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

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

Between:

Albert Carl Sweetland and Mary Patricia Addicott-Andrews

Plaintiffs

v.

GlaxoSmithKline Inc., GlaxoSmithKline LLC

Defendants

LIBRARY HEADING

Judge:	The Honourable Justice Michael J. Wood
Heard:	September 15, 2015 in Halifax, Nova Scotia
Subject:	Class Proceedings – Certification Criteria
Summary:	The Defendants were alleged to have produced and marketed Avandia, a medication for treatment of Type 2 diabetes. The Plaintiffs represent persons who ingested this medication and seek to certify a class proceeding in negligence. They claim Avandia causes or contributes to adverse cardiovascular conditions including heart failure, heart attack and stroke. Defendants oppose certification on basis that requirements not met, including lack of common issues on causation.
Issues:	Should the class proceeding be certified?
Result:	The Plaintiffs provided evidence to establish some of the certification criteria, but not the requirement that there be two or more class members who wished to have their claims adjudicated through a class proceeding. In addition, some of the proposed common issues were not acceptable and would not be certified. These include restitutionary claims, punitive

damages, and aggregate damages which could not be assessed until class members' individual causation and damages are proven after the common issues trial.

Court was not prepared to certify the class proceeding but granted leave to the Plaintiffs to provide additional evidence and submissions on the two or more members criteria. Also permitted Plaintiffs to provide redrafted common issues list. Once parties made submissions on these issues Court would make decision on certification motion.

SUPREME COURT OF NOVA SCOTIA
Citation: *Sweetland v. GlaxoSmithKline Inc.*, 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:
>
> - [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*"):
>
> - 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:
>
> 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.