CITATION: Martin v. Astrazeneca Pharmaceuticals Plc, 2012 ONSC 2744
COURT FILE NO.: 06-CV-314632CP
DATE: 20120507

ONTARIO

SUPERIOR COURT OF JUSTICE

PROCEEDING UNDER the *Class Action Proceedings Act, 1992*, S.O. 1992, C. 6

BETWEEN:	)	
	)	
JOANNE MARTIN, CORRINE MIDDLETON, BERNARD VAN KERREBROECK, and DON MARTIN	)	*James C. Orr, Megan B. McPhee* and *Ahmad Erfan*, for the plaintiffs
	)	
Plaintiffs	)	
	)	
– and –	)	
	)	*Frank J. McLaughlin, Brandon Kain* and *Sarah Chesworth*, for the defendants
ASTRAZENECA PHARMACEUTICALS PLC, ASTRAZENECA PHARMACEUTICALS, LITIGATION PLAN and ASTRAZENECA CANADA INC.	)	
	)	
Defendants	)	
	)	
	)	**HEARD:** November 23, 24, 25, 28 and 29, 2011

C. HORKINS J.

INTRODUCTION

[1] This is a motion for certification of a proposed class action pursuant to s. 5 of the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 ("*Class Proceedings Act*").

[2] The focus of this action is a drug called Seroquel and health risks that it is alleged to cause. Seroquel, also called quetiapine, is an antipsychotic medication that Health Canada has approved for use in the treatment of schizophrenia, the acute management of manic episodes with bipolar disorder and the acute management of depressive episodes associated with bipolar I and bipolar II disorder ("approved uses").

[3] Seroquel is also used to treat anxiety, sleep disorders, depression and dementia-related psychosis. These are known as off-label uses that Health Canada does not approve.

[4] The plaintiffs allege that the defendants designed, developed, manufactured and sold Seroquel for approved and "off-label" uses and are responsible for the health risks that the drug causes.

[5] The plaintiffs seek to certify this action on behalf of a class consisting of "all persons in Canada who were prescribed and who consumed Seroquel."

OVERVIEW OF THE PLEADINGS AND CERTIFICATION MOTION

[6] This action was commenced over five years ago. There have been several amendments to the statement of claim. On this motion, the defendants consented to the "Second Amended Fresh as Amended Statement of Claim" (the "statement of claim"). This amendment was required to remove Bernard Van Kerrebroeck as a representative plaintiff because he no longer wishes to act in this role. The defendants filed a statement of defence to an earlier version of the statement of claim.

[7] The statement of claim alleges that the plaintiff Joanne Martin was prescribed Seroquel in September 2005 as treatment for bipolar disorder. Ms. Martin consumed up to 600 mg of Seroquel on a daily basis for approximately 1 year, at which point she stopped consuming Seroquel. While taking Seroquel, Ms. Martin alleges that she experienced side effects, including significant weight gain (approximately 55 pounds) and problems with her balance which caused her to fall down frequently. After she stopped taking Seroquel, Ms. Martin pleads that she was able to lose a portion of the weight that she had gained and no longer experienced difficulties maintaining her balance. The plaintiff Don Martin is Joanne Martin's husband. He asserts a claim on behalf of all Family Law Act claimants.

[8] The statement of claim alleges that the plaintiff Corrine Middleton was prescribed Seroquel in June 2005 to treat stress and obsessive compulsive behavior. This was an off-label use. Ms. Middleton consumed up to 175 mg of Seroquel daily, for approximately 6 months, at which point she stopped consuming Seroquel. While taking Seroquel, Ms. Middleton alleges that she experienced side effects, including significant elevated blood sugars and weight gain (approximately 25 pounds), neuropathy, hyperglycemia, loss of energy, increased thirst, numbness in her hands and feet, and soreness in her feet. In addition, Ms. Middleton states that she was diagnosed with diabetes in or about November 2005. Ms. Middleton had tested negative for diabetes in October 2003. After she stopped consuming Seroquel, Ms. Middleton was able to lose a portion of the weight that she had gained as a result of taking Seroquel.

[9] The plaintiffs allege that Seroquel causes health risks that are described in para. 20 of the statement of claim as follows:

> Seroquel causes serious and sometimes fatal injuries to the liver, kidneys and pancreas. Its adverse effects include, but are not limited to, ketoacidosis, pancreatitis, diabetes mellitus, weight gain, impaired glucose regulation, hyperglycemia, blindness, cataracts, increased thirst and hypoglycemia. Other serious injuries include a potentially fatal condition referred to as neuroleptic malignant syndrome (NMS), tardive dyskinesia, which can cause potentially irreversible, involuntary movements and other serious health problems associated

with the onset of diabetes including heart disease, blindness, coma, seizures and death.

[10] Further it is alleged in para. 22 of the pleading that the "specific risk associated with Seroquel and the new onset of diabetes is nearly 3.34 times higher than older drugs used to treat schizophrenia" and that "Seroquel has a much greater increased association with the onset of diabetes mellitus than any other anti-psychotic on the market."

[11] The plaintiffs allege that the group of AstraZeneca companies are jointly responsible for all health risks associated with Seroquel and the damages that the plaintiffs and putative class have suffered. It is alleged that the defendants designed, developed, manufactured, promoted, distributed and sold Seroquel in Canada for the approved uses. It is also alleged that that they heavily marketed Seroquel for off-label uses.

[12] The plaintiffs allege in para. 21 of the pleading that the product warnings for Seroquel were "vague, incomplete or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians as well as consumer patients of the actual Health Risks associated with consuming Seroquel."

[13] Further, the plaintiffs allege that the defendants conspired and agreed together to submit false, inaccurate, incomplete, and misleading information to Health Canada and the FDA, conceal the Health Risks associated with the consumption of Seroquel, mislead the putative class members, health care providers and others about the safety and efficacy of Seroquel, delayed the amendment of package inserts and core data sheets to include warnings about the Health Risks associated with the consumption of Seroquel and engaged in a marketing campaign promoting the safety of Seroquel for off-label use, including use as a sleep aid and to treat anxiety, dementia-related psychosis and depression.

[14] The respective roles of the defendants are set out in the statement of defence. AstraZeneca plc is incorrectly named by the plaintiffs as "AstraZeneca Pharmaceuticals plc." AstraZeneca plc is a public limited company organized under the laws of England and Wales, with its registered office located in London, England. AstraZeneca plc was formed in 1999 following a merger between Zeneca Group plc and Astra AB (this defendant is referred to as "AZ UK").

[15] AstraZeneca plc is a holding company that indirectly owns 100% of AstraZeneca Canada Inc. ("AZ Canada") and AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharmaceuticals"). AstraZeneca plc does not carry on business in Canada and did not at any material time manufacture, package, label, test, study, store, market, sell and/or distribute Seroquel for use in Canada.

[16] AstraZeneca Pharmaceuticals ("AZ US") is an American company carrying on business as a Delaware limited partnership with its principal place of business in Wilmington, Delaware, U.S.A. AstraZeneca Pharmaceuticals is a brand name pharmaceuticals company that develops and manufactures prescription medicines in a number of therapeutic areas.

[17] AZ US, *inter alia*, manufactures, packages, labels, tests, studies, stores, markets, sells, and/or distributes Seroquel for prescription by licensed physicians throughout the United States pursuant to approval by the United States Food and Drug Administration (the "FDA"). AZ US does not carry on business in Canada.

[18] AZ Canada is an Ontario corporation carrying on business in Mississauga, Ontario. AstraZeneca Canada is a brand name pharmaceuticals company that develops prescription drugs in a number of therapeutic areas. Amongst other things, AstraZeneca Canada imports, packages, labels, tests, studies, stores, markets, sells, and/or distributes Seroquel for prescription by licensed physicians throughout Canada pursuant to approval by Health Canada.

[19] AZ Canada has no authority to act as the agent for AZ UK or any subsidiary of AZ UK, including AZ US.

[20] The statement of defence describes the development of Seroquel, its approved uses and the product warnings (what is known as the "product monograph"). In great detail, the defendants deny the allegations against them. They plead that they complied with all Health Canada requirements affecting Seroquel and that Seroquel is a safe and effective drug used to treat approved illnesses. Further, they deny that they marketed Seroquel for any off-label uses.

THE EVIDENCE

[21] Before reviewing the evidence, it is important to note the purpose of evidence on a certification motion. Evidence explains the background to the action. A certification motion is not the time "to resolve conflicts in the evidence or to engage in finely calibrated assessments of evidentiary weight": *Cloud v. Canada (Attorney General)*, [2004] O.J. No. 4924 at para. 50 (C.A.) ("*Cloud*").

[22] Motions for certification are procedural in nature and are not intended to provide the occasion for an exhaustive inquiry into factual questions that would fall to be determined at a trial when the merits of the claims of class members are in issue: see *Lambert v. Guidant Corp.* [2009] O.J. No. 1910 (S.C.J.) at para. 82, leave to appeal ref'd [2009] O.J. No. 4464 (S.C.J.) ("*Lambert*").

[23] A plaintiff's evidentiary burden on a certification motion is low and the plaintiff is only required to adduce evidence to show some "basis in fact" to meet the requirements of ss. 5(1) (b) to (e) of the test for certification as a class action: see *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at paras. 16-26 ("*Hollick*"); *Lambert* at paras. 56-74 (S.C.J.); *Cloud* at paras. 49 -52 (C.A.); *Grant v. Canada (Attorney General),* [2009] O.J. No. 5232 at para. 21 (S.C.J.); *Lefrancois v. Guidant Corp.*, [2009] O.J. No. 2481 at paras. 13-14 (S.C.J.), leave to appeal ref'd [2009] O.J. No. 4129 (Div. Ct.) ("*Lefrancois*"); *Ring v. Canada (Attorney General)*, [2010] N.J. No. 107 (Nfld. C.A.) ("*Ring*").

[24] A defendant is entitled to deliver evidence in rebuttal, but the standard of proof on the defendant is inversely heavy. On a certification motion, it is not enough for the defendant to establish on a balance of probabilities that the facts differ from those asserted by the plaintiff. Rather the onus is to show that that there is no basis in the evidence for the facts asserted by the

plaintiff. Evidence directed at the merits of the action may be admissible if it also bears on the requirements for certification. In determining the weight to be given to the defendant's rebuttal evidence, it is not the function of the court at the certification stage to decide factual issues in the same manner, and to the same extent, as when the court exercises its function as a trier of fact in the exercise of its ordinary jurisdiction: see *Lambert* at paras. 68-69.

[25] While the evidentiary threshold for meeting the statutory criteria is low, the court has a gatekeeper function and it must consider all of the admissible evidence and decide if the s. 5 criteria are satisfied. Evidence tendered on a motion for certification of a class proceeding must meet the usual criteria for admissibility: see *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540, (2005), 260 D.L.R. (4th) 488, at para. 31 ("*Ernewein*"), leave to appeal to SCC dismissed, [2005] S.C.C.A. No. 545; see also *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42, 87 C.P.C. (6th) 276 , at paras. 49-50 ("*Singer*"); *Schick v. Boehringer Ingelheim (Canada) Ltd.*, 2011 ONSC 63, ("*Schick*").

Sources of Evidence

[26] The parties filed extensive affidavit evidence. The plaintiffs each filed an affidavit as did Victoria Paris, a lawyer with the class counsel team. The plaintiffs also filed affidavits from two experts: Dr. William C. Wirshing and Dr. Laura M. Plunkett.

[27] Dr. Wirshing is a psychiatrist, the Vice President of research and continuing medical education at Exodus Inc. in Culver City, CA; Clinical Director of Exodus Real Recovery in Westlake Village, CA; Medical Director of Psychological Care and Healing in West Los Angeles, CA; and an Adjunct Professor of Psychiatry at the Keck School of Medicine at the University of Southern California in Los Angeles, CA. He has considerable experience treating patients who suffer from various mental illnesses. This experience includes many years of treating patients with a variety of medications including Seroquel. His affidavit replies to the defendants' expert opinions that deal with the alleged relationship between Seroquel and metabolic disorders, and related issues.

[28] Dr. Plunkett is a pharmacologist, toxicologist, United States Food and Drug Administration regulatory specialist and principal of a consulting company called Integrative Biostrategies, LLC. Integrative Biostrategies is a Houston-based consulting firm that works at the interface of biological science, regulatory affairs and business decisions to provide its clients with science-based solutions to issues associated with product development and stewardship. Before joining Integrative Biostrategies in 2001, Dr. Plunkett was the head of a consulting firm called Plunkett & Associates. Dr. Plunkett is board-certified as a Diplomate of the American Board of Toxicology. She has over twenty years of experience in the areas of pharmacology and toxicology, has worked in both government and academic research and has taught pharmacology and toxicology at the undergraduate and postgraduate levels.

[29] Dr. Plunkett offers her opinion on whether use of Seroquel is causally associated with adverse metabolic effects and whether the Canadian labelling contained appropriate warnings based on what was publically known about the potential metabolic side-effects of Seroquel.

[30] The defendants filed affidavit evidence from five experts: Dr. Barry Arnold, Dr. Eugene Barrett, Dr. Pierre Chue, Dr. Gwenderlyn Jansz and Anne Tomalin. They also filed a solicitor's affidavit from Katherine Stubits.

[31] Dr. Arnold was responsible for Drug and Patient Safety at AstraZeneca from October 1992 to June 2006. Since 2006, in his current role as European Union Qualified Person for Pharmacovigilance, he has continued to be actively involved in the defendants' safety surveillance and evaluation programs for Seroquel. Dr. Arnold was integral in developing and implementing the safety surveillance procedure detailed in his affidavit. His affidavit also speaks to the pharmacovigilance the defendants have engaged in with respect to Seroquel over the years and addresses some of the issues raised in Victoria Paris's affidavit.

[32] Dr. Barrett is an endocrinologist and a professor at the University of Virginia. He chaired the November 2003 Consensus Conference on the relationship between second generation antipsychotics and obesity, diabetes, and lipid disorders. His affidavit reviews his opinion on the lack of a causal relationship between Seroquel and diabetes. It also addresses the nature of the analysis that would have to be done to determine "general causation" and individual injury causation for diabetes and weight gain.

[33] Dr. Chue, a Canadian psychiatrist with considerable experience in the field of atypical antipsychotics, and Dr. Jansz, a family physician experienced in the treatment of mentally ill patients, provide evidence that address the role of Seroquel in treating mentally ill patients, the analysis in relation to "general causation" and individual injury causation, and address issues relating to the duty to warn and informed consent.

[34] Anne Tomalin is a Canadian regulatory expert with 40 years of experience dealing with Heath Canada and its regulations. She describes the comprehensive regulatory regime within which AZ Canada operates. Ms. Tomalin reviewed AZ Canada's regulatory filings for Seroquel. She offers an opinion regarding AZ Canada's compliance with its regulatory obligations.

[35] Finally, Kathy Stubits is a law clerk. Her affidavit attaches the proposed representative plaintiffs' medical records to provide an evidentiary basis for the opinions of Drs. Barrett and Chue.

Admissibility Issues

[36] The defendants take the position that some of the plaintiffs' evidence is inadmissible and should be struck. In their written argument the defendants say that the following evidence is contentious:

(1) Statements by Dr. Laura Plunkett, sworn November 23, 2007, which are outside of her area of expertise, and/or are bald and conclusory and made without the requisite foundation in fact;

(2) All statements that constitute boilerplate, opinion, speculation, and statements of medical or legal opinion contained in the affidavits of the plaintiffs, Joanne

Martin and Corrine Middleton, sworn November 22, 2007 and November 23, 2007 respectively;

(3) Documents attached to the solicitor's affidavit of Victoria Paris, sworn August 22, 2011. Her affidavit attaches 29 exhibits, 24 of which the defendants say are inadmissible; and

(4) Documents marked as exhibits to the cross-examination of the defence witness, Dr. Barry Arnold.

[37] Initially, the plaintiffs objected to significant portions of Dr. Arnold's affidavit and requested that the court strike certain paragraphs of his affidavit. The complaint was based on the plaintiffs' position that parts of the affidavit were inadmissible because Dr. Arnold did not have direct knowledge of the evidence in issue. Further they relied on Dr. Arnold's evidence on his cross-examination when he stated that he did not talk to anyone at AstraZeneca Canada before swearing his affidavit. This request to strike Dr. Arnold's evidence was withdrawn in the plaintiffs' Admissibility of Evidence factum where the plaintiffs state that all evidence should be placed before the court and the court can "decide what weight if any to give to the evidence" that the plaintiffs and defendants have filed.

[38] The proposal that the certification judge should weigh all the evidence is contrary to the direction in *Cloud*. Obviously there is a distinction between determining the admissibility of evidence and deciding what weight to attach to evidence that is admissible. As the gatekeeper, it is the role of the certification judge to determine admissibility. It is not the role of the certification judge to assess and weigh evidence and resolve conflicts in the evidence. When considering all of the admissible evidence that is before the court, the certification judge is assessing if there is some basis in fact for the s. 5(1) (b)-(e) criteria.

[39] This limitation on the role of the certification judge does not mean that the court should accept the plaintiffs' affidavit without regard for the defendants' evidence. The court must consider all of the admissible evidence, including the cross-examinations, to decide if there is some evidence to support the s. 5 test.

[40] The plaintiffs argue that courts in Ontario routinely adopt a more flexible approach to the admissibility of evidence on certification motions. I disagree. The plaintiffs rely on *LeFrancois* at para. 17 but it does not does not stand for the principle that admissibility rules should be relaxed on a certification motion.

[41] In *LeFrancois,* Cullity J. was dealing with a different evidentiary issue. Having already certified the action, there was a dispute about the cut off dates to limit the plaintiff class. The defendant wanted to submit further fresh evidence to show that without the proposed cut off, notices would be set to people who did not have one of the defective alarm defibrillators. The plaintiff argued that this evidence was available during the certification motion and should not be allowed. Cullity J. decided to allow the evidence because to deny it would result in people being included who had no need to be put on notice about the action. While the usual rule of evidence precluded the introduction of fresh evidence that was always available, the court chose not to apply such a rigid exclusion of evidence in this unique situation.

[42] *LeFrancois* does not stand for the general proposition that admissibility rules are relaxed on a certification motion. In fact there are numerous decisions confirming that evidence tendered on a certification motion must meet the usual criteria for admissibility: see *Schick* at para. 13; *Ernewein,* at para. 31; *Williams v. Canon Canada Inc.,* 2011 ONSC 6571 at para. 65; *Ring* at para. 21.

[43] Basic evidentiary rules that govern affidavits are set out in rules 4.06(2) and 39.01(4) of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194 that provide as follows:

> 4.06(2) An affidavit shall be confined to the statement of facts within the personal knowledge of the deponent or to other evidence that the deponent could give if testifying as a witness in court, except where these rules provide otherwise.
>
> 39.01(4) An affidavit for use on a motion may contain statements of the deponent's information and belief, if the source of the information and the fact of the belief are specified in the affidavit.

[44] The court's "gatekeeper" role dealing with expert evidence is clear. Such evidence can only be tendered through a properly qualified expert: see *R. v. Mohan*, [1994] 2 S.C.R. 9 at p. 20 ("*Mohan*"). This principle has been applied in several certification motions: see *Chopik v. Mitsubishi Paper Mills Ltd.* (2002), 26 C.P.C. (5th) 104 (S.C.J.); *Punit v. Wawanesa Mutual Insurance Co.* (2006), 45 C.C.L.I. (4th) 109, (S.C.J.); *Ernewein*; *Stewart v. General Motors of Canada Ltd.*, [2007] O.J. No. 2319 (S.C.J.) ("*Stewart*").

[45] When expert evidence is admissible and produced on a motion for certification, the nature and amount of investigation and testing required to provide a basis for a preliminary opinion will not be as extensive as would be required for an opinion given at trial. It follows that some lesser level of scrutiny is applied to the opinions offered, if they are otherwise admissible: see *Stewart* at para. 19.

[46] This motion for certification fails regardless of the admissibility issues. As explained below, the plaintiffs have not satisfied s. 5(1)(a). In these circumstances there is to need to embark on a consideration of the defendants' attack on the admissibility of the plaintiffs' evidence. However, I will deal with what I consider to be the main admissibility issue: the admissibility of Dr. Plunkett's evidence.

Defendants' Position - Admissibility of Dr. Plunkett's Evidence

[47] The defendants argue that several portions of Dr. Plunkett's affidavit should be struck because the opinions she provides are outside the scope of her qualifications. Other parts of her affidavit are inadmissible because the defendants say the opinions lack the cogency and factual foundation required for admission of expert evidence. Finally, the defendants say that several of Dr. Plunkett's assertions do not arise out of any direct knowledge and she fails to set out any basis for her assertions that would permit them to be tested.

[48] I will review Dr. Plunkett's qualifications and her opinion as it is set out in her affidavit and explained further on cross-examination. The defendants identify specific paragraphs in Dr.

Plunkett's affidavit that they say should be struck. As I review Dr. Plunkett's evidence I will deal with each of these paragraphs.

Dr. Plunkett's Qualifications

[49] Dr. Plunkett's qualifications are described in her affidavit and as well she was cross-examined on this issue. She describes herself as a "pharmacologist," a "toxicologist" and a "United States Food and Drug Administration (FDA) regulatory specialist." She is a consultant based in Houston. She holds a Ph.D. and conducted doctoral research relating to "cardiovascular pharmacology." Dr. Plunkett describes her expertise as relating to the fields of "pharmacology, toxicology, regulatory issues, and drug efficacy and risk-benefit analysis."

[50] When cross-examined, Dr. Plunkett agreed as follows. She is not a medical doctor and does not treat or diagnose patients or prescribe medications to them. She would "definitely" defer to psychiatrists in the diagnosis and treatment of psychiatric illnesses and would "absolutely" defer to endocrinologists in the diagnosis and treatment of diabetes. It is clear that Dr. Plunkett is not qualified to provide expert medical evidence and cannot opine on the risk-benefit analysis that is part of a medical decision to prescribe medication to a patient.

Review of Dr. Plunkett's Affidavit

[51] The following is a review of Dr. Plunkett's evidence. I will identify what parts of her evidence are objected to and rule on the admissibility as I progress through her evidence.

[52] Dr. Plunkett states in her affidavit that she reviewed the following material:

> a) scientific literature relating to the pharmacology and toxicology of anti-psychotic drugs in general and quetiapine (Seroquel) in particular;
>
> b) labelling for Seroquel as provided by the Physician's Desk Reference;
>
> c) the regulations of the U.S. Food and Drug Administration (FDA) relating to the development, approval, labelling and marketing of prescription drug products; and,
>
> d) warnings provided by Health Canada in relation to the use and consumption of quetiapine (Seroquel).

[53] Dr. Plunkett's affidavit provides a brief description of bipolar disorder and schizophrenia and the atypical anti-psychotic drugs used to treat these conditions. She reviews the difference between the older anti-psychotic drugs and the atypical ones that followed, such as Seroquel.

[54] The affidavit lists the symptoms that are treated with Seroquel including off-label uses. Dr. Plunkett explains how Seroquel is absorbed in the body and she lists the adverse effects ("health risks") of the drug. The defendants do not object to any of this evidence. They agree that Dr. Plunkett can opine on causation but not the product warnings.

[55] The health risks that Dr. Plunkett describes are as follows:

> 21. Seroquel use has been associated with deaths that have been attributed to severe liver, kidney, and pancreatic damage. Its adverse effects include, but are not limited to, ketoacidosis, pancreatitis, diabetes mellitus, weight gain, hyperglycemia, blindness, increased thirst, and hypoglycemia. Other serious injuries associated with Seroquel use include: a potentially fatal condition known as neuroleptic malignant syndrome (NMS); tardive dyskinesia, which can cause potentially irreversible, involuntary movements; and other serious health problems associated with the onset of diabetes including heart disease, blindness, coma, seizures and death ("Health Risks"). These Health Risks have been reported following both short-term and longer-term use of Seroquel.

[56] Dr. Plunkett states that it has been known for decades that many anti-psychotic drugs have effects to alter metabolism that can lead to weight gain and effects on glucose metabolism. Since 1999, it has been recognized that there are differences among the anti-psychotic drugs in relation to their propensity for inducing weight gain and changes in glucose metabolism, including the onset of diabetes. Further, since 2002 it has been recognized that clinically significant hyperglycemia and diabetic complications can occur during anti-psychotic treatment both with and without changes in weight gain.

[57] Dr. Plunkett states that between January 1997 and July 2002 there were numerous adverse drug event reports to the US Food and Drug Administration, including reports that patients taking Seroquel experienced significant Health Risks. Her affidavit attaches copies of journal articles that discuss the relationship between Seroquel and some of the Health Risks. Dr. Plunkett includes a very brief sentence for each article describing what the author concluded. All of the articles dealt with the risk of diabetes when consuming Seroquel. In one case Dr. Plunkett attached an article from the Wall Street Journal about a study, rather than the study itself.

[58] Dr. Plunkett relies on the above articles to provide the following opinion regarding the causal connection between Seroquel and the Health Risks. In paragraphs 31-32 of her affidavit she states:

> 31 When considered as a whole in a weight-of-the evidence assessment, the available scientific data indicate that Seroquel can cause physiological effects known to be risk factors for diabetes, including increased body weight and other metabolic effects, and can cause diabetes itself. The scientific data include case reports published on an ongoing basis since 1999, a survey of adverse drug reports, epidemiological data assembled since 1999, and animal data. In reaching this conclusion, I have considered each source of information as important in the analysis of the risks associated with the consumption of Seroquel and have used the information in a manner that is consistent with accepted methods for establishing causation in a weight-of-the-evidence analysis.
>
> 32. I believe that the available scientific data demonstrate that Seroquel consumption and use is associated with increased human Health Risks, including

> but not limited to an increased risk of clinically significant body weight gain, hyperglycemia, altered glucose metabolism, and an increased risk of diabetes and diabetes-related complications.
>
> [Emphasis added.]

[59] The defendants say that the opinion in the underlined portions of the above paragraphs should be struck because it lacks cogency and a factual foundation. When the defendants cross-examined Dr. Plunkett about this opinion, she conceded that she did not include the epidemiology studies that say there is no association between Seroquel and diabetes. As a result, the defendants say that this opinion is based on an unbalanced sampling of published research. Further, the defendants criticize the opinion because Dr. Plunkett provided no analysis for the opinion. In my view, the defendants' position is asking the court to assess and weigh Dr. Plunkett's evidence in these paragraphs, a task that is outside the scope of certification.

[60] Dr. Plunkett states that clinical trials performed with Seroquel as part of the drug development process are limited in their ability to identify risks associated with the drug's use in the general population. This is because drug development clinical trials are performed in either healthy volunteers or in patients that have often been pre-screened for the propensity to develop adverse effects such as hyperglycemia or diabetes, with such patients then usually excluded from studies. It is only after a drug has been placed on the market, and wider exposure is seen, that a true picture of the adverse effects associated with a drug can be observed. As a result, Dr. Plunkett believes that companies have a duty to carefully monitor their drugs after approval and during marketing for either the existence of new adverse events or a higher than expected incidence of known adverse effects. There is no objection to this evidence.

[61] The defendants object to the opinion in paragraph 35 of Dr. Plunkett's affidavit where Dr. Plunkett states that that "Seroquel is not unique in terms of its efficacy" and there are "safer alternative therapies." Paragraph 35 states as follows:

> Studies have shown that other anti-psychotic drugs have similar effectiveness to Seroquel but have less risk for hyperglycemia, weight gain, metabolic disturbances and diabetes. Therefore, there are safer alternative therapies that could be used that would also provide for effective treatment but with fewer side effects.

[62] Support for this opinion is given in paragraph 36 where Dr. Plunkett adds as follows:

> ...in the CATIE Schizophrenia Trial, a trial sponsored by the National Institute of Mental Health which is the largest trial conducted to date comparing efficacy and safety of some of the most prescribed anti-psychotic drugs, it was shown that clozapine was more effective than other atypical anti-psychotics (*i.e.*, Seroquel, Zyprexa, Risperdal). Further, when all of the atypical agents studied were examined, including Seroquel, none of the agents was more effective or better tolerated than the typical anti-psychotic, perphenazine.

[63] The defendants argue that the evidence in paragraph 35 is an assertion that should be struck because Dr. Plunkett did not state any foundation facts or rationale for this opinion. They say that the assertion that "safer" alternatives to Seroquel were available was made without having considered what alternatives were in fact available on the Canadian market at various times, whether these alternatives were "safer" and without even identifying the so called safer alternatives. However, Dr. Plunkett does add support for her opinion in paragraph 36. Once again, the defendants' position goes beyond the scope of challenge that is permitted on a certification motion. While the defendants have raised compelling reasons to question the usefulness of this opinion, this is a challenge that goes to the weight to be attached to this opinion, not its admissibility.

[64] The rest of Dr. Plunkett's affidavit discusses the warnings of the health risks associated with Seroquel. The defendants say that the following paragraphs seek to provide opinions outside Dr. Plunkett's area of expertise and are therefore inadmissible. Only the sentences underlined in para. 39 are in issue.

> 37. Despite the findings of the studies discussed above, AstraZeneca failed to warn Health Canada, the FDA, physicians, other health practitioners, and patients of the Health Risks associated with the consumption of Seroquel at the time these risks were first identified.
>
> 38. A review of the most recent product monograph for Seroquel that is available to both health professionals and consumers in Canada demonstrates that, in my opinion, the warnings related to risks of hyperglycemia and diabetes in particular are not adequate to convey the risks posed by Seroquel itself. In the health professional section of the monograph, the discussion of hyperglycemia and diabetes is put forth as an effect of anti-psychotics in general only. Moreover, the monograph section intended for consumers fails to even mention these health risks.
>
> 39 At the time that the Seroquel monograph in Canada failed to adequately warn physicians and consumers of the risks associated with use of the drug, other international regulatory bodies were requiring specific changes to product labelling related to the risks of hyperglycemia and diabetes that were associated with Seroquel, not anti-psychotics in general. For example, in Japan, physicians were being specifically warned to not use Seroquel in patients with a history of diabetes and to monitor patients for development of glucose abnormalities during treatment with Seroquel, regardless of their medical history. Additionally, in 2005 permission to market Seroquel in France had been denied due in part to the risk of hyperglycemia and diabetes associated specifically with Seroquel, again not anti-psychotics in general. Accordingly, I believe that the Defendants were not supplying physicians and consumers in Canada with risk information related to hyperglycemia and diabetes even though actions had been taken in other countries to warn physicians and patients of these risks. 40. I believe that the product warnings in place at the time were wholly inadequate to warn health care providers and patients of the significant Health Risks associated with the

> consumption of Seroquel. Nonetheless, Seroquel was marketed heavily by the Defendants as safe and effective for the treatment of bipolar disorder and schizophrenia, promising fewer side effects than other similar treatments including the other atypical anti-psychotics on the market. Further, Seroquel was being prescribed by physicians for treatment of conditions other than bipolar disorder and schizophrenia, which use I believe was known by the Defendants.
>
> ....
>
> 42. I believe that the Defendants knew of the Health Risks associated with ingesting Seroquel. I believe that the Defendants failed to disclose these risks because of the anticipated negative impact it would have on the sale and consumption of Seroquel.
>
> [Emphasis added.]

[65] This case is about the marketing, sale and use of Seroquel in Canada not the United States. It is about the Canadian regulatory system that approves drugs such as Seroquel for use in Canada. It is Health Canada's approval of Seroquel in Canada and the defendants' warnings (product monographs) that Health Canada approved that are relevant, not the actions of the FDA in the United States. Dr. Plunkett does not have the necessary expertise to opine on the regulatory regime in Canada, what Seroquel was approved for in Canada and whether the Canadian warnings were adequate.

[66] Dr. Plunkett's training and experience is entirely based in the United States. She has never worked or studied in Canada. Her only Canadian work appears to be the swearing of an affidavit dealing with Seroquel in the Quebec class action litigation. Dr. Plunkett admits that the Quebec affidavit is substantially identical to the one sworn for this motion. To the extent that Dr. Plunkett has regulatory expertise, it is purely American. She has no Canadian training or experience that could extend her American expertise to any of the Canadian regulatory issues in this litigation. She conceded that her affidavit says nothing at all about Canadian requirements for the approval or labelling of pharmaceutical products. While I appreciate that Dr. Plunkett has some expertise, it is grounded in her American work experience. Further, there is no evidence to show that such expertise is transferable to the regulation of drugs in Canada.

[67] An expert witness is properly qualified to express an opinion only if he or she is shown to have acquired special or peculiar knowledge through study or experience in respect of the matters on which he or she undertakes to testify (see *Mohan* at para. 27). It is clear that Dr. Plunkett does not have the relevant expertise. I conclude that paras. 37- 42 of Dr. Plunkett's affidavit are inadmissible (only the underlined portions of para. 39 are inadmissible).

Overview of Seroquel

[68] Seroquel is one of a class of medicines known as "atypical antipsychotics" or "second generation antipsychotics." Seroquel is approved in Canada for the treatment of schizophrenia and bipolar disorder, both of which are incurable psychotic illnesses.

[69] Before the second generation antipsychotics arrived on the market in Canada in the 1990s, these psychotic illnesses were treated with a class of medications known as first generation antipsychotics. The advent of first-generation antipsychotics in the middle of the last century marked a significant advancement in the treatment of these devastating illnesses. Previously, there was no effective treatment for these illnesses.

[70] While first generation antipsychotics are effective in treating some aspects of schizophrenia and bipolar disorder, they are strongly associated with many side effects, including disabling and stigmatizing neurological movement disorders, including extrapyramidal side effects and tardive dyskinesia. Tardive dyskinesia is irreversible in 50% of those afflicted. Indeed, the neurological side effects of first generation antipsychotics are so prevalent that the class of drugs became known as "neuroleptics."

[71] A search for medications with efficacy to treat psychotic illness but without the debilitating neurological side effect burden of first generation antipsychotics led to the development of the second generation antipsychotics. The second generation antipsychotics are referred to as "atypical" because they are better tolerated and have far less neurological effects than first generation antipsychotics. The second generation antipsychotics generally also have better efficacy in treating the negative, cognitive and affective symptoms of psychiatric illness.

[72] The individual response to these medications is highly variable in terms of both efficacy and side effects. Efficacy and tolerability cannot be accurately predicted in any given individual. Further, a person's own response to treatment may change over time.

[73] Today, second generation antipsychotics are recognized as the first line treatment for schizophrenia and bipolar disorder and use of first generation antipsychotics is no longer regarded as the standard of care in most clinical situations in Canada.

[74] Seroquel came to market in Canada in 1998 as the fourth second generation antipsychotic that Health Canada approved. The other second generation antipsychotics and their dates of approval are: Clozaril (clozapine) in 1991; Risperdal (risperidone) in 1994; and Zyprexa (olanzapine) in 1996.

[75] As described by Dr. Chue, it is generally accepted in clinical practice in Canada that Seroquel has the most benign side effect profile of the second generation antipsychotics. Dr. Wirshing agrees that Seroquel is the best in its class in terms of subjective tolerability and is in the "upper tiers" in terms of overall toxicity.

[76] All of the experts, including Dr. Wirshing and Dr. Plunkett, agree that Seroquel is an effective drug.

Approval of Seroquel in Canada

[77] In order to market a drug in Canada, a manufacturer must file a New Drug Submission and receive a Notice of Compliance from Health Canada.

[78] The Seroquel New Drug Submission consisted of 150 volumes of materials, which included, amongst other things, voluminous safety data, non-Canadian package inserts, a draft Seroquel Product Monograph and clinical trial reports. All of the data submitted as part of the New Drug Submission related to treatment of schizophrenia.

[79] Following a review of the New Drug Submission by a specialized group of scientists at Health Canada, Seroquel was first approved in Canada as safe and effective for the treatment of schizophrenia on December 2, 1997.

[80] On November 5, 2004, Health Canada approved Seroquel for the acute management of manic episodes associated with bipolar disorder. As of that date, prescribing and safety information relating to bipolar mania was added to the product monograph. Every prescription medicine in Canada is required to have a product monograph, which contains, *inter alia*, prescribing information, warnings, and other safety information for that medication.

[81] Health Canada approved Seroquel for the acute treatment of the depressive episodes associated with bipolar I and bipolar II disorder on August 18, 2008. In conjunction with that approval, further prescribing information and safety data relating to bipolar depression was added to the product monograph.

The Seroquel Product Monograph and the "Health Risks"

[82] The defendants' regulatory expert, Anne Tomalin, explains the role of the product monograph, how it is approved and its content. She describes Health Canada's review of a new drug submission as rigorous and exacting. The product monograph is subject to its own review by scientific experts with clinical and/or medical expertise. An excerpt from page 12 of her report discussed this evidence as follows:

> The Product Monograph is regarded as "labelling" in Canada. All labels must have a statement that says, "Product Monograph available on request", or a similar statement. Once approved, the manufacturer is required to distribute a copy of the Product Monograph to all physicians at the time of marketing the product. Also, a copy of the Product Monograph is posted on the Health Canada website.
>
> During the review of an NDS [New Drug Submission], the Product Monograph is reviewed sentence by sentence and word by word to ensure that the very best information is provided to Healthcare Professionals when the document is approved. The reviewer carefully compares the wording in the proposed Product Monograph contained within the NDS to their notes and understanding of the data in the submission. They also compare the wording to the wording of the Product Monographs of other similar products in Canada, and to the international labelling that is available for the drug. The reviewer then ensures that there is consensus within the Therapeutic Division at Health Canada in terms of the revisions required. When all of the revisions are ready, a Clarifax is sent to the company outlining all of the changes required. Frequently meetings or teleconferences are

set up to discuss the changes required to ensure that there is a clear reflection of the data in the NDS.

Contents of a Product Monograph: There are three parts to the Product Monograph:

• Part I is referred to as the Prescribing Information for healthcare professionals. If there is a package insert for the healthcare professional, it must be identical to Part I of the Product Monograph. Part I of the Product Monograph is provided to a publication called the Compendium of Pharmaceutical Specialties (CPS), which is published and provided free of charge to all physicians and pharmacists in Canada once a year.

• Part 2 is referred to as the Scientific Information and contains information on the animal and clinical studies used to approve the drug.

• Part 3 is referred to as the Consumer Information section of the Product Monograph. If there is a package insert for the patient, it must be identical to Part 3 of the Product Monograph.

The Original Product Monograph - December 1997

[83] As already noted, every prescription medicine in Canada is required to have a product monograph, which contains, *inter alia*, prescribing information, warnings, and other safety information for that medication.

[84] During Health Canada's review of the New Drug Submission, the draft product monograph is evaluated "sentence by sentence and word by word to ensure that the very best information is provided to Healthcare Professionals" (Anne Tomalin's report at p. 2122). The language in the product monograph is compared to the data in the New Drug Submission, the wording of product monographs of other similar medicines, and international labelling for the drug in question.

[85] Once the product monograph is approved and a Notice of Compliance is issued, pharmaceutical companies distribute the product monograph to physicians across Canada and an up to date copy is posted on Health Canada's website. In addition, all product labels are required to indicate that the product monograph is available upon request.

[86] The initial Seroquel product monograph, dated December 2, 1997, contained warnings and information about a number of the "Health Risks" based upon the clinical studies conducted in patients with schizophrenia. The 1997 product monograph included warnings for weight gain, tardive dyskinesia, cataracts, neuroleptic malignant syndrome, transaminase (liver enzymes) elevations, dizziness, impaired motor skills, dry mouth, seizures and death (in relation to neuroleptic malignant syndrome).

Revisions to the Product Monograph Regarding "Health Risks" Over Time

[87] Since December 1997, the Seroquel product monograph has been revised on 25 occasions. Nineteen of those revisions involved changes to the safety data contained in the product monograph.

[88] Changes to a product monograph are a normal part of the life-cycle of a medicine. As both Dr. Plunkett and Ms. Tomalin have noted, it is only after a drug has been used in a broader population and over a greater amount of time that a full understanding of all of its risks and benefits can be known. Accordingly, the defendants (as well as Health Canada) have developed and implemented a robust drug safety program to identify and assess safety signals to determine if the worldwide labelling for its medicines need to be updated.

[89] All of the defendants' medicines, including Seroquel, have a Core Data Sheet that contains the company's most up-to-date knowledge regarding the safety and efficacy of the medicine. In order to ensure that the Core Data Sheet contains the most current safety information, careful monitoring, evaluating, and reporting of adverse event reports takes place on a daily basis at the national level. In addition, the defendants routinely review the aggregate safety data for a medicine as a part of its SERM (Safety Evaluation and Review Meeting) process. Where new information results in a change to the safety profile of a medicine, the Core Data Sheet for the medicine is updated accordingly.

[90] The revised Core Data Sheet is then sent to regulatory staff in each country, including Canada, who work in consultation with the local regulatory authority to assess whether a change to that country's product monograph is warranted, and, if so, the content of that change. This assessment is based upon local regulatory standards, which differ between countries. Product monographs, therefore, vary from country to country. It is through this process that many of the changes to the Seroquel product monograph detailed below came about.

[91] The dates of changes to the safety information contained in the Seroquel product monograph from 1997 to 2011 in relation to diabetes and weight gain are as follows. A diabetes warning (including exacerbation of diabetes, hyperglycaemia, diabetic ketoacidosis, diabetic coma, and death) was added to the product monograph on December 16, 2003 at the request of Health Canada as part of class-wide labeling for second generation antipsychotics. The warning was expanded on two occasions - April 25, 2005 and October 9, 2007. In addition, the April 2005 revision to the product monograph for diabetes added a recommendation that patients should be monitored for polydipsia (i.e., excessive thirst).

[92] The original weight gain warnings in the product monograph were modified six times on the following dates: August 2, 2002; September 24, 2003; November 5, 2004; March 6, 2007; August 18, 2008; and May 19, 2009. The November 5, 2004 and August 18, 2008 revisions included the addition of weight gain data from the bipolar mania clinical trials and bipolar depression clinical trials, respectively, in conjunction with the approval of Seroquel for those indications.

THE LEGAL FRAMEWORK

[93] Subsection 5(1) of the *Class Proceedings Act* sets out the criteria for the certification of a class proceeding. The language is mandatory. The court is required to certify the action as a class proceeding where the following five-part test for certification is met:

> (a) the pleadings 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 the representative plaintiff or defendant;
>
> (c) the claims or defences of the class members raise common issues;
>
> (d) a class proceeding would be the preferable procedure for the resolution of the common issues; and
>
> (e) there is a representative plaintiff or defendant who,
>
> (i) would fairly and adequately represent the interests of the class,
>
> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
>
> (iii) does not have, on the common issues for the class, an interest in conflict with the interests of other class members.

[94] These requirements are linked: "There must be a cause of action, shared by an identifiable class, from which common issues arise that can be resolved in a fair, efficient and manageable way that will advance the proceeding and achieve access to justice, judicial economy and the modification of behaviour of wrongdoers." (*Sauer v. Canada (Attorney General),* [2008] O.J. No. 3419 (S.C.J.) at para. 14).

[95] Winkler J. pointed out in *Frohlinger v. Nortel Networks Corp,* [2007] O.J. No. 148 at para. 25 (S.C.J.)("*Frohlinger*"), that the core of a class proceeding is "the element of commonality." It is not enough for there to be a common defendant. Nor is it enough that class members assert a common type of harm. Commonality is measured qualitatively rather than quantitatively. There must be commonality in the actual wrong that is alleged against the defendant and some evidence to support this.

[96] The decision to certify is not merits-based. The test must be applied in a purposive and generous manner, to give effect to the important goals of class actions - providing access to justice for litigants; promoting the efficient use of judicial resources; and sanctioning wrongdoers and encouraging them to modify their behaviour: see *Western Canadian Shopping*

Centres Inc. v. Dutton, [2001] 2 S.C.R. 534 at paras. 26-29 (*"Western Canadian Shopping"*); *Hollick* at para. 15.

[97] In *Hollick,* at para. 25, the "some basis in fact" test was introduced when the court stated that "the class representative must show some basis in fact for each of the certification requirements set out in s. 5 of the Act, other than the requirement that the pleadings disclose a cause of action."

[98] Since it is not the role of the court on a certification motion to "find facts," I conclude that *Hollick* directs the court to confirm that there is some evidence to support the s. 5 (b) – (e) requirements. This interpretation of the test is consistent with the low burden that rests on the plaintiff as explained in *Hollick* at para. 16 and consistent with how the numerous courts have applied the "some basis in fact" test: see *Fresco v. Canadian Imperial Bank of Commerce*, [2009] O.J. No. 2531 (S.C.J.) at para. 61 (*"Fresco"*)).

5(1)(a) - Cause of Action

[99] There have been several amendments to the statement of claim. On this motion, the defendants consented to the "Second Amended Fresh as Amended Statement of Claim." This amendment was required to remove Bernard Van Kerrebroeck as a representative plaintiff because he no longer wished to act in this role. The amendment is granted on consent. The defendants filed a statement of defence to an earlier version of the statement of claim.

[100] The first criterion for certification is the disclosure of a cause of action. In *Cloud,* the Ontario Court of Appeal affirmed that the "plain and obvious" test from *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 (*"Hunt"*) that is used for Rule 21 motions is also used to determine whether the proposed class proceeding discloses a cause of action.

[101] Unless the claim has a radical defect or it is plain and obvious that it could not succeed, the requirement in s. 5(1)(a) will be satisfied. This determination is to be made without evidence and claims that are unsettled in the jurisprudence should be allowed to proceed.

[102] The pleading must be read generously to allow for inadequacies due to drafting frailties and the plaintiffs' lack of access to key documents and discovery information: see *Hunt* at 980; *Anderson et al. v. Wilson et al.* (1999), 44 O.R. (3d) 673 at 679 (C.A.).

[103] Before considering whether the plaintiffs have satisfied the s.5(1)(a) criterion, I will deal with a preliminary point that the plaintiffs raised. They take the position that because the defendants filed a statement of defence, they have taken a fresh step and are precluded from disputing the plaintiffs' compliance with s. 5(1)(a).

[104] The plaintiffs rely on *Bell v. Booth Centennial Healthcare Linen Services*, [2006] O.J. No. 4646 (S.C.J.) at paras. 5-6 (*"Bell"*) and *Tribar Industries Inc. v. KPMG LLP,* [2009] O.J. No. 959 (S.C.J.) at para. 22 (*"Tribar"*). Both are decisions of Brown J. that involved motions to strike pleadings under Rule 21. In each case the defendant had already filed a statement of defence. In *Bell,* at para. 6, Brown J. stated that the "filing of a statement of defence signifies that the claim contains a recognizable cause of action to which the defendant can respond and should

prevent a defendant from complaining subsequently about an irregularity in the statement of claim." However, in *Bell,* because the plaintiff did not object to the defendant bringing the motion, the court allowed it to proceed. In *Tribar,* the plaintiff raised the filing of the statement of defence as a bar to the motion and the court agreed. Brown J. noted, at para.22, that "[f]or courts to condone such a manner of pleading would strip the act of pleading over of any procedural significance and risk opening the door to interminable pleadings motions even after pleadings were closed."

[105] The defendants rely on three decisions where despite the filing of the statement of defence, the court granted leave to bring the Rule 21 motion:see *Seale & Associates Inc. v. Vector Aerospace Corp.* [2007] O.J. No. 1192 (S.C.J.); *Lynch v. Westario Power Inc.* [2009] O.J. No. 2927 (S.C.J.); *Markeljevic v. Financial Services Commission of Ontario* [2005] O.J. No. 2098 (S.C.J.). In these decisions the defendant did not concede in the statement of defence that a cause of action existed but rather disputed the existence of a cause of action in their pleading. The defendants in this action have taken the same approach and in paragraph 2 of their defence they plead that the statement of claim does not disclose a cause of action.

[106] It is not necessary to resolve these two lines of cases. The issue in this case is unique to a class proceeding. I do not accept the plaintiffs' position that the filing of a statement of defence should preclude the defendants from taking a position on the s.5(1)(a) criterion. This is not a Rule 21 motion. While the same "plain and obvious test applies, the burden rests on the plaintiffs to satisfy s. 5(1)(a). A defendant may agree that there is a cause of action or dispute this criterion. Either way the plaintiff must still satisfy the court that the s. 5(1)(a) criterion is met. If the defendant disputes the existence of a cause of action and files a statement of defence this does not alter the plaintiff's burden.

Analysis of the Causes of Action

[107] The plaintiffs say that they have pleaded the following causes of action: negligence and failure to warn, conspiracy and waiver of tort. In argument the plaintiffs agreed that waiver of tort is pleaded as a remedy.

[108] For the numerous reasons that follow, this pleading is seriously deficient. It is plain and obvious that the causes of action as pleaded will fail. The plaintiffs have not satisfied the s. 5(1)(a) criterion.

[109] Before considering whether the pleading discloses one or more of the causes of action, I will consider two fundamental problems with the way the causes of action are advanced against the defendants. First the description of each defendants' role is inconsistent with the alleged activities that are described in the pleading. Second, the pleading lumps the defendants together as a group and alleges that they are liable to the class for each cause of action.

Inconsistent Pleading

[110] There is a real disconnect between the description of the defendants in this pleading and the actions that the plaintiffs seek to hold the defendants responsible for. Paragraphs 7 to 12 of

the statement of claim describe the defendants and their respective roles. I have underlined the key excerpts to demonstrate this problem.

[111] In para. 9, it is alleged that AZ Canada was "involved in and/or responsible for the sales, distribution and marketing of Seroquel in Canada."

[112] In para. 11, it is alleged that the business of the three defendants "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."

[113] In para. 12, it is alleged that the defendants "all or any one of them, were carrying on business as, *inter alia*, the manufacturers and distributors of Seroquel in Canada." However, in para. 9, AZ Canada's role is limited to sales, distribution and marketing of Seroquel in Canada.

[114] In paragraph 19, the plaintiffs allege that the "[t]he Defendants designed, developed, tested, manufactured, distributed, marketed and sold Seroquel in Canada." This is inconsistent with the narrower description of each defendant's role set out in paragraphs 7 to 12.

[115] The scope of the defendants' alleged activities expands further in para. 26(a). The plaintiffs allege that the defendants owed them a duty of care and failed "to exercise reasonable care in designing, developing, researching, testing, manufacturing, analysing, recommending, merchandising, advertising, promoting, marketing, supplying and/or selling Seroquel." In para. 26(c) it is alleged that the defendants failed to "ensure that Seroquel was only promoted, marketed, advertised, recommended, merchandised, and sold for the uses approved by Health Canada."

[116] A defendant is entitled to know the precise nature of what it is alleged to have done. The inconsistencies in this pleading create confusion and a lack of clarity as to which defendant did what in relation to Seroquel. The problem is compounded by the next pleading problem.

The Enterprise Liability Allegations

[117] 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.

[118] The statement of claim alleges that the business of each defendant is "inextricably interwoven with that of the other and each is the agent of the other for the purpose of research, development, manufacture, marketing, sale and/or distribution of Seroquel in Canada." Courts have described this approach of lumping all defendants as one as the group or enterprise approach. It is the defendants' position that the enterprise liability allegation is deficient. For the reasons that follow, I agree.

[119] The plaintiffs fail to identify the specific acts undertaken by each defendant which support these causes of action. The only pleaded conduct that is personal to any defendant is that AZ Canada "was involved in and/or responsible for the sales, distribution and marketing of Seroquel in Canada." The defendants, AZ U.K. and AZ U.S., are identified simply as "affiliate[s]" of AZ Canada. There is no indication of which defendant was the designer or

manufacturer of Seroquel. 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.

[120] First, as a matter of pleading, it is inappropriate to simply "lump together" the three defendants. Allegations of enterprise liability were struck by Cumming J. in *Hughes v. Sunbeam Corp. (Canada)*, [2000] O.J. No. 4595 (S.C.J.) at paras. 48-49 ("*Hughes*"), var'd on other grounds (2002), 61 O.R. (3d) 433 (C.A.), leave to appeal to S.C.C. refused, [2002] S.C.C.A. No. 446. This was a proposed class action and the defendants brought a motion to strike the pleading before the certification motion. Cumming J. stated as follows:

> The Claim (para. 9) simply lumps together all corporate defendants (other than ULC) and then proceeds to generalize the various allegations as applicable to all defendants indiscriminately. For example, the Claim (para. 11) alleges that the representative plaintiff is the owner of an ionization smoke alarm manufactured by this amorphous collection of Sunbeam defendants. There is no identification of a particular manufacturer of his smoke detector until the Response (para. 2(a)).
>
> In my view, and I so find, the pleading does not disclose any reasonable cause of action based upon the allegation of a single group enterprise by the so-called Sunbeam defendants.

[121] Second, as a matter of substantive law, a parent corporation is not interchangeable with its subsidiary. As the Alberta Court of Appeal stated in *Cunningham v. Hamilton*, [1995] A.J. No. 476 (C.A.) at para. 4:

> ... It is true that Broken Hill operates a number of its worldwide companies as an integrated economic unit. But the mere fact it does so does not mean that for legal purposes, separate legal entities will be ignored absent some compelling reason for lifting the corporate veil. ...

[122] Accordingly, "[a] position as shareholder, even a controlling shareholder, in a manufacturer is an insufficient foundation in itself to impose a manufacturer's duty": *Harrington v. Dow Corning Corp.*, [1996] B.C.J. No.734 (S.C.J.) at para. 53 aff'd (2000), 193 D.L.R. (4th) 67 (B.C.C.A.), leave to appeal to S.C.C. refused, [2001] S.C.C.A. No. 21. The same rule applies where a manufacturer's duty is sought to be imposed on a subsidiary corporation for the actions of its parent. As the Ontario Court of Appeal noted in *Gregorio v. Intrans-Corp.* [1994] O.J. 1063 at para. 28, that is inappropriate "unless the subsidiary is under the complete control of the parent and is nothing more than a conduit used by the parent to avoid liability."

[123] 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:see *Sauer* at para. 89; *McCutcheon v. The Cash Store Inc.* (2006), 80 O.R. (3d) 644 (S.C.J.) at paras. 16-26; *Di Gennaro v. BMO Nesbitt Burns Inc.*, [2007] O.J. No. 3934 (S.C.J.) at paras. 7-11.

[124] As the court stated in the *Haskett v. Equifax Canada Inc.* (2003), 63 O.R. (3d) 577 (C.A.) at paras. 61-63, leave to appeal to S.C.C. refused, [2003] S.C.C.A. No. 208:

> ... In order to found liability by a parent corporation for the actions of a subsidiary, there typically must be both complete control so that the subsidiary does not function independently and the subsidiary must have been incorporated for a fraudulent or improper purpose or be used by the parent as a shield for improper activity....
>
> The pleading falls short of suggesting that the relationship of the respective related respondent corporations is that of a conduit to avoid liability, nor is there an allegation that the parent company controls the subsidiary for an improper purpose.
>
> For the above reasons, the claims against the companies as pleaded must be struck out as disclosing no reasonable cause of action.

[125] The statement of claim in this case does not satisfy this test. There is no pleading that AZ U.K. or AZ U.S. completely controlled AZ Canada or used it as a conduit to avoid liability for a fraudulent or improper purpose.

[126] 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. This type of pleading was found to be deficient in *Gardner v. The Queen*, [1984] O.J. No. 3162 (H.C.J.) at para. 21:

> These authorities satisfy me that the principal-agent relationship does not have to be explicitly stated in a statute or in an agreement entered into pursuant to that statute as is contended for by the applicant. They also support the inference that whether or not an agency relationship arises out of the factual context is a matter of law. However, an allegation of the bare conclusion of law is a bad pleading: see Paradis v. Vaillancourt et al., [1943] O.W.N. 359. No facts are pleaded by the plaintiff in the statement of claim so as to support the conclusion of law alleged therein that the Dominion Government was the Band's agent in entering the 1894 agreement. Consequently, the pleading in so far as it alleges the agency relationship as the basis for claiming damages for breach of contract offends the rules.

[127] Accordingly, the defendants cannot be liable for one another's conduct on this pleading. This is a critical failure, since no specific conduct is alleged against AZ U.K. and AZ U.S. at all. Further, no defendant, including AZ Canada, is individually identified as the designer or manufacturer of Seroquel. 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).

[128] I will now review the causes of action in the pleading.

The Negligence Claim is Deficient

[129] While the plaintiffs describe the cause of action simply as negligence and duty to warn, this is a pleading that covers different types of negligence, in addition to breach of the duty to warn. Based on the claim as asserted in paragraph 1 of the statement of claim, the negligence cause of action falls into three groups:

- negligent design, development and testing
- negligent manufacturing
- negligent distribution, marketing and sale.

[130] The statement of claim does not distinguish between these different negligence claims. Rather, it lumps them all together as negligence and provides particulars for this broad group. The plaintiffs wrongly assume that these distinct activities are identical and can be thrown into one single cause of action. As I explain below, these different forms of negligence are not the same. Therefore, to allege one cause of action is a flawed approach.

[131] There is also a complete failure to provide particulars of each type of negligence. Rule 25.06(1) of the *Rules of Civil Procedure* requires that a statement of claim "contain a concise statement of the material facts on which the party relies for the claim." This rule directs the disclosure of the "material" facts, which include facts that establish the constituent elements of the claim. The material facts are to be stated with precision and clarity.

[132] This pleading offends rule 25.06(1) because it fails to acknowledge the differences between the various types of negligent activity. Instead of precision and clarity, the pleading is muddled and vague. The defendants are entitled to know the material facts that the plaintiffs rely on to support each area of negligence. Generalized allegations of negligence are not sufficient: see *Khan v. Canada (A.G.),* [2009] O.J. No. 715 (S.C.J.) at para. 19, aff'd, 2009 ONCA 737, leave to appeal to S.C.C. refused, [2009] S.C.C.A. No. 516. As Strathy J. emphasized in *Cerqueira v. Ontario,* 2010 ONSC 3954 at para. 12, "defendants are entitled to know the case they must meet. The court must be fair to the plaintiff, but it must also be fair to the defendants."

[133] The lack of precision and clarity in this pleading is also obvious from the manner in which the plaintiffs deal with approved uses of Seroquel and off-label uses. The pleading asserts negligent activity for approved uses of Seroquel and off-label uses, without drawing a clear line between the two uses. There is no dispute that approved and off-label uses are factually distinct. The plaintiffs cannot lump the two together. Materials facts must be pleaded for each plaintiff and for each distinct cause of action that the plaintiff is alleging.

Negligent Design, Development and Testing

[134] This cause of action is advanced with respect to approved and off-label uses. Whether one looks at approved or off-label uses, the pleading is vague, there is no distinction drawn between approved and off-label uses and the pleading lacks essential elements that are necessary for this cause of action to survive. For example, in para. 1(b) the plaintiffs seeks a declaration

that the "defendants were negligent in the design, development, testing, manufacturing, distribution, marketing and sale of Seroquel, as defined." At para. 26(a), the plaintiffs allege that the defendants owed a duty of care to the plaintiffs to "exercise reasonable care in designing, developing, researching, testing, manufacturing, analyzing, recommending, merchandising, advertising, promoting, marketing, supplying and/or selling Seroquel." It is alleged in para. 28 that the plaintiffs' damages occurred as a result of the defendants' negligence and particulars of this negligence are set out. There is a reference to failing to adequately "test" Seroquel but no reference to particulars of negligence in the "design or development" of Seroquel.

[135] Further, in the facts that are pleaded in paras. 15-25, the only reference to the design, development and testing of Seroquel is the bare allegation in para. 19 that states "[t]he Defendants designed, developed, tested, manufactured, distributed, marketed and sold Seroquel in Canada."

[136] Aside from the problem that this is a vague and bare pleading, it lacks important elements that are necessary for such a claim to survive. The plaintiffs do not identify the alleged design defect, nor do they plead that a safer and economically feasible alternative to Seroquel would have been adopted but for the defendants' negligence. Indeed, they do not even plead that a safer and economically feasible alternative to Seroquel exists. Instead, the plaintiffs simply plead that the risk associated with Seroquel for the "new onset of diabetes is 3.34 times higher than older drugs used to treat schizophrenia such as "Haldol." There is no pleading of any alternative medicine that is safer and economically feasible to manufacture.

[137] These deficiencies are fatal. The statement of claim does not disclose sufficient material facts to sustain a cause of action for negligent design. The essential elements of this cause of action are set out in *Kreutner v. Waterloo Oxford Co-operative Inc.* (2000), 50 O.R. (3d) 140 (C.A.) at para. 8 as follows:

> For the purpose of this appeal, it is unnecessary to state definitively the ingredients of a claim based on the defective design of a product. However, to succeed in this case the plaintiffs are required to identify the design defect in Sherwood's valve, establish that the defect created a substantial likelihood of harm and that there exists an alternative design that is safer and economically feasible to manufacture: Rentway Canada Ltd. v. Laidlaw Transport Ltd. (1989), 49 C.C.L.T. 150, 16 M.V.R. (2d) 86 (Ont. H.C.J.), affirmed [1994] O.J. No. 50 (C.A.).

[138] Liability for negligent "development" and "testing" also requires the plaintiff to plead that a safer alternative to Seroquel would have resulted but for the defendants' negligence. However, no such facts are pled in the statement of claim. This point is stated in *Baker v. Suzuki Motor Co.*, [1993] A.J. No. 605 (Q.B.) at para. 75 as follows:

> However, the absence of testing alone cannot be proof of negligence unless the tests, had they been done, would have enabled the manufacturer to design the motorcycle in such a way that the fire would not have occurred. Without this type of evidence, this allegation of negligence must fail.

[139] There are additional problems with this pleading when one looks solely at the allegation that the defendants designed, developed and tested for off-label uses. The pleading simply does not make sense. The term "off-label" use is not defined in the pleading and the pleading does not allege what particular off-label uses the defendants are alleged to have designed, developed and tested. These material facts of the negligence claim are missing.

[140] There is no attempt to carve out the causes of action that the plaintiffs allege concerning off-label use as distinct from approved uses. Instead, unclear allegations of off-label use have simply been dropped into the negligence pleading.

[141] Ms. Middleton advances the claim for negligent design, development and testing in relation to off-label users. She alleges that she was prescribed Seroquel in or about June 2005 for an off-label use, specifically as treatment for stress and obsessive compulsive behaviour. Ms. Middleton consumed up to 175 mg of Seroquel on a daily basis for approximately 6 months, at which point she ceased consuming Seroquel. While taking Seroquel, Ms. Middleton alleges that she experienced, among other side effects, significant elevated blood sugars and weight gain (approximately 25 pounds), neuropathy, hyperglycemia, loss of energy, increased thirst, numbness in her hands and feet, and soreness in her feet. In addition, Ms. Middleton alleges that she was diagnosed with diabetes in or about November 2005. Ms. Middleton had tested negative for diabetes in or about October 2003. Upon ceasing the consumption of Seroquel, Ms. Middleton was able to lose a portion of the weight that she gained as a result of taking Seroquel.

[142] The statement of claim provides some clarity about the off-label use but only for the conspiracy cause of action. At para. 35, it is alleged that the defendants conspired and agreed together, "to engage in a marketing campaign promoting the safety of Seroquel for Off-Label Use, including use as a sleep aid and to treat anxiety, dementia-related psychosis and depression." Beyond this example, the pleading does not describe what is meant by the term off-label use.

[143] The lack of clarity in this statement of claim is even more apparent because the examples of off-label use in para. 35 do not include the off-label uses that Ms. Middleton's claim is based upon (stress and obsessive compulsive behaviour).

[144] In addition to these deficiencies there is a fundamental incoherency in asserting a claim for negligent design, development and testing in relation to off-label uses. This was recognized by Perell J. in the *Goodridge v. Pfizer Canada Inc.* (2010), 101 O.R. (3d) 202 (S.C.J.) at p.227 ("*Goodridge*"):

> Negligence in design involves the innovator making poor choices and managing risk poorly when deciding how a product should be planned or put together. But the harm caused to the consumers of generic gabapentin is not a result of a design choice. Neurontin was not designed for any use other than as an adjunct treatment of epilepsy. Neurontin was not designed by the Defendants choosing to accept the risk of a propensity of suicidal behaviour; rather, a propensity for suicidal behaviour was a side effect to watch for and, if observed, it was a side effect to be disclosed by giving adequate warnings to the users of the drug. There is no design

> flaw in the case at bar because design errors presuppose design choices. The Plaintiffs submitted that Neurontin was a drug with a fatal flaw. That remains to be proven, but assuming that the submission is true, its flaw was not a design flaw. The Defendants may have designed a drug that turned out to have a defect, but that is different than choosing to design a drug with a defect that could have been avoided by more careful decisions about how to design the drug. And, in any event, the Defendants made no design choices with respect to the off label uses of Neurontin.

[145] In summary the negligent design, development and testing cause of action is fatally flawed. It is plain and obvious that it will fail and therefore must be struck.

Negligent Manufacture

[146] The statement of claim asserts that the defendants were negligent in the "manufacturing" of Seroquel. However, the statement of claim says nothing at all about what was allegedly negligent about the manufacturing process. As well it is unclear who the plaintiffs say manufactured Seroquel. There is a complete lack of material facts in the pleading. Negligent manufacturing claims arise when something goes wrong in the manufacturing process. This is a distinct form of negligence that the plaintiffs simply lump together with the other types of negligence.

[147] In *Rowe (Guardian ad litem of) v. Sears Canada,* 2005 NLCA 65 at paras. 19- 21, the court reviews the differences between the types of negligence claims and in particular negligent manufacturing:

> Products negligence cases fall into three general classes: manufacturing defect, design defect and failure to warn. This case does not concern the third. In manufacturing defect cases something which should not be present is (the classic snail in the bottle of ginger beer) or something which should be present is not. Something goes wrong in the manufacturing process itself, or the handling of the product, which produces a product which is below the standard set by the manufacturer. Generally a high standard of care is imposed on manufacturers in cases of defect in manufacturing. This coupled with permitted inferences from circumstantial evidence has resulted in liability being imposed on manufacturers in the absence of precise evidence of how the manufacturing defect occurred. The proof of the presence of the defect and that the defect resulted in injury to the plaintiff permits the trial judge to draw an inference of negligence.
>
> Design defect is not the result of something having gone wrong in the production of the product but an error in the design of the product. The central question is whether a different design ought to have been used by the manufacturer. In cases of design defect it is the design specifications themselves which create the risk to the consumer. As is obvious, a finding that there had been a design defect results in a whole line of products being defective. A finding of manufacturing defect relates only to the item under consideration.

[148] It is plain and obvious that the statement of claim does not plead the material facts necessary to sustain a claim for negligent manufacturing. Accordingly, the statement of claim does not disclose a cause of action for negligent manufacturing and this pleading must be struck.

Negligent Distributing, Marketing and Sale

[149] Once again the decision to lump the different negligence claims together is a problem. The statement of claim fails to deal with the fact that each type of negligence is unique.

(a) Approved Uses

[150] The allegations of negligent distribution, marketing and sale in relation to the approved uses are deficient for several reasons.

[151] First, the plaintiffs do not plead that Seroquel's propensity to injure outweighed the value of its use. However, this is a critical element of any negligent distribution, marketing and sale claim. In the absence of material facts to this effect, the pleading cannot justify the conclusion that the defendants were negligent in choosing to distribute, market and sell Seroquel, only that the defendants may have breached their duty to warn. This was explained by the British Columbia Court of Appeal stated in *Harrington v. Dow Corning Corp.* 2000 BCCA 605, 193 D.L.R. (4th) 67, at paras. 42-43 and 45, leave to appeal to S.C.C. refused, [2001] S.C.C.A. No. 21:

> At the risk of oversimplifying a complex decision-path, I venture to suggest the first step in every products liability case alleging negligent design, manufacture, or marketing is the determination of whether the product is defective under ordinary use or, although non-defective, has a propensity to injure. Some American authorities refer to this step as "general causation", whether a product is capable of causing the harm alleged in its ordinary use.
>
> The second step is the assessment of the state of the manufacturer's knowledge of the dangerousness of its product to determine whether the manufacturer's duty was not to manufacture and distribute, or to distribute only with an appropriate warning. It may be prudent to refer to this as an assessment of the state of the art; it may be that a manufacturer did not but should have known of its product's propensity for harm.
>
> ....
>
> If the value of the product's use outweighed its propensity to injure such that distribution with a warning was appropriate, the third step will be an assessment of the reasonableness of the warning (whether direct or by a learned intermediary) given the state of the art and the extent of the risks inherent in the product's use.

[152] Second, and related to the above point, many of the negligent distribution, marketing and sale allegations are in fact allegations that the defendants and their employees simply breached the initial or continuing duties to warn. These allegations fail to disclose a cause of action for the

reasons discussed in connection with the duty to warn claim below. Indeed, Canadian courts have repeatedly recognized that "negligent marketing" is merely a synonym for breach of the duty to warn. As the Newfoundland Court of Appeal stated in *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1995] N.J. No. 150 (C.A.) at para. 82, var'd on other grounds, [1997] 3 S.C.R. 1210:

> Danger from products may be the result of negligence in manufacture, design or marketing. Here the finding of the trial judge is one of negligence in the marketing of the product, that is, failure to warn of the flammability of Thermaclad. ...

[153] Third, the remaining negligent distribution, marketing and sale allegations concern claims that the defendants or their employees misrepresented information about Seroquel. While these allegations are framed as particulars of a negligence *simpliciter* claim, it is clear that they are effectively allegations of negligent misrepresentation. They are therefore deficient given the plaintiffs' failure to plead any particulars of the misrepresentation, or that they relied upon the misrepresentations and suffered damages as a result. As Strathy J. stated in *Singer* at paras. 67-69 and 73:

> The plaintiff's claim in negligence, as summarized in his counsel's factum, is that the defendants owed a duty of care to the plaintiff and class members to provide them with accurate information on the labeling of the products and not to make false or misleading claims on the labeling, advertising and marketing of the products. The plaintiff claims that the defendants breached this duty and that he suffered damages. The plaintiff does not give particulars of his damages, other than to describe them as "economic and other damages". Nor does the plaintiff plead a causal link between the defendants' negligence and his alleged damages.
>
> The pleading is replete with references to "misleading representations", "misleading claims", "misleading statements", "misleading labeling and advertising" and includes allegations that the defendants knew or should have known that their products did not have the qualities they ascribed to them.
>
> In effect, rather than plead negligent misrepresentation, the plaintiff has pleaded that the representations made on the packaging were false due to the negligence of the defendants. The plaintiff asserts that this is a different cause of action in negligence, with different essential elements. I am not persuaded by this assertion. The plaintiff's claim is clearly in negligent misrepresentation, albeit improperly pleaded. This is clear from a reading of the statement of claim and from the common issues proposed by plaintiff, particularly common issues 1 to 4 (see below and see the attached appendix). As such, it suffers from the fatal defect that there is no pleading that the plaintiff relied on these misrepresentations and suffered damages as a result.
>
> ....

> I conclude that the pleading expressed in negligence is really a claim for negligent misrepresentation; it fails to plead reliance and, as such, plainly cannot succeed.

[154] As in *Singer*, the unparticularized pleadings of misrepresentation in this case fail to allege reliance by the plaintiffs or class members, and therefore do not satisfy s. 5(1)(a).

(b) OffLabel Uses

[155] In addition to the above deficiencies, the negligent distributing, marketing and sale cause of action has a further defect as it relates to off-label uses. It is deficient and will fail because the defendants did not have a duty to "ensure" that Seroquel was not distributed, marketed or sold for off-label uses. This is because doctors have the legal right to prescribe Seroquel for off-label uses, regardless of the defendants' conduct. This was explained by Perell J. in *Goodridge* at paras. 14 and 98 as follows:

> 14 Physicians may lawfully prescribe a drug for other than its authorized use as set out in the product monograph. This practice is called "off-label" prescribing. Prescribing a drug for off label uses is not illegal, and it is a common practice of physicians. Medical practitioners are free to endorse or recommend off-label uses for medications and often do so, particularly when their patient's ailments are proving resistant to approved drugs. ...
>
> ....
>
> 98 ... Although the drug innovator can control the manufacture of its own product, monitor for adverse reactions to its product and give warnings about its own product, the innovator is not in a position to stop the generic manufacturer from releasing the generic drug or to stop physicians from prescribing the generic drug for off label uses. This conduct is not the innovator's conduct, and, in my opinion, it would be unfair to impose a duty of care on the innovator for another's conduct when the innovator cannot control, qualify, or stop that conduct. In my opinion, it would not be fair or just to make the innovator liable for failing to do something that should and can only be done by others.

Failure to Warn Cause of Action

[156] The statement of claim alleges that the defendants breached their duty to warn of the dangers associated with consuming Seroquel including the "Health Risks" that are described in paragraph 20 of the pleading as follows:

> Seroquel causes serious and sometimes fatal injuries to the liver, kidneys and pancreas. Its adverse effects include, but are not limited to, ketoacidosis, pancreatitis, diabetes mellitus, weight gain, impaired glucose regulation, hyperglycemia, blindness, cataracts, increased thirst and hypoglycemia. Other serious injuries include a potentially fatal condition referred to as neuroleptic malignant syndrome (NMS), tardive dyskinesia, which can cause potentially irreversible, involuntary movements and other serious health problems associated

> with the onset of diabetes including heart disease, blindness, coma, seizures and death ("Health Risks").

[157] It is alleged that the product warnings were "vague, incomplete or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians as well as consumer patients of the actual Health Risks associated with consuming Seroquel." Further it is alleged at paras. 21 and 25 of the statement of claim that the defendants did not "sufficiently warn of the serious adverse Health Risks associated with consuming Seroquel" and that the product "label was particularly deficient when considering the labeling done in other countries."

[158] First, the statement of claim fails to provide sufficient particulars regarding the alleged breach of a duty to warn. There is no indication of which particular defendant breached a duty to warn or which defendant owed such a duty by virtue of having manufactured Seroquel. This type of deficiency was recognized by Cumming J. in *Hughes* at paras. 58-59:

> It is not clear from the pleading when the alleged duty to warn arose, either generally or in relation to each of the Sunbeam defendants. In alleging a failure with respect to a duty to warn, the pleading does not delineate this as an alternative, distinctive cause of action. Rather, the allegation of a breach of a duty to warn, being a failure to act, is blended together with the allegation of misrepresentation, that is, an improper action.
>
> The Claim does not specify which defendant failed in respect of the alleged duty to warn and at what time. Any duty to warn with respect to a given product is owed only by the manufacturer of that product.

[159] The statement of claim also fails to plead what warnings were given, how they were inadequate, and whether or how they could have been improved. A breach of the duty to warn requires a demonstration that the defendants failed to provide the appropriate level of specificity in the product monograph. The plaintiffs have not pleaded <u>any</u> material facts in relation to the actual warnings contained in the product monograph. This bare pleading does not disclose a tenable cause of action for duty to warn.

[160] The pleading makes reference to the warnings in generic terms. However, there is no dispute that the warning is the product monograph. The defendants say that the content of the product monograph is therefore incorporated by reference for the purpose of assessing the s. 5(1)(a) criterion. This approach is consistent with well established case law: see *Montreal Trust Co. of Canada v. Toronto-Dominion Bank* (1992), 40 C.P.C. (3d) 389 at 395-396 (Ont. (Gen. Div.)); *Lubarevich v. Nurgitz*, [1996] O.J. No. 1457 (Gen. Div.); *Vaughan v. Ontario (Minister of Health)* (1996), 49 C.P.C. (3d) 119 at 123 (Ont. (Gen. Div.)) and *Web Offset Publications Ltd. v. Vickery*, [1999] O.J. No. 2760 (C.A.).

[161] As the Ontario Court of Appeal stated in *Hickey-Button v. Loyalist College of Applied Arts & Technology* (2006), 267 D.L.R. (4th) 601 (Ont. C.A.) at para. 26 "[T]he determination required under s. 5(1)(a) is to be made by reference to the pleadings and any documents identified in the pleadings."

[162] When the product monograph is considered, the problems with this pleading are even more apparent. The lack of particularity is illustrated by the fact that the product monograph does contain sufficient warnings to respond to the representative plaintiffs' claims. For example, the statement of claim pleads that Ms. Martin suffered two "injuries" as a result of ingesting Seroquel: weight gain and balance problems. The Seroquel product monograph at the time when Ms. Martin was first prescribed Seroquel in September 2005 contained warnings regarding weight gain and effects on cognitive and motor performance. Similarly, Ms. Middleton pleads that she took Seroquel "for six months starting in June 2005 and suffered weight gain and diabetes," and yet the product monograph as of April 25, 2005 contained a warning for weight gain and an expansive warning regarding hyperglycaemia and diabetes. There are no particulars that allow the defendants to understand why the plaintiffs allege that the warning was deficient.

Conspiracy

[163] The plaintiffs advance a conspiracy cause of action against the defendants. The manner in which this claim is plead is fraught with problems. To appreciate the depth of the problem, it is helpful to review the law concerning conspiracy.

[164] In Canada, there are two types of civil conspiracy: (1) predominant purpose, or conspiracy to injure; and (2) unlawful means or unlawful conduct conspiracy: see *Canada Cement LaFarge Ltd. v. British Columbia Lightweight Aggregate Ltd.*, [1983] 1 S.C.R. 452. The plaintiffs do not allege a predominant purpose type of conspiracy in the statement of claim.

[165] The material facts pled in the statement of claim allege that the defendants' conduct was motivated by their own financial self-interest and was not undertaken for the primary purpose of injuring the class members.

[166] The elements of the "unlawful means" form of conspiracy are set out in *Agribrands Purina Canada Inc. v. Kasamekas*, 2011 ONCA 460 at para. 26 ("*Agribrands*") as follows:

> For the appellants to be liable for the tort of unlawful conduct conspiracy, the following elements must therefore be present:
>
> a) they act in combination, that is, in concert, by agreement or with a common design;
>
> b) their conduct is unlawful;
>
> c) their conduct is directed towards the [plaintiffs];
>
> d) the [defendants] should know that, in the circumstances, injury to the [plaintiffs] is likely to result; and
>
> e) their conduct causes injury to the [plaintiffs].

[167] To sustain a claim for unlawful means conspiracy, the statement of claim must concisely plead material facts in support of each of these elements. This was explained in *Normart*

Management Ltd. v. West Hill Redevelopment Co., [1998] O.J. No. 391 (C.A.) at para. 21 ("*Normart*") where Finlayson J.A. quoted from Bullen, Leake and Jacob's, *Precedents of Pleadings*, 12th ed. (London: Sweet & Maxwell, 1975), as follows:

> The statement of claim should [1] describe who the several parties are and their relationship with each other. It should [2] allege the agreement between the defendants to conspire, and [3] state precisely what the purpose or what were the objects of the alleged conspiracy, and it must then proceed to [4] set forth, with clarity and precision, the overt acts which are alleged to have been done by each of the alleged conspirators in pursuance and in furtherance of the conspiracy; and lastly, it must [5] allege the injury and damage occasioned to the plaintiff thereby.

[168] Claims for conspiracy have been struck out where they were bald, overly speculative, or simply restated legal principles rather than pleaded material facts. As the court stated in *Penson Financial Services Canada Inc. v. Connacher,* 2010 ONSC 2843 at para. 15:

> Rule 25.06(1) mandates a minimum level of material fact disclosure and if this level is not reached, the remedy is a motion to strike out the pleading. A proper pleading of conspiracy should enable a defendant to know the case he or she must meet. Conspiracy is a serious claim. A recitation of a series of events coupled with an assertion that they were intended to injure the plaintiff is insufficient, nor is it appropriate to lump some or all of the defendants together into a general allegation that they conspired: Normart Management Ltd. and J. G. Young & Son Ltd. v. Tec Park Ltd.
>
> [Emphasis added and footnotes omitted.]

[169] The plaintiffs are not entitled to plead a deficient case in conspiracy on the theory that more detailed evidence of the claim will arise from discovery. The "plaintiff cannot go on a fishing expedition at discovery to gather the facts to make a proper plea": see *Research Capital Corp. v. Skyservice Airlines Inc.*, [2008] O.J. No. 2526 (S.C.J.) at para. 23, var'd on other grounds, 2009 ONCA 418 ("*Research Capital*").

[170] The pleading of conspiracy in this case offends all of the above requirements. It lacks clarity, precision and the material facts necessary to support the constituent elements. For the reasons set out below, it is plain and obvious that the conspiracy claim will fail.

The Parties to the Conspiracy

[171] To begin with, the plaintiffs have failed to adequately plead the relationship between the alleged parties to the conspiracy. I refer to the inconsistencies in the pleading regarding each defendant's role and the flawed enterprise liability approach that is discussed above.

[172] The alleged conspiracy is dealt with in paras. 35 to 41 of the statement of claim. In para. 35, the plaintiffs allege as follows:

> 35. From at least 1997 at London, England, Wilmington, Delaware, Mississauga, Ontario and elsewhere the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously, and lacking *bona fides*, conspired and agreed together the one with the other and with persons unknown to: ...

[173] No particulars of the relationship between the individual defendants, or their unnamed "directors, officers, servants and agents", are alleged in relation to the conspiracy. This type of problem was identified in *Taylor v. Tamboril Cigar Co.*, [2005] O.J. No. 4182 (C.A.) at para. 1 ("*Taylor*") as follows:

> We are not persuaded that Lax J. erred in finding that the appellants' statement of claim failed to plead properly the claims for conspiracy, breach of fiduciary duty and breach of trust. With respect to conspiracy, we agree with the motion judge that the pleading does not provide the required particularity. Among other deficiencies, it does not plead the particulars of the relationship between these defendants and the other alleged conspirators. Indeed, it does not plead that these defendants are conspirators. ...

[174] The lack of clarity in the pleading continues because the plaintiffs assert that the defendants conspired with "persons unknown." Similar allegations of conspiracy have been struck out in other cases. For example, in *Robinson v. Medtronic, Inc.*, 2010 ONSC 1739 at paras. 17-18 and 20 ("*Robinson*"), the court struck a reference in a conspiracy pleading to "person unknown" because such words are not a proper pleading of a claim of civil conspiracy.

[175] In essence, the plaintiffs have simply lumped the defendants together without making any attempt to specify the nature of the defendants' relationship. Such a pleading cannot satisfy s. 5(1)(a). This was explained in *Research Capital* at para. 48:

> ...it is not an appropriate approach to pleading conspiracy to lump together several defendants and allege they conspired to do something, without providing the material facts and full particulars to support the plea, being: facts as to the parties to the conspiracy and their relationship; the agreement between the parties; the purpose or object of the conspiracy; acts done in furtherance of the conspiracy; and any injury to the plaintiff. As RCC did in its claim of conspiracy against Investments, it acknowledged it lacked the information to cite the requisite facts, but hoped to acquire information to establish conspiracy through oral and documentary discovery. Again, I find a plaintiff is not permitted to make a deficient claim and await discovery to gather the facts to make a proper plea.

[176] Paragraph 37 of the statement of claim provides a long list of the overt acts that the defendants are alleged to have done. However, these acts are alleged against the defendants as a group. The group enterprise approach continues through the statement of claim into the conspiracy cause of action. The overt acts are not attributed to any particular defendant. It is not possible for a specific defendant to know from the statement of claim what it is alleged to have been done as part of the conspiracy. Rather, all of the defendants are simply lumped into the general allegation that they committed the list of overt acts in furtherance of the conspiracy. This

"group" approach does not satisfy the degree of specificity that is required for a conspiracy claim.

[177] Courts have recognized that a conspiracy pleading requires a high degree of specificity. However, this is the consequence of alleging such a serious cause of action. If the plaintiff does not have knowledge of the specifics, then it is not appropriate to plead conspiracy: see *Balanyk v. University of Toronto,* [1999] O.J. No. 2162 (S.C.J.) at para. 29; *J.G. Young & Son Ltd. v. Tec Park Ltd.,* [1999] O.J. No. 4066 (S.C.J.) at paras. 6 and 9.

The Purpose or Objects of the Conspiracy

[178] The plaintiffs have also failed to adequately plead the purpose or objects of the conspiracy. Courts have struck out conspiracy claims where the plaintiff failed to plead the precise object of the conspiracy, or the purposes of a particular conspirator in entering into the agreement: see *Taylor,* at para. 1.

[179] In this case, the purpose and objects of the conspiracy are pleaded as follows:

> 36. The Defendants were motivated to conspire and their predominant purposes, concerns, and motivations were:
>
> a) to obtain approvals for Seroquel;
>
> b) to increase or maintain revenue;
>
> c) to increase or maintain profit;
>
> d) to increase or maintain market share;
>
> e) to avoid negative publicity and preserve public goodwill; and,
>
> f) to place corporate revenue and profit above the safety of the Class Members.
>
> [Emphasis in original.]

[180] In my view, the plaintiffs have simply plead a list of corporate activity that lacks the required precision.

The Overt Acts

[181] Paragraph 37 of the statement of claim lists 25 "acts, among others" that were "done by the Defendants and their servants, agents and employees." The level of detail that a conspiracy pleading requires is missing. There is no indication of the time, place, actor or facts behind any of the acts: see *Dewan v Burdet,* [2006] O.J. No. 5210 (S.C.J.) at para. 62, var'd on other grounds, 2007 ONCA 752.

[182] Further, much of the same conduct is pled in support of the negligence claim. Such allegations are plainly insufficient as explained in *Normart* at paras. 22 and 25 as follows:

> ... While there is a statement as to the general terms of the conspiracy, there is no detail with respect to overt acts in furtherance of the conspiracy and no indication of what damages were suffered as a result of the conspiracy as opposed to the breach of contract. ...
>
> ....
>
> ... Simply reciting a series of events and stating that they were intended to injure the appellant is hardly sufficient to establish a conspiracy at law particularly where the same facts have already been pleaded in support of an action for breach of contract. The basis in law of a stand alone conspiracy is simply not established.

[183] In summary, plaintiffs have failed to adequately plead the overt acts. Instead they have provided an unparticularized list of 25 acts.

The Unlawful Means

[184] The conspiracy pleading is also deficient because the plaintiffs do not sufficiently plead how the alleged acts amount to "unlawful" conduct for the purposes of the conspiracy tort. Paragraph 39 simply states that the "[d]efendants' conduct was unlawful because they knowingly marketed and sold Seroquel when they knew, or had reason to know, of the Health Risks associated with the consumption of Seroquel." This is the same allegation that is made for the negligence cause of action. This pleading does not address why such conduct is alleged to be unlawful.

[185] While the pleading alleges that the defendants breached various statutes, this does not assist in understanding why the conduct in question is "unlawful." Simply listing a group of statues and alleging that they were breached does not provide sufficient clarity: see *Philco Products Ltd. v. Thermonics, Ltd.*, [1940] S.C.R. 501 at para. 9; *Agribrands,* at para. 28.

[186] It is not possible to determine from the statement of claim whether all of the defendants engaged in the same unlawful act. This failing is particularly significant given that the defendants are resident in Canada (AZ Canada), the United States (AZ U.S.) and England (AZ U.K.), and the statement of claim alleges that their conduct is unlawful by virtue of violating both Canadian and American legislation.

[187] Alleging a breach of a foreign law as support for the allegation of unlawful means conspiracy is a problem. As the Supreme Court of Canada stated in *Pro Swing Inc. v. Elta Golf Inc.*, [2006] 2 S.C.R. 612 at para. 34 (and 100) "[i]t is well established that Canadian courts will not enforce a penal order, either directly or indirectly (Castel and Walker, at para. 8.3)."

Injury and Causation

[188] The plaintiffs have also failed to adequately plead the injury and causation elements of the conspiracy. The only reference to this element of the conspiracy claim is found in para. 41 where the plaintiffs plead that the "[d]efendants knew that the conspiracy would cause injury and losses to the Plaintiffs, the Class Members and other Family Class members, and it did." This is clearly inadequate.

[189] There is no allegation that the specific unlawful acts and/or the breaches of the various statutes caused the plaintiffs' injuries. There is also no allegation of what specific injuries the plaintiffs even suffered as a result of the conspiracy. These vague and unspecified allegations of causation are insufficient to meet the test in s. 5(1)(a).

[190] As noted above, the plaintiffs rely on the alleged breach of foreign statues. It is unclear how a violation of the U.S. Federal Food, Drug and Cosmetic Act could cause any injury to Canadian class members, when Health Canada undertakes its own independent review of pharmaceutical drugs, as it did for Seroquel.

Summary - s. 5(1) (a) criterion

[191] In summary, this is a statement of claim that offends the most basic rules governing pleadings. The deficiencies are numerous and fatal. It is plain and obvious that the causes of action in this pleading will fail. The plaintiffs have amended their statement of claim no less than five times, and the defendants have requested particulars. Yet the pleading still contains numerous significant deficiencies. The defendants' factum contains a detailed description of the deficiencies and requests the court to strike the pleading with no leave to amend. Despite being put on notice of the defence position, the plaintiffs made no effort to try and remedy their pleading. The amendment that they requested at the start of the hearing was solely to remove one of the representative plaintiffs.

[192] The plaintiffs have not satisfied the s. 5(1)(a) criterion and the action cannot be certified. I will nevertheless consider the remaining s. 5 criteria.

5(1)(b)- Identifiable Class

Legal Framework

[193] Subsection 5(1)(b) requires that there be "an identifiable class of two or more persons that would be represented by the representative plaintiff or defendant." The purpose of a class definition is: (a) to identify persons with a potential claim; (b) define who will be bound by the result; and (c) describe who is entitled to notice: *Bywater v. Toronto Transit Commission,* [1998] O.J. No. 4913, at para. 10 (Gen. Div.). To serve the mutual benefit of the parties, the class definition should not be unduly narrow or unduly broad.

[194] Class membership identification is not commensurate with the elements of the causes of action advanced on behalf of the class. There must be a rational connection between the class member and the common issues: see *Sauer* at para. 32

[195] In *Hollick*, the Supreme Court of Canada confirmed the test for determining if there is an "identifiable class." The plaintiff must define the class by reference to objective criteria, so that a given person can be determined to be a member of the class without reference to the merits of the action.

The Class Definition

[196] The plaintiffs propose the following class definitions:

a) all persons in Canada who were prescribed and who consumed Seroquel ("Patient Class"); and

b) the family members of the Patient Class, as defined by the Family Law Act and similar applicable provincial and territorial legislation ("Family Law Class").

[197] The defendants state that there are four reasons why the plaintiffs have not satisfied s. 5(1)(b). First, there is no basis in the evidence to show that there are persons other than the representative plaintiffs who are interested in being included in the class. Second, the plaintiffs have failed to establish some basis in fact for a rational relationship between the broad Patient Class, and the common issues. Third, the Patient Class members do not share the same interest in the outcome of this litigation. Fourth, the Patient Class definition is unnecessarily overly broad.

Two or More Persons

[198] The plaintiffs must provide some evidence of "two or more persons" who assert a claim. The plaintiffs state that the exact number and identity of class members is unknown. They rely on the affidavit evidence of Victoria Paris, a lawyer at the plaintiffs' law firm. The substance of this affidavit is information and belief. Ms. Paris was informed by Ms. McPhee, another lawyer at the plaintiffs' law firm.

[199] Ms. Paris states that in addition to the named plaintiffs, the firm has "been in contact with more than thirty potential class members, who consumed Seroquel for both on and off label uses." No further evidence about these potential class members is provided.

[200] As well, Ms. Paris states that there are proposed class actions in Alberta and British Columbia. The representative plaintiffs in the Alberta and British Columbia actions will seek to have their actions stayed if the Ontario action is certified. A third action was started in Quebec and the same class definition was proposed. The Quebec court denied certification for a variety of reasons, one being the absence of any evidence that a class exits. The decision denying certification is being appealed. This plaintiff therefore is still attempting to pursue his action in that province.

[201] The statements of claim in Alberta and British Columbia allege the following. The representative plaintiff in the Alberta action took Seroquel in 2002 for schizophrenia and suffered weight gain and diabetes. In the British Columbia action one plaintiff took Seroquel in 2004 for depression and bi-polar disorder and experienced rapid weight gain. The second

plaintiff in that action took Seroquel in 2001 for an antipsychotic disorder and experienced weight gain and diabetes. Aside from the fact that these statements of claim were issued, there is no evidence from the plaintiffs in these actions.

[202] Therefore we are left Ms. Martin and Ms. Middleton. As will be clear later in this decision, there are real problems with Ms. Martin's claim. Due to the narrowing of the common issues Ms. Martin's claim is no longer connected to the common issues and she is not representative of a class, assuming one exists. This leaves Ms. Middleton as the sole representative plaintiff and her claim is limited to off-label use.

[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.

The Class Definition is Over-Inclusive

[207] The defendants argue that the class definition is overly broad. It captures those who have taken Seroquel without any side effects. The plaintiffs do not dispute that Seroquel helps patients. As noted above, Health Canada has approved Seroquel for use in Canada and it continues to be used to treat patients who suffer from schizophrenia, acute management of mania episodes associated with bipolar disorder I and II and acute treatment of depressive episodes associated bipolar disorder I and II. Further, all of the experts, including Dr. Wirshing and Dr. Plunkett agree that Seroquel is an effective drug. Therefore, the class definition is bound to include those who have no claim against the defendants. It will also include those who have suffered side effects that are not covered by the common issues and/or not covered by the statement of claim. For these reasons, the defendants say the class definition is overly broad.

[208] A proposed class is not overbroad because it may include persons who ultimately will not have a claim against the defendants: see *Bywater* at para. 10; *Boulanger v Johnson & Johnson*, [2007] O.J. No. 179 (S.C.J.) at para. 22. However, it should not be defined wider than necessary: see *Hollick* at para. 21. Despite the fact that Seroquel was only introduced in Canada in 1997, the definition does not indicate a period of time that is in issue. Dr. Wirshing has no criticism of the product monograph from the time Seroquel was first introduced in Canada in 1997 until 2001. Therefore at a minimum, if I was certifying this action, the class should be bounded by a start date of 1997.

[209] Given the above problems with the class definition it fails to satisfy s. 5(1)(b) criterion.

5(1)(c) - Common Issues

Legal Framework

[210] Subsection 5(1) of the *Class Proceedings Act* requires that "the claims or defences of the class members raise common issues." Section 1 of the *Class Proceedings Act* defines "common issues" as:

> (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 ....

[211] For an issue to be common it must be a substantial ingredient of each class member's claim and its resolution must be necessary to the resolution of each class member's claim: see *Hollick* at para. 18.

[212] An issue will not be common if its resolution is dependent upon individual findings of fact that have to be made with respect to each individual claimant: see *Fehringer v. Sun Media Corp.*, [2002] O.J. No. 4110 (S.C.J), aff'd, [2003] O.J. No. 3918 (Div. Ct.).

[213] The underlying question is whether the resolution of a proposed common issue will avoid duplication of fact-finding or legal analysis: see *Western Canadian Shopping Centres Inc.*, at para. 39.

[214] The core of a class proceeding is the element of commonality; there must be commonality in the actual wrong that is alleged against the defendant and some evidence to support this: see *Frohlinger,* at para. 25; *Fresco,* at para. 21.

[215] An issue can be common even if it makes up a very limited aspect of the liability question and although many individual issues remain to be decided after its resolution: see *Cloud* at para. 53. It is not necessary that the answers to the common issues resolve the action or even that the common issues predominate. It is sufficient if their resolution will significantly advance the litigation so as to justify the certification of the action as a class proceeding.

[216] The common issues criterion is not a high legal hurdle, but a plaintiff must adduce some basis in the evidence to show that the issues are common: *Hollick* at para. 25. As Lax J. stated in *Fresco,* at para. 61 "[w]hile only a minimum evidentiary basis is required, there must be some evidence to show that this issue exists and that the common issues trial judge is capable of assessing it in common. Otherwise, the task for the common issues trial judge would not be to determine a common issue, but rather to identify one." [Emphasis added.]

[217] Finally, a plaintiff is not required to produce evidence on each element of a cause of action pleaded. As Lax J. stated in *Glover v Toronto (City),* [2009] O.J. No. 1523 at para. 56: "One cannot give meaning to the concept that the criterion in section 5(1)(a) is to be satisfied without evidence, but then require the plaintiffs to produce evidence for each of the material facts alleged."

Analysis of Proposed Common Issues

[218] Initially the plaintiffs' common issues focused on the causal connection between Seroquel and the extensive list of health risks described in the statement of claim. The defendants responded that this approach was fatal to certification because the common issues lacked commonality and there was no evidence to show that such a broad approach could be managed on class wide basis. In reply, the plaintiffs amended the common issues and described the health risks arising from the use of Seroquel as "weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom."

[219] The revised common issues that the plaintiffs wish to certify are as follows:

General Causation

(1) Can Seroquel cause weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom?

Off-Label Promotion

(2) Did the defendants, or any of them, promote, market, advertise, and/or recommend Seroquel for off-label uses? If the answer is yes, does this change the nature of the duty under common issue #3 or common issue #4, constitute unlawful conduct under common issue #7, and/or constitute behavior that would justify an election under common issue #8 or punitive damages under common issue #10?

Negligence/ Duty to Warn

(3) Did the defendants, or any of them, owe a duty of care to the Class in respect of the design, development, researching, testing, recommending, advertising, promoting and/or marketing of Seroquel as it relates to the risk of weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom? If so, what was the nature of the duty?

(4) Did the defendants, or any of them, owe a duty to the Class to warn that Seroquel can cause weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom, and if so, when did the duty to warn arise?

(5) If the answer to #3 and/or #4 is yes, did the defendants, or any of them, breach such duty? If so, what was the nature of the breach?

Conspiracy

(6) Did the defendants, or any two or more of the defendants, act in combination to conceal information from the Class and/or Health Canada relating to the safety and efficacy of Seroquel, as it relates to weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom?

(7) If the answer to #2 and/or #6 is yes, was the defendants' conduct unlawful in that it violated the Food and Drugs Act or the Food and Drug Regulations?

Waiver of Tort

(8) Can the Class elect to have damages determined through an accounting and disgorgement of the proceeds of the sale of Seroquel?

(9) If so, in what amount and for whose benefit is such accounting to be made?

Special, Aggravated and/or Punitive Damages

(10) Should one or any of the defendants pay special, aggravated and/or punitive damages to the Class?

Aggregate Assessment of Damages

(11) Can damages be determined on an aggregate basis on behalf of the Class?

Costs of Administration and Distribution

(12) Should one or any of the defendants pay the costs of administering and distributing the amounts to which the Patient Class and Family Law Class are entitled?

Prejudgment Interest

(13) Should one or any of the defendants be ordered to pay prejudgment interest?

Common issue # 1 – General Causation

Can Seroquel cause weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom?

[220] There are fatal problems with this common issue. The issue lacks commonality and the phrase "metabolic disturbances as well as secondary injuries flowing therefrom" is unclear. This phrase is repeated through many of the common issues. The following critique applies to the use of these words throughout the common issues.

Unclear Terminology

[221] I start with the phrase "related metabolic disturbances as well as secondary injuries flowing therefrom." What does this mean?

[222] The source of this common issue is *Heward v Eli Lilly & Co.* [2007] O.J. No. 404 at paras. 82-83. The only difference with the common issue in this case is the presence of weight gain that was absent in *Heward.* The focus in *Heward* was Zyprexa, another second generation antipsychotic drug. The court certified *Heward* and approved this common issue. The reasons in *Heward* do not discuss the meaning of metabolic injuries and secondary injuries. If the court had some evidence to explain these terms it is not apparent from the reasons.

[223] The wording of this common issue focuses on metabolic disturbance related to weight gain and diabetes. It is not clear if the "secondary injuries" are secondary to the metabolic disturbance or weight gain and diabetes. Are the metabolic disturbances and the secondary injuries some or all of a list of symptoms that are part of the health risks described in the statement of claim? The plaintiffs made a decision to revise the common issues when faced with the defendants' criticism. It is unclear if this imprecise reference to "metabolic disturbances" and "secondary injuries" is an attempt to broaden the scope of the common issues to capture the full list of health risks that were originally in this common issue.

[224] I questioned the plaintiffs about their use of the words "metabolic disturbances" as well as "secondary injuries flowing therefrom." In argument, plaintiffs' counsel explained that the

earlier version of the common issue was too broad and this was an attempt to narrow it. The suggestion that they are trying to narrow this common issue is at odds with their next explanation. Plaintiffs' counsel went on to explain that they do not wish to catalogue all of the so called related injuries because this might exclude from a common issue trial, a related relevant injury that is not on the list. In effect this common issue has not been narrowed. Rather, through the use of such nebulous words it seeks to include an undefined list of symptoms.

[225] Plaintiffs' counsel fairly conceded that there is no evidence that explains the term "metabolic disturbance and secondary injuries." Drs. Wirshing, Chue and Plunkett use the phrase "metabolic disturbance" without explaining it.

[226] It is not an answer to say that a common issue can be certified because it was certified in another case: see *Lambert,* at para. 121. It does not relieve the plaintiffs of the some evidence requirement. Further, it is not an answer to say that expert evidence will be led at trial to explain unclear terminology in a proposed common issue. The common issues trial judge should not be left wondering what was intended by the words "metabolic disturbances as well as secondary injuries flowing therefrom." A common issue that lacks clarity will cause unnecessary confusion as the case progresses: see *Toronto Community Housing Corp. v. Thyssenkrupp Elevator (Canada) Ltd.*, 2011 ONSC 4914 at para. 188.

[227] A certification judge cannot perform the task of assessing a common issue if it is unclear what it means. Some evidence from a medical expert explaining the phrase "metabolic disturbance as well as secondary injuries flowing therefrom" is required so the court can perform its task under s. 5. The plaintiffs have simply borrowed the words from *Heward* and assumed that the court will certify them in this case. That is not good enough. There must be some evidence to explain the meaning of the words together with some evidence that Seroquel can cause "related metabolic disturbances as well as secondary injuries flowing therefrom" and that this can be assessed in common.

[228] To emphasis the importance of defining medical terms used in a common issue, consider the following definition of "metabolic" found on Medicinenet.com. This site describes "Metabolic" as "Relating to metabolism, the whole range of biochemical processes that occur within us (or any living organism). Metabolism consists of anabolism (the buildup of substances) and catabolism (the breakdown of substances)." In my view this dictionary definition suggests that the term has wide application. It reinforces the importance of providing some evidence so the medical term in the common issue is understood.

[229] This leaves weight gain and diabetes. The defendants agree that there is some evidence that Seroquel can cause weight gain and diabetes. This evidence is obvious since the product monographs warn of these risks.

[230] As I will explain below, Ms. Martin's statement in her affidavit that she gained weight as a result of taking Seroquel, is not supported by her medical records. The result is a representative plaintiff whose own claim is not grounded in the common issue.

[231] The remaining consideration is whether this common issue, limited to weight gain and diabetes, can be assessed in common.

Lack of Commonality

[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.

[239] The prevalence of diabetes in our society is explained by Dr. Barrett in his report. He describes an epidemic of type 2 diabetes driven by diet and lack of exercise. In 2005, the Canadian Diabetes Association indicated that "5.5% of the population had diagnosed diabetes, which represented a 70% increase in diagnosed diabetes between 1998 and 2005." He goes on to state that "according to the Canadian Diabetes Association in 2005 2 of 3 Canadian adults and nearly 1 of 3 children age 12 to 17 were overweight or obese and are therefore at high risk of developing type 2 diabetes." To further emphasis the point he states that the "morbidly obese woman has a risk of developing diabetes that is ~6000% greater than that of a lean woman."

[240] The path that diabetes takes is also individual. Dr. Barrett states that "the complex natural history of type 2 diabetes has a natural time course through which each individual patient that develops diabetes will move. The likelihood of progressing along this pathway is determined by

their risk factor profile...As a result all these individuals may already have or be transiting towards diabetes in the absence of any new medication or intervention. This can only be assessed for the individual patient , based upon their risk factor profiles."

[241] Dr. Barrett explains that the diagnosis of diabetes requires a blood test. Further many people with type 2 diabetes "can be asymptomatic or have only very mild symptoms that are not recognized as due to diabetes." As a result, "the disease can be present and undiagnosed for a considerable period of time. It has been estimated that in the United States and Canada, approximately one quarter to one third of individuals with type 2 diabetes ...have not been diagnosed. Put somewhat differently, the date of diagnosis of disease frequently lags by years the date of true onset of disease, making undiagnosed diabetes a significant health issue."

[242] Further, Dr. Barrett states that diabetes is a "multi-factorial disease with multiple risk factors that predispose to its development." He adds as follows in para. 2D of his report:

> These risk factors are both genetic and environmental and strongly associate with disease development and have been used to guide screening strategies to identify early on those at highest risk. Significant risk factors for type 2 DM include age, family history of DM, obesity, race, ethnicity, history of gestational diabetes, and major neuropsychiatric disorders. In a given individual the risk for developing diabetes is a function of the combined risk factor burden he or she carries.

[243] Dr. Arnold also explains the challenges of evaluating whether a causal association exists between Seroquel and diabetes at paras. 71-76 of his affidavit:

> 71 Determining whether a causal association exists between SEROQUEL use and diabetes is a difficult task due to the nature of the disease process of diabetes, its prevalence in the general population and the psychiatric population in particular, and the low incidence of diabetes adverse events relative to the number patients taking the drug.
>
> 72 Diabetes is a progressive disease that begins sub-clinically and progresses to an impaired fasting glucose with glucose intolerance, and then to full-blown diabetes. According to the literature, the prevalence of diabetes in the general population is now approximately 10% and is greater in the schizophrenic population. Therefore, a percentage of patients taking SEROQUEL would be expected to develop diabetes and/or hyperglycaemia as part of the prevalence of the background risk in this population.
>
> 73 Because a percentage of patients treated with SEROQUEL would be expected to be diagnosed with diabetes as part of the natural incidence of that disease, individual adverse event reports of diabetes are of much more limited value than would be the case with adverse event reports for diseases that are less prevalent. Indeed, some disorders are reported so rarely and lack a natural cause that they are usually considered as drug-related unless demonstrated otherwise. Diabetes is not such a condition.

> 74 In the case of diabetes, because of its prevalence in society, it is far more complicated to assess the possible contribution of a medication such as SEROQUEL in an individual case report. To do so requires careful analysis of the individual's medical history, baseline medical condition, risk factors upon commencement of drug therapy, the changes during therapy, and the changes after therapy is discontinued. To compound this challenge, often the necessary information needed to assess an adverse event report cannot be obtained despite our follow-up protocols and best efforts to do so.
>
> 75 For these reasons, in evaluating whether there is a causal association between SEROQUEL and diabetes, it is necessary to analyse aggregate patient data to see whether the incidence of diabetes treated with SEROQUEL is higher than would be expected to occur without SEROQUEL treatment.
>
> 76 The results of the studies published in the scientific/medical literature over the years that have considered the association between SEROQUEL and diabetes have been inconsistent. A number of studies have assessed whether the use of SEROQUEL can increase patients' risk of diabetes, but many of the studies that did suggest an increased risk did not control for important risk factors. On the other hand, many of the studies which were better controlled for important diabetes risk factors failed to demonstrate any increased risk between SEROQUEL and diabetes. Therefore, it remains AstraZeneca's view that the evidence to date fails to demonstrate a causal association between SEROQUEL use and diabetes and, at most, any association suggested by some studies is extremely weak.

[244] Dr. Wirshing's evidence is also relevant. It is his opinion that Seroquel causes the patient to become obese. Assuming such weight gain, he states that "diabetes is not a forgone conclusion even from significant amounts of weight."

[245] When looking at whether Seroquel without weight gain can cause diabetes, Dr. Wirshing has seen this occur with individuals but he states that the causal connection is not shown in the group data. Even among the individuals, Dr. Wirshing states that there is no dose level for Seroquel above which you see a connection between Seroquel and weight gain and/or diabetes. This is important evidence because it reinforces the evidence of the defence experts that this issue cannot be answered on a common basis.

[246] Lastly, Ms. Martin's evidence highlights the individuality of determining if Seroquel caused weight gain and/diabetes. While taking Seroquel Ms. Martin states in her affidavit that she experienced several side effects including weight gain of 90lbs. She states that while she tested negative for diabetes in 2006, she experienced diabetic symptoms. Clearly on the issue of diabetes, an individualized inquiry would be required to determine if there was a causal connection between her consumption of Seroquel and the diabetic symptoms that she refers to.

[247] While Ms. Martin states that she gained weight after taking Seroquel, her medical records do not document the connection between Seroquel and the weight gain. Further even if she did

gain weight, identifying the cause requires an individual inquiry because she possessed multiple risks factors for weight gain aside from Seroquel. Dr. Chue reviewed these points in his report at p. 2007 as follows:

> According to the chart it would appear that Ms. Martin gained 100 lbs in the year prior to the day she was first prescribed Seroquel (September 21, 2005). The only other dated weight reference in the chart was on December 20, 2005 where it was noted that her weight was "approaching 3001bs". Given that 280 lbs following a weight gain of 100 lbs could be said to be approaching 300 lbs", it is not clear from the record that Ms. Martin gained any weight on Seroquel. If Ms. Martin did gain weight while taking Seroquel, there is nothing in her records to support her claim of weight gain attributable to Seroquel. Ms. Martin possessed multiple risk factors for weight gain including impaired mobility/sedentary lifestyle, sedative medications including Percocet and Oxycontin, pre-existing and longstanding obesity, bipolar disorder and age. Moreover, prior to treatment and concurrently with Seroquel, Ms. Martin had been treated with a number of medications Zyprexa, Epival and avil. These medications were continued after Seroquel and the dose of for example, the Epival actually increased. These are all psychotropics that are strongly associated with weight gain and their adverse effects in patients with risk factors are often additive (for example, weight gain especially Zyprexa with Epival). In fact, if any weight gain continued after Ms. Martin started taking Seroquel, the data suggest that prior and concomitant medications, physical disability and lifestyle factors caused the trajectory of progressive weight gain that began well before Ms. Martin started on the Seroquel. In my opinion, there is no evidence to support Ms. Martin's claim that Seroquel caused her to gain 55, 90 pounds or any weight at all.
>
> [Emphasis added.]

[248] In summary, the plaintiffs have not provided any evidence to show that a methodology exists whereby general population data (or some other approach) can be used to assess this issue in common and arrive at an answer that is of any use to the class. The result is that each putative class member must have this question determined on an individual basis.

[249] Because of the individuality of this general causation question and the lack of evidence that it can be answered in common, it becomes a "scientific question of interest." As the court stated in *Gariepy v. Shell Oil Co.* [2002] O.J. No. 2766 at para. 67, aff'd, [2004] O.J. No. 5309 (Div. Ct.) "answering the scientific question only starts you on the necessary journey to find the final answer to the liability question in any given case."

[250] The evidence in this case resembles the evidence in *Wuttunee*. The Saskatchewan Court of Appeal overturned the lower court's decision to certify. The defendant manufactured and distributed Vioxx, a pain relief medication that was voluntarily withdrawn from the market due to tests that suggested the drug caused an increased risk of heart attacks and strokes. As in this case, the plaintiffs in *Wuttunee* alleged that the medicine resulted in numerous types of unrelated health risks.

[251] The plaintiffs in *Wuttunee* proposed a common issue for general causation in relation to two different types of physical injuries - gastro-intestinal injuries, and adverse cardiovascular events. The Court of Appeal rejected this common issue as paras. 145-146 as follows:

> 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.
>
> 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.

[252] The same conclusions apply in this case. This is made clear by *Lavallee*, in which a similar class proceeding for failure to warn of multiple health risks in relation to Seroquel was brought against the same defendants in Quebec. Notably, the petitioner in Quebec relied on a virtually identical expert report of the same expert, Dr. Laura Plunkett, and the literature referred to in *Lavallee* includes the literature cited by Dr. Plunkett in her affidavit in this action.

[253] Jacques J. refused certification (or "authorization") in *Lavallee*. He found that the petitioner failed to satisfy any of the criteria in s. 1003 of the *Code of Civil Procedure*. Dealing with the general causation question, Jacques J. found that the multiplicity of alleged risks, risk factors, warnings and other individuating factors (e.g., learned intermediaries), coupled with the fact that Seroquel was not defective, meant that "individual trials would be required in the case of each member in order to determine the liability of the Respondents, if any." I agree with and adopt the court's conclusions in *Lavallee*.

[254] I reject this common issue.

Common issue # 2 – Off-Label Promotion

Did the Defendants, or any of them, promote, market, advertise, and/or recommend Seroquel for off-label uses? If the answer is yes, does this change the nature of the duty under common issue #3 or common issue #4, constitute unlawful conduct under common issue #7, and/or constitute behavior that would justify an election under common issue #8 or punitive damages under common issue #10?

Not Connected to the Statement of Claim

[255] This is a common issue that is not connected to the statement of claim. I start by repeating what is set out above under my analysis of s.5(1)(a): the statement of claim lacks a clear statement of the material facts concerning the off-label use claim. In paragraph 15 of the statement of claim the plaintiffs allege as follows:

> Seroquel is approved for use prescribed to combat schizophrenia and bipolar disorders. Seroquel is also marketed by the Defendants and prescribed by physicians for numerous "off-label" uses, including treatment for anxiety, sleep disorders, depression and dementia-related psychosis ("Off-label Uses"). Off-label Uses are not uses for which approval has been received from Health Canada.
>
> [Emphasis added.]

[256] It is alleged that the plaintiff Ms. Middleton was prescribed Seroquel in June 2005 for off-label uses described in para. 45 of the statement of claim as "stress and obsessive compulsive behavior", two uses not even referred to in paragraph 15 of the pleading.

[257] This demonstrates the lack of connection between this common issue and the representative plaintiff that purports to represent the off-label claims. There is no allegation, let alone any evidence, that the defendants promoted Seroquel to Ms. Middleton's physician for stress or obsessive compulsive disorder. Indeed, there is no evidence regarding the doctor's reasons for prescribing Seroquel to Ms. Middleton for off-label uses.

The Evidence – Off-Label Use of Seroquel

[258] There is evidence of numerous off-label uses for Seroquel. The expert evidence discloses at least 15 different types of off-label use: depression, substance abuse, post-traumatic stress, anxiety, behavioural disturbance in the elderly, autism, turrets, pervasive development disorders, control of impulsivity, agitation, sleep disturbance, aggression, dementia-related psychosis, obsessive compulsive disorder and other behavioural disorders.

[259] It is important to draw a distinction between the defendants' alleged off-label promotion, marketing, advertising, and/or recommending of Seroquel and the prescription of Seroquel for off-label uses by Canadian physicians. The evidence of both psychiatry experts, Dr. Chue and Dr. Wirshing, establishes that prescribing Seroquel for off-label uses is a common clinical practice that is regarded as acceptable within the medical community.

[260] Dr. Chue's evidence is that off-label use of second generation antipsychotics, including Seroquel, is a common, and indeed necessary practice. Physicians prescribe medicines that have not been approved for particular illnesses or patient groups, either because there are no approved medicines for a particular condition, or the medicines that are approved are ineffective or not tolerated in particular patients.

[261] Dr. Chue's evidence is that second generation antipsychotics have been widely used in the treatment of a variety of psychiatric disorders, including depressive disorders, substance abuse disorders, post-traumatic stress disorders, anxiety disorders, behavioural disturbance in the elderly, autism, turrets, pervasive development disorders, control of impulsivity, agitation, anxiety, sleep disturbance, aggression and behavioural disturbances in many different clinical situations. In his report Dr. Chue states as follows:

> These are off-label, non-approved indications, but nonetheless reflect widespread and generally accepted clinical practice because they are effective and helpful to patients suffering from these conditions. Physicians have a duty to treat illnesses, ameliorate symptoms and reduce distress, especially where not treating illnesses will have life-threatening consequences. Thus, on an individual basis, a trial of a medication on a risk-benefits basis is not only warranted, but required to reduce suffering, morbidity and mortality.

[262] Dr. Wirshing's opinion is that Seroquel has a unique receptor binding profile that gives it a broader range of properties than many of the antipsychotic medications. He testified that Seroquel's unique receptor binding profile and particular characteristics "encourages clinicians to use it for off-label uses." Dr. Wirshing has prescribed Seroquel for many off-label uses, including anxiety syndromes, affective syndromes, acute agitation, severe obsessive compulsive disease, panic syndromes, major depression and sleep.

No Evidence that Common Issue Exists

[263] The above evidence explains that there are many effective off-label uses for Seroquel. Further the evidence explains that such off-label use is widespread and generally accepted clinical practice. However, this is not some evidence to support the existence of this common issue. There is simply no evidence that the defendants or any of them, promoted, marketed, advertised, and/or recommend Seroquel for off-label uses in Canada or any evidence to suggest that such conduct is unlawful. Given the prevalence of off-label use by doctors one would think that the plaintiffs could present some evidence that the defendants promoted, marketed, advertised, and/or recommended off-label use of Seroquel in Canada. However, no evidence was provided.

[264] Dr. Plunkett is silent about this issue. Dr. Wirshing testified as follows:

> Q. You also said from your own experience which is considerable with this drug and this company, you were not of the view that AstraZeneca illegally promoted Seroquel off-label?
>
> A. Certainly not to me and not to my personal and specific knowledge.

Q. And the same is true obviously for Canada?

A. That's obviously true for Canada, yes, sir.

[265] The plaintiffs rely on evidence from Dr. Chue, Dr. Arnold and evidence about a settlement in the United States concerning Seroquel. A review of this evidence does not provide some evidence to support this common issue.

[266] Dr. Chue was asked during cross-examination about seminars or meetings that he attended in the United States that were organized and sponsored by what he loosely called AstraZeneca. Canadian and American doctors attended. He recalls that material about new indications for Seroquel would have been presented to the group of doctors during the meeting. The content of these seminars is approved by an agency in Canada called PAAB. It regulates how a drug company interacts with the doctors and the advertising that takes place. Dr. Chue stated that "I have never been in a meeting where any product has been promoted in terms of off-label use."

[267] The above evidence simply does not support this common issue. To the contrary, it is evidence that Dr. Chue never heard the defendants discuss off-label use and what the defendants told doctors during the seminars was regulated. Therefore it is not evidence of unlawful behavior.

[268] Dr. Arnold was asked about a document titled "Seroquel Commercial Brand Plan (2001)" and a section called "Contents - Seroquel Marketing Strategy, Seroquel Communication Strategy, Seroquel Operational Plan 2001," prepared by the Global Seroquel Commercial Team. Dr. Arnold agreed that this is an internal Seroquel document. It lists "Key Issues" including "Broaden the Seroquel use on and off label." Dr. Arnold does not know what this means.

[269] Under "Strategic Actions" the document states: "Broaden the use of Seroquel beyond its current label in a wide range of patient groups through aggressive communication of its unique profile, eg. mania, ADD, PDD." Dr. Arnold agreed that mania is a psychiatric condition and ADD may refer to Attention Deficit Disorder. He does not know what the Global Seroquel Commercial Team is but he surmised as follows:

> No, but I think we can surmise that within the Commercial function they have a team with global responsibility for the sales and marketing commercial plan for Seroquel, and my interpretation of this document is that it is very aspirational in nature. I have no idea how this communicated -- or how this developed into operational activities. This is just a plan.

[270] While this document talks about expanding the use of Seroquel and refers to off-label use, it was just a plan and it is not evidence of what happened in Canada.

[271] Dr. Arnold stated that the different defendant companies were structured so that that each had a "separate marketing company within each country and they are a business in their own right, with their own management structure, their own objectives....Sales and Marketing is you will have some sort of global strategy set by the center and then the local marketing company

will deliver the local operations." When Dr. Arnold was asked about the Global Seroquel Commercial Team he said that to his understanding it did not reflect what would have been done from a marketing perspective in Canada.

[272] The plaintiffs also rely on a Settlement Agreement from the settlement of the American Seroquel litigation. In the Settlement Agreement it refers to claims that AZ US promoted the sale and use of Seroquel for unapproved uses. AZ US settled the action without any admission of liability and paid $520,000,000. There are problems with this evidence. It was a settlement without an admission of liability and it involved allegations concerning the promotion and sale of Seroquel for off-label use in United States, not Canada. It cannot be used to satisfy the some evidence test in this Canadian action.

[273] In *Goodridge* at paras. 18-19, 36 and 41, Perell J. expressly rejected an attempt to use evidence about wrongful marketing activities in the United States as some evidence that it occurred in Canada. Evidence that the US company had paid a fine for wrongful off-label promotion of its drug and paid other amounts to settle civil liabilities, was rejected as some evidence to support an off-label use common issue in the Canadian action.

[274] I agree with and adopt the approach taken in *Goodridge*. The similarity between *Goodridge* and this case is apparent from paras. 18-19 and 36 in *Goodridge* as follows:

> As I have said, these wrongful marketing activities took place in the United States. On this certification motion, there is, however, no basis in fact to find that in Canada, Parke-Davis Canada was a participant in any of the activities promoting the off-label use of Neurontin. There is no evidence of any Canadian doctor or health practitioner having been influenced by any promotional activities emanating from the United States, and there is no evidence of any promotional activities taking place in Canada. ...
>
> Further, on this certification motion, there is no basis in fact for concluding that the Parke-Davis in the United States carried on any wrongful promotional activities in Canada. The Plaintiffs submitted that since Canadian doctors would have been aware of and have had available to them the publications and presentations in the United States, this amounted to the United States division of Parke-Davis promoting the off-label uses in Canada. I disagree, the marketing and promotion of Neurontin in Canada was conducted by and under the authority of Parke-Davis Canada, and there is no evidence of Parke-Davis Canada wrongfully promoting the off-label uses of Neurontin in Canada.
>
> ....
>
> Returning to the narrative, in May 2004, an information was laid against Pfizer Inc. in the United States District Court, District of Massachusetts, concerning Warner-Lambert's promotion of Neurontin for off-label uses in the United States, and the following month, Pfizer Inc. agreed, on behalf of Warner-Lambert, to plead guilty, and it agreed to pay a fine of more than $240 million and to pay amounts in settlement of civil liabilities...

[275] In this case, as in *Goodridge*, there is no evidence that AZ US was responsible for marketing activities in Canada. Dr. Arnold's evidence is that AZ Canada is a separate marketing company and while marketing strategy is created by a central global team, marketing in Canada is carried out by AZ Canada in accordance with Canadian regulations regarding promotional practices in the context of the Canadian PM. Nor is there any evidence that any physician in Canada was influenced by any off-label marketing by the defendants when deciding to prescribe Seroquel for off-label uses (assuming off-label marketing even occurred). As in *Goodridge*, the absence of such evidence is fatal to the certification of this common issue. I add that the above evidence distinguishes this case from *Andersen v. St Jude Medical Inc.*, 2010 ONSC 4708. In *Andersen*, there was evidence that the US parent company was responsible for the marketing activities of the Canadian subsidiary.

[276] In summary, there is simply no evidence that the defendants promoted, marketed, advertised, and/or recommended Seroquel for off-label uses. Assuming there was some evidence, there is simply no evidence of what might be "unlawful conduct."

No Commonality

[277] Even if there was some evidence of this common issue, there is no evidence that it is capable of being assessed in common. This is not a case where one type of off-label use is alleged.

[278] The common issue is presented in deceptively general terms. As Dr. Chue states at page 1982 of his report, Seroquel is used to treat a wide variety of illnesses as follows:

> ...in clinical practice, SGAs (and previously FGAs) have been widely used in the treatment of a variety of psychiatric disorders including depressive disorders, bipolar disorders all phases), substance abuse disorders, PTSD, anxiety disorders, behavioral disturbance in the elderly, autism, Tourettes, pervasive developmental disorder. They have also been used for the control of impulsivity, agitation, anxiety, sleep disturbance, aggression, and behavioral disturbances in many clinical situations (Beduin, 2010). These are off-label non-approved indications but nonetheless reflect widespread and generally accepted clinical practice because they are effective and helpful to patients suffering from these conditions.

[279] As noted, this evidence and the statement of claim disclose at least 15 different types of off-label uses for Seroquel. The broad nature of this allegation leads to lack of commonality. For example, if the defendants promoted Seroquel for use in treating substance abuse, the issue would not be an ingredient of a claim for a person who was treated for one of the other uses. For individuals like Ms. Martin who were prescribed Seroquel for an approved use, the issue of whether the defendants marketed Seroquel for non-approved uses is not an ingredient of their claims and is not necessary for the resolution of their claims.

[280] I reject this common issue.

Common issues 3 4 and 5 – Negligence issues

Common issue 3

Did the Defendants, or any of them, owe a duty of care to the Class in respect of the design, development, researching, testing, recommending, advertising, promoting and/or marketing of Seroquel as it relates to the risk of weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom? If so, what was the nature of the duty?

Common issue #4

Did the Defendants, or any of them, owe a duty to the Class to warn that Seroquel can cause weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom, and if so, when did the duty to warn arise?

Common issue # 5

If the answer to #3 and/or #4 is yes, did the Defendants, or any of them, breach such duty? If so, what was the nature of the breach?

[281] Common issues 3 and 4 and 5 are the negligence issues. The plaintiffs rely on what they call three areas of evidence to support these three issues. It is set out in their factum as follows:

> 1. Seroquel was introduced into the Canadian market in 1997. The chemical composition of Seroquel has remained the same since its introduction to market. While the level of knowledge may have changed over time, the possible side-effects associated with the use of Seroquel have not.
>
> 2. The approved target market for Seroquel has a number of risk factors for weight gain and metabolic disturbances. These risk factors may inform the appropriate standard of care.
>
> 3. The defendants are in possession of substantial information and data regarding the health risks associated with the consumption of Seroquel that is not available to the Class Members or the public. This information includes clinical data, results of internal studies, discussions with physicians and regulatory authorities, and adverse events data. This knowledge imbalance may inform the appropriate standard of care.

[282] Point 1 does not offer any evidence of these common issues. The date of Seroquel's introduction in the market place and its chemical composition is not some evidence of negligence or duty to warn. The third sentence in point 1 is simply a statement and counsel has not offered any source in the evidence to back this up. Point 2 also offers no evidence of these common issues and the second sentence is argument. Point 3 is not evidence but simply argument. The plaintiffs offered no evidence reference for these statements.

[283] It is worth noting that there is no common issue that asks if Seroquel is defective. As well, the statement of claim does not allege that this drug was defective. Such a question might ground the commonality of the negligence common issues. However, it is absent in this case because there is no evidence that would support such a question. To the contrary, the evidence from all of the experts is that Seroquel is an effective drug.

[284] The following review demonstrates that there is no evidence to show these common issues exist and are capable of being assessed in common.

Common issue 3

[285] Assuming there was some evidence to support this common issue, it would be impossible to manage it in common because the issue lumps all defendants and different types of negligence together and draws no distinction between approved uses and off-label uses of Seroquel.

[286] Dealing with common issue 3, the plaintiffs' own expert, Dr. Wirshing, gave the opinion that there is no issue about the research, design, development, marketing or testing of Seroquel. He testified as follows:

> Q. Okay. And just to knock off a few random points, Dr. Wirshing, you don't have any criticisms of AstraZeneca in respect to the research, design, development, pre-marketing, testing, that it carried out on Quetiapine?
>
> A. I don't believe I ever expressed an opinion in that regard, and certainly don't have any off the top of my head now.

[287] On his cross-examination, Dr. Wirshing also expressed the following opinions concerning Seroquel:

- Dr. Wirshing has no issue with the fact that Health Canada and the FDA approved Seroquel as being safe and effective for its indicated uses.
- Seroquel is safe and effective for its indicated uses.
- Seroquel is a useful medicine that works and is reasonably well-tolerated.
- Seroquel has good efficacy for both schizophrenia and bipolar disorder and is in the "upper tiers" amongst the other second-generation antipsychotics available in Canada in terms of its tolerability. It is a medicine that has very reasonable subjective tolerability.
- In his practice he prescribes Seroquel to approximately 15 to 20% of his patients for both on-label and off-label uses. He has prescribed Seroquel to approximately 10,000 patients and is of the opinion that its benefits outweigh its risks for many of his patients.

[288] Dr. Chue's evidence must also be considered because it shows that there is no evidence to support this common issue. In his report, at pg.13-14 Dr. Chue states :

> It is generally accepted in clinical practice that Seroquel has a more benign side effect profile than the other SGAs in Canada with low risks compared to others of agranulocytosis (Clozaril), cardiomyopathy (Clozaril), weight gain (Clozaril, Zyprexa), DM (Zyprexa, Clozaril), movement disorder (Risperdal, Invega), hyperprolactinemia (Risperdal, Invega), sexual dysfunction (Risperdal, Invega) and QTc prolongation (Zeldox, Invega).

In 2003, an Expert Review Panel of the Canadian Psychiatric association (CPA) on Efficacy and Effectiveness concluded in a report published in the Canadian Journal of Psychiatry that (Lalonde, 2003):

> *In terms of tolerability and safety, there are greater variations between the agents. Clozapine is associated with a minimal, yet definite, risk of life-threatening blood dyscrasias, which can be safely prevented by regular blood monitoring. Risperidone's tendency to cause EPS and hyperprolactinemia similarly limits its tolerability and acceptability for certain patients. Olanzapine may cause significant dosage-related EPS and weight gain and has also been linked to diabetes mellitus and hypertriglyceridemia. Of the 4 agents, quetiapine's tolerability and safety profile is the most benign.*

Seroquel is frequently chosen as a preferred treatment option in patients at risk of certain side effects, or for patients who have already experienced side effects with other SGAs.

The 2003 Expert Review Panel report also stated that:

> *... In addition, its favourable tolerability make it the atypical least likely to degrade quality of life for most patients with side effects. For some, however, quetiapine-associated somnolence can initially decrease their quality of life.*
>
> *The efficacy and tolerability profiles of quetiapine make it an attractive option in terms of patient acceptability.*
>
> *... Quetiapine's efficacy has been documented in a number of different settings and its favourable relative to the other atypical antipsychotics is particularly appealing for acceptability in the long-term.*

[289] Even if there was some evidence to support common issue 3, it fails because it is overly broad. Eight different activities are listed which would require an inquiry into the defendants' activity for each one over a 14 year period. In essence, it is a common issue that asks multiple questions.

Common issue 4 – Duty to Warn

[290] The last part of this question asks "when did the duty to warn arise." It assumes there is a single duty to warn. This ignores the fact that AZ Canada has an ongoing duty to warn. Further the evidence is clear: there was an evolution of knowledge and the question cannot be asked at one single point in time. The product monograph changed at different points in time and addressed weight gain and diabetes differently. There cannot be a single answer to this question that applies to the class for weight gain and diabetes. The lack of commonality is obvious.

Warnings re Weight Gain

[291] Dealing specifically with the first part of common issue 4 and failure to warn, there is simply no evidence to support this issue. To the contrary, there is evidence that warnings were given for diabetes and weight gain. There is no evidence that these warnings were inadequate. The extensive evidence regarding the warnings is set out below.

Summary of the Warnings – Weight Gain

[292] The defendants' warnings are set out in the product monographs that Health Canada approved. Anne Tomalin states that since the introduction of Seroquel and Health Canada's approval of the first product monograph, the product monograph has been updated 25 times and at least 19 of the updates have contained safety information within a 13 year period.

[293] A weight gain warning was in the initial product monograph in 1997. In his affidavit, Dr. Arnold describes the warnings for weight gain and the amendments over time. An excerpt from his affidavit follows (his use of "NDS" means New Drug Submission):

> **1996 NDS and December 1997 Product Monograph**
>
> In the NDS filed with Health Canada in 1996, weight gain was noted as one of the important side effects seen in the clinical trials. Section 19.1.7 of the NDS stated that a statistically significantly greater proportion of subjects treated with SEROQUEL, compared with subjects treated with placebo, developed clinically significant weight gain (Exhibit C).
>
> The initial SEROQUEL Product Monograph, dated 2 December 1997, included information on weight gain in both the Precautions and Adverse Reactions sections (Exhibit B). Under Precautions, the Product Monograph stated as follows:
>
> **Weight Gain**
>
> SEROQUEL was associated with weight gain. In clinical trials mean weight gain after 4-8 weeks of treatment was approximately 2.1 kg, after 18-26 weeks, 3.5 kg, and at 1 year, 5.6 kg.
>
> The Adverse Reactions section of the monograph stated:
>
> Weight Gain: As with other antipsychotics, SEROQUEL may be associated with weight gain. During acute therapy (up to 6 weeks) in placebo-controlled clinical trials, mean weight gain in patients taking SEROQUEL was 2.3 kilograms compared to a mean weight gain of 0.1 kilograms in patients taking placebo. In long-term trials average weight gain was 5.6 kilograms after one year of treatment (see PRECAUTIONS).

The Adverse Reactions section also included a table setting out certain adverse events reported in short-term, placebo-controlled Phase II-III schizophrenia trials, which included weight gain.

2 August 2002 Product Monograph

"Weight gain" was included in the list of possible side effects of SEROQUEL in the Information for the Consumer section that was introduced in the Product Monograph on 2 August 2002. Attached hereto and marked as Exhibit M is a true copy of the 2 August 2002 SEROQUEL Product Monograph.

24 September 2003 Product Monograph

On 24 September 2003, the Product Monograph was updated to incorporate weight gain data obtained from several uncontrolled, open label trials. The materials submitted to Health Canada for this label change included a PSUR, dated 14 September 2002; a SERM Justification Document; and clinical trial summaries. Attached hereto and marked as Exhibit N is a true copy of the 24 September 2003 SEROQUEL Product Monograph.

The weight gain data was revised in both the Precautions and the Adverse Reactions sections of the 24 September 2003 Product Monograph.

5 November 2004 Product Monograph

Health Canada approved AstraZeneca Canada's submission for a bipolar disorder - mania indication on 5 November 2004. The Product Monograph was updated in both the Precautions and Adverse Reactions sections to include additional weight gain data from the bipolar mania clinical trials. Weight gain was listed as a commonly observed adverse event in the short-term placebo-controlled bipolar disorder - mania trials, that being a side effect that occurred in 5% or more patients. Attached hereto and marked as Exhibit O is a true copy of the 5 November 2004 SEROQUEL Product Monograph.

6 March 2007 Product Monograph

In the Product Monograph, dated 6 March 2007, the Information for the Consumer section was updated to describe weight gain as a "common" side effect. Attached hereto and marked as Exhibit P is a true copy of the 6 March 2007 SEROQUEL Product Monograph.

18 August 2008 Updated Weight Gain Data in Conjunction with new Indication for Bipolar Depression

On 18 August 2008, Health Canada approved SEROQUEL for use of in the treatment of bipolar depression and approved a revised Product Monograph, which included weight gain data from the bipolar depression clinical trials.

Attached hereto and marked as Exhibit Q is a true copy of the 18 August 2008 SEROQUEL Product Monograph.

The new weight gain data was added to the Warnings and Precautions and the Adverse Reactions sections of the Product Monograph.

19 May 2009 Product Monograph Safety Update

AstraZeneca Canada filed a Notifiable Change Submission on 18 December 2008 to revise the SEROQUEL Product Monograph based on recent safety updates to the CDS following a SERM meeting on 9 July 2008. The revised Product Monograph was approved by Health Canada on 19 May 2009. Attached hereto and marked as Exhibit R is a true copy of the 19 May 2009 SEROQUEL Product Monograph.

Information about the cumulative results of all clinical trials on the frequency of clinically significant weight gain (based on 7% increase from baseline) that occurred in 9.6% of SEROQUEL-treated patients and 3.8% of placebo-treated patients was added to the Product Monograph at that time.

In addition, the revised Information for the Consumer section stated that weight gain has been reported "very commonly" in people taking SEROQUEL.

SERM's Consideration of Weight Gain

Weight gain data has been reviewed by SERM on three occasions (June 2000, February 2002, and July 2008). AstraZeneca Canada provided to Health Canada safety updates which included weight gain data (e.g., results from ongoing clinical trials and analyses of other published studies), on an ongoing basis.

[294] Dr. Chue also reviews the warnings for weight gain in part 6 of his report as follows:

The original product monograph of December 2, 1997 reported weight gain and included data from the pre-registration clinical trials. Since 1997, the product monograph on weight gain has been updated to include data from clinical trials in 2003, and data from clinical trials for the bipolar disorder indications in November 2004 and August 2008. Further clinical trial data was added in May 2009. In addition, the information for the consumers section of the product monograph which was added to the monograph in 2002, contained the notation of "some weight gain" as a "possible side effect". This notation was revised in March 2007 to a "common" side effect, and revised again in May 2009, with the statement that weight gain has been reported "very commonly" in people taking Seroquel.

Weight gain is a recognized side effect of Seroquel and indeed, most psychotropic agents including the SGAs (Rummel-Kluge, 2010). From the literature and clinical experience, weight gain occurring with Seroquel is significantly less than

> with Clozaril or Zyprexa and comparable with Risperdal in keeping with the generally accepted hierarchy of association. This is a clinical scenario where order of treatment plays a role since weight gain or weight gain trajectory established on a previous treatment is very difficult to reverse. Metabolic side effects can easily be misattributed to the new medication rather than the medications switched from.
>
> Furthermore, overweight and obesity are more prevalent in patients with schizophrenia and particularly bipolar disorder because of the illness itself, lifestyle and treatments. Of note, patients who are underweight before starting treatment may benefit from a treatment that restores normal body weight. Thus, appropriate treatments should avoid combinations of weight gain-inducing drugs and patients should be appropriately screened and counselled before starting treatment. Thereafter patients should be closely monitored according to a protocol and counselled throughout treatment with attention paid to the complications of weight gain and obesity. Patients should be referred for dietary and exercise consults and multidisciplinary programming provided to help patients manage weight gain through lifestyle change.
>
> In my clinical experience, weight gain with Seroquel is manageable and is rarely a reason for discontinuation.

[295] There is no evidence from the plaintiffs' experts to support this common issue. I have ruled that Dr. Plunkett's evidence is not admissible. However, even if it is admissible Dr. Plunkett offers no opinion at all about the warnings for weight gain.

[296] In Dr. Wirshing's affidavit he states that the "dataset that AstraZeneca had compiled on [Seroquel] prior to its launch in December 1997 in Canada clearly indicated that clinically significant weight gain was a common side effect of [Seroquel]." He acknowledges that the weight gain data was "detailed in the Canadian package insert from launch in 1997." What he calls the "package insert" and then the "product label" must be the product monograph since he reviewed all of them. He concludes in the report that the "product label" for diabetes was inadequate for diabetes. He does not include weight gain in this opinion.

[297] When Dr. Wirshing was cross-examined he stated that, in his opinion, the information regarding weight gain in the Canadian Seroquel PM was adequate from the outset. He testified as follows:

> Q. It's not your opinion that the Canadian product monograph warnings, let me restate it. You don't have the opinion that the Canadian product monograph warning in respect to weight gain was inadequate?
>
> A. ... As I recall, the Canadian label – the Canadian label has had a warning, albeit at a variable weight gain since the very beginning.
>
> Q. Right. And the warning since the very beginning on weight gain, you considered to have been adequate?

A. Correct. As I know from the reading of it, there was some discussion as to whether it was appropriate to change the magnitude of that warning.

Q. Right.

A. But the placement of the warning in that location is appropriate and yes, I have no specific complaints about that.

Warnings re Diabetes

[298] A diabetes warning (including exacerbation of diabetes, hyperglycaemia, diabetic ketoacidosis, diabetic coma, and death) was added to the product monograph on December 16, 2003 at the request of Health Canada as part of class-wide labeling for second generation antipsychotics. The warning was expanded on two occasions – April 25, 2005 and October 9, 2007. To be clear this means that from 1997 (when Seroquel was first approved for use) until December 2003, the Seroquel product monograph did not contain any warning about diabetes.

[299] Dr. Arnold offers a detailed review of the warnings and the reasons for same. An excerpt from his affidavit follows. Speaking about the 2003 "labeling" (a generic term for the product monograph) he states:

> 140. On or about 18 September 2003, Health Canada formally advised AstraZeneca Canada that it was implementing class labelling in Canada for the atypical antipsychotics in regard to glucose/diabetes. Health Canada advised AstraZeneca Canada that the class labelling was based on data available to Health Canada pertaining to all of the atypical antipsychotics. AstraZeneca did not have access to all of the data available to Health Canada, including the data submitted to Health Canada by the other manufacturers.
>
> 141. On 20 November 2003, AstraZeneca filed a Notifiable Change Submission to revise the SEROQUEL Product Monograph in accordance with the class labelling change regarding the use of antipsychotics and glucose dysregulation.
>
> 142. With this Submission, AstraZeneca Canada provided Health Canada with the 24 July 2003 Glucose Dysregulation Position Paper and the 22 September 2003 PSUR.
>
> 143. These revisions to the SEROQUEL Product Monograph were approved by Health Canada, effective 16 December 2003. Attached hereto and marked as Exhibit F is a true copy of the 16 December 2003 SEROQUEL Product Monograph.
>
> 144. A new section entitled "Hyperglycaemia" was added to both the Precautions and Adverse Reactions sections of the Product Monograph, which stated that exacerbation of pre-existing diabetes, hyperglycaemia, diabetic ketoacidosis, and diabetic coma, including some fatal cases, have been reported

very rarely with SEROQUEL use. Clinical monitoring was also recommended in patients with diabetes or with risk factors for diabetes.

145. In addition, the Information for the Consumer section was updated to recommend that, before starting SEROQUEL, patients tell their doctor if they have diabetes or a family history of diabetes.

[300] Speaking about the April 2005 revisions to the product monograph Dr. Arnold states:

Further Class Labelling Change regarding Hyperglycaemia: 25 April 2005

157. On 24 January 2005, Health Canada asked AstraZeneca Canada to file a further Notifiable Change in order to implement another class labelling update for all atypical antipsychotics to incorporate the wording from the U.S. class labelling regarding hyperglycaemia.

158. The wording for the label change was provided to AstraZeneca Canada by Health Canada. The additional text included more details regarding recommendations for clinical monitoring of patients treated with atypical antipsychotics. It also acknowledged that the relationship between atypical antipsychotics and hyperglycaemia is not completely understood.

159. AstraZeneca Canada implemented the proposed change to the SEROQUEL label, but informed Health Canada of our assessment that the data did not establish a causal relationship between SEROQUEL and diabetes.

160. The revised Product Monograph was approved by Health Canada on 25 April 2005.

[301] Speaking about the October 2007 revision to the product monograph Dr. Arnold states:

179. On 28 June 2007, AstraZeneca Canada submitted a Notifiable Change Submission to revise the SEROQUEL Product Monograph to accord with the changes to the CDS covering the glucose data from Trials 125, 126 and 127. The Submission included a Clinical Overview, entitled "Glucose Dysregulation", dated June 2007, which set out the rationale for the proposed label change.

180. The label change was approved by Health Canada on 9 October 2007. A reference to increases in blood glucose and hyperglycaemia, and occasional reports of diabetes, in clinical trials with SEROQUEL was added to the Warnings and Precautions section. In addition, the Warnings and Precautions section cross-referenced the new glucose data in the "Adverse Events" section which described the data from Trials 125, 126 and 127 of the label. The Information for the Consumer section was also revised, including a reference that increases in blood glucose and hyperglycaemia and occasional cases of diabetes have been reported with SEROQUEL.

[302] Dr. Plunkett discusses the Seroquel labeling for diabetes in her affidavit. I have ruled that Dr. Plunkett's evidence is inadmissible. If I am wrong, her evidence is not helpful and cannot assist the plaintiffs despite the low burden that applies. I say this for the following reasons.

[303] What did Dr. Plunkett review to offer her opinion about the warnings? Dr. Plunkett states in her affidavit that she reviewed the "labeling for Seroquel as provided in the Physicians' Desk Reference." This is the American equivalent to the Compendium of Pharmaceutical Specialties ("CPS"). It is not the product monograph, the warning that all drug manufacturers use and that Health Canada approves. As Anne Tomalin states, this American document has "no relevance in Canada." Dr. Plunkett states that she has also reviewed the regulations of the "U.S. Food and Drug Administration relating to the development, approval, labelling and marketing of prescription drug products but not the regulations of Health Canada." As well she says that she reviewed "warnings provided by Health Canada" regarding Seroquel.

[304] Dr. Plunkett then states in para. 38 of her affidavit that she looked at the "most recent product monograph for Seroquel" and in her opinion "the warnings related to hyperglycemia and diabetes ...are not adequate to convey the risks posed by Seroquel itself." She has two criticisms. First, she says that "[i]n the health professional section of the monograph, the discussion of hyperglycemia and diabetes is put forth as an effect of anti-psychotics in general only [and not specific to Seroquel] and second she says that "the monograph section intended for consumers fails to even mention these health risks."

[305] With this in mind I turn to her cross-examination evidence. When asked about what product monograph she looked at she said that she "would have to go back to [her] files." Defence counsel tried to clarify which product monograph she based her opinion on. She was shown the October 9, 2007 product monograph. This was the product monograph in place when she swore her affidavit on November 23 2007. It was at that time the "most recent product monograph" for Seroquel. It was posted on the Health Canada website that Dr. Plunkett said she accessed to get the product monograph.

[306] Although she stated in her affidavit that the product monograph had no information for consumers, this is not accurate. She agreed on cross-examination that the October 2007 product monograph does include a consumer section that sets out health risks.

[307] Dr. Plunkett's second criticism is that the warnings for diabetes were not specific to Seroquel. This is simply wrong. Dr. Plunkett agreed on cross-examination that the October 2007 product monograph does include Seroquel specific information.

[308] If Dr. Plunkett meant to address her criticism to an earlier product monograph, this was never stated, not even on re-examination. It is worth noting that the previous 2005 product monograph also had consumer information about diabetes and it had a warning specific to Seroquel.

[309] In summary, even if Dr. Plunkett's evidence is admissible, it does not assist the plaintiffs.

[310] Dr. Wirshing's opinion was served as reply evidence. In paragraph 51 and 81(c) of his affidavit he discussed the Seroquel warnings for diabetes as follows:

> Although the current label warns reasonably about the risks of diabetes and increases in cholesterol and triglycerides, AstraZeneca continues to flatly deny that [Seroquel] causes diabetes. Further, the current warning about hyperglycemia and diabetes is a comparatively recent addition--despite the fact that this expected toxicity (i.e., weight gain) was known (or should have been known) to the company since before launch in 1997.
>
> Their product label has, until recently been inadequate in its warnings about the impact on lipid and glucose metabolism, hyperglycemia, and diabetes.

[311] Dr. Wirshing was cross-examined about this evidence to clarify what product monograph he was referring to. Although he swore the affidavit in 2011, he was actually referring to the October 2007 product monograph. He agreed that he has no criticism of this 2007 product monograph as follows:

> Q. So from and after October of 2007, you have no criticism of the Canadian product monographs warning with respect to glucose, hyperglycemia, and diabetes?
>
> A. True.

[312] This confirms that there is no basis in the evidence for a failure to warn common issue from October 2007 forward.

[313] Defence counsel then questioned Dr. Wirshing about the time frame prior to October 2007. When cross-examined, Dr. Wirshing confirmed that he has no criticism of the absence of a diabetes warning from 1997-2002:

> Q. But it is true that for the first, say, five years. So from 1997 to 2002, you don't have a criticism of the absence of a warning about diabetes in the Canadian product Monograph?
>
> A. Yeah. It's a very fair question as to where that number lies. And given the overall environment, that's probably true. It's a disappointment for me to say that because I believe that all of the companies, AstraZeneca included, knew about the risk before 2002. If we're looking at all of the realities of the world that we live in and the competitive environment, I would be comfortable with 2001, certainly.

[314] So in the above exchange Dr. Wirshing first agrees that he has no criticism of the Seroquel product monograph from 1997-2002, but then he says he would be more comfortable with it from 1997-2001. However, he does not explain why he is more comfortable with it in 2001 than in 2002.

[315] The cross-examination continued and Dr. Wirshing was asked about the period from 1997-2001. It was noted that Dr. Wirshing did not discuss the 2003 product monograph in his report. When asked if the 2003 product monograph was an adequate warning, he said it was a

"clear improvement" but criticized this 2003 warning because in his view it was a "class" warning (i.e. warned about the risk of diabetes for the class of drugs and did not warn about diabetes specific to Seroquel.) However, cross-examination revealed that Dr. Wirshing was wrong because the 2003 product monograph does include data specific to Seroquel. Dr. Wirshing was given a chance to read the wording of the 2003 product monograph and he agreed that it spoke specifically about Seroquel.

[316] This narrowed the window of possible evidence from Dr. Wirshing regarding the failure to warn from 2001 to 2003 or 2002 to 2003. Dr. Wirshing never offers any evidence to explain why he is critical of the lack of warning from 2001-2002. So we are left with his bald statement and no explanation for why he feels more comfortable with the warning in 2002 rather than the one in 2001.

[317] Dr. Wirshing is not new to the Seroquel litigation. He filed an affidavit in the U.S. litigation and on agreement this is the affidavit that was filed in reply in this Ontario action. He has had every opportunity to address the warning issue with clarity and in particular explain his bald statement. While I recognize that the burden on the plaintiffs to offer some evidence is low, this bald statement is seriously deficient and cannot be used to satisfy the some evidence test. This is particularly so when the following evidence is considered.

[318] In 2003, a Consensus Conference reviewed the connection between the second generation antipsychotic drugs and diabetes and weight gain. A writing committee at the Conference published a report. Dr. Barrett was on this Committee and he reviewed the Conference and the report in his March 4, 2011 report as follows:

> The conference was convened in November 2003. I had the responsibility of chairing the writing committee. Prior to the conference, the writing committee reviewed the peer-reviewed literature related to second-generation antipsychotics. The committee consisted of endocrinologists, psychiatrists and obesity specialists. Presentations were made by investigators from the scientific academic community, pharmaceutical companies including Pfizer, Bristol-Myers Squibb, AstraZeneca, Eli Lilly, and Janssen, and the FDA related to extant data on the safety and efficacy of second-generation antipsychotics. The Consensus Statement was subsequently published in the journals Diabetes Care and the Journal of Clinical Psychiatry in February, 2004.

[319] After reviewing the extensive medical literature available at that time, Dr. Barrett states that the committee felt there was "sufficient data to suggest an association between both obesity and diabetes for two second-generation antipsychotic agents, specifically clozapine and Zyprexa. The committee was not prepared to make the same finding for four others, finding the evidence either lacking or not sufficiently persuasive." For Seroquel, the committee found that there was "evidence of an association with modest weight gain but the evidence was discrepant regarding allegations of an association with diabetes or glucose dysregulation." Despite the discrepant evidence the defendants nevertheless included a specific warning in the product monograph in 2003.

[320] In the face of this evidence from a panel of numerous experts, it cannot be suggested that Dr. Wirshing's bald statement offers some evidence of the failure to warn issue for the period of 2001-2003. The low burden requires something more than a bald statement from an expert witness who had every opportunity to explain himself.

[321] It is worth noting that it is a struggle to understand what the plaintiffs' experts have to say about the failure to warn issue. On such a key issue in this case, the plaintiffs argue that there is some evidence to support the failure to warn common issue. However, when the reader puts the pieces of this evidence together (without embarking on any weighing of the evidence) it becomes apparent that there is no evidence to support this core issue.

There is no Commonality in common issues 4 and 5

[322] The duty to warn common issue is not common to the class. To ask if the defendants owed a duty to warn the class cannot be answered in the abstract. The issue is too broad and offends the principle in *Rumley* as stated in para 29:

> 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.

[323] This common issue would result in an answer that is so general it would have no impact on the litigation. It would do nothing to advance the claims of the class. It is not even common as between the representative plaintiffs. The issue is stated in the broadest possible terms and masks the individual inquires that are required.

[324] As noted, the plaintiffs first proposed a group of common issues that focused on a long list of health risks. This was then narrowed on reply to weight gain diabetes and the unclear phrase "and/or related metabolic disturbances as well as secondary injuries flowing therefrom."

[325] The narrowing of the health risks in the common issues to diabetes and weight gain means that all of Ms. Martin's health risks are dropped except for weight gain. She does not allege diabetes. It is not an ingredient of her claim. Even more problematic, there is no evidence to anchor her weight gain claim.

[326] Properly understood, the duty to warn issue is not a single question for the entire class. You cannot owe a duty to an amorphous class of people that are situated differently. There is evidence of this lack of commonality in Dr. Barrett's report in section 2D as follows:

> Each disorder has its own population prevalence, constellation of predisposing factors, pathogenesis and natural history. As such it is clear that to evaluate the possible relationship between each alleged health risk and Seroquel, it will be necessary to consider the known natural history and prevalence of each disorder, the known risk factors for developing that disorder and diagnostic characteristics used to diagnose the specific disorder and how each of these are reflect in the medical history and presentation of individual patients

[327] There can be no single duty owed to the class as a group. Consider the variability of this case. The common issues describe two specific health risks (diabetes and weight gain). The warnings for diabetes are not the same as the warning for diabetes. For each risk the warnings changed over time. There are 15 different types of uses. Three are approved and the rest are off-label.

[328] In summary, there is no evidence to support this common issue or show that it can be managed in common. It is rejected.

Common issues 6 and 7 –Conspiracy Claim

Common issue # 6

Did the Defendants, or any two or more of the Defendants, act in combination to conceal information from the Class and/or Health Canada relating to the safety and efficacy of Seroquel, as it relates to weight gain, diabetes and/or related metabolic disturbances as well as secondary injuries flowing therefrom?

Common issue # 7

If the answer to #2 and/or #6 is yes, was the Defendants' conduct unlawful in that it violated the Food and Drugs Act or the Food and Drug Regulations?

[329] As noted in the s. 5(1)(a) analysis, there are 5 elements to an unlawful conduct conspiracy claim. This common issue only covers two of the five elements: did they act in combination to conceal information and was this conduct unlawful. As a result, this common issue as framed cannot decide the conspiracy claim.

[330] The plaintiffs describe seven pieces of evidence to support the conspiracy common issue. The following three clearly have nothing to do with concealing information. They are stated in para. 162 of the plaintiffs' factum as follows:

> d) The Defendants' internal emails confirm that their own commercial interests governed the company's direction with respect to scientific research, dissemination of critical information, and product labelling;
>
> f) The Defendants agreed to award funding for preclinical work based on the work's ability to demonstrate a competitive advantage for Seroquel. If the preclinical work risked results that were not clearly advantageous to Seroquel, funding was denied; and,
>
> g) In April 2001, the Defendants considered the removal of the descriptor "limited" before "weight gain" in the Seroquel CDS. The Defendants' commercial team successfully resisted the amendment on the basis that it might damage Seroquel, despite the concerns raised by the Defendants' corporate representative, Dr. Arnold.

[331] The remaining four pieces of evidence as set out in the plaintiffs' factum appear to talk about concealment. The evidence is described as follows:

a) As set out above, the evidence indicates that the Defendants may have violated s. 9 of the Food and Drugs Act through their off-label marketing of Seroquel and in failing to warn of the health risks associated with the use of Seroquel;

b) As set out above, the Defendants' internal documents reveal that they acted together to conceal unfavourable studies, cherry-pick data, reject research that could result in unfavourable findings and downplay significant negative data;

c) In 1997, the Defendants used a "smoke and mirrors job" to conceal a "cursed study" from U.S. and Canadian regulators;

e) The Defendants' internal emails confirm that the Defendants buried a number of trials that yielded unfavourable results, including Trials 15, 31, 56, and a trial called "COSTAR", and cherry-picked and suppressed data;

[332] It is important to look at the actual evidence that points a, b, c and e refer to. There are two documents that the plaintiffs rely on as some evidence of concealment. Both documents were obtained from the files of AZ US in the US Seroquel litigation.

[333] The first is an "Internal Memorandum" from Richard Lawrence dated February 12, 1997. The plaintiffs assert that this document is some evidence that the defendants concealed a study (Study 15) from Health Canada. The memorandum states as follows:

> Subject: US/Canada Investigator Meeting and Study 15
>
> I am not 100% comfortable with this data being made publically available at the present time...however I understand that we have little choice .... Lisa has done a great "smoke and mirrors" job!
>
> Adopting the approach Don has outlined should minimize (and dare I venture to suggest) could put a positive spin (in terms of safety) on this cursed study.
>
> Athena, with Mark Sahl having left I am not certain who is replacing him. Whoever it is ... ought they speed a reserve press release through?
>
> Richard

[334] The "cursed study" is Study 15 noted in the reference line. The memorandum was sent to eight people. Plaintiffs' counsel marked the Internal Memorandum as an exhibit on Dr. Arnold's cross-examination but did not ask him any substantive questions about it. This memorandum makes no reference whatsoever to concealing information from Health Canada.

[335] The second document that the plaintiffs rely on is an email chain which contains an email from John Tumas to a group of people in December 1999. He uses the word "buried" in relation to three studies. The relevant excerpt is as follows:

> There has been a precedent set regarding "cherry picking" of data. This would be the recent Velligan presentations of cognitive function data from Trial 15 (one of the buried trials). Thus far I am not aware of any repercussions regarding interest in the unreported data.
>
> That does not mean that we should continue to advocate this practice. There is growing pressure from outside the industry to provide access to all data resulting from clinical trials conducted by industry. Thus far we have buried Trials 15, 31, 56 and are now considering COSTAR.
>
> The larger issue is how do we face the outside world when they begin to criticize us for suppressing data. One could say that our competitors indulge in tis practice. However until now, I believe we have been looked upon by the outside world favorably with regard to ethical behavior. We must decide if we wish to continue to enjoy this distinction. The reporting of COSTAR results will not be easy. We must find a way to diminish the negative findings. But in my opinion we cannot hide them.

[336] In the chain of emails is a response from Jim Gavin who talks about the data from COSTAR. He states that selectively using data from COSTAR "is pushing it too far in my opinion and might prove extremely damaging in the long term...and would destroy our current high standing in the publishing community."

[337] Dr. Arnold was not asked if any of the people referred to in these documents worked for AZ Canada. He was not asked any substantive questions about the content of these documents.

[338] There is no question that these two documents talk about the studies being buried and suppressing data. However there is no evidence about the nature of the information that was buried or concealed. These documents do not say that the studies were concealed from Health Canada. Further these documents do not talk about concealing information relating to the "safety and efficacy of Seroquel, as it relates to weight gain, diabetes" which is the focus of this common issue. Further there is no evidence that AZ Canada was involved or that any of the matters referred to in the documents occurred in Canada.

[339] The defendants' evidence from Dr. Arnold and Ann Tomalin (that is not challenged) refutes the plaintiffs' position that these documents offer some evidence of conspiracy. While the above memorandum and emails talk about study 15 being buried, it is the evidence of Dr. Arnold and Ann Tomalin that this study was given to Health Canada.

[340] Dr. Arnold was the global Head of Drug Safety for the defendants for the majority of the period of time in question. Dr. Arnold expressly states that AstraZeneca at all times acted in the interests of patient safety in relation to its consideration of Seroquel's safety. He also states that AstraZeneca "at no time misinformed or failed to inform Health Canada, Canadian physicians or

patients of the true safety profile of Seroquel as known and understood by AstraZeneca based on... evaluation of the currently available scientific knowledge and data." Ann Tomalin, the Canadian pharmaceutical regulatory specialist reviewed all of AstraZeneca's submissions to Health Canada. In her opinion, AstraZeneca Canada complied fully with its regulatory obligations. Ms. Tomalin was not cross-examined.

[341] Dr. Arnold explains that the trials 15, 31, 53 and 56 were schizophrenia related efficacy studies. Study 15, the one that is described as being buried, was in fact given to Health Canada. It is listed in the table of contents that accompanied the New Drug Submission to Health Canada for Seroquel in September 1996. Dr. Arnold and Ann Tomalin both confirm that study 15 was part of this submission to Health Canada. Additionally, AZ Canada filed an Integrated Summary of Safety Information with Health Canada as part of the New Drug Submission for Seroquel and this contained efficacy and safety data from Trial 15.

[342] The evidence from Dr. Arnold and Ms. Tomlin explains that trials 31, 53 and 56 were not part of the pre-registration clinical trial program. They were efficacy studies not designed to support a new indication, so there was no requirement to submit these reports to Health Canada. In any event, AZ Canada submitted: (a) an interim report for and weight gain data from Study 31 to Health Canada; (b) weight gain data from Study 53 to Health Canada; and (b) the full clinical Study 56 to Health Canada. Therefore, as Ms. Tomalin states, these studies, including Study 15, were not concealed from Health Canada. In addition, the serious suspected adverse drug reactions that occurred in these trials were shared with Health Canada.

[343] The evidence also establishes that the defendants' decision to not submit these four studies for publication in journals was appropriate and consistent with industry standards at the time. It is Ms. Tomalin's opinion that there was no requirement at the time to publish all clinical studies in Canada, and it was not industry practice to do so. Dr. Arnold's evidence is that Trials 15, 31, 53 and 56 were not submitted to journals for publication because the studies failed to prove their hypotheses, or suffered from design flaws. This was consistent with the pharmaceutical industry practice at the time.

[344] In summary, the Internal Memorandum and emails that the plaintiffs rely on for the conspiracy common issue do not provide some evidence to support common issue 6. Lastly the plaintiffs provided no evidence that any of the defendants' conduct was unlawful in that it violated the Food and Drugs Act or the Food and Drug Regulations.

Common issues # 8 – 13 Remedial Issues

8 - Can the Class elect to have damages determined through an accounting and disgorgement of the proceeds of the sale of Seroquel?

9 - If so, in what amount and for whose benefit is such accounting to be made?

10 - Should one or any of the Defendants pay special, aggravated and/or punitive damages to the Class?

11 - Can damages be determined on an aggregate basis on behalf of the Class?

12- Should one or any of the Defendants pay the costs of administering and distributing the amounts to which the Patient Class and Family Law Class are entitled?

13 -Should one or any of the Defendants be ordered to pay prejudgment interest?

[345] Common issues 8 -13 are remedial. Given the lack of evidence to support any of the liability common issues, there is no evidence that grounds the remedial common issues. It follows that there is no reason to certify these remedial issues: see *Kafka v Allstate,* [2011] O.J. No. 1683 at para. 199 aff'd [2012] O.J. No. 1551. In these circumstances, I will briefly comment on these common issues.

[346] Common issues 8 and 9 deal with the remedy of an accounting and disgorgement of the proceeds of the sale of Seroquel. The plaintiffs refer to these issues as waiver of tort. They say that this common issue addresses the question of whether the class has the right to elect between compensatory tort damages and a restitutionary remedy of disgorgement.

[347] The plaintiffs argue that where, on a class-wide basis, there exists a sufficient causal connection between the wrongful conduct and the amount for which the defendant could be ordered to account, waiver of tort may appropriately be certified as a common issue.

[348] The statement of claim only pleads two forms of wrongdoing in connection with the plaintiffs' reservation of their right to elect disgorgement through the remedy of waiver of tort:

(a) deliberately withholding and/or concealing information about the Health Risks and harmful side-effects of Seroquel in order to gain approval from Health Canada and to market and sell Seroquel to the Plaintiffs in Canada; and

(b) deliberately and aggressively promoting, marketing, advertising, recommending, merchandising, and selling Seroquel for Off-label Use when they knew or ought to have known that such use was not approved by Health Canada.

[349] As discussed, there is no basis in evidence for the assertions that the defendants wrongfully concealed information from Health Canada, or wrongfully promoted Seroquel for off-label uses. Accordingly, there is no basis in fact for any remedy of disgorgement for wrongdoing. For this reason alone, this common issue is rejected.

[350] Common issue 10 asks if one or any of the defendants should pay special, aggravated and/or punitive damages to the class. Whether the defendants should pay special damages will depend on what special damages are being claimed. This is an individual matter. The statement of claim seeks different types of such special damages, including medical testing and monitoring, "hospital accounts, x-ray accounts, doctors' accounts, drugs, transportation, clothing, personal effects and other related expense." Determining whether the class members are entitled to any such damages is an inherently individual exercise and requires an examination of each type of special damage sought by each class member. Entitlement to aggravated damages in this case is

not a common issue. As Strathy J. said in *Banerjee v. Shire Biochem Inc.*, 2010 ONSC 889, 88 C.P.C. (6th) 328 (S.C.J.) at para. 35:

> ...the issue of aggravated damages cannot form a common issue. Aggravated damages are assessed on an individual basis as part of general non-pecuniary damages: see Carom v. Bre-X Minerals Ltd., above, at para. 83, and Kotai v. The Queen of the North, 2007 BCSC 1056, [2007] B.C.J. No. 1573, at paras. 40-42. Accordingly, the word "aggravated" should be removed from common issue (g).

[351] As framed this common issue focuses on whether punitive damages should be awarded and not the quantum. The question of whether a defendant's conduct justifies an award of punitive damages has been accepted as a common issue in many class actions: see *Boulanger*, at para. 22; *Cloud*; *Heward*; *Peter v. Medtronic*, [2007] O.J. No. 4828 (S.C.J.), leave to appeal refd [2008] O.J. No. 1916 (Div. Ct.); *Andersen v. St. Jude Medical Inc.*, [2003] O.J. No. 3556 (S.C.J.) at para. 81, leave to appeal ref'd [2005] O.J. No. 269 (Div. Ct.); *Serhan v. Johnson and Johnson*, [2004] O.J. No. 2904 (S.C.J.), aff'd [2006] O.J. No. 2421 (Div. Ct.), leave to appeal to C.A. ref'd, leave to appeal to S.C.C. ref'd, [2006] S.C.C.A. No. 494; and *Robinson v. Rochester Financial Ltd.*, 2010 ONSC 463, leave to appeal ref'd, 2010 ONSC 1899, (Div. Ct.).

[352] A punitive damage claim does not always have the commonality necessary for a common issue. The case of *Robinson v. Medtronic*, [2009] O.J. No. 4366 (S.C.J.), aff'd 2010 ONSC 3777 (Div. Ct.) is an example. This was a product liability claim against the manufacturer of a medical device used to treat heart disease. The court refused to certify punitive damages as a common issue. The common issues associated with the negligence and conspiracy claims were not going to be dispositive of the defendant's liability because proof of causation and proof of damages depended on individual trials. The potential entitlement to punitive damages was therefore inextricably linked to the effect of the defendant's conduct on individual plaintiffs. The same problem arises in his case which makes this issue unsuitable for certification.

[353] I accept that common issues 12 and 13 have been certified in other cases. However, they fail here because there is no underlying liability common issue that has been accepted.

5(1)(d) - Preferable Procedure

[354] Subsection 5(1)(d) of the *Class Proceedings Act,* requires that a class proceeding be the preferable procedure for the resolution of the common issues. The preferability requirement has two concepts at its core: first, whether the class action would be a fair, efficient and manageable method of advancing the claim and second, whether the class action would be preferable to other reasonably available means of resolving the claims of class members.

[355] The preferability inquiry is conducted through the lens of the three goals of class actions: access to justice, judicial economy and behaviour modification and by taking into account the importance of the common issues to the claims as a whole including the individual issues: see *Cloud* at para. 73; *Hollick* at paras. 27-28; and *Markson v. MBNA Canada Bank,* 2007 ONCA 334 at para. 69.

[356] In determining whether a class proceeding is the preferable procedure for resolving the common issues, the court must consider not just the common issues, but rather, the claims of the class in their entirety: see *Hollick* at para. 29.

[357] The preferable procedure requirement can be met even when there are substantial individual issues. However, a class proceeding will not satisfy the preferable procedure requirement when the common issues are overwhelmed or subsumed by the individual issues, such that the resolution of the common issues will not be the end of the liability inquiry but only the beginning.

[358] In this case there is no single common issue that will significantly advance the litigation for the class. Consider what is left having reviewed each of the common issues: there is some evidence that common issue 1 exists. There is no benefit to certifying this common issue because the defendants concede that Seroquel can cause weight gain and diabetes. This point is obvious since the product monographs warn of these risks. Such a concession does nothing to move the class members' claims ahead. There is no commonality to the question. An individual inquiry is required to decide if Seroquel caused weight gain and/or diabetes for each class member.

[359] The rest of the liability common issues collapse because they do not have a basis in fact and lack commonality. As well, the conspiracy common issues only deal with two elements of this cause of action and in any event fail to satisfy the some evidence test. The remaining elements are left for individual trials.

[360] In this situation, there is simply no reason to conclude that a class action would be a fair, efficient and manageable method of advancing the claim.

5(1)(e) – A Representative Plaintiff with a Workable Litigation Plan

[361] The final requirement for certification is that there be a representative plaintiff who will fairly and adequately represent the interests of the class, has produced a suitable litigation plan and does not have a conflict of interest on the common issues with other class members. The capability of the proposed representative to provide fair and adequate representation is an important consideration. The standard is not perfection, but the court must be satisfied that "the proposed representative will vigorously and capably prosecute the interest of the class ..." *Western Canadian Shopping Centres Inc.* at para. 41.

The Representative Plaintiff

[362] There are several concerns regarding the proposed representative plaintiffs in this action.

[363] Their level of interest and ability to vigorously and capable prosecute this action is questionable given the following evidence. When the representative plaintiffs were cross-examined they conceded that they have not read any of the product monographs that ground the duty to warn allegations against the defendants. This leads me to seriously question their level of interest and commitment. In *Singer* the representative plaintiff demonstrated the same lack of

interest. He was not aware of the existence of the product monograph for the sunscreen product in question. This was one of many reasons why the representative plaintiff was rejected.

[364] There is further evidence of the representative plaintiffs' lack of interest. When cross-examined Ms. Martin stated that she does not know the difference between the three defendants and she thought they were all the same. Ms. Middleton knew that she had sued more than one defendant but does not know the difference between them.

[365] More serious is the lack of evidence to show that the claims of the representative plaintiffs are anchored in the class action. Ms. Martin alleges that as a result of taking Seroquel in 2005 she experienced transient weight gain, balance problems and involuntary movements. The last two of these complaints have been eliminated from the revised common issues. This leaves weight gain which in her case was transient. The statement of claim alleges that Ms. Martin gained approximately 55 pounds while taking Seroquel. There is no evidence that her weight gain was as a result of taking Seroquel. Ms. Martin states in her affidavit that she gained 90 pounds while taking Seroquel. However, her medical records state that she actually gained 100 pounds in the year before she started taking Seroquel and while she was taking Zyprexa (another second generation antipsychotic). Ms. Martin, claimed during her cross-examination that her doctor made a mistake in her chart and that she gained the weight the following year her use of Seroquel. However, there is no evidence from her doctor who made the notations on the medical chart. More serious is the following evidence. As detailed earlier in this judgment, the product monograph in place in 2005, when Ms. Martin took Seroquel, contained a warning for weight gain and the plaintiffs have not provided any evidence that the warning for weight gain was inadequate.

[366] Ms. Middleton took Seroquel in 2005 for stress and obsessive compulsive behavior, both of which are off-label uses. She took Seroquel at a low dose for six months. Ms. Middleton says that as a result of taking Seroquel, she gained 25 lbs and was diagnosed with diabetes. However, the product monograph in place in 2005 warned about these two side effects and as already noted there is no evidence that this warning was inadequate. As a result, there is no evidence that anchors Ms. Middleton's claim in this action.

[367] A class action must have a representative plaintiff who has a real interest in the dispute and will provide fair representation to the class. The representative plaintiff must be able to instruct counsel and to exercise independent judgment concerning the important issues that will arise during the progress of the litigation. There must be an informed representative plaintiff with a genuine claim that is supported with some evidence and anchored in the claim. Both representative plaintiffs fail to satisfy these requirements.

[368] For the reasons set out above, the representative plaintiffs are not adequately informed about this action and do not have a real interest in this action. They are not suitable representative plaintiffs.

The Litigation Plan

[369] The production of a workable litigation plan serves two purposes. First, it assists the court in determining whether the class proceeding is the preferable procedure and second it allows the

court to determine if the litigation is manageable: see *Carom v. Bre-X Minerals Ltd.*, (1999), 44 O.R. (3d) 173 (S.C.J.), aff'd (1999), 46 O.R. (3d) 315 (Div. Ct.), rev'd on other grounds (2000), 51 O.R. (3d) 236 (C.A.).

[370] The amount of detail in a litigation plan will vary according to the circumstances and complexity of each case. However, a plan that simply sets out the usual steps that occur in any litigation is not acceptable: see *Bellaire,* at para.52.

[371] The plan must provide sufficient detail that corresponds to the complexity of the litigation. The litigation plan will not be workable if it fails to address how the individual issues that remain after the determination of the common issues are to be addressed: see *Caputo v. Imperial Tobacco Ltd.*, (2004), 236 D.L.R. (4th) 348 (S.C.J) ("*Caputo*") at para. 76.

[372] As stated in *Caputo*, at para. 78, the plan should contain "details as to the knowledge, skill and experience of the class counsel involved, an analysis of the resources required to litigate the class members claims to conclusion, and some indication that the resources available are sufficiently commensurate given the size and complexity of the proposed class and the issues to be determined."

[373] While the plaintiffs litigation plan provides much of the usual detail that the court expects to see in a plan, it becomes a work of fiction because there are no common issues that have been accepted.

[374] The plaintiffs have not satisfied s. 5(1)(e) criterion.

CONCLUSION

[375] In summary, I make the following orders:

(1) The plaintiffs are granted leave to delete Bernard Van Kerrebroeck as a plaintiff in this action and to amend the Amended Fresh as Amended Statement of Claim

(2) The plaintiffs' motion seeking certification of this action as a class proceeding is dismissed.

[376] If the parties cannot agree on costs, they must deliver written submissions to the court by June 15, 2012, in accordance with a schedule to be agreed upon by counsel. This schedule must allow for a brief reply.

Justice C. Horkins

C. Horkins J.

Released: May 7, 2012