QUEEN'S BENCH FOR SASKATCHEWAN

Citation: **2015 SKQB 286**

Date: **2015 09 17**
Docket: QBG 1611 of 2009
Judicial Centre: Saskatoon

BETWEEN:

DAWN DEMBROWSKI and ALINA POPA

PLAINTIFFS

- and -

BAYER INC., BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER HEALTHCARE LLC, and BERLEX LABORATORIES, INC.

DEFENDANTS

Counsel:

E.F. Anthony Merchant, Q.C., Casey R. Churko, Anthony A. Tibbs, K. Linh Pham and Matthew Baer	for the plaintiffs
Robert W. Leurer, Q.C., Jason W. Mohrbutter and Joanne V. Colledge-Miller	for the defendants

JUDGMENT
September 17, 2015

GABRIELSON J.

[1] The plaintiff Dawn Dembrowski [Dembrowski] has applied for certification of this action as a class action pursuant to *The Class Actions Act*, SS 2001, c C-12.01 [*CAA*].

[2] As a result of the application, the defendants brought two motions which counsel requested be heard prior to the application for certification. The first was an application to strike portions of the affidavits of Dr. Anick Bérard [Bérard] and Dr. B. Burt Gerstman [Gerstman], whose affidavits had been filed by the applicant. The second was a request that the court strike certain portions of Dembrowski's brief of law dated February 27, 2015, filed in support of the application to certify the action as a class action.

[3] All three applications were heard concurrently and judgment was reserved to this date.

Background

[4] The proposed class action relates to two brands of birth control pills sold by the defendant Bayer Inc. and/or its affiliated defendants [Bayer]. The birth control products are known as Yasmin and Yaz. Both Yasmin and Yaz are hormonal combined oral contraceptives [COCs]. COCs combine two hormones, a progestin and estrogen. COCs use different types of progestins and different levels of estrogen. The progestin used in Yasmin and Yaz is the hormone drospirenone [DRSP]. Yasmin and Yaz both contain 20 milligrams of DRSP and differ slightly in the amount of estrogen each contains. There is also a slight difference in the dosing regime. Yasmin and Yaz are often referred to as fourth-generation COCs. Some earlier COCs often referred to as second-generation COCs contain the progestin levonorgestrel [LNG].

[5] Bayer has been marketing Yasmin in Canada since 2004 and Yaz since 2008. It is alleged in the amended statement of claim that Yasmin and Yaz are marketed by the Bayer as having the same efficiency as other birth control pills in preventing pregnancy, but with additional benefits including the treatment of premenstrual syndrome and preventing or reducing acne.

[6] The plaintiffs allege in the statement of claim that the DRSP progestin component in Yasmin and Yaz materially increases two serious health risks: (1) thrombosis – stroke, deep-vein thrombosis, pulmonary embolism, heart attack; and (2) gallbladder disease or removal; when compared to women who use second-generation COCs with an LNG component.

[7] The plaintiffs further allege that the defendants marketed Yasmin and Yaz without adequately disclosing the increased hazards associated with using Yasmin and Yaz as compared to second-generation COCs and that the defendants knew or ought to have known that the risk of using Yasmin or Yaz included severe and life-threatening complications and side effects.

[8] The plaintiffs allege that they and other users of Yasmin and Yaz suffered personal injury as well as economic and non-economic damages as a direct and proximate result of their use of Yasmin and Yaz. They further allege that the defendants unjustly enriched themselves and deprived the plaintiffs of a fair marketplace. On behalf of themselves and the class members, the plaintiffs claim general, special, compensatory and aggravated damages; punitive or exemplary damages; and pre-judgment interest.

Statutory Provisions

[9] The requirements for certification are set out in s. 6(1) of the *CAA*. Section 6(1) states:

> 6(1) Subject to subsections (2) and (3), the court shall certify an action as a class action on an application pursuant to section 4 or 5 if the court is satisfied that:
>
> (a) the pleadings disclose a cause of action;
>
> (b) there is an identifiable class;

> (c) the claims of the class members raise common issues, whether or not the common issues predominate over other issues affecting individual members;
>
> (d) a class action would be the preferable procedure for the resolution of the common issues; and
>
> (e) there is a person willing to be appointed as a representative plaintiff who:
>
> > (i) would fairly and adequately represent the interests of the class;
> >
> > (ii) has produced a plan for the class action that sets out a workable method of advancing the action on behalf of the class and of notifying class members of the action; and
> >
> > (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[10] Section 2 of the *CAA* defines class and common issues as follows:

> "class" means two or more persons with common issues respecting a cause of action or a potential cause of action;
>
> ...
>
> "common issues" means:
>
> > (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.

[11] While the notice of application for certification filed by Dembrowski in October of 2013 requested a class and a subclass and contained six common issues, by the date of the hearing of the application, counsel for Dembrowski specified only one class and only three common issues. The draft order filed by Dembrowski at the time of the hearing of the application was as follows:

> 1. The within action is hereby certified as a multi-jurisdictional class action.

2. The class is Canadian women who, between December 10th, 2004 and the date of this order, were prescribed and ingested the combination oral contraceptives Yasmin or Yaz (generic name: drospirenone and ethinyl estradiol) and were subsequently diagnosed as having had arterial or venous thromboembolism or gallbladder disease, or who, because of a family relationship to such individuals, may assert a claim under the *Fatal Accidents Act*, RSY 2002, c 86, *Family Compensation Act*, RSBC 1996, c 126, *Fatal Accidents Act*, RSNWT 1988, c F-3, *Fatal Accidents Act*, RSA 2000, c F-8, *Fatal Accidents Act*, SNu 2010, c 14, *The Fatal Accidents Act*, RSS 1978, c F-11, *The Fatal Accidents Act*, RSM 1987, c F50, *Family Law Act*, RSO 1990, c F. 3, *Fatal Accidents Act*, RSNB 1973, c F-7, *Fatal Injuries Act*, RSNS 1989, c 163, *Fatal Accidents Act*, RSPEI 1988, c F-5, *Fatal Accidents Act*, RSNL 1990, c F-6. Excluded from the class are individuals who are class members in *Schwoob v. Bayer Inc.* in the Ontario Superior Court of Justice, Docket 52030/10.

3. Dawn Dembrowski of Saskatoon, Saskatchewan is hereby appointed as the Representative Plaintiff for the class.

4. The nature of the claims asserted on behalf of the class and the relief claimed for the class is [*sic*] damages, disgorgement, and statutory compensation in negligence, waiver of tort, and under family compensation legislation on the grounds that Bayer breached its duty to warn that Yasmin and Yaz, which contained drospirenone, posed a greater risk of arterial and venous thromboembolism and gallbladder disease than combination oral contraceptives that contained levonorgestrel.

5. The common issues for the class are:

> 1. Can use of Yasmin or Yaz cause or contribute to an increased risk of arterial and venous thromboembolism and gallbladder disease/removal compared to using levonorgestrel-containing combination oral contraceptives?
>
> 2. If the answer to #1 is "yes", did Bayer breach a duty to warn of the increased risks of Yasmin and Yaz over levonorgestrel-containing combination oral contraceptives?
>
> 3. Should Bayer disgorge all or any of its revenue or profits from its sales of Yasmin or Yaz in Canada? If so, to whom, for what period, and in what amount?

6. Class members may opt out of the class action by, within 60 days of publication of notice of certification, delivering an opt-out form (Schedule 1), to the a [*sic*] post office box registered to and maintained by the Representative Plaintiff.

[12] Bayer takes issue with the application in respect to each of the requirements for certification listed in s. 6(1) of the *CAA*. While Bayer acknowledges that the applicant, Dembrowski, would attempt to fairly and adequately represent the interests of the class and that her interest is not in conflict with the interests of other class members, Bayer takes issue with the requirement of s. 6(1)(e)(ii) of the *CAA* and submits that the litigation plan put forward by Dembrowski is deficient and irremediable.

[13] The issues to be determined are therefore as follows:

1. Preliminary matters:

   (a) application to strike portions of Dembrowski's legal brief;

   (b) application to strike portions of the affidavits of Bérard and Gerstman.

2. Statutory requirements for certification:

   (a) Do the pleadings disclose a cause of action? (s. 6(1)(a))

   (b) Is there an identifiable class? (s. 6(1)(b))

   (c) Do the claims of the class members raise common issues whether or not the common issues predominate over other issues affecting individual members? (s. 6(1)(c))

   (d) Would a class action be the preferable procedure for the resolution of the common issues? (s. 6(1)(d))

   (e) Is there an adequate representative plaintiff? (s. 6(1)(e))

Analysis

1. Preliminary Matters

(a) Application to Strike Portions of Dembrowski's Legal Brief

[14] Bayer applies to strike three paragraphs in Dembrowski's brief of law dated February 27, 2015, being the last sentence of para. 77, the portion of the last sentence of para. 137 and a portion of the first sentence of para. 138. Bayer submits that the portions of the paragraphs complained of are scandalous and vexatious assertions. Bayer submits that the legal brief filed on behalf of Dembrowski is part of the public record and that there is a propensity for class actions to be widely published such that the impugned statements should be struck out by the court ordering that a black line be drawn through them. The response of counsel for Dembrowski is that he does not care if the portions of the brief referred to are struck or not, but he questions whether the court has jurisdiction to strike portions of arguments from briefs submitted on legal issues.

[15] Rule 7-9(1) and (2) of *The Queen's Bench Rules* gives the court a general power to strike out parts of pleadings or other documents as follows:

> 7-9(1) If the circumstances warrant and one or more conditions pursuant to subrule (2) apply, the Court may order one or more of the following:
>
> (a) that all or any part of a pleading or other document be struck out;
>
> ...
>
> (2) The conditions for an order pursuant to subrule (1) are that the pleading or other document:
>
> ...
>
> (b) is scandalous, frivolous or vexatious;
>
> ...

[16] I am satisfied that the phrase "other document" found in Queen's Bench Rule 7-9 is broad enough to encompass a brief of law. In the case of *Moss (Re)*, 2004 MBQB 265, 198 Man R (2d) 95, reversed but not on this point 2005 MBQB 46, 9 CBR (5th) 80, leave to appeal refused 2005 MBCA 59, 192 Man R (2d) 305, the court dismissed the self-represented litigant's application to strike the trustee's brief of law. However, at para. 34, the court did state that it recognized that a brief of law may well constitute an "other document" subject to being struck according to Manitoba *Queen's Bench Rules*, Man Reg 553/88.

[17] A court also has inherent jurisdiction to control its own process and has a "residual power to ensure due process of law, to prevent improper vexation or oppression, to do justice between the parties, and to secure a fair trial between them." *Fortugno v Wickstrom*, 2005 SKQB 53 at para 14, 259 Sask R 315, and *Halstead v Anderson* (1993), 115 Sask R 257 (QB) at para 24.

[18] In the case of *Paulsen v Saskatchewan (Ministry of Environment)*, 2013 SKQB 119 at para 45, 418 Sask R 96, Ryan-Froslie J. (as she then was) commented upon the word scandalous in respect to an application to strike a pleading pursuant to the former Rule 173(c) at para. 45:

> 45 An action is scandalous when it impugns the opposite party or makes degrading charges or allegations of misconduct or bad faith. ...

[19] In *Bank of Montreal v Giesbrecht*, 2005 SKQB 18, Barclay J. also reviewed the law of vexatious pleadings and stated at paras. 11 and 14:

> [11] An action or defence is vexatious if it lacks justification and is intended to annoy or embarrass the opponent or if it is not intended to lead to any practical result. ...
>
> ...

> [14] From *Odgers on High Court Pleading and Practice*, 23rd ed. (London: Sweet & Maxwell/Stevens, 1991) at 188:
>
> > ... Where unnecessary matter in a pleading contains any imputation on the opponent or makes any degrading charges or allegations of misconduct or bad faith against him or anyone else then it becomes scandalous and will be struck out.

[20] I am satisfied that in the circumstances of this case, the paragraphs in the brief to which Bayer takes issue with meet the definition of scandalous and vexatious. To allege that the defendants "lied", "killed" or are a party to "corruption" are scandalous and vexatious statements and are irrelevant to the issues before the court in the certification hearing. I am also satisfied that there is no evidentiary basis currently before the court for these allegations. Accordingly, I order that the offending portions of Dembrowski's brief be struck and that the registrar place a black line through those portions of the brief dated February 27, 2015 as referred to in para. 14 hereof. The offending portions of the brief will not be subject to further publication.

(b) Application to Strike Portions of the Experts' Affidavits

[21] In support of the application for certification, Dembrowski filed an affidavit of Bérard sworn May 21, 2014, and two affidavits of Gerstman, one sworn May 30, 2014 [first Gerstman affidavit] and a reply affidavit of Gerstman sworn October 17, 2014 [second Gerstman affidavit]. Bayer applies to strike out portions of each of these affidavits as follows:

1. In respect to the Bérard affidavit:

   (a) paragraph 15;

   (b) paragraph 16; and

   (c) all of Exhibit "C".

2. In respect to the Gerstman affidavits:

(a) the following portions of the first Gerstman affidavit:

(i) a portion of Exhibit "B" attached to this affidavit being found at page 18 "Question 2";

(ii) a portion of Exhibit "B" found at page 18 being a part of "Question 3"; and

(iii) a portion of Exhibit "B" found at page 19 entitled "Question 4"; and

(b) An order striking out portions of the second Gerstman affidavit being paras. 8, 10, 15, 16, 18 to 22, 25, 31 to 33, 36 and a portion of 42.

[22] The grounds listed in Bayer's notice of application to strike the affidavits are that the alleged offending portions of the affidavits are matters of opinion on subjects that are not within the affiants' expertise contrary to Queen's Bench Rule 5-37(2) and further that the affidavits do not meet the requirements for the admissibility of expert opinion evidence set out in *R v Mohan*, [1994] 2 SCR 9 at 20 [*Mohan*]. Finally, in respect to paras. 8, 16, 22, 31 and 33 of the second Gerstman affidavit, Bayer takes the position that such portions are inadmissible because they are argument and/or not fact or proper opinion contrary to Rule 13-30.

[23] The response of Dembrowski's counsel to this application to strike portions of the affidavits is to point out that both Bérard and Gerstman are epidemiologists and therefore have the expertise necessary to give opinion evidence on epidemiology studies done by others, which evidence will assist the judge or jury in making findings of fact which arise from the epidemiology studies which could not

be understood or made without expert evidence. Furthermore, while Dembrowski's counsel acknowledges that an expert cannot give evidence on an ultimate issue, he submits that an expert can give evidence to assist in formulating whether there is a case to be met on a procedural basis by way of a class action.

[24] The application to strike portions of the affidavits is brought pursuant to Rules 5-37, 7-9 and 13-30. These rules provide as follows:

> **5-37**(1) In giving an opinion to the Court, an expert appointed pursuant to this Division by one or more parties or by the Court has a duty to assist the Court and is not an advocate for any party.
>
> (2) The expert's duty to assist the Court requires the expert to provide evidence in relation to the proceeding as follows:
>
> (a) to provide opinion evidence that is objective and non-partisan;
>
> (b) to provide opinion evidence that is related only to matters that are within the expert's area of expertise; and
>
> (c) to provide any additional assistance that the Court may reasonably require to determine a matter in issue.
>
> (3) If an expert is appointed pursuant to this Division by one or more parties or by the Court, the expert shall, in any report the expert prepares pursuant to this Division, certify that the expert:
>
> (a) is aware of the duty mentioned in subrules (1) and (2);
>
> (b) has made the report in conformity with that duty; and
>
> (c) will, if called on to give oral or written testimony, give that testimony in conformity with that duty.
>
> **7-9**(1) If the circumstances warrant and one or more conditions pursuant to subrule (2) apply, the Court may order one or more of the following:
>
> (a) that all or any part of a pleading or other document be struck out;

> (b) that a pleading or other document be amended or set aside;
>
> (c) that a judgment or an order be entered;
>
> (d) that the proceeding be stayed or dismissed.
>
> (2) The conditions for an order pursuant to subrule (1) are that the pleading or other document:
>
> (a) discloses no reasonable claim or defence, as the case may be;
>
> (b) is scandalous, frivolous or vexatious;
>
> (c) is immaterial, redundant or unnecessarily lengthy;
>
> (d) may prejudice or delay the fair trial or hearing of the proceeding; or
>
> (e) is otherwise an abuse of process of the Court.
>
> **13-30**(1) Subject to subrule (2), an affidavit must be confined to facts that are within the personal knowledge of the person swearing or affirming the affidavit.
>
> (2) In an interlocutory application, the Court may admit an affidavit that is sworn or affirmed on the basis of information known to the person swearing or affirming the affidavit and that person's belief.
>
> ...
>
> (5) If an affidavit based on information and belief is filed and does not adequately disclose the grounds of that information and belief, the Court may direct that the costs of the affidavit shall be paid personally by the lawyer filing the affidavit.

[25] In *Hollick v Toronto (City)*, 2001 SCC 68 at para 25, [2001] 3 SCR 158 [*Hollick*], the court confirmed that in class actions, the plaintiff will have to establish an evidentiary basis for certification and that this is done by affidavits.

[26] However, any affidavits filed must comply with *The Queen's Bench Rules* and must meet the standard of admissibility of evidence, including that of the use of expert witnesses. In the case of *Brooks v Canada (Attorney General)*, 2009

SKQB 509, 347 Sask R 158 [*Brooks*], Zarzeczny J. also dealt with an application to strike affidavits filed by the plaintiff in support of the certification application. In referencing Rule 319 of the former *Queen's Bench Rules* (now Rule 13-30), Zarzeczny J. stated at para. 39:

> **39** Insofar as expert opinion evidence is concerned, the Supreme Court, in the seminal case of *R. v. Mohan*, [1994] 2 S.C.R. 9 (S.C.C.), outlined the four pre-conditions that must be satisfied before expert opinion evidence can be admitted, namely:
>
> (1) That the proffered opinion evidence is relevant;
>
> (2) That it is necessary to assist the court;
>
> (3) That it is tendered by a properly qualified expert (defined as a person shown to have acquired special or peculiar knowledge through study or experience in respect of the matters which he or she undertakes to testify); and
>
> (4) That it is not subject to an exclusionary rule.
>
> **40** These criterion are as equally applicable to certification proceedings in a class action as they are to any other civil or criminal proceeding (see *Risorto, infra* [*Risorto v State Farm Mutual Automobile Insurance Co.* (2007), 38 CPC (6th) 373]; *White v. Merck Frosst Canada*, [2004] O.J. No. 623 (S.C.J.)).

[27] Similar statements in respect to the need for the trial judge to exercise a gatekeeper function to carefully assess and identify the scope of the expertise of an expert witness have been expressed in other Saskatchewan cases such as *Vigoren v Nystuen*, 2006 SKCA 47 at para 67, 266 DLR (4th) 634; *Alves v First Choice Canada Inc.*, 2010 SKQB 104, [2010] 9 WWR 301; *Field v GlaxoSmithKline Inc.*, 2011 SKQB 16, 329 DLR (4th) 290 [*Field*]. However, the authorities have also recognized that a more generous approach as to admissibility may be taken depending on the nature of the issue and the certification being considered. See *Brooks* at para 43.

[28] Each of the affidavits objected to will have to be considered based upon the above-noted criteria.

[29] The statement of expertise for Bérard dated May 22, 2014 signed by counsel for Dembrowski and filed in accordance with Rule 5-39(2) states as follows:

> I propose to tender Dr. Anick Berard as an expert witness in this matter. The area of expertise in which the expert is tendered to offer an opinion is: pharmacoepidemiology, epidemiology, clinical science, and regulatory affairs.

[30] The statement of expertise filed by Dembrowski's counsel in respect to Gerstman, which is also dated May 22, 2014, states:

> I propose to tender Dr. Gerstman as an expert witness in this matter. The area of expertise in which the expert is tendered to offer an opinion is: Epidemiology.

[31] Epidemiology has been described as follows:

> Epidemiology is the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Various methods can be used to carry out epidemiological investigations: surveillance and descriptive studies can be used to study distribution; analytical studies are used to study determinants.

See: The World Health Organization (<www.who.int/topics/epidemiology/en/>) (3 September 2015).

(i) The Bérard Affidavit

[32] In the Bérard affidavit, there are two opinions attached as Exhibits "B" and "C". Exhibit "B" dealt with an epidemiological study Bérard had done regarding a connection between DRSP and gallbladder disease. Bayer takes no objection to this Exhibit "B" report. Bérard's conclusion after this study was that there was a "plausible mechanism of action leading to such an outcome with the use of this particular oral contraceptive." However, the defendants do object to paras. 15 and 16

of Bérard's affidavit, which provide:

> 15. I have also been asked by counsel in the above referenced matter to address the following issue:
>
> > Did Yaz/Yasmin product monographs provide an adequate warning that Yaz/Yasmin can cause, contribute to, or increase the risk of a venous thromboembolism ("VTEs") and gallbladder disease?
>
> 16. A copy of my report is attached hereto as **Exhibit "C".**

[33] Bérard's conclusion in her report, which is marked as Exhibit "C", was as follows:

> Following my analysis, it is my opinion that Yaz/Yasmin product monographs, package inserts and labels have failed to warn the patients about the risk of VTE, CVD and gallbladder disease. Risks identified in the scientific literature have constantly been minimized in these documents, and Canadian documents have not kept up with the US documents.

[34] I am satisfied that Bérard does not have sufficient expertise to provide opinion evidence in respect to the adequacy of the product monograph for Yasmin and Yaz. However, she does have experience in pharmacoepidemiology, which is the study of uses and effects of drugs on populations. In cross-examination by the defendants' counsel on her affidavit, Bérard was asked to comment on what an epidemiologist does. At question 90 she stated:

> **Q** Okay. Well, I appreciate that, actually. Because you're an epidemiologist. You're here to talk about statistics.
>
> **A** No. Yes. This is part of it. Epidemiologists use statistics, but it's a small portion of what they used to actually formulate an option [*sic*]. So, but you're lucky I'm a statistician as well. So all of this to say, an epidemiologist will assess association or will quantify association within a study. And they will assess causation looking at the overall literature.
>
> **Q** The – your words. You're not here to talk about clinical significance. It's fair to say then that you cannot offer an

> opinion at all on whether any difference between drospirenone and second generation COC's is clinically significant at all. Is that fair?
>
> **A** I'm here to talk about the causal relationship between a use of the drug here, which is Yaz and Yasmin, and a risk, which is the risk of gallbladder disease here.
>
> [Emphasis added]

[35] Again at questions 335-36, Bérard was asked the following questions and responded:

> **Q** The causation to an epidemiologist is population based, correct?
>
> **A** Yes. We use populations.
>
> **Q** You're not trying to do individual specific causation, correct?
>
> **A** But we - there are two answers to your question. We use population based epidemiologic findings to assess individual, you know, in an individual, what is your risk, what is your, you know, what I'm going to prescribe to you and all of that.
>
> So we will use population data, and this is how we do – of course I am not a physician. You've told me that many times today, and I agree with you. But even physicians, which I am not, will use population data to actually tell or prescribe their patients individually.

[36] Accordingly, while I agree that Bérard does not have the expertise to comment upon the product monograph for Yasmin and Yaz, in my opinion, she does have the expertise to review the monographs and provide the court with her analysis from an epidemiology point of view of the risks of usage of these drugs based upon studies done by others and what information is contained in these monographs and whether these monographs warned of the risk of venous thromboembolism [VTE], arterial thromboembolism [ATE], and gallbladder disease. Bérard has no regulatory

experience or expertise but her opinion does not speak to whether the monographs meet regulatory requirements. Rather, her opinion speaks to whether the Canadian monograph documents warn of these risks and how these documents compare to United States monograph documents. Accordingly, I am not prepared to strike paras. 15 and 16 of the Bérard affidavit as requested by Bayer.

(ii) The First Gerstman Affidavit

[37] As with the objection to the Bérard affidavit, Bayer objects to Gerstman's opinion evidence with respect to the adequacy of the product monographs for Yasmin and Yaz, which is found in that portion of Gerstman's opinion attached as Exhibit "B" to his first affidavit. Bayer's position is that Gerstman was initially trained and employed as a practising veterinarian and accordingly he has no expertise in respect to drugs manufactured for usage by women. Bayer does acknowledge however that Gerstman holds a Ph.D. in epidemiology and that he is and has been an epidemiology professor at various American universities. Bayer also acknowledges that Gerstman does have some regulatory experience in the United States, having at one time worked for the American Food and Drug Administration [FDA] as an epidemiologist, but Bayer submits that he has no regulatory experience in Canada and, therefore, that his opinion regarding the operation of Canada's prescription medicine regulatory regime is only based upon an assumption that Canada's system operates the same way as that of the United States.

[38] The objection listed by Bayer was to Exhibit "B" attached to the first Gerstman affidavit and was stated by Bayer to be as follows:

> (a) The following portion … at page 18 of 22:
>
> *Question #2 (at page 18 of 22): Did the Bayer group of companies and Berlex Laboratories ("the Defendants") fail to adequately warn of the health disorders noted*

above?

I believe the companies have demonstrated over-reliance on their own funded studies to the exclusion of studies done by independent investigators when presenting risks about their product to the public. Thus, to the extent that the label fails to acknowledge the increases in risk demonstrated in independent studies, the company has failed to adequately warn consumers.

(b) The sentence, forming part of the discussion under the heading "Question #3" found at page 18 of 22 of the Saskatchewan Report, which reads "*I believe the company has been over-reliant on studies from a single group of Dinger's Centre for Epidemiology and Health Research Group for its conclusions.*"

(c) The following portion of the Saskatchewan Report found at page 19 of 22:

Question #4: Did the Canadian warnings, labels, and monographs keep up with those of the US?

I would be happy to review this information if the Canadian warnings, labels, and monographs are provided.

[39] While Gerstman acknowledged in his cross-examination that he had no direct knowledge about the information submitted to Health Canada with respect to Yasmin and Yaz, he stated that he was proceeding on the basis of what he could assume by reading the product monographs for both drugs. Gerstman also acknowledged in cross-examination on his affidavit that he had no direct experience with Health Canada's practices in approving prescription medicines.

[40] Bayer submits that the proposed evidence of Gerstman in respect to the sufficiency of product monographs in Canada "stands in direct parallel" to the proposed evidence offered by the applicants for certification in the case of *Martin v Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744, 27 CPC (7th) 32 [*Martin*]. In *Martin*, the issue was whether the product monographs and labels approved by Health Canada for the prescription medication Seroquel sufficiently warned of adverse side

effects. The court in that case found that an affidavit filed by the plaintiffs from a Dr. Plunkett should be struck because the opinions she provided were outside the scope of her qualifications. Dr. Plunkett's qualifications were that she was a pharmacologist with a Ph.D. who had conducted doctoral research relating to cardiovascular pharmacology. Her affidavit and opinion however also dealt with the defendants' failure to warn regarding the risks associated with the use of the drug Seroquel and her belief that the defendants were not supplying physicians and consumers in Canada with risk information even though actions had been taken in other countries to warn physicians and patients of these risks. It should be noted that the court in *Martin* did not strike out the portion of her opinion affidavit that referred to what was being done in other countries regarding warnings to patient and healthcare providers. At para. 59 of the *Martin* case, the court stated that Dr. Plunkett had conceded she did not include certain epidemiology studies that stated that there was no association between Seroquel and diabetes. The court therefore ruled that Dr. Plunkett had provided an unbalanced sampling of public research. That is not a concern in the current case where Gerstman is a pharmacoepidemiologist who was also trained in advanced epidemiologic methods, drug surveillance and drug safety. In my opinion, epidemiology studies and analyses of these studies are within Gerstman's area of expertise unlike that of Dr. Plunkett in the *Martin* case.

[41] Bayer also refers to the *Brooks* case and *McKinnon v Martin (Rural Municipality, No. 122)*, 2010 SKQB 374, 361 Sask R 249 [*McKinnon*] as instances where the courts have refused to accept opinion evidence from a chemical engineer and a medical doctor respectively because they were testifying based upon research rather than having the qualifications in the area of their opinion.

[42] It is significant to note that in the *Brooks* case, the court recognized that the type of evidence being provided by the expert was in the area of epidemiology,

toxicology, immunology and endocrinology and ruled that these areas of opinion were outside the areas of expertise of a chemical engineer. In contrast, in the application before me, Gerstman is a pharmacoepidemiologist and for the most part has given his opinion in the area of epidemiology.

[43] In *McKinnon*, a medical doctor specializing in radiology, was asked to give an opinion regarding the health effects of wind turbine noise. The only basis for his opinion was some limited experience in surveying some 22 persons who had lived beside a wind turbine. The court ruled that, as he did not have any specialized training in any of the issues necessary to provide an opinion in respect to these health effects, he could not render such an opinion. Once again, Gerstman's training and experience is in the area of pharmacoepidemiology. The fact that he was at one time a veterinarian rather than a medical doctor does not mean that he is unqualified to render an opinion in the area of pharmacoepidemiology, which for the most part he has done.

[44] I am satisfied that Bayer has established that Gerstman does not have expertise or experience with respect to the requirements of Health Canada's prescription medicine regulatory regime as alleged by Bayer. However, Gerstman does have experience based upon his pharmacoepidemiological expertise and his review of the various studies referred to in his first affidavit to provide an opinion as to whether Bayer failed to adequately warn of the health disorders which he noted. Likewise, he has the expertise and experience to render an opinion as to whether Bayer has been "overly reliant" on studies from a single group or its conclusions. I accept that he does not have the expertise or experience to provide opinion evidence regarding Health Canada's prescription medicine regulatory regime. However, I do not find that any of the objections taken in respect to the first Gerstman affidavit relate to or refer to Health Canada's prescription medicine regulatory regime. I also

find that Gerstman's evidence meets the four-part *Mohan* test. I therefore dismiss Bayer's application to strike portions of the first Gerstman affidavit.

(iii) The Second Gerstman Affidavit

[45] The second Gerstman affidavit is a reply affidavit sworn October 17, 2014. In it, Gerstman reviews the affidavits of Bayer's experts, that of Dr. Denise Black sworn September 25, 2014, that of Dr. Stephen Wood sworn September 25, 2014, and that of Ms. Mary Alison Maloney sworn September 26, 2014. For the most part, Gerstman reviews these affidavits as an epidemiologist and challenges some of their comments and conclusions from an epidemiological basis. He is entitled to do that and his opinion regarding the information that these affidavits contain, following his epidemiological analysis, will assist the court in determining the appropriate amount of weight that their opinions might receive, but only on an epidemiological basis rather than a clinical basis. Therefore, I decline to strike those portions of the affidavit requested because Gerstman does have the relevant experience in epidemiological studies and his opinions in this regard could be helpful to the court in determining the issues in the certification. His opinion meets the *Mohan* test.

[46] However, Bayer has also asked that paras. 8, 16, 22, 31 and 33 be deemed inadmissible because they are argument and are not fact or proper opinion contrary to Rule 13-30. To the extent that an affidavit contains argumentative statements, it would be improper. See *Field* at para 35. Therefore, insofar as Gerstman comments upon the sufficiency of the qualifications of Bayer's affiants, Dr. Black, Dr. Wood and Ms. Maloney, I find such comments to be argumentative statements and therefore improper. I therefore order that paras. 8, 16, 22, and 31 of the second Gerstman affidavit be struck. I decline to strike any of the remaining paragraphs requested.

2. Statutory Requirements for Certification

General principles regarding certification in class actions

[47] In *Hollick* at para 15, Chief Justice McLachlin stated that class actions have three advantages over individual suits, which advantages she listed as judicial economy by avoiding unnecessary duplication of fact-finding and legal analysis; economy of scale by spreading fixed litigation costs over the class members, thereby providing for increased access to justice; and finally, potential modification of behaviour which might cause or be causing harm to the public.

[48] At para 15 of *Hollick*, Chief Justice McLachlin concluded:

> **15** ... it is essential therefore that courts not take an overly restrictive approach to the legislation, but rather interpret the Act in a way that gives full effect to the benefits foreseen by the drafters.

[49] Although *Hollick* dealt with class action proceedings in Ontario, other cases have confirmed that the three objectives Chief Justice McLachlin referred to for class action proceedings also apply in Saskatchewan. In *Thorpe v Honda Canada Inc.*, 2011 SKQB 72, [2011] 8 WWR 529 [*Thorpe*], Popescul J. (as he then was), also referenced *Hollick* and its objectives and concluded at para. 31 that:

> 31 ... Essentially the jurisprudence directs that the courts should be finding ways to grant appropriate certification applications, rather than finding excuses why they ought not be certified.

[50] The Supreme Court of Canada also pointed out in the recent case of *Pro-Sys Consultants Ltd. v Microsoft Corporation*, 2013 SCC 57 at para 103, [2013] 3 SCR 477 [*Pro-Sys Consultants*], that certification is a "meaningful screening device", but that the standard for assessing evidence of certification does not give rise to "a determination of the merits of the proceeding".

[51] As well as considering these basic general principles, I must also consider whether the statutory prerequisites for certification under s. 6(1) of the *CAA* are met. I will therefore review each of the five subsections of s. 6(1) and the evidence presented by Dembrowski and Bayer in respect thereto.

(a) The First Statutory Requirement

Do the pleadings disclose a cause of action? – CAA s. 6(1)(a)

[52] In *Pro-Sys Consultants*, Rothstein J. described the test on whether the pleadings disclose a cause of action at para. 63:

> **63** The first certification requirement requires that the pleadings disclose a cause of action. In *Alberta v. Elder Advocates of Alberta Society*, 2011 SCC 24, [2011] 2 S.C.R. 261 ("*Alberta Elders*"), this Court explained that this requirement is assessed on the same standard of proof that applies to a motion to dismiss, as set out in *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959, at p. 980. That is, a plaintiff satisfies this requirement unless, assuming all facts pleaded to be true, it is plain and obvious that the plaintiff's claim cannot succeed (*Alberta Elders*, at para. 20; *Hollick v. Toronto (City)*, 2001 SCC 68, [2001] 3 S.C.R. 158, at para. 25).
>
> [Emphasis added]

[53] However, the Supreme Court of Canada in *Pro-Sys Consultants* was dealing with the British Columbia *Class Proceedings Act*, RSBC 1996, c 50, whereas the Saskatchewan Court of Appeal has consistently stated that the test in Saskatchewan regarding s. 6(1)(a) of the *CAA* is slightly higher based upon the case of *Hoffman v Monsanto Canada Inc.*, 2007 SKCA 47, 283 DLR (4th) 190, where Cameron J.A. stated at para. 50:

> **50** ... the representative plaintiffs must persuade the court that there exists a plausible basis for supposing the defendants could be liable to the claims of the class. This is a way of saying, simply and effectively, that the representative plaintiff has to satisfy the judge that the pleadings disclose an apparently authentic or genuine cause

> of action on the basis of the facts as pleaded and the law that applies. ...
>
> [Emphasis added]

[54] As I am dealing with the Saskatchewan legislation, I must apply Saskatchewan law and accordingly, I must apply the plausible basis test developed by our Court of Appeal. See also *Saskatchewan Crop Insurance Corp. v Hicks*, 2009 SKCA 12 at para 12, [2009] 6 WWR 627; *Alves v First Choice Canada Inc.*, 2011 SKCA 118 at para 17, [2012] 2 WWR 259.

[55] The starting point in determining whether defendants could be liable for the claims of the class is to review the statement of claim. As was stated by Ball J. in the case of *White v GlaxoSmithKline Inc.*, 2010 SKQB 174 at para 24, 358 Sask R 6:

> 24 ... the statement of claim is of central importance: it informs inquiries into whether there is a genuine or authentic cause of action; whether there is an identifiable class in existence; and whether common issues are shared across that class. Those inquiries in turn inform the analysis as to whether a class action is the preferable procedure for the resolution of the common issues and whether there is an appropriate person willing to be appointed as a representative plaintiff.

[56] In this case, in the amended statement of claim, which was filed September 30, 2013, the plaintiffs allege:

(i) para. 38 - that the defendants knew or should have known that the use of Yasmin or Yaz created an increased risk to consumers of serious personal injury, including but not limited to gallbladder disease, blood clots and strokes;

(ii) para. 51 - that the defendants failed to adequately warn physicians and consumers, including the plaintiffs and class members of these risks, or that they were significantly higher when compared with the use of

second-generation COCs;

(iii) para. 60 - that as a result of their use of Yasmin or Yaz, the plaintiffs suffered personal injury, economic and non-economic damages and will continue to suffer the same in the future.

[57] The causes of actions alleged by the plaintiffs in the amended statement of claim are in negligence, breach of warranty (express and/or implied), negligent misrepresentation and violations of the *Food and Drugs Act*, RSC 1985, c F-27, s 9; the *Competition Act*, RSC 1985, c C-34, s 52, and *The Consumer Protection Act*, SS 1996, c C-30.1, s 14 (since rep by *The Consumer Protection and Business Practices Act*, SS 2004, c C-30.2). However, in his final submissions before me on this certification application, counsel for Dembrowski restricted his submissions to the claims in negligence, waiver of tort and a derivative claim on behalf of family members.

[58] In his submissions before me, counsel for Bayer acknowledged that the pleadings disclosed an authentic and genuine cause of action in duty to warn, but submitted that the plaintiffs were required to show by evidence that there was a material risk of harm which Bayer, as manufacturer, had breached. Furthermore, Bayer submitted that, as manufacturer, Bayer had no duty to provide what Bayer considers to be inaccurate or immaterial information to consumers. Finally, Bayer submitted that waiver of tort as a remedy cannot be used as an alternative remedy in the context of a negligence action, but rather applies only to proprietary claims where a defendant has illegally obtained property from a plaintiff.

[59] I am satisfied that the applicant has met the plausible basis test and that the pleadings do disclose a cause of action in negligence and a derivative claim on behalf of family members. In respect to the claim in negligence, assuming that the

facts as pled are true, the applicant has established:

(a) that Bayer manufactured and sold Yasmin and Yaz and that as manufacturer Bayer owed a duty of care to the users of these products;

(b) that Yasmin and Yaz, which contained DRSP as the progestin component, may have a higher risk of certain side effects such as thrombosis and gallbladder disease or removal than second-generation COCs;

(c) that Bayer marketed Yasmin and Yaz without adequately disclosing these increased risks; and

(d) that as a result of the use of Yasmin and Yaz, the representative plaintiffs suffered serious personal injuries from blood clots, a stroke and/or a pulmonary embolism.

I am therefore satisfied that the requirements of s. 6(1)(a) of the *CAA* have been met in respect to the claim in negligence. I am also satisfied that it would logically follow that there could be a derivative claim on behalf of family members. As the position of Dembrowski on this certification action is to restrict her application to a claim in negligence, I am not required to consider the other potential causes of action listed in the amended statement of claim.

[60] Accordingly, I find that the requirements of s. 6(1)(a) of the *CAA* have been met.

(b) *The Second Statutory Prerequisite*

Is there an identifiable class? – CAA s. 6(1)(b)

[61] In the submissions to me at the certification hearing, counsel for Dembrowski proposed the following class:

> 2. The class is Canadian women who, between December 10th, 2004 and the date of this order, were prescribed and ingested the combination oral contraceptives Yasmin or Yaz (generic name: drospirenone and ethinyl estradiol) and were subsequently diagnosed as having had arterial or venous thromboembolism or gallbladder disease, or who, because of a family relationship to such individuals, may assert a claim under the *Fatal Accidents Act*, RSY 2002, c 86, *Family Compensation Act*, RSBC 1996, c 126, *Fatal Accidents Act*, RSNWT 1988, c F-3, *Fatal Accidents Act*, RSA 2000, c F-8, *Fatal Accidents Act*, SNu 2010, c 14, *The Fatal Accidents Act*, RSS 1978, c F-11, *The Fatal Accidents Act*, RSM 1987, c F50, *Family Law Act*, RSO 1990, c F. 3, *Fatal Accidents Act*, RSNB 1973, c F-7, *Fatal Injuries Act*, RSNS 1989, c 163, *Fatal Accidents Act*, RSPEI 1988, c F-5, *Fatal Accidents Act*, RSNL 1990, c F-6. Excluded from the class are individuals who are class members in *Schwoob v. Bayer Inc.* in the Ontario Superior Court of Justice, Docket 52030/10.

[62] Bayer submits that the class proposed is inappropriately broad and over-inclusive. Bayer submits there is no basis in fact to assert a claim on behalf of women who have suffered any injury other than VTE. Bayer therefore wishes to exclude from the class those who suffered either ATE or gallbladder disease. Bayer also submits that the class described as those who suffered a diagnosed VTE must also be subject to some defined temporal limit to reflect the period of time for which there is no basis in fact for an alleged breach of the duty to warn. Finally, Bayer submits that it is inappropriate to include any residents of Ontario or Quebec.

[63] The standard of proof required with respect to this issue of an identifiable class was confirmed by Rothstein J. in *Pro-Sys Consultants* at para. 99:

> **99** "... the class representative must show some basis in fact for each of the certification requirements set out in ... the Act, other than the requirement that the pleadings disclose a cause of action" ... .
>
> [Emphasis in original]

See also *Pederson v Saskatchewan (Minister of Social Services)*, 2015 SKCA 87 at para 20.

[64] In respect to this burden, in the text by Ward K. Branch, *Class Actions in Canada*, looseleaf (Rel 40, June 2015) vol 1 (Toronto: Canada Law Book Inc., 2015), the author outlines the test to be applied when determining if there is an identifiable class. At page 4-12, he stated:

> **4.230** It is the representative plaintiff's burden to establish the existence and scope of any class with certainty. That definition should be pleaded in the statement of claim. The purpose of the class definition is threefold: (a) it identifies those persons who have a potential claim for relief against the defendant; (b) it defines the parameters of the lawsuit so as to identify those persons who are bound by its results; and (c) it describes who is entitled to notice. The courts will consider whether the definition of the purported class provides a basis by which members of the class can reasonably be identified in an objective manner. The definition must allow the court to assess whether or not a particular person falls within the class.
>
> **4.240** The fact that the exact number of class members or the identity of each member is unknown is not a bar to certification.

[65] I am satisfied in this case that there is some basis in fact for the proposed class of consumers of Yasmin and Yaz that meets the criteria referred to in the above-noted text. Women who took Yasmin or Yaz after it was marketed in Canada and who suffered an adverse result in the nature specified are an identifiable class who have a potential claim. The affidavit evidence of Khanh Linh Pham, a student-at-law at the firm of Dembrowski's counsel, states that 1,988 individuals from every province in Canada have submitted personal information through the firm's

online database specific to the Yasmin and Yaz litigation and that a significant number have indicated adverse reactions in the category listed in the proposed class. Obviously, if the determination of common issues should result in a narrowing of the class in respect to the claim of those who experienced ATE or gallbladder disease, that would affect the definition of the class, but as it currently stands, the proposed class does create an objectively identifiable class as required by s. 6(1)(b) of the *CAA*.

[66] The Ontario action referred to in the proposed class definition has a temporal limitation of November 30, 2011 which is a date that the product monographs of Yasmin and Yaz were changed to provide additional warnings of possible adverse effects in the use of both drugs. In *Schwoob v Bayer Inc.*, 2013 ONSC 2207 [*Schwoob*], the court accepted this temporal limit because that was the plaintiffs' choice as a stronger position. However, as was pointed out in that case, it is not necessary to provide such a temporal limit and I decline to require the applicant here to do so.

Multi-jurisdictional class action considerations

[67] At the hearing of this application, counsel for Dembrowski filed a draft order in which the class was defined as excluding individuals who are class members in *Schwoob*. However, it should be noted that the amended statement of claim filed September 30, 2013, defined the class as all persons in Canada excluding residents of Ontario as class members. Furthermore, the notice of application for certification filed October 9, 2013 defined the class as, "all persons in Canada, excluding residents of Ontario and Quebec who at any time before the date of the certification order were prescribed or ingested Yasmin or Yaz."

[68] In her affidavit which was filed in support of the application for certification at para. 33, Dembrowski attached as an exhibit a copy of the *Schwoob*

certification decision in Ontario. In *Schwoob*, the plaintiffs proposed two classes, defined at para. 20 as follows:

> (1) All persons resident in Ontario who were prescribed and used combination oral contraceptives Yasmin and/or YAZ, which were manufactured, marketed, and/or sold or otherwise placed into the stream of commerce in Canada by the defendant between their respective introductions onto the Canadian market until November 30, 2011; and
>
> (2) All persons resident in Ontario who by virtue of a personal relationship to any one or more of the persons described above have a 'Family Law Act' derivative claim for damages.

The hearing judge approved that definition.

[69] At para. 34 of her affidavit filed in support of her application for certification, Dembrowski confirmed that she has been advised by her legal counsel that there is also a class action before the Quebec Superior Court wherein the court certified the class action on behalf of women who have taken Yasmin or Yaz in Quebec. A copy of this certified class action was not attached to her affidavit nor was it filed before me. I could not find any decision in this regard using a computer search.

[70] At the hearing of this application, Mr. Baer, Ontario counsel in the *Schwoob* class action, indicated that the Ontario action has continued to move forward since it was certified. The timeline given was as follows:

April 13, 2013 – The certification order granted.

September 5, 2013 – The application for leave to appeal was dismissed.

October 29, 2014 – The parties agree regarding the notice.

November 10, 2014 – The notice of certification was published.

February 2015 – The opt-out period ended.

[71] Mr. Baer indicated that counsel for the parties in *Schwoob* had been negotiating a discovery plan and that they are lining up witnesses for the common issue trial. Mr. Baer indicated that the plaintiffs in *Schwoob* have no issue with the application now before me to certify a Canada-wide class action in terms of the draft order filed. Mr. Baer also indicated he had spoken to counsel for the plaintiffs in the Quebec class action, Mr. Desmeules of the Siskinds law firm, who authorized him to advise me that the plaintiffs in the Quebec action do not oppose the inclusion of other Quebec residents in the Saskatchewan action and believe that the plaintiffs' counsel in all three actions can work together in determining the liability of the defendants.

[72] Section 6(2) of the *CAA* deals with the process that should be followed in circumstances where another class action has already been commenced elsewhere in Canada involving the same subject matter. The jurisdiction to grant a multi-jurisdictional class action has been confirmed to be *intra vires* the Province of Saskatchewan in *Thorpe*. As in that case, I find that this court does have jurisdiction to certify a national class action. However, in light of the fact that there are already class actions certified in two other jurisdictions, Quebec and Ontario, which have obviously progressed beyond that of the proposed Saskatchewan action, I decline to include Quebec and Ontario in the class to be certified in Saskatchewan. Quebec is a civil law jurisdiction, and I have no evidence as to what effect, if any, the laws of the Province of Quebec would have upon the jurisdiction of a Saskatchewan court. I am therefore satisfied that the definition of class as proposed in the plaintiff's original notice of application for certification which excluded residents of Ontario and Quebec, including their estates, is an appropriate exclusion from the class for the purposes of this certification in Saskatchewan.

(c) *The Third Statutory Prerequisite*

Do the claims raise common issues? – CAA s. 6(1)(c)

[73] In the original notice of application for certification filed October 9, 2013, Dembrowski proposed six common issues. However, at the certification hearing, the order sought was for only three common issues, which are as follows:

> 1. Can use of Yasmin or Yaz cause or contribute to an increased risk of arterial and venous thromboembolism and gallbladder disease/removal compared to other available oral contraceptives?
>
> 2. If the answer to #1 is "yes", did Bayer breach a duty to warn of the increased risks of Yasmin and Yaz over levonorgestrel-containing combination oral contraceptives?
>
> 3. Should Bayer disgorge all or any of its revenue or profits from its sales of Yasmin or Yaz in Canada? If so, to whom, for what period, and in what amount?

[74] In *Hollick*, McLachlin C.J. defined the test for this requirement when she wrote at para. 18:

> **18** ... As I wrote in Western Canadian Shopping Centres [*Western Canadian Shopping Centres Inc. v Dutton*, 2001 SCC 46, [2001] 2 S.C.R. 534], the underlying question is "whether allowing the suit to proceed as a representative one will avoid duplication of fact-finding or legal analysis". Thus an issue will be common "only where its resolution is necessary to the resolution of each class member's claim" (para. 39). Further, an issue will not be "common" in the requisite sense unless the issue is a "substantial ... ingredient" of each of the class members' claims.

[75] Common issues is defined in s. 2 of the *CAA* as follows:

> **2** In this Act:
>
> ...
>
> "common issues" means:

> (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.

[76] The analysis considering common issues was recently commented upon by the Supreme Court of Canada in the *Pro-Sys Consultants* case at para. 108, where the court stated:

> **108** In *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46, [2001] 2 S.C.R. 534, this Court addressed the commonality question, stating that "the underlying question is whether allowing the suit to proceed as a [class action] will avoid duplication of fact-finding or legal analysis" (para. 39). I list the balance of McLachlin C.J.'s instructions, found at paras. 39-40 of that decision:
>
> (1) The commonality question should be approached purposively.
>
> (2) An issue will be "common" only where its resolution is necessary to the resolution of each class member's claim.
>
> (3) It is not essential that the class members be identically situated *vis-à-vis* the opposing party.
>
> (4) It not necessary that common issues predominate over non-common issues. However, the class members' claims must share a substantial common ingredient to justify a class action. The court will examine the significance of the common issues in relation to individual issues.
>
> (5) Success for one class member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent.

[77] In respect to common issues, counsel for Dembrowski submitted that, at the certification hearing, the court is to identify common issues, not resolve them. He also submitted that Dembrowski is not under an obligation to challenge Bayer's merits-based evidence and that the expert opinion evidence which Dembrowski filed should not be subjected to exacting scrutiny. Counsel submitted that there need

merely be a controversy or point of contention to resolve where "the plaintiffs join issue with the defendants". Counsel referred to the case of *Wheadon v Bayer Inc.*, 2004 NLSCTD 72, 237 Nfld & PEIR 179, application for leave to appeal dismissed 2005 NLCA 20, 246 Nfld & PEIR 157, leave to appeal refused [2005] SCCA No 211 (QL), where Barry J. stated at paras 114-117 (NLSCTD):

> **114** Bayer accepts that an application for class certification is not a trial, and that the merits of contentious factual and legal issues cannot be resolved on a class certification application. Bayer submits, however, that on a certification application the Court must examine the evidentiary record to determine whether there are, indeed, colourable claims involving contentious facts that raise legitimate common issues for trial. Bayer argues the representative plaintiff must provide the Court with a factual record sufficient to ground the relief sought and not merely rely upon unsupported allegations in a pleading.
>
> **115** As previously discussed under "The Evidentiary Threshold", the burden for a plaintiff on an application for certification of an action as a class proceeding was established in Hollick as a requirement to show merely "some basis in fact" for each of the certification requirements, other than that the pleadings disclose a cause of action. The adequacy of the evidentiary record supporting the application for certification will vary in the circumstances of each case.
>
> **116** The evidence before this Court is that all statins, including Baycol, carried the risk of adverse side effects, including rhabdomyolysis. Baycol was withdrawn because of continuing reports of rhabdomyolysis when Baycol was co-prescribed with gemfibrozil, and when therapy was prescribed at the highest available dose. Bayer notes the Lennox affidavit filed on behalf of the Plaintiffs, which cites a comparison taken from the Canadian Adverse Drug Reaction Newsletter of reports of adverse events, including rhabdomyolysis, among six statins in Canada. Bayer claims it is well established that reports of suspected adverse reactions must not be used to estimate the incidence of adverse reactions. Even so, says Bayer, this publication discloses that there were fewer reports of myopathy with Baycol than with several of the other statins included in the comparison, and only one-fourth the number of reports of myopathy with Baycol than reported with Atorvastatin ("Lipidor"), introduced to the market only one year earlier. Bayer argues that, therefore, even the evidence presented by the Plaintiffs does not give rise to a colourable claim for the proposed representative Plaintiffs or others who assert similar

> claims, for the purpose of determining whether any common issues arise.
>
> **117** I do not accept this argument. As noted above under "The Evidentiary Threshold", I find that Wheadon and McCullough have established some basis in fact for common issues by deposing that they ingested Baycol and suffered injury, when this is considered in the context of the information supplied by the Lennox affidavit. I will now consider each of the proposed common issues in turn.

[78] Bayer submits that the proposed common issues centre upon matters of a general nature with an absence of an evidentiary foundation and do not substantively advance the plaintiffs' claims. Bayer submits that "common issues" are the engine that drives the class action and that the court must perform its gatekeeper role in connection with the requirement of common issues before certifying the action as a class action. Bayer submits there is no basis in fact for the proposed common issues based upon the evidentiary record filed by the applicant. Finally, Bayer submits that the court must be alert to superficial commonality which would not advance the resolution of any of the individual claims. Bayer refers to the case of *Rumley v British Columbia*, 2001 SCC 69, [2001] 3 SCR 184, where McLachlin C.J. stated at para 29:

> **29** There is clearly something to the appellant's argument that a court should avoid framing commonality between class members in overly broad terms. As I discussed in Western Canadian Shopping Centres, supra, at para. 39, the guiding question should be the practical one of "whether allowing the suit to proceed as a representative one will avoid duplication of fact-finding or legal analysis". It would not serve the ends of either fairness or efficiency to certify an action on the basis of issues that are common only when stated in the most general terms. Inevitably such an action would ultimately break down into individual proceedings. That the suit had initially been certified as a class action could only make the proceeding less fair and less efficient.

[79] I will consider the submissions of counsel for both Dembrowski and Bayer in respect to the law regarding common issues. I will review each of the common issues proposed to determine if they meet the test of "some basis in fact" set

by the courts as the appropriate test in determining each of the individual statutory requirements set out in s. 6(1)(b) to (e) of the *CAA*: *Pro-Sys Consultants* at para 99.

Common Issue No 1. — Can use of Yasmin or Yaz cause or contribute to an increased risk of arterial and venous thromboembolism and gallbladder disease/removal compared to other available oral contraceptives?

[80] This first common issue is one of causation. Both parties refer to epidemiological studies as appropriate evidence to consider when determining if there is some basis in fact for this question. Counsel for Bayer conceded that there is some basis in fact that the use of Yasmin or Yaz can cause or contribute to an increased risk of VTE but submitted that a reference to other available oral contraceptives is overly broad because the sole evidence that is provided is in respect to the risk of DRSP compared to LNG, and in any event a determination, even in respect to VTE, would do little to advance to conclusion the claims of any individual class member.

[81] It is my opinion that there is clearly some basis in fact for the general causation issue regarding the VTE adverse health effect as outlined in the epidemiology study evidence contained in the affidavits of Gerstman and further confirmed by the amendments made to the product monographs on November 30, 2011, which specifically references at page 8 that the risk of VTE with DRSP containing COCs is higher when compared to users of LNG containing COCs.

[82] I am also satisfied that Gerstman's first affidavit (attachment #3) and Gerstman's second affidavit, para. 27, also identify an FDA-sponsored study [the Sidney study] from 2011, which study indicates that DRSP carries an unfavourable ATE risk deferential, even though the study was only in respect to women aged 35 to 55. While this study may be of a limited nature, it does provide evidence to meet the some basis in fact requirement to advance the plaintiffs' claims.

[83] The final causation issue is in respect to the sufficiency of the gallbladder disease allegations. In this regard, Bérard's opinion was relied upon by the applicant to establish that there was some basis in fact for this general causation question regarding Yasmin and Yaz's effect on gallbladder disease. Bérard's report dated April 23, 2014 references a "plausible mechanism of action leading to a relationship between the use of DRSP and the risk of gallbladder disease." She concluded her opinion with a statement that "further evidence needs to accumulate before a causality assessment could be done". However, in cross-examination on her opinion, Bérard stated that one of the epidemiological studies which she referred to had found that there was a clinical difference regarding the risk of gallbladder disease, that there was a mechanism that could explain the increased risk, and that this risk ought to have been mentioned to patients. (See page 59, para. 197 to page 61, para. 201 of the cross-examination of Bérard dated December 2, 2014.)

[84] I recognize that Bayer has filed opposing expert opinions which suggest that in a clinical setting, physicians will still routinely prescribe Yasmin and Yaz to their patients and that the Society of Obstetricians and Gynecologists still recommends usage of fourth-generation COCs containing DRSP, including Yasmin and Yaz, stating that the benefits of these products outweigh the risks. However, as mentioned previously, certification applications are not the place where the merits of the lawsuits are to be determined, but only where a procedural method for such determination is established. Similar general causation questions have been certified in many other pharmaceutical cases including the *Schwoob* case which involved almost an identical common issue. It is my opinion therefore that common issue No. 1 is an appropriate common issue.

Common Issue No 2. — If the answer to #1 is "yes", did Bayer breach a duty to warn of the increased risks of Yasmin and Yaz over levonorgestrel-containing combination oral contraceptives?

[85] A common issue relating to the duty to warn of increased risks is also found in many Canadian prescription pharmaceutical class actions. See *Wilson v Servier Canada Inc.* (2000), 50 OR (3d) 219 at para 107 (Ont Sup Ct); *Heward v Eli Lilly & Co.* (2007), 39 CPC (6th) 153 at para 91 (QL) (Ont Sup Ct) [*Heward*]; *Goodridge v Pfizer Canada Inc.*, 2010 ONSC 1095 at para 122, 101 OR (3d) 566 [*Goodridge*]; *Stanway v Wyeth Canada Inc.*, 2011 BCSC 1057 at para 54, 10 CPC (7th) 51; *Bartram (Litigation guardian of) v GlaxoSmithKline Inc.*, 2012 BCSC 1804 at para 38, affirmed 2013 BCCA 462, 369 DLR (4th) 111; and *Schwoob* at para 35.

[86] Bayer's position is that this proposed common issue is too vague and abstract because any question must refer specifically to the product monographs which contain manufacturers' warnings. Bayer points out that there are 10 approved Health Canada monographs regarding Yasmin since it was first marketed in 2004 and six regarding Yaz since it was first marketed in 2008. Dembrowski's position however is that notwithstanding the changes in the product monographs, at no time did the monograph "clearly, completely or currently" explain the difference in risks between the different generations of COCs. A similar position was taken by the plaintiff in the *Heward* case where the court stated at para. 90:

> **90** ... The position of the plaintiffs - supported by the evidence of Dr Chue - is that none of the representations adequately warned class members of the risks of which they had knowledge, or reasonably ought to have been aware. If a court at trial found that later, but not earlier, warnings were adequate, a nuanced response such as that referred to by McLachlin C.J. in *Rumley*, at para 32, would be possible.

[87] I am satisfied that there is some basis in fact for this common issue as a duty to warn of an increased risk based upon the affidavit evidence of Gerstman and

the epidemiological studies referred to in his affidavits. As was referred to in the *Heward* case, the court will determine based upon the common issue at what point in time, warnings were adequate, if at all.

Common Issue No 3 — Should Bayer disgorge all or any of its revenue or profits from its sales of Yasmin or Yaz in Canada? If so, to whom, for what period, and in what amount?

[88] Counsel for Dembrowski points out that there is precedent for this common issue in Canada and referred to the *Heward, Goodridge* and *Schwoob* cases. Counsel submitted that if the plaintiffs "elected" to request such a remedy, there would be no need to consider individual damages or causation issues because the court could award an aggregate monetary award.

[89] Bayer's position is that this would not be an appropriate common issue because the vast majority of women who took Yasmin or Yaz not only suffered no damages, but actually derived the intended benefit from taking these drugs. Furthermore, Bayer submits that if liability was shown to exist, there would be a decision to be made by each individual woman as to whether she chose to waive her personal injury damages and instead pursue a restitutionary remedy. Accordingly, counsel for Bayer submitted that the issue of waiver of tort is not a compatible common issue.

[90] Dembrowski's counsel acknowledged in the brief filed in support of the application and in submissions before me that the waiver of tort claim is a request for an aggregate monetary award. Aggregate monetary awards can only be awarded in class actions in the circumstances prescribed in s. 31 of the *CAA*. Section 31 provides for three conditions that must be met in order for the court to make an aggregate monetary award:

> 31(1) The court may make an order for an aggregate monetary award respecting all or any part of a defendant's liability to class members and may give judgment accordingly if:
>
> (a) monetary relief is claimed on behalf of some or all class members;
>
> (b) no questions of fact or law other than those relating to the assessment of monetary relief remain to be determined in order to establish the amount of the defendant's monetary liability; and
>
> (c) the aggregate or a part of the defendant's liability to some or all class members can reasonably be determined without proof by individual class members.

[91] While requirement (a) is clearly met in the circumstances of this case, I am not satisfied that requirements (b) or (c) have been established. Even if the applicant received a favourable ruling on common issues 1 and 2, in order to have a viable cause of action, the individual plaintiffs must prove that they suffered loss or injury as a result of the defendants' breach of duty. In the *Pro-Sys Consultants* case at paras. 131 to 134, in part, Rothstein J. stated:

> **131** ... The aggregate damages provisions of the *CPA* relate to remedy and are procedural. They cannot be used to establish liability (*2038724 Ontario Ltd. v. Quizno's-Canada Restaurant Corp.*, 2010 ONCA 466, 100 O.R. (3d) 721, at para. 55). The language of s. 29(1)(b) specifies that no question of fact or law, other than the assessment of damages, should remain to be determined in order for an aggregate monetary award to be made. As I read it, this means that an antecedent finding of liability is required before resorting to the aggregate damages provision of the *CPA*. This includes, where required by the cause of action such as in a claim under s. 36 of the *Competition Act*, a finding of proof of loss. I do not see how a statutory provision designed to award damages on an aggregate basis can be said to be used to establish any aspect of liability.
>
> ...
>
> **133** ... The *CPA* was not intended to allow a group to prove a claim that no individual could. Rather, an important objective of the *CPA* is to allow individuals who have provable individual claims to band together to make it more feasible to pursue their claims.

> **134** The question of whether damages assessed in the aggregate are an appropriate remedy can be certified as a common issue. However, this common issue is only determined at the common issues trial after a finding of liability has been made. ...
>
> [Emphasis added]

See also *Wakelam v Johnson & Johnson*, 2014 BCCA 36 at para 93, [2014] 5 WWR 7.

[92] I am satisfied that the proposed third common issue is not appropriate until such time as liability has been established based upon individual member's personal circumstances. In this case, the defendants have not conceded liability to any members of the class. In the case of *Fulawka v Bank of Nova Scotia*, 2012 ONCA 443, 352 DLR (4^{th}) 1, the court stated at para. 124:

> **124** There is a crucial distinction between the test for certifying common issues under s. 5(1)(c) and the question of whether an aggregate assessment of monetary relief may be certified as a common issue. As referred to above, at para. 81, and as amply developed in class proceedings jurisprudence, the proposed common issues do not have to be determinative of the defendant's liability to members of the class for an action to be certified. In contrast, the language of s. 24(1)(b) reveals that in order to be an appropriate case for an aggregate assessment, the resolution of the common issues must be capable of establishing the defendant's monetary liability to at least some members of the class. It is not enough that the resolution of the common issues could lead to injunctive or declaratory relief in favour of the class.

[93] Similarly, in the circumstances of this case, resolution of the first two common issues would not establish the defendants' liability to the individual members of the class until such time as it is established that such individual suffered personal injury or loss as a result of having ingested Yasmin or Yaz. This is not a case where damage to each member of a class is a given. Here, some users of Yasmin and Yaz, may have had a benefit and no adverse reaction. There remains a factual issue to

be determined before liability is established. Accordingly, this common issue does not meet the requirements of s. 31(1)(b) or (c) of the *CAA*. Although a similar common issue was approved on certification in the *Schwoob* case, that certification was granted prior to *Pro-Sys Consultants*. Accordingly, I am not prepared to grant this third common issue as appropriate for certification in this action.

(d) *The Fourth Statutory Requirement*

Would a class action be the preferable procedure for resolving the common issues? – CAA s. 6(1)(d)

[94] Chief Justice McLachlin in *Hollick* explained the test in meeting this requirement when she stated:

> **28** The report of the Attorney General's Advisory Committee makes clear that "preferable" was meant to be construed broadly. The term was meant to capture two ideas: first the question of "whether or not the class proceeding [would be] a fair, efficient and manageable method of advancing the claim", and second, the question of whether a class proceeding would be preferable "in the sense of preferable to other procedures such as joinder, test cases, consolidation and so on": Report of the Attorney General's Advisory Committee on Class Action Reform, supra, at p. 32. In my view, it would be impossible to determine whether the class action is preferable in the sense of being a "fair, efficient and manageable method of advancing the claim" without looking at the common issues in their context.
>
> **29** The Act itself, of course, requires only that a class action be the preferable procedure for "the resolution of the common issues" (emphasis added), and not that a class action be the preferable procedure for the resolution of the class members' claims. I would not place undue weight, however, on the fact that the Act uses the phrase "resolution of the common issues" rather than "resolution of class members' claims". ...

[95] Bayer's position is that a class procedure is not preferable for the present action because it would "not be a fair, efficient and manageable method for

resolving the claims of individual women"; that it will not result in judicial economy or access to justice; and that it will not do anything to achieve behavioural modification in a manner better than the existing individual actions that are now under way. Bayer submits that the evidence filed indicates that there are five individual actions commenced and proceeding in Ontario, notwithstanding that there is also a certified Ontario proceeding in *Schwoob*. In response, counsel for Dembrowski submits that the certification process promotes access to justice when plaintiffs sue drug manufacturers because they are complex cases and that experts are too expensive for individual actions.

[96] I am satisfied that the current action meets the preferable procedure test established in *Hollick*. There is little doubt that, although individual actions are possible and have been brought in some jurisdictions, actions against drug manufacturers are difficult and expensive. The complex expert evidence already provided in this action involved extensive cross-examination and many pages of evidence. Having to duplicate such evidence in each individual claim would not be an efficient or cost effective use of resources. Determining the first two common issues at one time is a manageable method of advancing the individual claims. Should the common issues be decided against the defendants, there is likely to be immediate behaviour modification that may not have happened with scattered individual actions. The outcome of individual actions would not attract the same public scrutiny. The fact that there may be individual issues which are left to be determined after the common issues does not bar certification or suggest that a class action would not be the preferable procedure. Therefore, I confirm that I am satisfied that there is some basis in fact for the requirement that a class action is the preferable procedure for determining the common issues.

(e) *The Fifth Statutory Prerequisite*

Is there an adequate representative plaintiff? – CAA s. 6(1)(e)

[97] Section 6(1)(e) of the *CAA* requires that the court be satisfied that the person requesting certification as a representative plaintiff who would adequately represent the interests of the class and does not have a conflict in doing so. In determining whether there is adequate representation, the court will look at the litigation plan submitted by the proposed representative plaintiff to determine if there is a workable method of advancing the litigation on behalf of the class and of notifying class members of the proceedings.

[98] In this case, the amended statement of claim identifies two individuals, Dembrowski and Alina Popa, as plaintiffs. However, it is only Dembrowski who has applied for certification as a representative plaintiff for all members of the class. No explanation for this was presented at the certification hearing nor did either counsel refer to it as an issue. I do not, however, consider that to be a bar to certification as the *CAA* does not require that all named plaintiffs in a class action jointly apply for certification.

[99] In the affidavit attached to her application for certification, Dembrowski also attached, as an exhibit, a proposed litigation plan. When counsel for Bayer raised objections to this litigation plan in the brief of law filed in opposition to the certification application, counsel for Dembrowski expanded upon the litigation plan in a reply brief of law. I am, however, reluctant to consider representations in counsel's brief as to possible revisions of Dembrowski's litigation plan. At the hearing of the application, counsel for both parties concentrated on the other statutory requirements and did not address directly the issues which had been raised in the briefs concerning the litigation plan.

[100] In light of my findings concerning the common issues and in particular that a waiver of tort will not be a common issue, a revised litigation plan will be required before the statutory requirements of s. 6(1)(e) can be considered. I therefore order that a revised litigation plan be filed within 15 days of the date of these reasons and that any further submissions counsel may wish to make on it be filed within 30 days after the revised litigation plan has been filed. It is my expectation that this revised litigation plan will deal with many of the concerns raised by counsel for Bayer as well as the responses to these concerns which were made by Dembrowski's counsel in the reply brief of law. I will then be in a position to make a final ruling on whether the proposed litigation plan is satisfactory and whether the provisions of s. 6(1)(e) have been met.

Conclusion

[101] For the reasons above, I find that the requirements for certification in s. 6(1)(a) through (d) of the *CAA* are satisfied. I will deal with the requirements of s. 6(1)(e) if and when a revised litigation plan has been filed, which as previously indicated should be within 15 days of the release of these reasons. Further submissions may be made by counsel in respect to the revised litigation plan if received within 30 days of the filing of the revised litigation plan. Oral submissions can also be made if requested.

[102] Since the hearing of the application for certification, counsel for Dembrowski filed a letter to the court requesting that the court consider awarding costs of the application to the applicant. Further submissions from counsel for both parties on this issue may also be made both in written briefs of law and oral submissions, if requested.

[103] The application for certification is adjourned to a date to be determined

following the filing of the further material requested above.

J.
N.G. GABRIELSON