stahle and Torrijos LLP), McPhadden Samac Tuovi Haté, Higgerty Law (counsel, Clint Docken, formerly of Docken & Company), and Chea Crosbie Barristers.

(oo) **"Released Parties"** shall mean the Defendants as well as their respective predecessors, successors, parents, subsidiaries, affiliates, associated companies and divisions, and each of their respective current and former shareholders, officers,

directors, employees, lawyers, attorneys, agents, insurers, trustees, assigns, owners, consultants, suppliers, distributors and partners.

(pp) **"Settlement Agreement"** shall mean this Avandia National Settlement Agreement, inclusive of the recitals and exhibits attached hereto.

(qq) **"Settlement Approval Notice"** shall mean the notice approved by the Supreme Court of Nova Scotia, substantially in the full and abridged forms attached hereto as Exhibit "H", which advises Class Members of the approval of the settlement provided for in this Settlement Agreement.

(rr) **"Settlement Approval Order"** shall mean the order of the Supreme Court of Nova Scotia approving the settlement provided for in this Settlement Agreement.

(ss) **"Settlement Notice Order"** shall mean the order of the Supreme Court of Nova Scotia that approves the Settlement Approval Notice.

(tt) **"Settlement Payment"** shall mean the payment of an amount not to exceed CAD$8,750,000, inclusive of all interest, taxes, costs, Class Counsel Legal Fees, and Claims Administration Costs, as compensation for the Settling Claimants and the Provincial Health Insurers.

3. ORDERS APPROVING SETTLEMENT

The Settlement Approval Order

3.1 The Plaintiffs shall, as soon as is reasonably possible, file a motion with the Supreme Court of Nova Scotia seeking the Settlement Approval Order.

3.2 Defendants' retain their rights to appeal the certification of the Nova Scotia Proceeding in the event that the Settlement Approval Order is not obtained or this Settlement Agreement is otherwise terminated in accordance with its provisions.

The Dismissal Orders

3.3 Once the Supreme Court of Nova Scotia has granted the Settlement Approval Order, the Defendants will file motions seeking the Dismissal Orders.

3.4 Class Counsel and Related Counsel Firms will support the Defendants in seeking the Dismissal Orders.

4. NOTICE TO THE CLASS

The Notices

4.1 The Parties hereby agree to the form, contents and method of dissemination of the Notices, as specified in the draft Hearing Notice Order, Settlement Approval Notice Order and Notice Plan, subject to the Supreme Court of Nova Scotia's approval of same, which shall be sought by way of the Plaintiffs' motion.

4.2 The costs of publishing and distributing the Hearing Notice, including the associated professional fees, will be shared equally by the Parties; provided, however, that Defendants' share of such costs and fees and any other contribution towards disbursements and administration expenses shall not, under any circumstance, exceed CAD$250,000.00.

Notice of Termination

4.3 If this Settlement Agreement is terminated and the Court orders that a notice of termination be given to the Class, the Defendants will cause the notice of termination, in a form approved by the Supreme Court of Nova Scotia, to be published and disseminated as such Court directs.

4.4 The Parties shall share equally in any costs incurred in the publication and distribution of the notice of termination.

Cooperation

4.5 The Parties shall cooperate, assist one another and the Claims Administrator and undertake all reasonable actions in order to ensure that the Notices are disseminated in a timely manner by the Claims Administrator.

5. THE SETTLEMENT BENEFITS

Allocation of Settlement Payment

5.1 The Maximum Settlement amount of up to CAD$6,750,000 will be allocated, calculated, and payable as follows:

(a) The Defendants shall pay the Minimum Settlement Amount of CAD$4,116,666.67, inclusive of:

(i) CAD$250,000.00 as a contribution towards disbursements and administration expenses;

(ii) CAD$3,666,666.67 for up to 200 Settling Claimants (as defined in Section 5.3), including the Pre-Approved Claimants, who satisfy the criteria for a myocardial infarction ("MI"), coronary artery bypass grafting ("CABG"), and cardiac stenting procedures ("Stenting") claim, as set out in the Compensation Protocol and in the Claims Administration Protocol; and

(iii) CAD$200,000.00 for up to 60 Settling Claimants who meet the criteria for payment of a congestive heart failure ("CHF") claim, as set out in the Compensation Protocol and in the Claims Administration Protocol.

(b) The Defendants shall pay up to an additional CAD$2,633,333.33 based on the following:

(i) CAD$18,333.33 for each Settling Claimant who meets the criteria for payment of a MI, CABG, or Stenting claim, as set out in the Compensation Protocol and

in the Claims Administration Protocol, in excess of the 200 Settling Claimants referred to in section 5.1(a)(ii), up to an aggregate total of 300 such claimants (i.e., up to an additional CAD$1,833,333.33, reaching an aggregate total of CAD$5,500,000 for such claims, regardless of whether more than 300 such claims are made); and

(ii) CAD$3,333.33 for each Settling Claimant who meets the criteria for payment of a CHF claim, as set out in the Compensation Protocol and in the Claims Administration Protocol, in excess of the 60 Settling Claimants referred to in section 5.1(a)(iii), up to an aggregate total of 300 such claimants (i.e., up to an additional CAD$800,000, reaching an aggregate total of CAD$1,000,000 for such claims, regardless whether more than 300 such claims are made).

(c) To the extent that there are more than 300 Settling Claimants who meet the criteria for payment of an MI, CABG, or Stenting claim, then any unused portion of the aggregate capped total of CAD$1,000,000 available for payment of Settling Claimants who meet the criteria for payment of a CHF claim, may be used for Settling Claimants who meet the criteria for payment of MI, CABG, or Stenting claims in excess of 300.

(d) The Defendants' maximum payment caps for MI, CABG, and Stenting claims and for CHF claims shall in no way limit the number of claimants who shall be afforded an opportunity to settle, and may settle, such claims. For clarity, if more claims come forward to be paid than would permit CAD$18,333.33 to be paid for each MI, CABG, or Stenting claim and/or more than CAD$3,333.33 to be paid for each CHF claim because of the caps on the Defendants' payment obligation, then such per claim averages would effectively be adjusted downward, on a pro rata basis, on account of payment to the greater number of Settling Claimants.

(e) Except for the Pre-Approved Claimants, the validity of all claims for payment shall be adjudicated in accordance with the Compensation Protocol and the Claims Administration Protocol by the Claims Administrator.

(f) No Class Member shall be eligible to receive a settlement payment under both section 5.1(a)(ii) and 5.1(a)(iii).

Payment by Defendants

5.2 The Defendants shall, no later than thirty (30) business days after the Effective Date, pay CAD$4,116,666.67 (less such amount paid by Defendants for the costs of publishing and distributing the Hearing Notice and associated professional fees pursuant to section 4.2) into the Administrative Account, controlled by the Claims Administrator, to be held in trust for the benefit of the Class and Provincial Health Insurers.

5.3 The Defendants shall, no later than thirty (30) business days after the receipt of a report from the Claims Administrator on the number of Approved Claimants who have provided fully executed and witnessed Releases in the form provided ("Settling Claimants"), pay the balance of the Settlement Payment as determined pursuant to section 5.1(b) into the Escrow Account, controlled by the Claims Administrator, to be held in trust for the benefit of the Class Members and Provincial Health Insurers.

Taxes and Interest

5.4 All interest earned on the monies in the Administrative Account and in the Escrow Account shall accrue to the benefit of the Class and Provincial Health Insurers and shall become and remain part of the Escrow Settlement Payment.

5.5 All taxes payable on any interest which accrues in relation to the Settlement Payment shall be the responsibility of the Class and Provincial Health Insurers and shall be paid by

Class Counsel or the Claims Administrator, as appropriate, from the Escrow Settlement Payment.

6. DISTRIBUTION OF THE SETTLEMENT PAYMENT

6.1 On or after the Effective Date, the Claims Administrator shall distribute the Escrow Settlement Payment to pay, *pro rata*, the claims of Settling Claimants, in accordance with the Compensation Protocol and the Claims Administration Protocol, including, from the *pro rata* share allocated to each Settling Claimant, ten percent (10%) payment to the corresponding Provincial Health Insurer, after payment of the following:

(a) to pay Class Counsel Legal Fees, as approved by the Supreme Court of Nova Scotia;

(b) to pay all of the costs and expenses reasonably and actually incurred in connection with the provision of Settlement Approval Notice in accordance with the Notice Plan;

(c) to pay the remaining Claims Administration Costs, including the professional fees of the Claims Administrator; and

(d) to pay any taxes required by law to be paid to any governmental authority.

6.2 Payments made to the Provincial Health Insurers shall be in full and final satisfaction of all subrogated claims and independent actions for recovery of claims (Rights of Recovery) they may have in relation to the use of Avandia by Settling Claimants, for the costs of services (pursuant to the legislation of each jurisdiction, as set out in Exhibit "G"), whether already provided or to be provided to Settling Claimants, and the Provincial Health Insurers shall have no other claim of recovery (pursuant to the legislation of each jurisdiction, as set out in Exhibit "G") in relation to the Settling Claimants.

7. TERMINATION OF THE SETTLEMENT AGREEMENT

General

7.1 Termination rights are as follows:

(a) The Defendants shall have the right to terminate this Settlement Agreement in the event that:

(i) the Opt Out Threshold is exceeded;

(ii) any of the Provincial Health Insurers or Related Counsel Firms were not to confirm, or were to rescind, their approval of this Settlement Agreement or were to object to court approval of the settlement provided for in this Settlement Agreement;

(iii) a Dismissal Order were to be denied by one or more of the Courts; or

(iv) a Dismissal Order entered by one or more of the Courts were to be reversed on appeal.

(b) Each of the Parties shall have the right to terminate this Settlement Agreement in the event that:

(i) the Settlement Approval Order were to be denied and, following appeal, the denial of the Settlement Approval Order were to become a Final Order; or

(ii) the Settlement Approval Order were to be entered, but reversed on appeal and the reversal were to become a Final Order.

Effect of Termination

7.2 In the event this Settlement Agreement is terminated in accordance with its terms:

(a) it shall be null and void and shall have no force or effect, and the Parties shall not be bound by its terms, except as specifically provided in this Settlement Agreement;

(b) all negotiations, statements and proceedings relating to this Settlement Agreement shall be deemed to be without prejudice to the rights of the Parties, and the Parties shall be deemed to be restored to their respective positions existing immediately before this Settlement Agreement was executed; and

(c) Non-Refundable Expenses shall not be returned to the Defendants.

Survival

7.3 Notwithstanding section 7.2(a) of this Settlement Agreement, if this Settlement Agreement is terminated, the provisions of this section, and sections 4.3, 4.4 and 7.4 through 7.7, and the definitions applicable thereto of this Settlement Agreement, shall survive termination and shall continue in full force and effect. The definitions and Schedules shall survive only for the limited purpose of interpreting these sections of this Settlement Agreement, but for no other purposes.

Accounting

7.4 If this Settlement Agreement is terminated, Class Counsel shall account to the Supreme Court of Nova Scotia and the Parties for all payments made from the administrative Account and/or the Escrow Account by no later than ten (10) days after such termination.

Termination Orders

7.5 If this Settlement Agreement is terminated, Class Counsel shall, within thirty (30) days after termination, apply to the Supreme Court of Nova Scotia, on notice to the Claims Administrator, for an order:

(a) declaring this Settlement Agreement null and void and of no force or effect except for the provisions of those sections listed in section 7.3 of this Settlement Agreement; and

(b) requesting an order setting aside the Settlement Approval Order in accordance with the terms of this Settlement Agreement.

7.6 Subject to section 7.7 of this Agreement, the Parties shall consent to the orders sought in any motion made pursuant to section 7.5 of this Settlement Agreement.

7.7 If there is any dispute about the termination of this Settlement Agreement, the Supreme Court of Nova Scotia shall determine any dispute by motion on notice to the Parties.

8. OPT OUT PROVISIONS

Opting Out

8.1 Class Members may exclude themselves from the Class by exercising their rights to opt out pursuant to section 19 of the *Class Proceedings Act*, SNS 2007, c 28, by submitting a complete and signed Opt Out Form to Wagners in accordance with the Hearing Notice Order, within sixty (60) days of the Hearing Notice Date.

8.2 Class Members who do not opt out shall be bound by the Settlement Approval Order.

8.3 In the event that an Opt Out seeks to retain Class Counsel or any Related Counsel Firms for any purpose related to the Proceeding, Class Counsel or any Related Counsel Firms hereby agree to refuse to represent the Opt Out.

Opt Out Report

8.4 Class Counsel shall provide Defendants' Counsel with a report advising as to the number of Opt Outs, the reasons for their opting out and details of the Opt Out's individual claim, if known, and a copy of all information provided, including the Opt Out Form, within thirty (30) days of the Opt Out Deadline.

Opt Out Threshold

8.5 In the event the Opt Out Threshold is exceeded, the Defendants may terminate this Settlement Agreement by giving notice in writing to Class Counsel of their intent to do so within thirty (30) days of the report referenced in section 8.4. The failure to deliver notice in accordance with this section shall be deemed a waiver of the Opt Out Threshold.

8.6 The Defendants shall maintain their right to waive the Opt Out Threshold.

9. RELEASES AND DISMISSALS

Exclusive Remedy

9.1 This Settlement Agreement shall be the exclusive remedy for all claims by, through, or under Class Members who do not Opt Out, including subrogation claims respecting their Avandia use.

9.2 On the Effective Date, each Class Member who does not Opt Out, whether or not he or she submits a claim or otherwise receives compensation, shall be deemed by this Settlement Agreement to have completely and unconditionally released, forever discharged, and acquitted the Released Parties from any and all claims arising out of the purchase and use of Avandia in Canada prior to the Hearing Notice Date.

9.3 In order to receive a settlement payment, a Claimant shall release all Avandia-related claims against any and all individuals and entities alleged to have Avandia-related liability, including all Defendants in the Avandia litigation in Canada, and against all GSK entities, their predecessors and successors, and all parents, subsidiaries, and affiliates and their representatives and, in any event, shall be deemed to release all Avandia-related claims upon receipt of their settlement payment.

9.4 In consideration of the Settlement Payment as aforesaid, Class Counsel and Related Counsel Firms agree, on behalf of the Class Members, that any prosecution of a settled claim

in breach of section 9.2 shall cause irreparable harm to the Released Parties, in respect of which a stay or injunction is an appropriate remedy. For the same consideration, Class Counsel agree on behalf of Class Members to cooperate with the Released Parties in seeking such a stay or injunction.

Third-Party Contribution or Indemnity Claims

9.5 Class Members who do not opt out and who commence or continue litigation against any person or entity who may make a claim for contribution and/or indemnity against the Defendants and/or any Released Party, shall limit the value and right of recovery of such claim against such person or entity to the quantum of damages, interest, costs and all losses and other compensation proven and apportioned against such person or entity, severally and not jointly with the Defendants and/or any Released Party.

10. SUBMITTING CLAIMS

10.1 Claims shall be submitted by Class Members, who do not Opt Out, by the Claim Deadline in the manner contemplated by the Compensation Protocol and the Claims Administration Protocol, or in any other manner approved by the Court.

11. LIMITATION DEFENCE

11.1 Except as provided herein, no Class Member who satisfies the criteria for payment pursuant to the Compensation Protocol and the Claims Administration Protocol shall be considered ineligible to receive a payment pursuant to this Settlement Agreement on the basis of any statute of limitation or repose, prescription period, or any other limitation or prescription defence.

11.2 Nothing in this Settlement Agreement shall constitute or be deemed to constitute a waiver by the Defendants of defences based on statutes of limitation or repose, prescription periods or any other limitation or prescription defence with respect to any Class Member who Opts Out.

12. AMENDMENTS TO THE SETTLEMENT AGREEMENT

12.1 The Parties may amend this Settlement Agreement in writing, by consent and upon approval of the Supreme Court of Nova Scotia.

13. LEGAL FEES AND DISBURSEMENTS

Fee Approval

13.1 Class Counsel shall bring a motion to the Supreme Court of Nova Scotia for the determination of Class Counsel Legal Fees to be paid from the Settlement Payment.

13.2 Class Counsel shall not be precluded from making additional motions to the Supreme Court of Nova Scotia for expenses incurred as a result of implementing the terms of this Settlement Agreement. All amounts awarded on account of Class Counsel Legal Fees shall be paid from the Escrow Settlement Payment.

13.3 The Released Parties hereby acknowledge and agree that they are not parties to the motions concerning the approval of Class Counsel Legal Fees, they will have no involvement in the approval process to determine the amount of Class Counsel Legal Fees and they will not take any position or make any submissions to the Courts concerning Class Counsel Legal Fees.

Individual Claims

13.4 Class Members who retain lawyers to assist them in making their individual claims for compensation pursuant to this Settlement Agreement or to appeal the classification or rejection of their claim for compensation, shall be responsible for the legal fees and expenses of such lawyers.

13.5 If a Class Member retains Class Counsel to assist him or her in making his or her individual claim for compensation under this Settlement Agreement, Class Counsel hereby agree to cap their fees at fifteen (15) percent of the amount awarded to that Class Member.

13.6 Class Counsel shall request that the order approving Class Counsel Fees provides that the fee applicable to Class Members who retain non-Class Counsel lawyers to assist them in making their individual claims for compensation pursuant to this Settlement Agreement, including lawyers in Related Counsel Firms, be capped at fifteen (15) percent of the amount awarded to that Class Member.

14. MISCELLANEOUS PROVISIONS

Ongoing Authority

14.1 The Supreme Court of Nova Scotia shall retain exclusive and continuing jurisdiction over the approval, implementation and administration of this Settlement Agreement.

Recitals

14.2 The Parties represent and warrant that the recitals referred to in section 1 are accurate and agree that they form part of this Settlement Agreement.

Entire Agreement

14.3 This Settlement Agreement, including its recitals and exhibits, constitutes the entire agreement by and among the Parties with regard to the subject matter of this Settlement Agreement and, on the Effective Date, shall supersede any previous agreements and understandings between the Parties with respect to the subject matter of this Settlement Agreement.

Counterparts

14.4 This Settlement Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

Party Notification

14.5 Any notification, request, instruction or other document to be given by any Party to any other Party to this Settlement Agreement (other than class notification) shall be in writing.

Class Member Notification

14.6 All communications from the Claims Administrator to Class Members may be made by regular mail to such person's last mailing address provided by such person to the Claims Administrator.

Governing Law

14.7 For the purpose of the settlement of the Nova Scotia Proceeding, this Settlement Agreement shall be governed by and interpreted pursuant to the laws of Nova Scotia.

Severability

14.8 If any provision of this Settlement Agreement is held to be void or invalid, the same shall not affect any other provision and the remainder shall be effective as though such provision had not been contained herein.

Dates

14.9 Dates referred to in this Settlement Agreement may be altered with the written consent of the Parties and, as necessary, with the approval of the Courts.

French Translation

14.10 Defendants' Counsel shall prepare a French translation of this Settlement Agreement.

14.11 The Defendants shall be responsible for the costs incurred to translate settlement documents into French, as necessary or required by the Quebec court. The text of the translation shall be subject to approval by Class Counsel.

14.12 In case of any ambiguity or dispute about interpretation, the English version is official and shall prevail.

English Language Clause

14.13 Les parties ont convenu que cette Entente soit rédigée en anglais.

Raymond F. Wagner, Q.C.
WAGNERS

Charles Wright
SISKINDS LLP

CONSUMER LAW GROUP INC.
Per: Jeff Orenstein

David Woodfield
GOWLING WLG (CANADA) LLP
Lawyers for the Defendants

Exhibit A

Compensation Protocol for Claims Submitted Pursuant to the Avandia National Settlement Agreement

("Compensation Protocol")

1. Claimant Eligibility

To be eligible to receive a settlement payment pursuant to the Settlement Agreement, a claimant must:

i. be, or if acting in a representative capacity, be representing the interest of a Canadian resident; and
ii. demonstrate, from contemporaneous medical records, one of the following cardiac events:
    a. received a final diagnosis of a myocardial infarction (which includes a final diagnosis in medical records generated in the course of medical care that interpret clinical signs and/or diagnostic tests as establishing the occurrence of an MI at or about such time or, alternatively for purposes of this criterion, death from a cardiac event in the absence of any other cause of death);
    b. received a final diagnosis of initial onset or exacerbation of congestive heart failure ("CHF") (which includes a final diagnosis in medical records generated in the course of medical care that interprets clinical signs and/or diagnostic tests as establishing the initial onset or exacerbation of CHF at or about such time);
    c. underwent a coronary artery bypass graft (CABG); or
    d. underwent a percutaneous coronary intervention with stent placement.
iii. demonstrate, from contemporaneous medical or pharmacy records, at least 30 days of uninterrupted Avandia usage at the time of, or within one year prior to, such cardiac event; and
iv. demonstrate, from contemporaneous medical or pharmacy records, that such Avandia use occurred prior to December 2010, or that an uninterrupted period of such use began prior to December 2010.

2. Allocation of Settlement

The Settlement Payment will be allocated among (i) MI, CABG, or stenting claims and (ii) CHF claims, pursuant to the Settlement Agreement. No claimant shall be eligible to receive settlement payment for both a MI, CABG, or stenting claim and a CHF claim. In the event that an Approved Claimant meets the criteria for more than one type of claim, the Approved Claimant will receive compensation for the MI, CABG, or stenting claim and not the CHF claim.

Damages attributable to individuals who are entitled to make claims under the *Family Law Act*, RSO 1990, c F.3, s 61 and similar legislation and common law in other provinces, will be allocated to the Approved Claimant.

3. Quantum of Settlement

Compensation for (i) MI, CABG, and stenting claims and (ii) compensation for CHF claims will be allocated from two distinct pools of funds. Approved Claimants will receive benefits in proportion to the cumulative points they are awarded under this Compensation Protocol.

Base Points		
LEVEL	**CARDIAC EVENT**	**POINTS**
1	Myocardial Infarction (which requires a final diagnosis in medical records generated in the course of medical care that interpret clinical signs and/or diagnostic tests as establishing the occurrence of an MI at or about such time or, alternatively for purposes of this criterion, death from a cardiac event in the absence of any other cause of death)	100 points
2	Coronary Artery Bypass Graft (CABG),	75 points
3	Percutaneous Coronary Intervention with Stent Placement	50 points
4	Congestive Heart Failure (which requires a final diagnosis in medical records generated in the course of medical care that interprets clinical signs and/or diagnostic tests as establishing the initial onset or exacerbation of CHF at or about such time)	50 points

Age Adjustment	
Age	a) 0- 20 years = + 30 points b) 21-31 years = + 20points c) 31- 40 years = + 10 points d) 41- 50 years = + 5 points e) 51- 60 years = +/- 0 points f) 61- 70 years = - 10 points g) 71- 80 years = - 20 points h) 81+ years = - 30 points

Risk Factor Adjustment		
Class Members who swear a Risk Factor Declaration and submit the required records. If medical records submitted clearly contradict the Declaration, no compensation will be payable and any entitlement to compensation will be forfeited.		50% increase to cumulative point value.
The existence of **any** of the following risk factors makes an Approved Claimant ineligible for the Risk Factor Adjustment.		
A	Pre-existing congestive heart failure	Approved Claimants who received a diagnosis of congestive heart failure before their cardiac event.
B	Prior MI	Approved Claimants who suffered an MI before their cardiac event.
C	Pre-existing Coronary Artery Disease ("CAD")	Approved Claimants who received a diagnosis of coronary artery disease (CAD) before their cardiac event.
D	Smoking	Approved Claimants who smoked cigarettes or cigars within one (1) year of their cardiac event.
E	High Cholesterol	Approved Claimants who received a diagnosis of high cholesterol or were on a statin on or before their cardiac event.
F	Hypertension	Approved Claimants who received a diagnosis of hypertension or were on an anti-hypertensive medication on or before their cardiac event.
G	Obesity	Approved Claimants whose medical records indicate obesity or a BMI of ≥ 30 at or before their cardiac event.
I	Alcohol Abuse	Approved Claimants diagnosed with alcoholism, alcohol dependence, or alcohol abuse, or a similar reference, within two (2) years of their cardiac event.
J	Illegal Drug Use	Approved Claimants with evidence of the use of illegal drugs (including, but not limited to, cocaine, LSD and heroin, but excluding marijuana) within two (2) years of their cardiac event.

Claims Administration Protocol for Claims Submitted Pursuant to the Avandia Settlement Agreement

("Claims Administration Protocol")

Administration of the Settlement Agreement[1] and the submission, processing, approval, compensation, and appeal of individual claims made pursuant to the Settlement Agreement shall be governed by this Claims Administration Protocol. This Claims Administration Protocol shall be implemented by the Claims Administrator, subject to the ongoing authority and supervision of the Supreme Court of Nova Scotia.

1. Purpose of the Claims Administration Protocol

The purpose of this Claims Administration Protocol is to provide further guidance to the Claims Administrator to help ensure that:

a) only Approved Claimants who satisfy the eligibility criteria set out in the Compensation Protocol will receive compensation from the Settlement Payment;
b) similarly situated Approved Claimants will be treated as uniformly as possible; and
c) Approved Claimants will receive timely compensation in a way that minimizes, to the extent reasonably possible, the Claims Administration Costs and other transaction costs associated with implementation and administration of the Settlement Agreement.

2. Reporting Obligations of the Claims Administrator

● days after the Claim Deadline, the Claims Administrator shall provide a written report to Class Counsel and to Defendants indicating the total number of Approved Claimants who meet the criteria for payment of a MI, CABG, or stenting claim, and the total number of Approved Claimants who meet the criteria for payment of a CHF claim, as set out in the Compensation Protocol ("Approved Claimant Report").

3. Claim Form and Claim Deadline

The status of a Class Member as an Approved Claimant requires, in addition to the requirements set forth in the Settlement Agreement and Compensation Protocol, that the Class Member properly complete, execute and submit the claim form developed by the Claims Administrator in consultation with Class Counsel (the "Claim Form") to the Claims Administrator by the Claim Deadline. The Claims Administrator may develop such other forms as it deems necessary for the implementation and administration of the Settlement Agreement in accordance with the purpose of this Claims Administration Protocol.

Claims that are not properly and timely submitted to the Claims Administrator by the Claim Deadline will be denied by the Claims Administrator.

4. Evidence Required for Proof of Injury

This section lists the information and documentation (the "Evidence") that must be provided as sufficient proof of each level of "Injury" (as that term is defined in the Compensation Protocol).

[1] Unless otherwise indicated or required by context, capitalized terms in this Claims Administration Protocol have the meanings assigned to them in the Settlement Agreement.

a) Mandatory Evidence

A Class Member must submit proof, by way of contemporaneous medical records, which may include contemporaneous physician records supplemented by a letter from the physician providing any needed clarification of the contents of the record, and/or contemporaneous pharmacy records, as follows:

a) contemporaneous medical records demonstrating one or more of the following cardiac events:
   i. a final diagnosis of a Myocardial Infarction ("MI") (which includes a final diagnosis in medical records generated in the course of medical care that interpret clinical signs and/or diagnostic tests as establishing the occurrence of an MI at or about such time or, alternatively for purposes of this criterion, death from a cardiac event in the absence of any other cause of death);
   ii. underwent a Coronary Artery Bypass Graft;
   iii. underwent percutaneous coronary intervention with stent placement;
   iv. a final diagnosis of initial onset or exacerbation of Congestive Heart Failure (which includes a final diagnosis in medical records generated in the course of medical care that interprets clinical signs and/or diagnostic tests as establishing the initial onset or exacerbation of CHF at or about such time) and
b) contemporaneous medical and/or pharmacy records demonstrating Avandia consumption for at least 30 days at the time of, or within one year prior to, such cardiac event; and
c) contemporaneous medical and/or pharmacy records demonstrating that the 30 days of Avandia use occurred prior to December 2010, or that an uninterrupted period of such use began prior to December 2010.

b) Optional Risk Factor Adjustment Evidence

Class Members who are seeking the Risk Factor Adjustment must:

a) submit a Risk Factor Adjustment Declaration; and
b) submit a copy of his or her general practitioner's medical records for the 2 years before he or she suffered the cardiac event.

A failure to report true or accurate information may result in the rejection of Class Members' claims.

5. Claims Processing Guidelines

If, during claims processing, the Claims Administrator finds that technical deficiencies exist in a Class Member's Claim Form or Evidence, the Claims Administrator shall notify the Class Member, by way of letter sent through first class regular mail, of the technical deficiencies and shall allow the Class Member 60 days from the date of mailing to correct the deficiencies. If the deficiencies are not corrected within the 60 day period, the Claims Administrator shall reject the claim and the Class Member shall have no further opportunity to correct the deficiencies. "Technical deficiencies" shall not include missing the Claim Deadline or failure to provide sufficient Evidence to support the Class Member's claim. In the event that a Class Member has requested but not yet received the Mandatory Evidence, the Class Member must submit true copies of the records requests that were made and this will be deemed a "technical deficiency".

6. Claimant Notification and Claim Appeals

a) Notification

The Claims Administrator shall notify each Class Member by way of a letter sent through first class regular mail as to the approval or rejection of his or her claim and the points awarded to the Class Member.

b) Appeals

Class Members will be granted a 30-day period from the date of mailing to appeal the rejection and/or classification of their claims. In accordance with Rule 11 of the *Nova Scotia Civil Procedure Rules*, appeals will be reviewed and assessed by the Designated Settlement Judge or Referee. Appeals will be made in writing to such Judge or Referee, supported only by the documentation provided to the Claims Administrator. Following the outcome on appeal, there shall be no right of further appeal or review.

Defendants shall have the right to request, from time to time, Claims and Evidence from the Claims Administrator for the purposes of reviewing the accuracy of the Compensation Protocol. Within 5 days of the Defendants receiving the Approved Claimant Report, Defendants shall notify the Claims Administrator whether they desire an opportunity to review the Claim Forms and Evidence submitted by specified Class Members. If so notified, the Claims Administrator shall promptly provide the specified Claims Forms and Evidence to Defendants. Within 10 days following receipt of such Claims Forms and Evidence, Defendants shall notify the Claims Administrator whether they wish to appeal the approval or classification of any claim. The Claims Administrator may then change the evaluation made or notify Defendants that the Claims Administrator does not agree that any change is warranted. In the event that the Claims Administrator make no change to the initial classification, Defendants shall have a right, exercisable within 10 days following receipt of the Claims Administrator's notification, to seek a review of said determination to the Designated Settlement Judge or Referee, as applicable. The decision of such Judge or Referee is final and binding and shall not be subject to any further appeal or review.

7. Releases

Each Approved Claimant shall have 45 days from the date of mailing of a notice from the Claims Administrator approving his or her claim to deliver to the Claims Administrator a fully and properly executed Release, in the form attached hereto. Any Approved Claimant who does not return a fully and properly executed Release by such deadline shall be deemed to have forfeited a right to payment.

RELEASE

IN CONSIDERATION OF the sum of ● ($●) and other good and valuable consideration, the receipt and sufficiency of which are hereby irrevocably acknowledged, the undersigned, ●, on behalf of himself or herself and all other individuals and entities who may claim damages due in any way to the use of Avandia by the undersigned (or if the undersigned was not an Avandia user, damages due in any way to the use of Avandia by the associated Avandia user), including all derivative claimants, successors, assigns, trustees, executors, representatives, heirs, and any other persons claiming by, through, under or on account of Avandia use by the undersigned or the associated Avandia user (hereinafter collectively referred to as the "Releasor"), releases any and all Avandia-related claims, actions, causes of action, claims over, indemnities, losses, covenants and liabilities, in equity or at law, that the Releasor, or any of them, now has or may have for or by reason of any cause, matter or thing whatsoever existing up to the present time, and thereby forever releases and discharges any and all claims against any and all individuals and entities that may have any Avandia-related liability, including GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC, their parents, subsidiaries and affiliated, related, predecessor or successor companies or entities and each of their respective directors, officers, shareholders, employees, servants, agents, trustees, successors, administrators, assigns, insurers and re-insurers, both present and former (hereinafter collectively referred to as the "Releasees").

AND THE RELEASOR ACKNOWLEDGES and agrees that s/he has not been induced to execute this Release by reason of any representation or warranty of any nature or kind whatsoever and that there is no condition express or implied or collateral agreement affecting the said release.

AND FOR THE SAID CONSIDERATION the Releasor covenants and agrees not to make claim or to commence or take proceedings against any of the Releasees, including any person, firm, partnership, business or corporation who or which might claim contribution from, or to be indemnified by, GLAXOSMITHKLINE INC. or GLAXOSMITHKLINE LLC, under the provisions of any statute or otherwise in respect of those matters to which this release applies.

AND IT IS UNDERSTOOD that Releasees, and each of them, do not admit any liability to the Releasor or others and that such liability is specifically and expressly denied.

IN WITNESS WHEREOF the Releasor ● has hereunto set his/her hand and seal this _____day of _____, 201_.

Witness ●

Risk Factor Declaration

I, _____, from the City

of_____, in the province of_____,

SOLEMNLY DECLARE:

1. Prior to suffering my Cardiac Event, I was **not** diagnosed with **any** of the following:
   i. congestive heart failure (CHF);
   ii. myocardial infarction (heart attack);
   iii. coronary artery disease (CAD);
   iv. high cholesterol and/or prescribed cholesterol lowering medication;
   v. high blood pressure and/or prescribed blood pressure lowering medication;
   vi. obesity; or
   vii. alcohol dependency/alcohol addiction (within two (2) years of my cardiac event)

2. I did **not** smoke cigarettes or cigars within one (1) year of my cardiac event.

3. I did **not** use illegal drugs (including, but not limited to, cocaine, LSD and heroin, but excluding marijuana) within two (2) years of my cardiac event.

4. I acknowledge and understand that this Declaration is an official Court document sanctioned by the Court that presides over the Settlement, and submitting this Declaration to the Claims Administrator is equivalent to filing it with a Court.

Enclosed in support of this Declaration are my medical records required pursuant to the Compensation Protocol which I understand may be reviewed by the Claims Administrator to confirm the contents of this Declaration.

After reviewing the information that has been supplied in this Declaration I declare under penalty of perjury that the information provided in this Declaration and Claim Form is true and correct to the best of my knowledge, information and belief.

I hereby consent to the disclosure of the information contained herein to the extent necessary to process this claim for benefits. I hereby authorize the Claims Administrator to contact me as required in order to administer the claim.

Date: _____

_____
Claimant's Signature (or Claimant's Representative)

_____
Printed Name of Claimant (or Claimant's Representative)

Date: _____

_____
Signature of Claimant's Lawyer (if any)

_____
Printed Name of Claimant's Lawyer

Date: _____

_____
Signature of Witness

_____
Printed Name of Witness

Exhibit B

Province	Plaintiffs' Counsel	Action
NS	Wagners	Albert Carl Sweetland v. Glaxosmithkline Inc. et al. Court File Hfx. No. 315567
NS	Merchant Law Group	Ronald Finck v. Glaxosmithkline Inc. et al. Court File No. SH-300379
ON	Kim Orr Barristers	Brenda Lloyd, Gary Lloyd and Francesca Imbesi v. Glaxosmithkline Inc. et al Court File No. CV-11-434420-00CP
ON	McPhadden, Samac, Merner, Touvi	Waheed v. Glaxosmithkline Inc. et al. Court file No. CV-09-385922CP
ON	Siskinds	Victor Vinerskis v Glaxosmithkline Inc. Court File No. 6809-12
ON	Siskinds	Richard Fontaine and Barbara Fontaine v Glaxosmithkline Inc. Court File No. 3777/14
ON	Siskinds	Jayanthina Ravindrakumar v Glaxosmithkline Inc. Court File No. 4084-14
NFL	Merchant Law Group	Catherine Morris v. Glaxosmithkline Inc. et al. Court File No. 0597
NFL	Russell Accident Law (Formerly Ches Crosbie Barristers)	Clyde Wiseman v. GlaxoSmithKline Inc. et al Court File No. 2582 CP
NB	Wagners	Gregory Ring v. Glaxosmithkline Inc. et al Court File No. MC 405-13
MB	Merchant Law Group	Andrew Kernel v. Glaxosmithkline Inc., et al. Court File No. CI07-01-53523
MB	Deeley, Fabbri, Sellen	Bonnie Latimer v. Glaxosmithkline Inc. Court File No. CI 07-01-51859
AB	Merchant Law Group	Debbie Allison, et al. v. Glaxosmithkline Inc., et al. Court File No. 0701-08275
AB	Docken & Company	Ralito Bernales v. GlaxoSmithKline Consumer Healthcare Inc, et al Court File No. 1001-14991 and Court File No. 1301-05007
BC	Merchant Law Group	Lanny Michael Honour v. Glaxosmithkline Inc., et al Court File No. 073210
PEI	Wagners	Yvon Lamoureux v. Glaxosmithkline Inc., GlaxoSmithKline PLC, et al Court File No. SI-GS-255577
QC	Arias Sanguinetti Wang and Torrijos LLP (Formerly Consumer Law Group)	Donna Woods v. GlaxoSmithKline Inc. and GlaxoSmithKline PLC Court File No. 500-06-000409-074
SK	Merchant Law Group	Estate of Iris Edith Wall and Vic Wall v. Glaxosmithkline Inc., et al. Q.B.G. No. 1073/2007

Exhibit C

NOTICE OF CERTIFICATION AND SETTLEMENT
APPROVAL HEARING IN THE CANADIAN AVANDIA LITIGATION

Read this Notice carefully as it may affect your rights

NOTICE OF CERTIFICATION AND SETTLEMENT
A Canada-wide settlement has been reached in the Avandia Class Action. The Class Action sought compensation for cardiovascular injuries which were allegedly related to the use of Avandia. The Defendants deny the allegations made in the lawsuits and make no admission as to the truth of these allegations. Class Counsel is aware of additional similar Avandia litigation in Canada, a list of which may be accessed online at: www.XXX. The settlement, if approved, will also resolve these actions.

THE SETTLEMENT REQUIRES COURT APPROVAL
In order for the Settlement to become effective, it must be approved by the Supreme Court of Nova Scotia. The Court must be satisfied that the Settlement is fair, reasonable and in the best interest of the Class. **The Settlement Approval Hearing is scheduled for January 29, 2019 at 9:30 a.m. at The Law Courts Building, 1815 Upper Water Street, Halifax, Nova Scotia.**

WHO IS INCLUDED IN THE CLASS ACTION?
If approved, the Settlement applies to: (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and (b) the spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

WHO REPRESENTS THE CLASS
Albert Carl Sweetland & Barbara Fontaine, c/o Wagners.

WHAT IF I DON'T WANT TO BE IN THE CLASS ACTION?
If you are a Primary or Family Class Member and do not wish to be bound by the Class Action and/or by the Settlement (if approved), you must Opt Out. To Opt Out, you must fully complete and submit an Opt Out Form to [to be decided by Justice Wood] by the Opt Out Deadline of DATE, 2018. Opt Out Forms are available at www.XXX or may be requested from [to be decided by Justice Wood]. **If you Opt Out, you will not be able to make a claim for compensation under the Settlement.**

WHAT SETTLEMENT HAS BEEN REACHED FOR THE CLASS ACTION?
The Settlement provides for a Minimum Settlement Amount of $4,116,666.67 (CND) and up to a Maximum Settlement Amount of $6,750,000.00 (the "Settlement Payment"), depending on the number of approved claims. The Settlement Payment will be used to pay compensation for Approved Claimants, the claims of provincial health insurers, the costs of notice and administration and Class Counsel Legal Fees. Approved Claimants must satisfy the eligibility criteria set out in the Compensation Protocol. You can review the Settlement documents by contacting Class Counsel or visiting the settlement website at www.XXX.

Compensation is available for Class Members who used Avandia for at least thirty continuous days commencing before December 2010 and who suffered one of the following injuries within no more than year of such use: myocardial infarction (heart attack), congestive heart failure, coronary artery bypass graft (CABG surgery), and percutaneous coronary intervention with stent placement. Other eligibility considerations described in the Settlement Agreement will affect how much compensation you receive.

PARTICIPATION IN THE SETTLEMENT
If the Settlement is approved, you must submit a Claim Form to the Claims Administrator by the Claims Deadline. Information about how and when to apply for settlement funds will be provided in a future notice and will be posted online at: www.XXX.

OBJECTING TO THE SETTLEMENT AND OPPORTUNITY TO APPEAR
If you wish to object to the Settlement, you must submit a written objection to [to be decided by Justice Wood] by no later than DATE, 2018 at the address listed in this Notice. [To be decided by Justice Wood] will file copies of all objections with the Court. Do not send an objection directly to the Court. You may also attend the Settlement Approval Hearing and, if you submitted a written objection to [to be decided by Justice Wood], you may make oral submissions to the Court.

CLAIMS ADMINISTRATOR
RicePoint Administration Inc.
1480 Richmond Street, Suite 204
London, Ontario, Canada, N6G 0J4
Email: support@ricepoint.com
Toll Free: 1 (866) 432-5534

CLASS COUNSEL

Siskinds LLP	**Wagners**
680 Waterloo St.	1869 Upper Water St.
London, ON	Halifax, NS
N6A 3V8	B3J 1S9
Tel: 877-672-2121	Tel: 902-425-7330
avandia@siskinds.com	classaction@wagners.co

There is **no charge** to speak with Class Counsel.

LEGAL FEES
At or following the Settlement Approval Hearing, Class Counsel will request approval for payment of fees, disbursements and applicable taxes. Class Counsel have pursued this lawsuit on a contingency basis and will seek approval from the Nova Scotia Court for such payment in accordance with the terms of their retainer agreement

Avandia Litigation

A Canada-wide settlement has been reached in the Avandia Class Action. The settlement applies to Canadians who were prescribed Avandia before [Insert Date of Hearing Notice].

Compensation may be available to Class Members who suffered one of the following injuries:

- Heart attack
- Congestive heart failure
- Coronary artery bypass graft (CABG)
- Coronary intervention with stent placement

This settlement must be approved by the Court. Class Members who do not wish to participate in the lawsuit must opt out by [insert opt out deadline]. More information is available online at [www.settlementwebsite.com]

Exhibit D

Avandia Class Action Notice Plan

Capitalized terms used in this Notice Plan have the meanings assigned in the Settlement Agreement.

The Hearing Notice and the Approval Notice (the "Notices") shall be distributed in the following manner:

Direct Notice

1. Class Counsel will send the Notices (full form) directly to all Class Members known to Class Counsel and Related Counsel. Where the person is located in Quebec (or otherwise specifically requests), the Notices will be sent in English and French.

2. The Notices (full form), and/or the Opt Out Form will be provided by Class Counsel to any person who requests it.

3. Class Counsel will post the Notices (full form), in English and French, on their websites;

4. The Notices (full form) will be posted on the *Registre des actions collectives du Québec*.

Digital News Notice

5. A digital notice campaign will be established by the Claims Administrator using banner advertisements (abridged form) directing potential Class Members to the Settlement Website where they will be able to obtain more information about the Settlement Agreement. The banner adverstisements will be displayed on the following online news sources, in English and French as proportionate to the population:

(a) theglobeandmail.com

(b) nationalpost.com

(c) calgaryherald.com

(d) vancouversun.com

(e) thestarphoenix.com

(f) winnipegfreepress.com

(g) thechronicleherald.ca

(h) thetelegram.com

(i) theguardian.pe.ca

(j) telegraphjournal.com

(k) journaldemontreal.com

(l) journaldequebec.com

Settlement Website

6. The Notices (full form) will be posted in English and French on the website created by the Claims Administrator for the purpose of this Settlement Agreement (the "Settlement Website"). All Notices will direct potential Class Members to the Settlement Website where they will be able to obtain more information about the Settlement Agreement, review the Settlement Agreement and related documents, download the Opt Out Form and claim forms and communicate with the Claims Administrator.

Press Release

7. A national press release will be issued in English and French through Canada Newswire.

8. Class Counsel may apply to the Court on notice to the Defendants for approval to make any further distribution of Notices to Class Members as may be deemed necessary to facilitate their interests in the settlement.

Exhibit E

OPT OUT FORM
CANADIAN AVANDIA LITIGATION

This is an **opt out form**. You should only fill out this form if you want to be **excluded** from the Avandia class action. The class action relates to cardiovascular injuries allegedly related to the use of Avandia. The Defendants deny the allegations made in the class action. If you have any questions, contact class counsel (Wagners) toll free at 1-800-465-8794 or online at classaction@wagners.co.

This form must be submitted no later than [60 days after Hearing Notice]

You may submit this form one of three ways:

- By email to classaction@wagners.co: To submit the form by email, fill it out and scan it and send the attachment to classaction@wagners.co.
- By mail to:

  Avandia Opt Out
  c/o

  Wagners
  1869 Upper Water St.
  Halifax, NS, B3J 1S9

If you do not submit this form in time, you will not be able to opt out. In the case of email and fax submissions, the form will be deemed to have been submitted when received. In the case of mail submissions, the form will be deemed to have been submitted when postmarked.

For more information about the Canadian Avandia litigation, see the "Long Form Notice" available at http://www.wagners.co/current-class-actions/avandia and the settlement website at "www.xxx".

Class Counsel are:

SISKINDS LLP
680 Waterloo Street
P.O. Box 2520
London, ON, N6A 3V8

(800) 461-6166 x2367
(519) 672-2121 x2367
avandia@siskinds.com

WAGNERS
1869 Upper Water St.
Halifax, NS, B3J 1S9

(800) 465-8794
(902)425-7330
classaction@wagners.co

Personal Information
Please provide the following information about yourself, or, if you are filing this Opt Out Form as the legal representative of a Class Member, please provide the following information about the Class Member.

Name used by the person who consumed Avandia:

Last Name	First Name	Middle Initial	Health Card Number	Date of Birth

Current or last known residence address used by the person who consumed Avandia:

Street Address		
City	Province/Territory	Postal Code
( )	( )	
Daytime Phone Number	Evening Phone Number	E-mail Address

Legal Representative Information (if applicable)
If you are filing this Opt-Out Form as the legal representative of a Class Member or a Class Member's estate, please provide the following information about ***yourself*** and attach a copy of your court approval or other authorization to represent the Class Member identified in "Personal Information" above.

Last Name	First Name	Middle Initial
Street Address		
City	Province/Territory	Postal Code
( )	( )	
Daytime Phone Number	Evening Phone Number	E-mail Address
Relationship to Class Member		

Please attach a copy of a court order or other official document(s) demonstrating that you are the duly authorized legal representative of the Class Member and check the box below describing the Class Member's status:

[ ] minor (court order appointing guardian or property or custody order, if any, or sworn affidavit of the person with custody of the minor). Date of birth of the minor:_____

[ ] a mentally incapable person (copy of a continuing power of attorney for property, or a Certificate of statutory guardianship);

[ ] Certificate of Appointment as Estate Trustee. Date of death:_____

Please provide the particulars in question. If you do not know or are uncertain of the answer, please so indicate.

Avandia Use Information

Date when first prescribed Avandia: _____

Prescribing physician(s) _____

Date of discontinuance of Avandia (If applicable) _____

Injury Information

Which of the following injuries did you suffer?

- ☐ received a final diagnosis of a myocardial infarction (which includes a final diagnosis in medical records generated in the course of medical care that interpret clinical signs and/or diagnostic tests as establishing the occurrence of an MI at or about such time or, alternatively for purposes of this criterion, death from a cardiac event in the absence of any other cause of death);
- ☐ received a final diagnosis of initial onset or exacerbation of congestive heart failure ("CHF") (which includes a final diagnosis in medical records generated in the course of medical care that interprets clinical signs and/or diagnostic tests as establishing the initial onset or exacerbation of CHF at or about such time);
- ☐ underwent a coronary artery bypass graft (CABG); or
- ☐ underwent a percutaneous coronary intervention with stent placement.

Date of injury: _____

Location/facility where injury was treated_____

Treating physician(s) _____

Lawyer Information (if applicable)
If you or the Class Member have hired a lawyer in connection with a claim arising from the Class Member's Avandia use, in any way, please provide the following information about the lawyer:

Last Name	First Name	Middle Initial
Street Address		
City	Province/Territory	Postal Code
( )	( )	
Office Phone Number	Fax Number	E-mail Address
Law Society Number		

If a claim has been filed:

Date of Issuance	Court File No	Jurisdiction of Filing

Acceptance and Acknowledgement

I have read the foregoing and reviewed and understand the Long Form Notice. I understand that by checking the box below, I am indicating my intention to OPT OUT of the class action relating to Avandia.

[ ] I hereby opt out of the Avandia class action

I understand that by opting out:

- **I will not be a member of the class and will <u>never</u> be eligible to receive any compensation through the class action opted out of.**
- **All family members who might otherwise be Class Members by virtue of a personal relationship with me are deemed to have opted out as well.**
- **I will not be entitled to participate in the designated class action.**
- **I will not be entitled to participate in the class action settlement.**

By signing this form, I acknowledge that I have reviewed and understand the Long Form Notice

Date Signature (Class Member or Executor, Administrator, or Personal Representative)

To be effective as an election to opt out, this Form must be completed, signed and sent, as outlined above, **no later than [date], 2018**

The consequences of returning this Opt-Out Form are explained in the Long Form Notice. If you have questions about using or completing this Form, contact your lawyer or Class Counsel at (800) 465-8794.

THE INFORMATION CONTAINED IN THIS FORM WILL BE PROVIDED TO THE DEFENDANTS. ALL INFORMATION PROVIDED WILL REMAIN CONFIDENTIAL WITHIN THIS PROCEEDING.

4839-8791-6406, v. 1

EXHIBIT F

PROVINCIAL HEALTH INSURER RELEASE

IN CONSIDERATION OF the sum of ● ($●) paid to the Provincial or Territorial Health Insurer as good and valuable consideration, the receipt and sufficiency of which are hereby irrevocably acknowledged, the undersigned, ●, on behalf of the Minister/Department of Health (hereinafter "Releasor"), releases any and all claims, causes of action, claims over, indemnities, losses, covenants and liabilities for the Provincial or Territorial Health Insurer's Rights of Recovery (as defined in the Settlement Agreement) for the [insured services or analogous term], pursuant to [province specific legislation], in equity or at law, whether by way of subrogation rights or by independent right of action, arising in any way from the use of Avandia by the Settling Claimants listed on the attached Schedule that the Releasor now has or may have for or by reason of any cause, matter or thing whatsoever existing up to the present time, and thereby forever releases and discharges any and all such claims against GLAXOSMITHKLINE INC. and GLAXOSMITHKLINE LLC, their parents, subsidiaries and affiliated, related, predecessor or successor companies or entities and each of their respective directors, officers, shareholders, employees, servants, agents, trustees, successors, administrators, assigns, insurers and re-insurers, both present and former (hereinafter collectively referred to as the "Releasees").

AND THE RELEASOR ACKNOWLEDGES and agrees that s/he has not been induced to execute this Release by reason of any representation or warranty of any nature or kind whatsoever and that there is no condition express or implied or collateral agreement affecting the said release.

AND FOR THE SAID CONSIDERATION the Releasor covenants and agrees not to make a claim or to commence or take proceedings against any of the Releasees, including any person, firm, partnership, business or corporation who or which might claim contribution from, or to be indemnified by, GLAXOSMITHKLINE INC. or GLAXOSMITHKLINE LLC, in respect of those matters to which this release applies.

AND IT IS UNDERSTOOD that Releasees, and each of them, do not admit any liability to the Releasor or others and that such liability is specifically and expressly denied.

IN WITNESS WHEREOF the Releasor ● has hereunto set his/her hand and seal this _____day of _____, 2018.

Witness

On behalf of the [Province]
Minister/Department of Health

Exhibit G

Provincial Health Insurer Legislation

Province/ Territory	Legislation	Right of Recovery
Nova Scotia	*Health Services and Insurance Act*, RSNS 1989, c 197	"costs of care, services and benefits"
New Brunswick	*Medical Services Payment Act*, RSNB 1973, c M-7	"entitled services"
Prince Edward Island	*Health Services Payment Act,* RSPEI 1988, c H-2	"basic health services"
Newfoundland and Labrador	*Medical Care and Hospital Insurance Act,* 2016 cM-5.01	"insured services"
Ontario	*Health Insurance Act,* RSO 1990 c H 6	"insured services"
Manitoba	*Health Services Insurance Act,* CCSM, 2015 c H35	"insured services"
Saskatchewan	*The Health Administration Act,* RSS 2014, c E-13.1	"health services"
Quebec	*Health Insurance Act*, 2017 CQLR c A-29	"insured services"
Yukon	*Hospital Insurance Services Act,* RSY 2002, c 112	"insured services"
Northwest Territories and Nunavut	*Hospital Insurance and Health and Social Services Administration Act,* RSNWT 1998, c T-3	"insured services"
Alberta	*Crown's Right of Recovery Act,* SA 2009, c C-35	"cost of health services"
British Columbia	*Healthcare Costs Recovery Act,* SBC 2008 c. 27	"health care services"

Exhibit H

<u>NOTICE OF SETTLEMENT APPROVAL</u>
<u>CANADIAN AVANDIA LITIGATION</u>

Read this Notice carefully as it may affect your rights

NOTICE OF SETTLEMENT APPROVAL
A Canada-wide settlement was reached in the Avandia Class Action. The Class Action sought compensation for cardiovascular injuries which were allegedly related to the use of Avandia. The Defendants deny the allegations made in the lawsuit and make no admission as to the truth of these allegations.

This Notice advises you that on [date], following publication of a Hearing Notice, the Supreme Court of Nova Scotia issued the Settlement Order approving the national Settlement Agreement (the "Settlement") as being fair, reasonable and in the best interest of Class Members.

The Settlement Order and Settlement can be reviewed online at http://www.wagners.co/current-class-actions/avandia.

WHO IS AFFECTED BY THE SETTLEMENT?
The Settlement applies to: (a) All persons in Canada, including their estates, who were prescribed and ingested Avandia (the "Primary Class"); and (b) the spouses (including common-law spouses and same-sex spouses), children, grandchildren, parents, grandparents and siblings of deceased members of the Primary Class (the "Family Class").

WHAT ARE THE TERMS OF THE SETTLEMENT?
The Settlement provides for a Minimum Settlement Amount of $4,116,666.67 (CND) and up to a Maximum Settlement Amount of $6,750,000.00 (the "Settlement Payment"), depending on the number of approved claims. The Settlement Payment will be used to pay compensation for Approved Claimants, the claims of provincial health insurers, the costs of notice and administration and Class Counsel Legal Fees. Approved Claimants must satisfy the eligibility criteria set out in the Compensation Protocol. Not all Class Members will be eligible for compensation.

Compensation is available for Class Members who used Avandia for at least thirty continuous days commencing before December 2010 and who suffered one of the following injuries within no more than year of such use: myocardial infarction (heart attack), congestive heart failure, coronary artery bypass graft (CABG surgery), and percutaneous coronary intervention with stent placement. Other eligibility considerations described in the Settlement Agreement will affect how much compensation you receive.

PARTICIPATION IN THE SETTLEMENT
To be eligible for any compensation under the Settlement, a Class Member must file a claim with the Claims Administrator on or before the Claims Deadline of DATE, 2019.

A detailed instruction package on how to file a claim and Claim Form are currently available from the Claims Administrator by telephone, email or in writing at the address noted below. Class Members are also invited to contact Class Counsel if they have questions about the Settlement.

WHO REPRESENTS ME?

Siskinds LLP
680 Waterloo St.
London, ON
N6A 3V8
Tel: 877-672-2121
avandia@siskinds.com

Wagners
1869 Upper Water St.
Halifax, NS
B3J 1S9
Tel: 902-425-7330
classaction@wagners.co

WHAT ARE THE LEGAL FEES?
Class Counsel's legal fees, disbursements and applicable taxes will be paid out of the Settlement. At the Approval Hearing, Class Counsel requested and received the Court's approval for payment of their fees and disbursements and applicable taxes in the amount of $XX.

Class Members may retain their own lawyers to assist them in making individual claims under the Settlement and will be responsible for any fees charged by such lawyers, although a lawyer is not necessary. Fees charged by Class Counsel and Related Counsel Firms for such services will not exceed 15% of any individual amounts recovered.

CLAIMS ADMINISTRATOR
The Courts have appointed RicePoint Administration Inc. as the Claims Administrator for the Settlement.

If you have questions about the Settlement and/or would like to obtain more information and/or copies of the Settlement and related documents, please contact the Claims Administrator at:

RicePoint Administration Inc.
1480 Richmond Street, Suite 204
London, Ontario, Canada, N6G 0J4
Email: support@ricepoint.com
Toll Free: 1 (866) 432-5534

Avandia Litigation

Were you prescribed Avandia before December 2010 and suffered one of the following injuries?

- Heart attack
- Congestive heart failure
- Coronary artery bypass graft (CABG)
- Coronary Intervention with Stent Implantation

If so, you may be entitled to compensation from a class action settlement.

APPLY NOW at [www.settlementwebsite.com]

Form 39.89

2009 Hfx No. 315567

This is Exhibit "F" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

4833-5886-7933 v. 15

Pending Avandia Proceedings
(status as of July 9, 2018)

Province	Counsel	Action	Status
NS	Wagners	*Albert Carl Sweetland v. GlaxoSmithKline Inc. et al* Court File Hfx. No. 315567	Action certified as a class proceeding
NL	Russell Accident Law (Formerly Ches Crosbie Barristers)	*Clyde Wiseman v. GlaxoSmithKline Inc. et al* Court File No. 2582 CP	Putative class action – no steps taken since filing
NL	Merchant Law Group	*Catherine Morris v. GlaxoSmithKline Inc. et al.* Court File No. 0597	Putative class action – no steps taken since filing
NB	Wagners	*Gregory Ring v. GlaxoSmithKline Inc. et al* Court File No. MC 405-13	Putative class action – no steps taken since filing
PEI	Wagners	*Yvon Lamoureux v. GlaxoSmithKline Inc.et al* Court File No. SI-GS-255577	Putative class action – no steps taken since filing
QB	Orenstein & Associates	*Donna Woods v. GlaxoSmithKline Inc. et al* Court File No. 500-06-000409-074	Petition filed seeking *recours collectif*. Temporary stay granted in February 2017
ON	McPhadden, Samac, Merner, Touvi	*Waheed v. GlaxoSmithKline Inc. et al.* Court File No. CV-09-385922CP	Putative class action. Stayed in 2013 following carriage motion
ON	Kim Orr Barristers (Merchant Law Group)	*Brenda Lloyd, Gary Lloyd and Francesca Imbesi v. GlaxoSmithKline Inc. et al* Court File No. CV-11-434420-00CP	Putative class action. Adjourned *sine die* in December 2014
ON	Siskinds	*Victor Vinerskis v GlaxoSmithKline Inc.* Court File No. 6809-12	Individual action
ON	Siskinds	*Richard Fontaine and Barbara Fontaine v GlaxoSmithKline Inc.* Court File No. 3777/14	Individual action
ON	Siskinds	*Jayanthina Ravindrakumar v GlaxoSmithKline Inc.* Court File No. 4084-14	Individual action
MB	Merchant Law Group	*Andrew Kernel v. GlaxoSmithKline Inc., et al.* Court File No. CI07-01-53523	Putative class action – no steps taken since filing
MB	Deeley, Fabbri, Sellen	*Bonnie Latimer v. GlaxoSmithKline Inc.* Court File No. CI 07-01-51859	Individual Action
SK	Merchant Law Group	*Estate of Iris Edith Wall and Vic Wall v. GlaxoSmithKline Inc., et al* Q.B.G. No. 1073/2007	Stayed on consent pending resolution of *Lloyd* action in Ontario
AB	Merchant Law Group	*Debbie Allison, et al. v. GlaxoSmithKline Inc., et al* Court File No. 0701-08275	Putative class action – no steps taken since filing
BC	Merchant Law Group	*Lanny Michael Honour v. GlaxoSmithKline Inc., et al* Court File No. 073210	Putative class action – no steps taken since filing

Form 39.09

2009 Hfx No. 315567

This is Exhibit "G" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

4633-1886-7033, v. 1

BETWEEN:

Court File No. 6809-12

ONTARIO
SUPERIOR COURT OF JUSTICE

VICTOR VINERSKIS

Plaintiff

- and -

GLAXOSMITHKLINE INC.

Defendant

STATEMENT OF CLAIM

TO THE DEFENDANT

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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 April 30, 2012

Issued by _____
Local registrar

Address of court office: London Court House
Superior Court of Justice
80 Dundas Street
London, ON N6A 6A3

TO: GlaxoSmithKline Inc.
7333 Mississauga Rd N
Mississauga, ON L5N 6L4

CLAIM

1. The Plaintiff claims:

   (a) Pecuniary damages in the amount of $859,300.00;

   (b) Non-Pecuniary damages in the amount of $250,000.00

   (c) Punitive, aggravated and exemplary damages in the amount of $100,000.00;

   (d) Pre-judgement and post-judgement interest pursuant to the *Courts of Justice Act*, R.S.O. 1990, c.C.43 as amended, or as otherwise awarded by this Honourable Court;

   (e) Costs on a substantial indemnity basis, plus applicable taxes; and

   (f) Such further and other relief as this Honourable Court may deem just or the nature and circumstance of this proceeding require.

THE PARTIES

2. The Plaintiff Victor Vinerskis (hereinafter referred to as "Victor") is an individual residing in Stoney Creek, Ontario.

3. The Defendant, GlaxoSmithKline Inc. (the "Defendant" and/or "GSK") is a federal corporation incorporated pursuant to the laws of Canada, with its head office situated in Mississauga Ontario with regional offices in Montreal Quebec, Halifax Nova Scotia, Ottawa Ontario, Winnipeg Manitoba, Calgary Alberta, and Vancouver British Columbia. It is a subsidiary of the GlaxoSmithKline PLC and the GlaxoSmithKline family of companies.

4. At all material times, GSK was engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling and/or selling Avandia in Canada. The development of Avandia for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling

and promotional activities regarding Avandia and other actions central to the allegations of this lawsuit, were undertaken by GSK in Ontario and elsewhere.

THE DRUG

5. Avandia (rosiglitazone) is a pharmaceutical designed for use in treatment of type II diabetes mellitus. Avandia was the first drug available in Canada to directly treat insulin resistance.

6. Avandia was available in the U.S. as early as June 1999 and received a Notice of Compliance from Health Canada on or about March 21, 2000. The Defendant began selling Avandia in Canada soon after that date.

7. The Defendant did not provide adequate safety data to consumers, physicians or Health Canada with respect to Avandia. The Defendant knew or ought to have known that Avandia was unsafe, defective, unreasonably dangerous and not fit for its intended purpose(s).

THE RISKS

8. Avandia is associated with an increased risk of causing ischemic cardiovascular events, including but not limited to myocardial infarction, congestive heart failure, stroke, and/or death.

9. As early as 1999, safety concerns linked to Avandia use were or ought to have been known by the Defendant, and ought to have been communicated to regulators, physicians, pharmacists and consumers.

10. According to an investigation by the United States Senate Committee on Finance ("Committee"), in or about 1999, GSK had embarked on a campaign to defuse cardiovascular concerns associated with Avandia use.

11. The Committee investigation found that GSK also had knowledge in or about 2000 and 2001 that Avandia use was associated with increased adverse events (including heart attack) compared to a competitor drug.

12. In 2004 the results of a GSK study (namely "Avandia 211 Cardiac Heart Failure Study") showed more ischemia-related adverse events with Avandia use than placebo.

13. In or about September 2005 GSK shared the preliminary results of a meta-analysis study it conducted in respect of Avandia with the U.S. FDA (with a more complete version provided to the FDA in or about August 2006). The results of GSK's own analysis showed persons taking Avandia had a 31% higher risk of suffering an adverse cardiovascular event.

14. In or about March 2007, GSK's own studies, ADOPT and DREAM in particular, along with others, demonstrated that increased cardiovascular risks were associated with Avandia use.

15. In or about May 21, 2007, Drs. Nissen and Wolski published a study in the New England Journal of Medicine which showed a 43% higher risk for myocardial infarction in those taking Avandia compared to other diabetes drugs or placebo. The rate of suffering a myocardial infarction among Avandia users was 1.99% compared to 1.51% in those taking placebo or other diabetes medications. The study also revealed a 64% elevated risk of death from cardiovascular causes.

16. GSK's own analysis of Dr. Nissen and Dr. Wolski's study supported the conclusions regarding the increased risk for ischemic events and death associated with Avandia use.

17. From 2007 through 2010 numerous additional studies were conducted and reported, showing ischemic risks associated with Avandia use. These studies, along with various health advisory committee deliberations in both Canada and the U.S. (along with the Committee investigation) prompted those regulators to limit Avandia's use.

18. In Canada, Avandia's use was first restricted in or about November 2007. From that time, Avandia was no longer approved as monotherapy for type II diabetes mellitus or in combination with other diabetes therapies except where those other therapies were contraindicated or not tolerated in patients with any stage of heart failure. A similar restricted use of Avandia was implemented in the U.S. in or about September 2010.

19. Elsewhere, around the world, Avandia was removed from various markets due to safety concerns: In Saudi Arabia, Avandia was removed from that market in or about March 14, 2010; in Europe, the European Medicines Agency ("EMA") removed Avandia from its market in or about July 2010 (and reconfirmed this decision in September 2010); and in New Zealand, Avandia was withdrawn from the market in or about February 2011.

SAFETY UPDATES

20. There were numerous safety updates in both Canada and the U.S. with respect to a variety of risks associated with Avandia use, including cardiovascular risks. These updates however were inadequate and/or untimely as compared to what GSK knew or ought to have known and when they knew or ought to have known it.

21. In the U.S., the FDA issued a Safety Alert on Avandia with respect to the potentially significant risk of heart attack and heart-related deaths in patients taking Avandia, on or about May 21, 2007.

22. In or about July 2007, the U.S. FDA, following an advisory committee meeting, added information about the possibility of ischemic cardiovascular risk to the drug's existing boxed warning (in addition to requiring GSK to conduct a head-to-head cardiovascular safety trial of Avandia against the other anti-diabetic drug in its class, (this study revealed Avandia increased the risk of heart attack by 16%, heart failure by 23% and death by 14% compared to a similar drug in the same class).

23. On August 14, 2007, GSK was required by the U.S. FDA to update Avandia's label to include a "black box" warning regarding cardiac injuries as follows:

> Thiazolidinediones, including rosiglitazone, cause or exacerbate cardiac injuries in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.

> AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS).

24. On or about November 19, 2007, the U.S. "black box" warning regarding myocardial ischemia, in particular, was updated as follows:

> WARNING: CONGESTIVE HEART FAILURE AND MYOCARDIAL ISCHEMIA
>
> A meta-analysis of 42 clinical studies (mean duration 6 months; 14, 237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14, 067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

25. In Canada, the product monograph was updated in or about November 13, 2001 to include a contraindication in patients with acute heart failure.

26. On or about May 30, 2007, Health Canada issue a safety advisory with respect to cardiac safety and Avandia use. The advisory was in response to the Drs Nissen and Wolsky study, published in the New England Journal of Medicine. The advisory highlighted the fact that Avandia should not be used if the patient was suffering from heart problems (and the importance of having patients with underlying heart problems speak with their physicians regarding their continued Avandia use).

27. In November 2007, Health Canada issued another advisory regarding the new restrictions on Avandia use. Specifically, the advisory states that Avandia is no longer approved as monotherapy or in combination with certain other anti-diabetic treatments except where other anti-diabetic treatments are contraindicated and that Avandia is contraindicated in patients with any stage of heart failure.

28. At all material times, the Defendant, through their servants and agents, failed to adequately warn Victor and his physicians that the risks of suffering an ischemic cardiovascular event from using Avandia was higher than while utilizing other available and effective treatments.

29. At all material times the Defendant knew or ought to have known that the risks of using Avandia included severe and life threatening complications and side effects.

30. At all material times, the Defendant through its servants and agents negligently, recklessly and/or carelessly marketed, distributed and/or sold Avandia without adequate instructions or warnings of the product's serious side effects and unreasonably dangerous risks.

THE PLAINTIFF'S EXPERIENCE

31. Victor was prescribed and commenced using Avandia in or about August 2001. A little more than one month after first commencing Avandia, Victor suffered an acute anterolateral myocardial infarction.

32. Victor continued to be prescribed and continued to use Avandia following this 2001 cardiac event. In or about December 2003, Victor suffered *a* non-ST-segment elevation myocardial infarction and heart failure and underwent coronary angiography and stent implantation to treat same.

33. In or about March 2005, Victor was observed to suffer from edema in his hands and feet associated with his Avandia use.

34. In or about December 2007 Victor's Avandia treatment was discontinued.

35. Victor used Avandia in accordance with the package label and consumer information pamphlet and in the manner it was intended to be used.

36. Victor did not have a history of cardiac illness and was in good health, apart from his diabetes, prior to commencing his use of Avandia. Victor was an athlete, both coaching and

playing basketball in addition to being an avid golfer. His ability to participate in these activities has been gravely diminished.

37. In the time period before and during Victor's use of Avandia, he received no warnings about the increased risk of suffering an ischemic cardiac event from using Avandia.

38. Victor's heart attacks were a direct result of his use of Avandia and the Defendant's negligence.

39. Had Victor been aware of the increased risk of suffering a heart attack and/or other serious side effects from using Avandia compared to other available diabetes treatments, he would never have used Avandia and would have chosen a safer treatment. Furthermore, had GSK warned Victor's physicians of the increased risk of suffering a heart attack and/or other serious side effects from using Avandia compared to other available diabetes treatments, his physicians may have monitored him for heart risk, prior to him suffering two attacks. But for GSK's wrongful conduct, Victor would not have incurred his damages.

40. As a result of Victor's heart attacks and their effect on his health, Victor, on the advice of his physician, was forced to retire early from his long-time career as a corrections officer. His retirement pension was adversely affected by the early start of his retirement and as a result Victor has suffered economic loss.

41. Victor's personal relationships were also greatly affected. The multiple heart attacks and the associated injuries to his health and functioning contributed to the breakdown of his marriage of 20 years.

42. The Plaintiff pleads that his damages were caused by the negligence of the Defendant, their servants and agents.

CAUSES OF ACTION

43. The Defendant at all material times owed a duty of care to:

(a) Ensure that Avandia was fit for its intended or reasonably foreseeable use;

(b) Conduct appropriate testing to determine whether and to what extent use of Avandia posed serious health risks, including the suffering of an ischemic event, including but not limited to myocardial infarction and/or death;

(c) Properly, fairly and adequately warn Victor and his physicians that use of Avandia carries the risk of causing an ischemic event, including but not limited to myocardial infarction and/or death;

(d) Ensure that prescribing physicians were kept fully and completely informed of all risks associated with Avandia;

(e) Monitor, investigate, evaluate and follow up on adverse reactions associated with Avandia use; and

(f) Properly inform Health Canada and other regulatory agencies of the elevated risks of suffering an ischemic event, including but not limited to myocardial infarction and/or death, caused by the use of Avandia.

44. The Defendant negligently breached its duty of care.

45. The Plaintiff states that his damages were cause by the negligence of the Defendant. Such negligence includes but is not limited to the following:

(a) The Defendant failed to ensure that Avandia was not dangerous to recipients during the course of its use and that the drug was fit for its intended purpose and of merchantable quality;

(b) The Defendant failed to adequately test Avandia in a manner that would fully disclose the magnitude of the risks associated with its use, including the risk of suffering an ischemic event, including but not limited to myocardial infarction and/or death;

(c) The Defendant, both before and after Avandia was approved by Health Canada, failed to give Health Canada complete and accurate information as its became available;

(d) The Defendant failed to conduct any or any adequate follow-up studies on the efficacy and safety of Avandia;

(e) The Defendant failed to conduct any or any adequate long-term studies of the risks of continued use of Avandia;

(f) The Defendant failed to provide Victor and his physicians with any or any adequate warning of the risks associated with use of Avandia, including the risk of suffering an ischemic event, including but not limited to myocardial infarction and/or death;

(g) The Defendant failed to provide Victor and his physicians with any or any adequate information and warnings respecting the correct usage of Avandia;

(h) The Defendant failed to warn Victor and his physicians about the need for comprehensive regular medical monitoring to ensure the early discovery of side effects related to using Avandia;

(i) The Defendant failed to adequately monitor, evaluate and act upon reports of adverse reactions to Avandia in Canada and elsewhere;

(j) The Defendant failed to provide any or any adequate updated and current information to consumers and their physicians respecting the risks and efficacy of Avandia as it came available from time to time;

(k) The Defendant failed to provide adequate warnings of the potential hazards of Avandia on package labels;

(l) The Defendant failed to warn Victor, his physicians and Health Canada about the need for comprehensive medical monitoring to ensure the early discovery of side effects relating to Avandia use;

(m) The Defendant failed to provide adequate warnings of the risks associated with Avandia, including the risk of suffering an ischemic event, including but not

limited to myocardial infarction and/or death in all persons receiving Avandia, on the customer information pamphlets in Canada;

(n) The Defendant, after noticing problems with Avandia, failed to issue adequate warnings, timely recall the drug, publicize the problem and otherwise act properly and in a timely manner to alert the public, including adequately warn the Plaintiff and his physicians of the drugs' inherent dangers, including but not limited to the danger of suffering an ischemic event, including but not limited to myocardial infarction and/or death, in all persons receiving Avandia;

(o) The Defendant failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of Avandia and the risks associated with the drug;

(p) The Defendant 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;

(q) The Defendant misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Avandia and its associated risks, including the risk of suffering an ischemic event, including but not limited to myocardial infarction and/or death, in all persons receiving Avandia compared to other available diabetes treatments;

(r) The misrepresentations made by the Defendant were unreasonable and in the face of the risks that were known or ought to have been known to the Defendant;

(s) The Defendant failed to timely cease the manufacture, marketing and/or distribution of Avandia when they knew or ought to have known that this drug cause or could cause an ischemic event, including but not limited to myocardial infarction and/or death;

(t) The Defendant failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* RSC 1985, c F-27, as amended, and its associated regulations;

(u) The Defendant failed to properly supervise their employees, their subsidiaries and their affiliated corporations;

(v) The Defendant actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Avandia; and

(w) The Defendant breached other duties of case to consumers, details of which breaches are known only to the Defendant;

(x) In all of the circumstances of this case, the Defendant applied callous and reckless disregard for the health and safety of Victor.

46. The risks associated with the use of Avandia, including the risk of suffering an ischemic event, including but not limited to myocardial infarction and/or death in all persons using Avandia, were in the exclusive knowledge and control of the Defendant. The extent of the risks was not known and could not have been known to consumers including the Plaintiff, and was not known by the Plaintiff. Victor's injuries would not have occurred but for the negligence of the Defendant in failing to ensure that Avandia was safe for use or, in the alternative, for providing an adequate warning of the risks associated with using Avandia to Victor and his physicians.

47. Avandia was defective because it is unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by Victor or his physicians. Any benefit from using Avandia was outweighed by the serious and undisclosed risks of its use when used as GSK intended. The benefits of Avandia did not outweigh the risks for Victor, given that there were alternative diabetes treatments that are efficacious for treating diabetes and carry less serious risks than Avandia.

DAMAGES

48. Had Victor and/or his physicians known of the significant increased risk of suffering an ischemic event associated with Avandia, including, but not limited to heart attack and/or death, compared to other available diabetes treatments, he would never have used Avandia and would not have suffered multiple heart attacks.

49. As a result of the negligence of the Defendant, Victor suffered considerably including conscious pain, mental anguish and emotional distress. Victor has suffered considerably: endured multiple heart attacks, and developed permanent impairments. He has required hospitalization, treatment, investigations, and testing. He is at risk of developing further impairments in the future. The Plaintiff, Victor claims damages for his pain and suffering and loss of enjoyment of life. The Plaintiff, Victor, claims damages for his past, present, and future pecuniary losses, including his extraordinary living expenses and care costs, including medical care and other related services, to the date of trial and into the future. The Plaintiff also claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of GSK.

50. The Plaintiff pleads and relies upon the provision of the *Negligence Act*, R.S.O. 1990, Chapter N.1, as amended, the *Food and Drugs Act*, R.S.C. 1985, c.F.27, as amended and its regulations and the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended.

PLACE OF TRIAL

51. The Plaintiff proposes that this action be tried in London, Ontario.

April 30, 2012

Siskinds LLP
Barristers & Solicitors
680 Waterloo Street
London, ON N6A 3V8

Michael J. Peerless LSUC#: 34127P
Matthew D. Baer LSUC#: 48227K
Sabrina Lombardi LSUC#: 52116R
Tel: (519) 672-2121
Fax: (519) 672-6065

Lawyers for the Plaintiff

Form 39.09

VINERSKIS Plaintiff and GLAXOSMITHKLINE INC. Defendant

Court File No:

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding commenced at LONDON

STATEMENT OF CLAIM

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Barristers & Solicitors
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London, ON N6A 3V8

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Lawyers for the Plaintiff

2009 Ills No. 315567

This is Exhibit "H" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

Court File No. 377/14

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

RICHARD FONTAINE and BARBARA FONTAINE

Plaintiffs

- and -

GLAXOSMITHKLINE INC.

Defendant

STATEMENT OF CLAIM

TO THE DEFENDANT

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 August 1, 2014 Issued by

Local registrar

Address of court office: London Court House
Superior Court of Justice
80 Dundas Street
London, ON N6A 6A3

TO: GlaxoSmithKline Inc.
7333 Mississauga Rd N
Mississauga, ON L5N 6L4

CLAIM

1. The Plaintiffs claim:

   (a) On behalf of the Plaintiff, Richard Fontaine:

      (i) Pecuniary general damages in the amount of $500,000.00;

      (ii) Non-pecuniary general damages in the amount of $350,000.00; and

      (iii) Special damages in the amount of $100,000.00;

   (b) On behalf of the Plaintiff, Barbara Fontaine, damages pursuant to the *Family Law Act* in the amount of $100,000.00;

   (c) Punitive, aggravated and exemplary damages in the amount of $100,000.00;

   (d) Pre-judgment and post-judgment interest pursuant to the *Courts of Justice Act*;

   (e) Their costs of this action; and

   (f) Such further and other relief as this Honourable Court may deem just or the nature and circumstance of this proceeding require.

THE PARTIES

2. The Plaintiff, Richard Fontaine ("Mr. Fontaine"), is an individual residing in Thunder Bay, Ontario with his wife, the Plaintiff, Barbara Fontaine ("Mrs. Fontaine").

3. The Defendant, GlaxoSmithKline Inc. (the "Defendant" or "GSK"), is a corporation incorporated pursuant to the laws of Canada, with its head office situated in Mississauga, and regional offices in Montreal, Halifax, Ottawa, Winnipeg, Calgary and Vancouver.

4. At all material times, GSK was engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling and/or selling Avandia in Canada, including Ontario.

AVANDIA

5. Avandia (GSK's propriety name for rosiglitazone) is a pharmaceutical designed for use in treatment of type II diabetes mellitus. Cardiovascular disease is the most common cause of morbidity and mortality for people suffering from type II diabetes mellitus. Avandia was the first drug available in Canada to directly treat insulin resistance, which may cause type II diabetes mellitus.

6. Avandia was available in the U.S. as early as June 1999 and received a Notice of Compliance from Health Canada on or about March 21, 2000. The Defendant began selling Avandia in Canada soon after that date.

7. The Defendant did not provide adequate safety data to consumers (including Mr. Fontaine), physicians and other healthcare providers, and Health Canada with respect to Avandia. The Defendant knew or ought to have known that Avandia was unsafe, defective, and unreasonably dangerous.

THE RISKS ASSOCIATED WITH USING AVANDIA

8. Avandia is associated with causing an increased risk of ischemic cardiovascular events, including myocardial infarction (heart attack) and stroke, as well as non-ischemic events, including congestive heart failure ("CHF"), and/or death.

9. Ischemia refers to the restriction of the supply of blood to the body's organs, such as the heart or the brain, depriving these organs of oxygen and possibly resulting in myocardial infarction or stroke, respectively.

10. CHF denotes a failure of proper heart function that inhibits the heart's ability to pump sufficient blood to the rest of the body.

11. As early as 1999, an increased risk of adverse cardiovascular events was linked to Avandia use. This risk was known or ought to have been known to the Defendant, and ought to have been communicated to regulators, physicians, pharmacists, other healthcare providers and consumers (including Mr. Fontaine).

12. According to an investigation by the United States Senate Committee on Finance (the "Committee"), in or about 1999, GSK had embarked on a campaign to defuse cardiovascular concerns associated with Avandia use.

13. The Committee investigation found that GSK also had knowledge in or about 2000 and 2001 that Avandia use was associated with increased adverse events compared to a competitor drug.

14. At the time of its Canadian marketing approval, in 2000, Avandia was known to be associated with increased risk of CHF.

15. Five pre-approval trials were conducted by GSK. Those trials revealed that more ischemic cardiovascular events occurred in patients taking Avandia than in those taking comparable drugs. The "relative risk" of ischemic events for Avandia patients was 1.80, meaning that these patients were 1.8 times to suffer such an event than patients taking a comparable drug. The outcomes of these trials were not made publicly available at the time.

16. In 2004, the results of a 52-week GSK study involving patients with pre-existing CHF (the "Avandia 211 Cardiac Heart Failure Study") revealed greater CHF and ischemic adverse events with Avandia use than with placebo. These findings were shared with the United States Food and Drug Administration ("FDA") in 2006.

17. An internal GSK document from 2005 titled "Further Interim Results from Retrospective Analysis of Cardiovascular Events in Clinical Trials" states that "[t]hese data lend credence to the hypothesis that small degrees of fluid retention may be an important contributor to the development or worsening myocardial ischemia in high risk patients" and "that patients with severe coronary artery disease may be acutely sensitive to changes in fluid status, and that fluid retention could contribute to a reduction in functional capacity and to the development of ischemic symptoms."

18. In October 2005, GSK shared the preliminary results of a pool of randomized controlled trials ("RCTs") it conducted in respect of Avandia with the FDA. GSK clinical trials involving 11,586 participants showed a 29% increased risk of myocardial infarction for

patients taking Avandia. A GSK observational study involving more than 14,000 participants showed a 31% increased risk of myocardial ischemic events for Avandia patients.

19. A GSK meta-analysis of the results of 42 RCTs involving Avandia-treated patients showed persons taking Avandia had a 30% significantly higher risk of suffering myocardial ischemic events; the results of the FDA's meta-analysis of same demonstrated a 40% significantly higher risk of these events.

20. In or about September and December 2006, respectively, GSK's studies, Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication ("DREAM"), and A Diabetes Outcome Progression Trial ("ADOPT"), demonstrated that increased cardiovascular risks were associated with Avandia use.

21. On or about May 21, 2007, Drs. Nissen and Wolski published "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes" (the "Nissen Study") in the New England Journal of Medicine. The Nissen Study was a meta-analysis of 42 trials comparing Avandia use with placebo or active comparators to assess the effect of Avandia on cardiovascular outcomes. The Nissen Study showed a 43% higher risk for myocardial infarction in patients taking Avandia. The rate of suffering a myocardial infarction among Avandia users was 1.99% compared to 1.51% in those taking placebo or other diabetes medications. The study also revealed that Avandia users had a 64% elevated risk of death from cardiovascular causes.

22. GSK sought to undermine the results of the Nissen Study.

(a) First, GSK published an unplanned, interim analysis of its then incomplete "Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes" ("RECORD") trial, which the authors acknowledged had limited statistical power. The RECORD trial revealed that patients in the Avandia group were more than twice as likely to suffer congestive heart failure than patients in the control group. The incidence of myocardial infarction was also higher among the Avandia group, but the results were found to be not statistically significant. Subsequent studies of participants' medical records suggest a significant underreporting of myocardial infarctions.

(b) Second, GSK submitted a letter to the editor of Lancet criticizing the results of the Nissen Study and stating that its own RECORD study provides "compelling evidence" of cardiovascular safety of Avandia. GSK submitted this letter notwithstanding that it was already known to GSK that the RECORD trial was under-powered to answer questions regarding cardiovascular safety.

(c) Third, GSK's "Dear Healthcare Professional" correspondence published by Health Canada further sought to undermine the results of the Nissen Study by stating that the Nissen Study included studies where patients were using Avandia in combination with other drugs in a manner that was not approved in Canada. This statement was misleading in that the Nissen Study found that the overall risk of cardiovascular events in Avandia users was greater even when the studies with non-approved combinations were excluded.

23. In September 2007, a research team led by Dr. Sonal Singh published a study in the Journal of the American Medical Association that showed that Avandia use for at least 12 months was associated with a "significantly increased risk of myocardial infarction and heart failure."

24. In December 2007, a research team led by Dr. Lorraine Lipscombe published a study in the Journal of the American Medical Association that showed that Avandia treatment in older patients was associated with a statistically significant increased risk of CHF and myocardial infarction compared to other diabetes treatments.

25. In November 2008, a research team led by Dr. Winkelmayer published a study in the Archives of Internal Medicine that showed that Avandia treatment in older patients was associated with a 13% greater risk of CHF.

26. In 2010, the European Medicines Agency Committee on Medical Products for Human Use (the "EMA") reviewed the available data for the benefits and risks associated with Avandia and indicated that Avandia is associated with an increased risk of heart attacks and strokes. The EMA noted that diabetic patients are already at increased risk of these conditions and diabetic treatment should aim at reducing these risks.

SAFETY UPDATES, RESTRICTIONS & REMOVAL FROM INTERNATIONAL MARKETS

27. The studies identified above, among others, along with various health advisory committee deliberations in both Canada and the U.S. (including the Committee investigation) prompted those regulators to direct that the warnings be amended and limit Avandia's use.

28. There were numerous safety updates in both Canada and the U.S. with respect to a variety of risks associated with Avandia use, including cardiovascular risks. These updates however were inadequate and/or untimely as compared to what GSK knew or ought to have known and when they knew or ought to have known it.

29. In Canada, Avandia's use was first restricted in or about November 2007. Since that time, Avandia has not been approved as monotherapy for type II diabetes mellitus or in combination with other diabetes therapies except where those other therapies were contraindicated or not tolerated in patients with any stage of heart failure. A similar restricted use of Avandia was implemented in the U.S. in or about September 2010.

30. In July 2007, the FDA, following an advisory committee meeting, required GSK to conduct a head-to-head cardiovascular safety trial of Avandia and the other anti-diabetic drug in its class (which subsequently revealed that Avandia increased the risk of heart attack by 16%, heart failure by 23% and death by 14%), and recommended that information be added to Avandia's existing "boxed warning" regarding the possibility of ischemic cardiovascular risk.

31. On or about August 14, 2007, GSK was directed by the FDA to update Avandia's label to include the following "boxed warning" regarding CHF:

> Thiazolidinediones, including rosiglitazone, cause or exacerbate cardiac injuries in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.

> AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS).

32. On or about November 19, 2007, the U.S. "boxed warning" was updated to include information regarding myocardial ischemia:

> WARNING: CONGESTIVE HEART FAILURE AND MYOCARDIAL ISCHEMIA
>
> A meta-analysis of 42 clinical studies (mean duration 6 months; 14, 237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14, 067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

33. In Canada, the Avandia product monograph was updated on or about November 13, 2001, to include a contraindication regarding CHF. This warning only cautioned that Avandia *could* exacerbate the risk of CHF, not that it *does* exacerbate the risk. Further, the warning spoke only to the risk of the exacerbation of CHF; it did not warn that it could cause CHF in patients with no prior history of the condition.

34. The 2001 product monograph also stated that Avandia is not "indicated for patients with NYHA Class III or IV CHF unless the benefits exceed the risks" despite the existence of no evidence that Avandia held any benefits that could outweigh the risks of CHF.

35. The 2001 product monograph stated that Avandia is indicated for treatment of type 2 diabetes mellitus as monotherapy or in combination with other anti-diabetic drugs such as metformin or sulfonylurea, whereas the 2007 Nissen Study showed that the risk of myocardial infarction was highest in patients taking Avandia in combination with metformin.

36. In 2004, the "Precautions" section of the product monograph was revised to state:

> In postmarketing experience with rosiglitazone, adverse events potentially related to volume expansion (e.g. congestive heart failure, pulmonary edema, and pleural effusions) have been reported.

The product monograph failed to provide information about the number or incidence of these events and did not acknowledge Avandia use as the possible cause.

37. In May 2007, Health Canada issued a safety advisory with respect to cardiac safety and Avandia use. The advisory was issued in response to the Nissen Study, and highlighted that Avandia should not be used in patients suffering from heart problems. The advisory emphasized the importance of having patients with underlying heart problems speak with their physicians regarding their continued use of Avandia.

38. In November 2007, Health Canada issued another advisory regarding the new restrictions on Avandia use. Specifically, the advisory stated that Avandia is no longer approved as monotherapy or in combination with certain other anti-diabetic treatments except

where other anti-diabetic treatments are contraindicated, and that Avandia is contraindicated in patients with any stage of heart failure.

39. In November 2010, Health Canada issued a public communication that advised that Avandia patients speak to their doctors "to revisit their diabetes treatment." Since this communication, Health Canada has required that Avandia only be prescribed on the condition that patients execute a consent form acknowledging awareness that Avandia may increase the risk of serious heart problems and of the existence of other diabetes treatment options.

40. Elsewhere around the world, Avandia was removed from various markets due to safety concerns: In Saudi Arabia, Avandia was removed from that market in or about March 14, 2010; in Europe, the European Medicines Agency removed Avandia from its market in or about July 2010 (and reconfirmed this decision in September 2010); and in New Zealand, Avandia was withdrawn from the market in or about February 2011.

41. At all material times, the Defendant, through its servants and agents, failed to adequately warn Mr. Fontaine, and his physicians and other healthcare providers that the risks of suffering an ischemic or non-ischemic cardiovascular event with Avandia usage was higher than with usage of other available and effective treatments.

42. At all material times, the Defendant knew or ought to have known that the risks of using Avandia included severe and life threatening complications and side effects.

43. At all material times, the Defendant through its servants and agents negligently, recklessly and/or carelessly marketed, distributed and/or sold Avandia without adequate

instructions or warnings of the product's serious side effects and unreasonably dangerous risks.

THE PLAINTIFF'S EXPERIENCE

44. Mr. Fontaine was prescribed and commenced using Avandia on or about April 17, 2004.

45. On or about June 26, 2005, Mr. Fontaine suffered an anterolateral wall myocardial infarction. Electrocardiogram testing demonstrated "massive anterolateral and inferior ST segment elevation."

46. As a result of the myocardial infarction, on or about June 27, 2005, Mr. Fontaine underwent cardiac catheterization.

47. Mr. Fontaine continued to be prescribed and continued to use Avandia following the June 26, 2005 cardiac event.

48. On or about February 16, 2006, Mr. Fontaine was diagnosed with CHF.

49. On or about February 16, 2006, on the advice of his treating physician, Mr. Fontaine's Avandia treatment was discontinued.

50. Mr. Fontaine used Avandia in accordance with the package label and consumer information pamphlet and in the manner it was intended to be used.

51. Mr. Fontaine did not have a history of cardiac illness prior to commencing his use of Avandia.

52. In the time period before and during Mr. Fontaine's use of Avandia, he received no warnings about the increased risk of suffering a cardiac event, including myocardial infarction and/or CHF from using Avandia.

53. Mr. Fontaine's heart attack and CHF were both a direct result of his use of Avandia and the Defendant's negligence.

54. Had Mr. Fontaine been aware of the increased risk of suffering a heart attack, developing CHF and/or other serious side effects from using Avandia compared to other available diabetes treatments, he would never have used Avandia and would have chosen a safer treatment. Furthermore, had GSK warned Mr. Fontaine's physicians and other healthcare providers of the increased risk of suffering a heart attack, developing CHF and/or other serious side effects from using Avandia compared to other available diabetes treatments, his physicians and other healthcare providers may have monitored him for heart risks prior to him suffering an attack and developing CHF. But for GSK's wrongful conduct, Mr. Fontaine would not have incurred his damages.

55. As a result of Mr. Fontaine's heart attack, development of CHF and their effects on his health, Mr. Fontaine can no longer engage in sexual intercourse, requires a scooter for transportation as he is unable to walk even short distances, is in constant pain and experiences frequent shortness of breath.

56. As a result of his heart attack, development of CHF and their effects on his health, Mr. Fontaine was forced to retire early from his long-time career as a bus driver. As a result of his early retirement, Mr. Fontaine has suffered pecuniary losses, including a loss of income.

57. The Plaintiffs plead that their damages were caused by the negligence of the Defendant, its servants and agents.

NEGLIGENCE

58. The Defendant at all material times owed Mr. Fontaine a duty of care to:

(a) Ensure that Avandia was fit for its intended or reasonably foreseeable use;

(b) Conduct appropriate testing to determine whether and to what extent use of Avandia posed serious health risks, including the suffering of a cardiac event, including myocardial infarction and CHF;

(c) Properly, fairly and adequately warn Mr. Fontaine, and his physicians and other healthcare providers that use of Avandia carries the risk of causing a cardiac event, including myocardial infaretion and CHF;

(d) Ensure that prescribing physicians and other healthcare providers were kept fully and completely informed of all risks associated with Avandia;

(e) Monitor, investigate, evaluate and follow up on adverse reactions associated with Avandia use; and

(f) Properly inform Health Canada and other regulatory agencies of the elevated risks of suffering a cardiac event, including myocardial infarction and CHF, caused by the use of Avandia.

59. The Defendant negligently breached its duty of care.

60. The Plaintiffs state that their damages were caused by the negligence of the Defendant. Such negligence includes but is not limited to the following:

(a) The Defendant failed to adequately test Avandia in a manner that would fully disclose the magnitude of the risks associated with its use, including the risk of suffering myocardial infarction and CHF;

(b) The Defendant, both before and after Avandia was approved by Health Canada, failed to give Health Canada complete and accurate information as it became available;

(c) The Defendant failed to conduct adequate follow-up studies on the efficacy and safety of Avandia;

(d) The Defendant failed to conduct adequate long-term studies of the risks of continued use of Avandia;

(e) The Defendant failed to provide Mr. Fontaine, and his physicians and other healthcare providers with adequate warning of the risks associated with use of Avandia, including the risk of suffering myocardial infarction and CHF;

(f) The Defendant failed to provide Mr. Fontaine, and his physicians and other healthcare providers with adequate information and warnings respecting the correct usage of Avandia;

(g) The Defendant failed to warn Mr. Fontaine, and his physicians and other healthcare providers about the need for comprehensive regular medical monitoring to ensure the early discovery of side effects related to Avandia use;

(h) The Defendant failed to adequately monitor, evaluate and act upon reports of adverse reactions to Avandia in Canada and elsewhere;

(i) The Defendant failed to provide adequate and current information to consumers and their physicians and other healthcare providers respecting the risks and efficacy of Avandia as such information came available from time to time;

(j) The Defendant failed to provide adequate warnings of the potential hazards of Avandia on package labels;

(k) The Defendant failed to warn Mr. Fontaine, and his physicians and other healthcare providers, and Health Canada about the need for comprehensive medical monitoring to ensure the early discovery of side effects relating to Avandia use;

(l) The Defendant failed to provide adequate warnings of the risks associated with Avandia, including the risk of suffering myocardial infarction and CHF in all persons receiving Avandia, on the customer information pamphlets in Canada;

(m) The Defendant, after noticing problems with Avandia, failed to issue adequate warnings, timely recall the drug, publicize the problem and otherwise act properly and in a timely manner to adequately warn Mr. Fontaine, and his

physicians and other healthcare providers of Avandia's inherent dangers, including the danger of suffering myocardial infarction and CHF;

(n) The Defendant failed to establish any adequate procedures to educate its sales representatives, prescribing physicians and other healthcare providers respecting the correct usage of Avandia and the risks associated with the drug;

(o) The Defendant represented that Avandia was safe and fit for its intended purpose when it knew or ought to have known that these representations were false;

(p) The Defendant misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Avandia and its associated risks, including the risk of suffering myocardial infarction and CHF, compared to other available diabetes treatments;

(q) The misrepresentations made by the Defendant were unreasonable in the face of the risks that were known or ought to have been known to the Defendant;

(r) The Defendant failed to timely cease the manufacture, marketing and/or distribution of Avandia when it knew or ought to have known that this drug causes or could cause myocardial infarction and CHF;

(s) The Defendant failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* RSC 1985, c F-27, as amended, and its associated regulations;

(t) The Defendant failed to properly supervise its employees, subsidiaries and affiliated corporations; and

(u) The Defendant actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Avandia.

61. The risks associated with the use of Avandia, including the risk of myocardial infarction and CHF, were in the exclusive knowledge and control of the Defendant. The extent of these risks was not known and could not have been known to the Plaintiffs. Mr. Fontaine's injuries would not have occurred but for the negligence of the Defendant in failing to ensure that Avandia was safe for use or, in the alternative, but for providing an adequate warning of the risks associated with using Avandia to Mr. Fontaine, and his physicians and other healthcare providers.

62. Avandia is defective because it is unreasonably dangerous, beyond the dangers that could reasonably have been contemplated by Mr. Fontaine, and his physicians and/or other healthcare providers. Any benefit from using Avandia was outweighed by the serious and undisclosed risks of its use when used as GSK intended. The benefits of Avandia did not outweigh the risks for Mr. Fontaine given that there were alternative diabetes treatments that are efficacious for treating diabetes and carry less serious risks than Avandia.

63. The Defendant knew or ought to have known of the risks associated with the use of Avandia, including the risk of suffering myocardial infarction or CHF. By not disclosing these risks and by attempting to downplay the outcome of studies conducted by third-parties, the Defendant acted in callous and reckless disregard for the health and safety of Mr. Fontaine.

DAMAGES

64. Had Mr. Fontaine, and his physicians and/or other healthcare providers known that Avandia significantly increases the risk of heart attack and CHF, compared to other available diabetes treatments, he would never have used Avandia and would not have suffered a heart attack and developed CHF.

65. As a result of the negligence of the Defendant, Mr. Fontaine has endured conscious pain, mental anguish and emotional distress. Mr. Fontaine has suffered considerably: he has had a heart attack, developed CHF and other permanent impairments. He has required hospitalization, treatment, investigations and testing. He is at risk of developing further impairments in the future. Mr. Fontaine claims damages for his pain and suffering and loss of enjoyment of life. Mr. Fontaine claims damages for his past, present and future pecuniary losses, including his extraordinary living expenses and care costs, medical care and other related services, to the date of trial and into the future.

66. Mr. Fontaine also claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of GSK.

67. Mrs. Fontaine claims damages pursuant to the provisions of the *Family Law Act* for, among other things, loss of guidance, care and companionship, her pecuniary losses, expenses and the services she rendered as a result of the injuries to her husband, Mr. Fontaine.

68. The Plaintiffs plead and rely upon the provisions of the *Negligence Act*, RSO 1990, c N.1, as amended, the *Food and Drugs Act*, RSC 1985, c F.27, as amended and its regulations,

the *Family Law Act*, RSO 1990, c F.3 and the *Courts of Justice Act*, RSO 1990, c C.43, as amended.

PLACE OF TRIAL

69. The Plaintiffs propose that this action be tried in London, Ontario.

August 1, 2014

Siskinds LLP
Barristers & Solicitors
680 Waterloo Street
London, ON N6A 3V8

Charles M. Wright LSUC #: 36599Q
Linda J. Visser LSUC #: 52158I
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Lawyers for the Plaintiffs

Court File No:

FONTAINE et al Plaintiffs	and GLAXOSMITHKLINE INC. Defendant

ONTARIO
SUPERIOR COURT OF JUSTICE
Proceeding commenced at London, ON

STATEMENT OF CLAIM

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Lawyers for the Plaintiffs

Form 39.03

2009 Hfx No. 315567

This is Exhibit "I" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme
Court of Nova Scotia

4833-1600-7825 v. 1

Court File No. 4084-14

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

JAYANTHINA RAVINDRAKUMAR

Plaintiff

- and -

GLAXOSMITHKLINE INC.

Defendant

STATEMENT OF CLAIM

TO THE DEFENDANT

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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 September 18, 2014

Issued by _____
Local registrar

Address of court office: London Court House
Superior Court of Justice
80 Dundas Street
London, ON N6A 6A3

TO: GlaxoSmithKline Inc.
7333 Mississauga Rd N
Mississauga, ON L5N 6L4

CLAIM

1. The Plaintiff claims:

   (a) Pecuniary general damages in the amount of $500,000.00;

   (b) Non-pecuniary general damages in the amount of $350,000.00;

   (c) Special damages in the amount of $100,000.00;

   (d) Punitive, aggravated and exemplary damages in the amount of $100,000.00;

   (e) Pre-judgment and post-judgment interest pursuant to the *Courts of Justice Act*;

   (f) Her costs of this action; and

   (g) Such further and other relief as this Honourable Court may deem just or the nature and circumstance of this proceeding require.

THE PARTIES

2. The Plaintiff, Jayanthina Ravindrakumar ("Ms. Ravindrakumar"), is an individual residing in Scarborough, Ontario.

3. The Defendant, GlaxoSmithKline Inc. (the "Defendant" or "GSK"), is a corporation incorporated pursuant to the laws of Canada, with its head office situated in Mississauga, and regional offices in Montreal, Halifax, Ottawa, Winnipeg, Calgary and Vancouver.

4. At all material times, GSK was engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling and/or selling Avandia in Canada, including Ontario.

AVANDIA

5. Avandia's non-propriety name is rosiglitazone. Avandia is a pharmaceutical designed for use in treatment of type II diabetes mellitus. Cardiovascular disease is the most common

cause of morbidity and mortality for people suffering from type II diabetes mellitus. Avandia was the first drug available in Canada to directly treat insulin resistance, which may cause type II diabetes mellitus.

6. Avandia was available in the U.S. as early as June 1999 and received a Notice of Compliance from Health Canada on or about March 21, 2000. The Defendant began selling Avandia in Canada soon after that date.

7. The Defendant did not provide adequate safety data to consumers (including the Plaintiff), physicians and other healthcare providers, and Health Canada with respect to Avandia. The Defendant knew or ought to have known that Avandia was unsafe, defective and unreasonably dangerous.

THE RISKS ASSOCIATED WITH USING AVANDIA

8. Avandia is associated with causing an increased risk of ischemic cardiovascular events, including myocardial infarction (heart attack) and stroke. Ischemia refers to the restriction of the supply of blood to the body's organs, such as the heart or the brain, which results in a shortage of oxygen to those organs. The lack of oxygen, in turn, can result in myocardial infarction or stroke, depending on where the ischemic event occurs. If the ischemic event occurs in the blood vessels supplying the heart, the lack of oxygen will result in myocardial infarction. If the ischemic event occurs in blood vessels supplying the brain, the lack of oxygen will result in stroke.

9. In the case of Avandia, more research has been conducted regarding myocardial infarction than stroke. This is likely because cardiovascular events are the most common complications in patients with type II diabetes and the main goal of treatment should be to reduce this complication. However, there are studies indicating that Avandia increases the risk of stroke.

10. Avandia is also associated with causing an increased risk of non-ischemic events, including congestive heart failure.

11. As early as 1999, an increased risk of ischemic cardiovascular events was linked to Avandia. This risk was known or ought to have been known to the Defendant, and ought to have been communicated to regulators, physicians, pharmacists, other healthcare providers and consumers (including the Plaintiff).

12. According to an investigation by the United States Senate Committee on Finance (the "Committee"), in or about 1999, GSK had embarked on a campaign to defuse cardiovascular concerns associated with Avandia use.

13. The Committee investigation found that GSK had knowledge in or about 2000 and 2001 that Avandia use was associated with increased adverse events compared to a competitor drug.

14. Five pre-approval trials were conducted by GSK. Those trials revealed that more ischemic cardiovascular events occurred in patients taking Avandia than in those taking comparable drugs. The "relative risk" of ischemic events for Avandia patients was 1.80, meaning that these patients were 1.8 times more likely to suffer such an event than patients taking a comparable drug. The outcomes of these trials were not made publicly available at the time.

15. In 2004, the results of a 52-week GSK study involving patients with pre-existing congestive heart failure (the "Avandia 211 Cardiac Heart Failure Study") revealed greater congestive heart failure and ischemic adverse events with Avandia use than with placebo. These findings were shared with the United States Food and Drug Administration ("FDA") in 2006.

16. An internal GSK document from 2005 titled "Further Interim Results from Retrospective Analysis of Cardiovascular Events in Clinical Trials" states that "[t]hese data lend credence to the hypothesis that small degrees of fluid retention may be an important contributor to the development or worsening myocardial ischemia in high risk patients" and "that patients with severe coronary artery disease may be acutely sensitive to changes in fluid status, and that fluid retention could contribute to a reduction in functional capacity and to the development of ischemic symptoms."

17. In October 2005, GSK shared the preliminary results of a pool of randomized controlled trials ("RCTs") it conducted in respect of Avandia with the FDA. GSK clinical trials involving 11,586 participants showed a 29% increased risk of myocardial infarction for patients taking Avandia. A GSK observational study involving more than 14,000 participants showed a 31% increased risk of myocardial ischemic events for Avandia patients.

18. A GSK meta-analysis of the results of 42 RCTs involving Avandia-treated patients showed persons taking Avandia had a 30% significantly higher risk of suffering myocardial ischemic events; the results of the FDA's meta-analysis of same demonstrated a 40% significantly higher risk of these events.

19. In or about September and December 2006, respectively, GSK's studies, Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication ("DREAM"), and A Diabetes Outcome Progression Trial ("ADOPT") demonstrated that increased cardiovascular risks were associated with Avandia use.

20. On or about May 21, 2007, Drs. Nissen and Wolski published a study ("Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes", the "Nissen Study") in the New England Journal of Medicine. The Nissen Study was a meta-analysis of 42 trials comparing Avandia with placebo or active comparators in order to assess the effect of Avandia on cardiovascular outcomes. The Nissen Study showed a 43% higher risk for myocardial infarction in patients taking Avandia. The rate of suffering a myocardial infarction among Avandia users was 1.99% compared to 1.51% in those taking placebo or other diabetes medications. The study also revealed that Avandia users had a 64% elevated risk of death from cardiovascular causes.

21. GSK sought to undermine the results of the Nissen Study.

   (a) First, GSK published an unplanned, interim analysis of the then incomplete "Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes" ("RECORD") trial. The authors acknowledged that the analysis had limited statistical power. The RECORD trial revealed that patients in the Avandia group were more than twice as likely to suffer congestive heart failure

than patients in the control group. The incidence of myocardial infarction was also higher among the Avandia group, but the results were found to be not statistically significant. Subsequent studies of participants' medical records suggest a significant underreporting of myocardial infarctions.

(b) Second, GSK submitted a letter to the editor of The Lancet criticizing the results of the Nissen Study and stating that its own RECORD study provides "compelling evidence" of cardiovascular safety of Avandia. GSK submitted this letter notwithstanding that it was already known to GSK that the RECORD trial was under-powered to answer questions regarding cardiovascular safety.

(c) Third, GSK's "Dear Healthcare Professional" correspondence published by Health Canada further sought to undermine the results of the Nissen Study by stating that the Nissen Study included studies where patients were using Avandia in combination with other drugs in a manner that was not approved in Canada. This statement was misleading in that the Nissen Study found that the overall risk of cardiovascular events in Avandia users was greater even when the studies with non-approved combinations were excluded.

22. In September 2007, a research team led by Dr. Sonal Singh published a study in the Journal of the American Medical Association that showed that Avandia use for at least 12 months was associated with a "significantly increased risk of myocardial infarction and heart failure."

23. In December 2007, a research team led by Dr. Lorraine Lipscombe published a study in the Journal of the American Medical Association that showed that Avandia treatment in older patients was associated with a statistically significant increased risk of congestive heart failure and myocardial infarction compared to other diabetes treatments.

24. A higher mortality rate was observed among Avandia users in a study by Wolfgang Winkelmayer and others published in the November 2008 issue of the Archives of Internal Medicine. The study revealed a 15% greater mortality among Avandia patients than Actos patients (Actos is an alternative drug to Avandia). While finding a higher mortality rate, the

study did not reveal differences in diagnosed myocardial infarctions and strokes among Avandia and Actos users. The authors considered that cardiovascular disease represents more than 75% of mortality in patients with diabetes and concluded that there must "almost certainly be a link." On that basis, they hypothesized that many of the deaths were due to myocardial infarctions or strokes, but that cardiovascular deaths might have occurred before a diagnosis was made.

25. In 2010, the Committee report on Avandia referenced a GSK Diabetes Franchise Cardiology Advisory Report wherein a physician recommended listing cardiovascular deaths, myocardial infarction and strokes separately in the warning label.

26. In 2010, the European Medicines Agency Committee on Medical Products for Human Use (the "EMA") indicated that the risks of taking Avandia outweigh the benefits. The EMA reviewed the available data for the benefits and risks associated with Avandia. That review showed that there was an increased risk of heart attacks and strokes. The EMA indicated that diabetic patients are already at increased risk of these conditions and diabetic treatment should aim at reducing these risks.

SAFETY UPDATES, RESTRICTIONS & REMOVAL FROM INTERNATIONAL MARKETS

27. In the United States, from the outset, the Avandia warning labels contained a statement regarding congestive heart failure. In Canada, the product monograph was updated in November 2001 to include a contraindication in patients with acute heart failure. However, there was no statement regarding the risk of ischemic cardiovascular events. An ischemic cardiovascular event affecting the heart (a heart attack or myocardial infarction) is not the same as a heart failure. In a heart attack, the heart is injured as a result of the heart's muscle being deprived of oxygen. With congestive heart failure, the heart functions improperly and is not able to pump enough blood to the rest of the body.

28. The studies identified above, among others, along with various health advisory committee deliberations in both Canada and the U.S. (along with including the Committee investigation), prompted those regulators to direct that the warnings be amended and limit Avandia's use.

29. There were numerous safety updates in both Canada and the U.S. with respect to a variety of risks associated with Avandia use, including ischemic cardiovascular risks. These updates however were inadequate and/or untimely as compared to what GSK knew or ought to have known and when it knew or ought to have known it.

30. In July 2007, the FDA, following an advisory committee meeting, required GSK to conduct a head-to-head cardiovascular safety trial of Avandia and the other anti-diabetic drug in its class (which subsequently revealed that Avandia increased the risk of heart attack by 16%, heart failure by 23% and death by 14%), and recommended that information be added to Avandia's existing "boxed warning" regarding the possibility of ischemic cardiovascular risk.

31. On or about August 14, 2007, GSK was directed by the FDA to update Avandia's label to include the following "boxed warning" regarding congestive heart failure:

> Thiazolidinediones, including rosiglitazone, cause or exacerbate cardiac injuries in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.
>
> AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS).

32. On or about November 19, 2007, the U.S. "boxed warning" was updated to include information regarding myocardial ischemia:

> WARNING: CONGESTIVE HEART FAILURE AND MYOCARDIAL ISCHEMIA

> A meta-analysis of 42 clinical studies (mean duration 6 months; 14, 237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14, 067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

33. In May 2007, Health Canada issued a safety advisory with respect to cardiac safety and Avandia use. The advisory was issued in response to the Nissen Study, and highlighted that Avandia should not be used in patients suffering from heart problems. The advisory emphasized the importance of having patients with underlying heart problems speak with their physicians regarding their continued use of Avandia.

34. In November 2007, Health Canada issued another advisory regarding the new restrictions on Avandia use. Specifically, the advisory stated that Avandia was no longer approved as monotherapy or in combination with certain other anti-diabetic treatments except where other anti-diabetic treatments are contraindicated, and that Avandia was contraindicated in patients with any stage of heart failure.

35. In November 2010, Health Canada issued a public communication that advised that Avandia patients speak to their doctors "to revisit their diabetes treatment." Since this communication, Health Canada has required that Avandia only be prescribed on the condition that patients execute a consent form acknowledging awareness that Avandia may increase the risk of serious heart problems and of the existence of other diabetes treatment options.

36. Elsewhere around the world, Avandia was removed from various markets due to safety concerns: In Saudi Arabia, Avandia was removed from that market in or about March 14, 2010; in Europe, the European Medicines Agency removed Avandia from its market in or about July 2010 (and reconfirmed this decision in September 2010); and in New Zealand, Avandia was withdrawn from the market in or about February 2011.

37. Notwithstanding that there was evidence linking Avandia to an increased risk of stroke, GSK has not amended the Avandia warning to include any information about the increased risk of stroke.

38. At all material times, the Defendant, through its servants and agents, failed to adequately warn Ms. Ravindrakumar, and her physicians and other healthcare providers that the risks of suffering an ischemic cardiovascular event (including stroke) with Avandia usage was higher than use of other available and effective treatments.

39. At all material times, the Defendant knew or ought to have known that the risks of using Avandia included severe and life threatening complications and side effects (including stroke).

40. At all material times, the Defendant through its servants and agents negligently, recklessly and/or carelessly marketed, distributed and/or sold Avandia without adequate instructions or warnings of the product's serious side effects and unreasonably dangerous risks.

THE PLAINTIFF'S EXPERIENCE

41. Ms. Ravindrakumar was prescribed and commenced using Avandia in or around December 2001.

42. In or around September 2008, Ms. Ravindrakumar experienced, *inter alia*, left arm and facial numbness. Investigations demonstrated a left caudate lacunar infarct (stroke).

43. Since the September 2008 stroke, Ms. Ravindrakumar continues to experience related issues, including left arm numbness and severe shoulder pain. She has difficulty lifting with her left upper extremity.

44. Since the September 2008 stroke, Ms. Ravindrakumar's issues have left her unable to perform her employment duties as a quality control worker, which required her to, *inter alia*, carry heavy loads. Ms. Ravindrakumar was forced to take early retirement.

45. In or around May 2009, on the advice of her treating physician, Ms. Ravindrakumar's Avandia treatment was discontinued.

46. Ms. Ravindrakumar used Avandia in accordance with the package label and consumer information pamphlet and in the manner it was intended to be used.

47. Ms. Ravindrakumar did not have a history of cardiovascular illness prior to commencing her use of Avandia.

48. Ms. Ravindrakumar does not smoke or consume alcohol.

49. In the time period before and during Ms. Ravindrakumar's use of Avandia, she received no warnings about the increased risk of suffering an ischemic cardiovascular event (including stroke) from using Avandia.

50. Ms. Ravindrakumar's stroke was a direct result of her use of Avandia and the Defendant's negligence.

51. Had Ms. Ravindrakumar been aware of the increased risk of suffering a stroke and/or other serious side effects from using Avandia compared to other available diabetes treatments, she would never have used Avandia and would have chosen a safer treatment. Furthermore, had GSK warned Ms. Ravindrakumar's physicians and other healthcare providers of the increased risk of suffering a stroke and/or other serious side effects from using Avandia compared to other available diabetes treatments, her physicians and other healthcare providers may have monitored her for cardiovascular risks, prior to her suffering a stroke. But for GSK's wrongful conduct, Mrs. Ravindrakumar would not have incurred her damages.

52. The Plaintiff pleads that her damages were caused by the negligence of the Defendant, its servants and agents.

NEGLIGENCE

53. The Defendant at all material times owed Ms. Ravindrakumar a duty of care to:

(a) Ensure that Avandia was fit for its intended or reasonably foreseeable use;

(b) Conduct appropriate testing to determine whether and to what extent use of Avandia posed serious health risks, including the suffering of an ischemic cardiovascular event, including stroke;

(c) Properly, fairly and adequately warn Ms. Ravindrakumar, and her physicians and other healthcare providers that use of Avandia carries the risk of causing an ischemic cardiovascular event, including stroke;

(d) Ensure that prescribing physicians and other healthcare providers were kept fully and completely informed of all risks associated with Avandia;

(e) Monitor, investigate, evaluate and follow up on adverse reactions associated with Avandia use; and

(f) Properly inform Health Canada and other regulatory agencies of the elevated risks of suffering an ischemic cardiovascular event, including stroke, caused by the use of Avandia.

54. The Defendant negligently breached its duty of care.

55. The Plaintiff states that her damages were caused by the negligence of the Defendant. Such negligence includes but is not limited to the following:

(a) The Defendant failed to adequately test Avandia in a manner that would fully disclose the magnitude of the risks associated with its use, including the risk of suffering an ischemic cardiovascular event, including stroke;

(b) The Defendant, both before and after Avandia was approved by Health Canada, failed to give Health Canada complete and accurate information as it became available;

(c) The Defendant failed to conduct adequate follow-up studies on the efficacy and safety of Avandia;

(d) The Defendant failed to conduct adequate long-term studies of the risks of continued use of Avandia;

(e) The Defendant failed to provide Ms. Ravindrakumar, and her physicians and other healthcare providers with adequate warning of the risks associated with use of Avandia, including the risk of suffering an ischemic cardiovascular event. The Defendant failed to provide any warning of the risk of stroke;

(f) The Defendant failed to provide Ms. Ravindrakumar, and her physicians and other healthcare providers with adequate information and warnings respecting the correct usage of Avandia;

(g) The Defendant failed to warn Ms. Ravindrakumar, and her physicians and other healthcare providers about the need for comprehensive regular medical monitoring to ensure the early discovery of side effects related to using Avandia;

(h) The Defendant failed to adequately monitor, evaluate and act upon reports of adverse reactions to Avandia in Canada and elsewhere;

(i) The Defendant failed to provide adequate and current information to consumers and their physicians and other healthcare providers respecting the risks and efficacy of Avandia as such information came available from time to time;

(j) The Defendant failed to provide adequate warnings of the potential hazards of Avandia on package labels;

(k) The Defendant failed to warn Ms. Ravindrakumar, and her physicians and other healthcare providers, and Health Canada about the need for comprehensive medical monitoring to ensure the early discovery of side effects relating to Avandia use;

(l) The Defendant failed to provide adequate warnings of the risks associated with Avandia, including the risk of suffering an ischemic cardiovascular event (including stroke), on the customer information pamphlets in Canada;

(m) The Defendant, after noticing problems with Avandia, failed to issue adequate warnings, timely recall the drug, publicize the problem and otherwise act properly and in a timely manner to adequately warn the Plaintiff, and her physicians and other healthcare providers of Avandia's inherent dangers, including the danger of suffering an ischemic cardiovascular event (including stroke);

(n) The Defendant failed to establish any adequate procedures to educate its sales representatives, prescribing physicians and other healthcare providers respecting the correct usage of Avandia and the risks associated with the drug;

(o) The Defendant represented that Avandia was safe and fit for its intended purpose when it knew or ought to have known that these representations were false;

(p) The Defendant misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Avandia and its associated risks, including the risk of suffering an ischemic cardiovascular event (including stroke), compared to other available diabetes treatments;

(q) The misrepresentations made by the Defendant were unreasonable in the face of the risks that were known or ought to have been known to the Defendant;

(r) The Defendant failed to timely cease the manufacture, marketing and/or distribution of Avandia when it knew or ought to have known that this drug causes or could cause an ischemic cardiovascular event, including stroke;

(s) The Defendant failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* RSC 1985, c F-27, as amended, and its associated regulations;

(t) The Defendant failed to properly supervise its employees, subsidiaries and affiliated corporations; and

(u) The Defendant actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Avandia.

56. The risks associated with the use of Avandia, including the risk of suffering an ischemic cardiovascular event (including stroke), were in the exclusive knowledge and control of the Defendant. The extent of the risks was not known and could not have been known by the Plaintiff. Ms. Ravindrakumar's injuries would not have occurred but for the negligence of the Defendant in failing to ensure that Avandia was safe for use or, in the alternative, but for providing an adequate warning of the risks associated with using Avandia to Ms. Ravindrakumar, and her physicians and other healthcare providers.

57. Avandia is defective because it is unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by Ms. Ravindrakumar, and her physicians and/or other healthcare providers. Any benefit from using Avandia was outweighed by the serious and undisclosed risks of its use when used as the Defendant intended. The benefits of Avandia did not outweigh the risks for Ms. Ravindrakumar, given that there were alternative diabetes treatments that are efficacious for treating diabetes and carry less serious risks than Avandia.

58. The Defendant knew or ought to have known of the risks associated with the use of Avandia, including the risk of suffering an ischemic cardiovascular event. By not disclosing these risks and by attempting to downplay the outcome of studies conducted by third-parties, the Defendant acted in callous and reckless disregard for the health and safety of the Plaintiff.

DAMAGES

59. Had Ms. Ravindrakumar, and her physicians and/or other healthcare providers known of the significant increased risk of suffering an ischemic cardiovascular event (including stroke) associated with Avandia compared to other available diabetes treatments, she would never have used Avandia and would not have suffered the stroke.

60. As a result of the negligence of the Defendant, Ms. Ravindrakumar has endured conscious pain, mental anguish and emotional distress. Ms. Ravindrakumar has suffered considerably: she has endured at least one stroke and other permanent impairments. She has required hospitalization, treatment, investigations and testing. She is at risk of developing further impairments in the future. Ms. Ravindrakumar claims damages for her pain and suffering and loss of enjoyment of life. Ms. Ravindrakumar claims damages for her past, present, and future pecuniary losses, including her extraordinary living expenses and care costs, including medical care and other related services, to the date of trial and into the future.

61. Ms. Ravindrakumar also claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendant.

62. The Plaintiff pleads and relies upon the provision of the *Negligence Act*, RSO 1990, c N.1, as amended, the *Food and Drugs Act*, RSC 1985, c F.27, as amended and its regulations and the *Courts of Justice Act*, RSO 1990, c C.43, as amended.

PLACE OF TRIAL

63. The Plaintiff proposes that this action be tried in London, Ontario.

September 18, 2014

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Lawyers for the Plaintiffs

RAVINDRAKUMAR, Plaintiff and GLAXOSMITHKLINE INC., Defendant

Court File No: 4084-14

ONTARIO
SUPERIOR COURT OF JUSTICE
Proceeding commenced at LONDON

STATEMENT OF CLAIM

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Lawyers for the Plaintiff

Form 59.09

2009 Hfx No. 315567

This is Exhibit "J" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme Court of Nova Scotia

2013 ONSC 5792
Ontario Superior Court of Justice

Waheed v. Glaxosmithkline Inc.

2013 CarswellOnt 13883, 2013 ONSC 5792, 117 O.R. (3d) 680, 233 A.C.W.S. (3d) 295, 46 C.P.C. (7th) 180

Abdul Waheed and Talat Waheed, Plaintiffs and Glaxosmithkline Inc., Glaxosmithkline PLC, Glaxosmithkline services Unlimited, Smithkline Beecham PLC, Smithkline Beecham Corporation and Smithkline Beecham (Cork) Limited, Defendants

Edward Belobaba J.

Heard: September 13, 2013
Judgment: October 8, 2013
Docket: CV-09-385922CP

Counsel: Bryan McPhadden, Idan Erez, for Plaintiffs in the Waheed Action
James Orr, Megan McPhee, Tanya Jemec, for Plaintiffs in the Lloyd Action
J. Hanet, for Defendants in both Actions

Subject: Civil Practice and Procedure
Related Abridgment Classifications
Civil practice and procedure
V Class and representative proceedings
V.2 Representative or class proceedings under class proceedings legislation
V.2.b Certification
V.2.b.i Plaintiff's class proceeding
V.2.b.i.H Miscellaneous

Headnote

Civil practice and procedure --- Parties — Representative or class proceedings under class proceedings legislation — Certification — Plaintiff's class proceeding — Miscellaneous

Law firm A won carriage motion over law firm B — Three years passed and law firm A did not proceed with certification motion — Law firm B brought motion to replace law firm A as carriage counsel — Motion dismissed — Law firm B did not show that most class proceedings were certified in less than three years — Law firm B provided no evidence of actual prejudice or harm to putative class members — Explanation for delay provided by law firm A was credible.

Table of Authorities

Cases considered by *Edward Belobaba J.*:

Fantl v. Transamerica Life Canada (2009), 2009 CarswellOnt 2383, 2009 ONCA 377, 72 C.P.C. (6th) 1, 249 O.A.C. 58, 95 O.R. (3d) 767 (Ont. C.A.) — referred to

Martin v. Astrazeneca Pharmaceuticals PLC (2012), 2012 CarswellOnt 6210, 2012 ONSC 2744, 27 C.P.C. (7th) 32 (Ont. S.C.J.) — referred to

Martin v. Astrazeneca Pharmaceuticals PLC (2013), 2013 CarswellOnt 2904, 2013 ONSC 1169 (Ont. Div. Ct.) — referred to

Ontario New Home Warranty Program v. Chevron Chemical Co. (1999), 37 C.P.C. (4th) 175, 46 O.R. (3d) 130, 1999 CarswellOnt 1851 (Ont. S.C.J.) — referred to

Rattray v. Woodbury County (2010), 614 F.3d 831 (U.S. C.A. 8th Cir.) — considered

Statutes considered:

Class Proceedings Act, 1992, S.O. 1992, c. 6

s. 12 — considered
Securities Act, R.S.O. 1990, c. S.5
s. 138.14 [en. 2002, c. 22, s. 185] — referred to

MOTION by law firm B to replace law firm A as carriage counsel.

Edward Belobaba J.:

1 Law Firm A wins a carriage motion over Law Firm B. Almost three years go by and Firm A has still not proceeded with the certification motion. Firm B brings a motion to replace Firm A as carriage counsel on the basis of unreasonable delay. Does this court have the jurisdiction to hear this "carriage transfer motion"? If so, under what circumstances can Firm A be replaced? What is the test?

Background

2 Kim Orr Barristers P.C. ("Kim Orr") is counsel in two proposed class actions involving a diabetes medication called Avandia that is manufactured and distributed by Glaxosmithkline. One is the Lloyd Action, commenced in 2007 by the Merchant Law Group, and the other is the Imbesi Action, commenced in 2010 by Kim Orr. In 2010, Kim Orr and Merchant agreed that Kim Orr would be the lead counsel in both actions and the two firms would work together.

3 McPhadden Samac Tuovi ("MCST") is counsel for the plaintiffs in the Waheed Action, another Avandia action that was commenced in 2009.

4 In November, 2010, carriage motions brought by Kim Orr and MCST were heard by Justice Strathy. After the hearing but before the release of the court's decision, the parties agreed to settle the carriage motion on the basis that Kim Orr would be appointed counsel for the plaintiffs in the Lloyd class action, and the Waheed and Imbesi Actions would be (effectively) stayed. The parties agreed that the MCST consortium would be permitted to participate in the class action but only at Kim Orr's discretion and that no steps could be taken without Kim Orr's approval. This agreement resulted in a consent carriage order dated November 19, 2010.

5 Almost three years have passed and Kim Orr has still not brought a motion for certification. MCST says the delay has been unreasonable and Kim Orr should be removed as carriage counsel on the proposed Avandia class action. MCST says that it has prepared a certification record and is ready bring a motion for certification immediately. MCST asks that it be granted carriage of the proposed class action.

Analysis

(1) Jurisdiction

6 Does this court have jurisdiction to entertain a carriage transfer motion? In my view it does, and to its credit, Kim Orr did not suggest otherwise. Although the occasions will be rare, circumstances may require that carriage counsel be removed and replaced. The procedural vehicle is s. 12 of the *Class Proceedings Act, 1992*, [1] ("CPA"):

> The court, on the motion of a party or class member, may make an order it considers appropriate respecting the conduct of the class proceeding to ensure its fair and expeditious determination and, for the purpose, may impose such terms on the parties as it considers appropriate.

7 Section 12 of the CPA has been described by this court as "a flexible tool for adapting procedures on a case-specific basis." [2] The Court of Appeal has added that the scope of s. 12 is far-reaching and is engaged "from the inception of an intended class proceeding" and "continues throughout the 'stages' of the proceeding until a final disposition, including the implementation of the administration of a settlement or, where applicable, a resolution of all individual issues." [3]

In short, a class action management judge has a wide-ranging supervisory jurisdiction under s. 12 of the CPA and this includes motions to remove and replace carriage counsel on the basis of unreasonable delay.

(2) The test on a "carriage transfer" motion

8 This issue has not been litigated before. There are no cases on point. [4] In my view, any test for the removal and replacement of plaintiffs' counsel in a proposed or actual class action proceeding [5] must recognize that as a general rule class counsel, acting on plaintiffs' instructions, should be able to run the lawsuit as they see fit. This includes deciding the shape, content and pace of the litigation. Class counsel may choose to slow matters down because of pending appeals, or developments in other jurisdictions, or indeed for any good reason that class counsel believes is in the best interests of the proposed or actual class. Generally speaking, no carriage transfer motion should ask the court to review and second-guess the action or inaction of class counsel.

9 However, on occasion, and these occasions will be rare, a carriage transfer motion will be justified. One such case is where there is clear and unreasonable delay. In my view, the court should intervene to replace carriage counsel on the ground of unreasonable delay where the moving party can satisfy each of the following four criteria:

> (i) The delay is clearly unreasonable by current class action litigation standards;
>
> (ii) There is evidence of actual prejudice or harm to the putative class members;
>
> (iii) The explanation for the delay is inadequate; and,
>
> (iv) A court order requiring Firm A to bring the certification motion within an expedited time period (failing which it will be replaced by Firm B) is not, in all the circumstances, either workable or in the best interests of the class.

(3) Applying the test to the facts herein

10 MCST's carriage transfer motion fails on each of the four criteria. First, MCST failed to show that most class proceedings are certified in less than three years. It is well-known that class proceedings generally move at a glacial pace. (One need only recall the difficulty that plaintiffs' have in securities class actions of even commencing an action within the prescribed three-year time limit. [6]) If a moving party alleges unreasonable delay on the part of carriage counsel, it must provide comparative evidence to support this submission. No such evidence was provided.

11 Secondly, MCST provided no evidence of any actual prejudice or harm to any of the putative class members. For example, MCST could have filed an affidavit from the plaintiffs in the Waheed Action explaining why Kim Orr's delay was unreasonable and how it was adversely affecting them. No such evidence was provided.

12 Thirdly, the explanation for the delay as provided by Kim Orr - the need to co-ordinate with experts in the parallel American proceeding and await the outcome of appeal proceedings in a related pharmaceutical case [7] - was credible and certainly could not be described as "inadequate."

13 Finally, during the course of the hearing, Kim Orr advised the court that it would be filing the certification motion in the Lloyd Action by the middle of November, just two months away. [8] MCST could not show that Kim Orr's undertaking to bring the certification motion within the next two months was somehow unworkable or not in the best interests of the proposed class.

14 In sum, none of the four suggested criteria for the removal and replacement of carriage counsel have been satisfied.

Disposition

15 The carriage transfer motion is dismissed without costs.

16 I am denying costs because it was obviously this motion and the threat of being replaced as carriage counsel that encouraged Kim Orr to commit to filing a certification motion within two months. The putative class members in the Lloyd Action were thus the unintended beneficiaries of the MCST carriage transfer motion. I advised Kim Orr at the conclusion of the hearing that I was not inclined to award costs. However, if Kim Orr thought otherwise, it should forward its costs submissions within 14 days. No such submissions have been received. No costs are awarded.

17 My thanks to both sides for their courtesy and their assistance. I am particularly grateful that Kim Orr abandoned the various procedural arguments that were theoretically available and agreed to litigate the motion on its merits.

Motion dismissed.

Footnotes

1 S.O. 1992, c.6.

2 *Ontario New Home Warranty Program v. Chevron Chemical Co.* [1999 CarswellOnt 1851 (Ont. S.C.J.)], 1999 CanLII 15098 at 41

3 *Fantl v. Transamerica Life Canada*, 2009 ONCA 377 (Ont. C.A.) at para. 39.

4 There are only a handful of American cases on point. For example, in *Rattray v. Woodbury County*, 614 F.3d 831 (U.S. C.A. 8th Cir. 2010), the U.S. Court of Appeals for the 8th Circuit held that a 14-month delay between complaint and certification raised questions about the adequacy of class counsel and the representative plaintiffs. After reviewing the record, the Court concluded that counsel's explanations for the delay were inadequate and replaced the representative plaintiff (and class counsel.)

5 Class action lawyers will understand that, strictly speaking, MCST is not asking to replace Kim Orr as carriage counsel on the Avandia (Lloyd) Action but to be appointed carriage counsel on the Avandia (Waheed) Action. That is, on the Avandia class action, the Lloyds would be replaced as representative plaintiffs by the Waheeds and MCST would take Kim Orr's place as carriage counsel on the Avandia (Waheed) class action.

6 *Securities Act*, R.S.O. 1990, c. S.5, s. 138.14.

7 *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 (Ont. S.C.J.), aff'd 2013 ONSC 1169 (Ont. Div. Ct.).

8 I directed that the certification motion be filed by Kim Orr no later than November 29, 2013.

Form 39.09

2009 Hfx No. 315567

This is Exhibit "K" referred to in the Affidavit of Madeleine Carter affirmed before me on the 14th day of December, 2018.

Signature

RAYMOND F. WAGNER, Q.C.
A Barrister of the Supreme Court of Nova Scotia

RICEPOINT
A Computershare company

RicePoint's Administration Inc. - Overview

RicePoint Administration Inc. is a Canadian class action administrator wholly owned by Computershare; a global leader in transfer agency and share registration, employee equity plans, mortgage servicing, proxy solicitation stakeholder communications as well as notice and administrative services for class action settlements.

RicePoint's parent company, Computershare, is a $6 billion publicly-traded company which, among its many business lines, provides global financial services centering on communications with customers on behalf of our corporate clients. Computershare employs over 16,000 people and does business with more than 16,000 clients in more than 21 countries. RicePoint has one of the largest infrastructures in the class action industry, and is backed by superior data security, call center support and technology. In addition to the immense resources and capabilities brought to bear through Computershare, RicePoint can execute all operations in-house with zero outsourcing; a capacity which allows for full quality control over each aspect of service.

Under the RicePoint brand, we have administered over 60 Canadian settlements of varying size and complexity, and have distributed more than $2.5 billion in settlement funds over the last 15 years. Our core team is located in London, Ontario while operations, including a 75 seat call centre in Montreal, are spread out across Canada. Our administration and notice reach extends into the United States and internationally under Computershare's KCC LLC brand.

KCC has administered over 6,500 class action settlements and handled thousands of distribution engagements in other contexts as well. KCC's infrastructure includes call centers with over 1,200 seats, claims intake facilities that can open and scan 200,000 claims in a single day, and document production capabilities that print and mail millions of documents annually. Last year, their disbursement services team distributed over half a trillion dollars.

RicePoint Team

RicePoint's experienced team of experts knows first-hand the intricacies contained in every aspect of settlement administration, and approach each matter with careful analysis and procedural integrity. Each client is assigned a team of experienced consultants, specialists and technology experts who serve as knowledgeable, reliable and accessible partners that have earned a reputation for exceeding clients' expectations.

Our personnel have considerable experience which includes years of practice with RicePoint and related endeavors. RicePoint's professionals have extensive training, both on-the-job and formal, such as undergraduate and advanced business, information technology and law degrees, and they possess and/or have had licenses and certificates in disciplines that are relevant to class action administration.

Practice Areas & Services

RicePoint is a Canadian industry leader in class action settlement administration. We deliver subject matter expertise to a variety of practice areas including: Price Fixing; Securities; Pharmaceutical and Medical Devices; Product Liability; Consumer Protection; Government; Labour and Employment; and Privacy. Our services include: pre-settlement consulting; notice

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design and execution; claims administration; escrow management and disbursement; data management; call centre support.

Medical Experience

RicePoint's notice and claims administration experience in the medical sector includes the following engagements:

Case Name	
Fosamax Fosavance Class Action	*Peters et al. v. Merck Frosst Canada Ltd et al.*
Kugel Mesh Class Action	*Bard Canada Inc. et al. v. Lylene E. Roveredo et al.*
Vioxx Class Action	*Mignacca et al. v. Merck Frosst Canada Ltd. et al.*
Fleet Phospo-Soda Class Action	*Quinton et al. v. C.B. Fleet Holding Co. et al.*
Tequin Class Action	*Conlon v. Bristol-Myers Squibb Canada Co. et al.*

For a full listing of our claim and notice experience, please see the table below or visit our website at www.ricepoint.com .

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RicePoint Representative Cases

ADMINISTRATION	SETTLEMENT FUND	TYPE
CRT (cathode ray tube) Class Action	CAD $49,800,000	Price Fixing
Polyether Polyol Products Class Action	CAD $13,300,000	Price Fixing
Manitoba Flood Class Action	CAD $90,283,000	Government
TrueSTEAM Humidifier Canadian Class Action	Individual Entitlements	Product Liability
Ford Explorer Class Action	Individual Entitlements	Consumer - Automotive
Volkswagen/Audi 3.0-Litre Emissions Canada Class Action	CAD $290,500,000	Consumer - Automotive
Auto Parts Class Action – Wire Harness Systems	CAD $25,500,000	Price Fixing
IKO Organic Shingles Class Action	CAD $7,500,000	Product Liability
Polyurethane Foam Products Class Action	CAD $38,200,000	Price Fixing
Dundee Securities Class Action	CAD $5,000,000	Securities
Home Capital Group Inc. Securities Litigation	CAD $29,500,000	Securities
Volkswagen/Audi 2.0-Litre Emissions Canada Class Action	CAD 2,100,000,000	Consumer - Automotive
ParkLane Donations for Canada Charitable Gift Program	CAD $17,500,000	Consumer
Fosamax Fosavance Class Action	CAD $6,375,000	Pharmaceutical
Kaba Ilco Settlement	Individual Entitlements	Product Liability
CUPE Pension Class Action	Individual Entitlements	Consumer
Ontario CashStore Settlement	CAD $10,000,000	Consumer
Canadian Cooling Compressors Class Action	CAD $4,770,000	Price Fixing
Baja Mining Corp. Securities Class Action	CAD $11,000,000	Securities

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Canadian SRAM Class Action	CAD $4,850,000	Price Fixing
IMAX Securities Litigation	CAD $3,750,000	Securities
Eastern Ontario Gas Price Fixing Class Action	CAD $1,300,000	Price Fixing
Agnico Eagle Mines Ltd. Securities Litigation	CAD $17,000,000	Securities
Assante Wealth Management Class Action	CAD $10,000,000	Consumer
Donnybrook Securities Class Action	CAD $5,500,000	Securities
Cash Store Financial Services Inc. Class Action	CAD $13,780,000	Securities
Canadian DRAM Class Action	CAD $80,000,000	Price Fixing
Jitec Inc. Securities Litigation	CAD $9,850,000	Securities
Canadian LCD Class Action	CAD $37,623,000	Price Fixing
Aftermarket Auto Lights Canadian Class Action	CAD $1,370,000	Price Fixing
Aftermarket Filters Canadian Class Action	CAD $350,000	Price Fixing
Seven Oaks Home for the Aged Class Action	CAD $1,200,000	Consumer
Canadian NVIDIA GPU Settlement	CAD $1,900,000	Product Liability
ParkLane Donations Canada Gift Program	CAD $28,000,000	Consumer
Kugel Mesh Class Action	CAD $1,375,000	Medical Devices
Sino-Forest EY Settlement Securities Litigation	CAD $117,000,000	Securities
Zungui Haixi Corporation Securities Litigation	CAD $10,850,000	Securities
Chocolate Products Price-Fixing Class Action	CAD $23,200,000	Price Fixing
CCAC Pension Class Action	CAD $7,500,000	Labour & Employment
OPSEU Local 330 Surplus Benefits	CAD $1,780,000	Labour & Employment

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Easyhome Ltd. Securities Litigation	CAD $2,250,000	Securities
OSSTF District 17 Trust Surplus	CAD $6,673,000	Labour & Employment
Vioxx Class Action	CAD $33,112,500	Pharmaceutical
Gammon Gold Inc. Securities Litigation	CAD $13,250,000	Securities
GBC MS Class Action	N/A	Product Liability
Arctic Glacier Income Fund Securities Litigation	CAD $13,750,000	Securities
Voyageur Colonial Class Action	CAD $1,330,000	Labour & Employment
Redline Communications Securities Litigation	CAD $3,600,000	Securities
Canadian Superior Energy Securities Litigation	USD $5,200,000	Securities
Ethylene Propylene Diene Monomer Class Action	CAD $4,249,537	Price Fixing
Fleet Phospo-Soda Class Action	CAD $11,995,000	Pharmaceutical
MyTravel Canada Holidays Inc. Class Action	CAD $2,250,000	Consumer
Gildan Activewear Securities Litigation	USD $22,500,000	Securities
PetroKazakhstan Inc. Securities Litigation	CAD $9,900,000	Securities
SunOpta Inc. Securities Litigation	USD $11,250,000	Securities
CP Ships Ltd. Securities Litigation	CAD $12,800,000	Securities
TVI Pacific Securities Litigation	CAD $2,100,000	Securities
Hydrogen Peroxide Class Action	CAD $20,490,000	Price Fixing
Tequin Class Action	CAD $5,000,000	Pharmaceutical