IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Stanway v. Wyeth Canada Inc.,*
2011 BCSC 1057

Date: 20110804
Docket: S111075
Registry: Vancouver

Between:

Dianna Louise Stanway

Plaintiff

And

Wyeth Canada Inc., Wyeth Pharmaceuticals Inc., Wyeth Holdings Canada Inc., Wyeth Canada, Wyeth Ayerst International Inc. and Wyeth

Defendants

Before: The Honourable Madam Justice Gropper

Corrected Judgment: The text of the judgment was corrected at paragraphs 7 and 82 where changes were made on August 15, 2011

Reasons for Judgment on Certification

Counsel for the Plaintiff:	D. Lennox N.C. Hartigan
Counsel for the Defendants:	W. McNamara T.J. Walsh R.C. Sutton
Place and Date of Hearing:	Vancouver, B.C. March 9-11, 2011
Place and Date of Judgment:	Vancouver, B.C. August 4, 2011

INTRODUCTION

[1] Ms. Stanway seeks to certify her class action against the defendants, Wyeth Canada Inc., Wyeth Pharmaceuticals Inc., Wyeth Holdings Canada Inc., Wyeth Canada, Wyeth Ayerst International Inc. and Wyeth (collectively, Wyeth"). She alleges that she contracted ductal and lobular breast cancer as a result of consuming its products, Premarin in combination with progestin and Premplus.

[2] Premarin is conjugated estrogen derived from a natural source. Conjugated estrogen such as Premarin was first marketed in Canada in 1941. It became widely used in the 1960s. An estrogen plus progestin regimen became widespread in the late 1970s when hormone therapy added a progestin (a synthetic form of progesterone) to estrogen to counter an increased risk of endometrial cancer associated with taking estrogen alone. Premarin and Premplus are prescribed to women to treat the symptoms of menopause and are known as hormone therapy ("HT").

[3] In her statement of claim, the plaintiff alleges that the defendants were negligent in their marketing, testing, manufacturing, labelling, distribution, promotion and sale of Premarin taken with progestin and Premplus. The plaintiff also alleges that the defendants breached the British Columbia *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 [*BPCPA*], by engaging in solicitations, offers, advertisements and promotion of the sale and supply of Premarin taken with progestin and Premplus which had the effect of deceiving consumers regarding the efficacy and safety of HT.

[4] Four conditions are necessary to a class action: the class must be capable of clear definition; there must be issues of fact or law common to all class members; success for one class member on a common issue must mean success for all; the class representative must adequately represent the class: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46, [2001] 2 S.C.R. 534 at paras. 38-42.

[5] The advantages of a class action were outlined by the Supreme Court of Canada in *Hollick v. Toronto (City)*, 2001 SCC 68, [2001] 3 S.C.R. 158 at para. 15:

> [C]lass actions provide three important advantages over a multiplicity of individual suits. First, by aggregating similar individual actions, class actions serve judicial economy by avoiding unnecessary duplication in fact-finding and legal analysis. Second, by distributing fixed litigation costs amongst a large number of class members, class actions improve access to justice by making economical the prosecution of claims that any one class member would find too costly to prosecute on his or her own. Third, class actions serve efficiency and justice by ensuring that actual and potential wrongdoers modify their behaviour to take full account of the harm they are causing, or might cause, to the public.

LEGISLATION

[6] The relevant enactments are:

(a) *Class Proceedings Act*, R.S.B.C. 1996, c. 50 [*CPA*], ss. 4 and 5:

> **Class certification**
>
> 4 (1) The court must certify a proceeding as a class proceeding on an application under section 2 or 3 if all of the following requirements are met:
>
> (a) the pleadings disclose a cause of action;
>
> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
>
> (e) there is a representative plaintiff 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, an interest that is in conflict with the interests of other class members.
>
> (2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, the court must consider all relevant matters including the following:
>
> > (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members;
> >
> > (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;
> >
> > (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings;
> >
> > (d) whether other means of resolving the claims are less practical or less efficient;
> >
> > (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.
>
> **Certification application**
>
> 5 (1) An application for a certification order under section 2 (2) or 3 must be supported by an affidavit of the applicant.
>
> ...
>
> (7) An order certifying a proceeding as a class proceeding is not a determination of the merits of the proceeding.

(b) *BPCPA*, ss. 4-6:

> **Deceptive acts or practices**
>
> 4 (1) In this Division:
>
> **"deceptive act or practice"** means, in relation to a consumer transaction,
>
> > (a) an oral, written, visual, descriptive or other representation by a supplier, or

(b) any conduct by a supplier

that has the capability, tendency or effect of deceiving or misleading a consumer or guarantor;

"representation" includes any term or form of a contract, notice or other document used or relied on by a supplier in connection with a consumer transaction.

(2) A deceptive act or practice by a supplier may occur before, during or after the consumer transaction.

(3) Without limiting subsection (1), one or more of the following constitutes a deceptive act or practice:

(a) a representation by a supplier that goods or services

(i) have sponsorship, approval, performance characteristics, accessories, ingredients, quantities, components, uses or benefits that they do not have,

...

(b) a representation by a supplier

...

(vi) that uses exaggeration, innuendo or ambiguity about a material fact or that fails to state a material fact, if the effect is misleading,

...

(viii) that appears in an objective form such as an editorial, documentary or scientific report if the representation is primarily made to sell goods or services, unless the representation states that it is an advertisement or promotion, (d) a prescribed act or practice.

Prohibition and burden of proof

5 (1) A supplier must not commit or engage in a deceptive act or practice in respect of a consumer transaction.

(2) If it is alleged that a supplier committed or engaged in a deceptive act or practice, the burden of proof that the deceptive act or practice was not committed or engaged in is on the supplier.

(c) *Supreme Court Rules*, R. 9-5(1):

> **Scandalous, frivolous or vexatious matters**
>
> (1) At any stage of a proceeding, the court may order to be struck out or amended the whole or any part of a pleading, petition or other document on the ground that
>
> > (a) it discloses no reasonable claim or defence, as the case may be,
> >
> > (b) it is unnecessary, scandalous, frivolous or vexatious,
> >
> > (c) it may prejudice, embarrass or delay the fair trial or hearing of the proceeding, or
> >
> > (d) it is otherwise an abuse of the process of the court, and the court may pronounce judgment or order the proceeding to be stayed or dismissed and may order the costs of the application to be paid as special costs.
>
> **Admissibility of evidence**
>
> (2) No evidence is admissible on an application under subrule (1)(a).

PROPOSED CLASS DEFINITION AND COMMON ISSUES

[7] Ms. Stanway seeks to certify a class defined as:

> Women who were prescribed Premplus, or Premarin in combination with progestin, in Canada during the Class Period and ingested Premplus, or Premarin in combination with progestin and were thereafter diagnosed with breast cancer.
>
> The “Class Period” runs from January 1, 1977 until December 1, 2003, inclusive.
>
> Common Issues
>
> 1. certifying the following issues as common issues:
>
> > (a) Is there a causal connection between the use of Premplus, or Premarin in combination with progestin, and breast cancer and if so, what is the nature and extent of the connection?
> >
> > (b) Did the Defendants, or any of them, owe a duty of care to class members?
> >
> > (c) Did the Defendants, or any of them, breach a duty of care to class members, and if so, when?
> >
> > (d) If the Defendants, or any of them, breached a duty of care owed to class members, were the Defendants, or any of them, guilty of conduct that justifies punishment?

(e) If the answer to common issue 1(d) is "yes" and if the aggregate compensatory damages awarded to class members does not achieve the objectives of retribution, deterrence and denunciation in respect of such conduct, what amount of punitive damages is awarded against the Defendants, or any of them?

2. certifying the following issues as common issues for class members who ingested Premplus or Premarin that was supplied in British Columbia:

(a) Did the Defendants' solicitations, offers, advertisements, promotions, sales and supply of Premplus and Premarin for personal, family or household use by class members fall within the meaning of "consumer transactions" under the *Business Practices and Consumer Protection Act* ("BPCPA")?

(b) With respect to the supply in British Columbia of Premplus and Premarin to class members for their personal, family or household use, are the Defendants, or any of them, "suppliers" as defined in the BPCPA?

(c) Are the class members "consumers" as defined by the BPCPA?

(d) Did the Defendants, or any of them, engage in conduct that constituted deceptive acts or practices contrary to the BPCPA as alleged in the Amended Statement of Claim?

EVIDENCE ON A CERTIFICATION APPLICATION

[8] The plaintiff, as the class representative, must provide the court with sufficient evidence to support certification. The plaintiff must show "some basis in fact" for each of the certification requirements, other than the requirement that the pleadings disclose a cause of action. The evidentiary threshold is not onerous: *Hollick* at paras. 21, 25.

[9] The defendants may respond with evidence of their own to challenge certification but there is a heavier evidentiary burden on the defendants: the defendants must show that there is no basis in the evidence for the facts asserted by the plaintiff.

[10] The court does not decide factual issues in the same manner as it would as a trier of fact: *Lambert v. Guidant Corp.*, 72 C.P.C. (6th) 120 (Ont. S.C.J.), at paras. 68-69, leave to appeal ref'd 82 C.P.C. (6th) 367 (Ont. Div. Ct.). At the

certification stage, the court does not apply a "likely to succeed" test of the plaintiff's claim: *Lambert* at paras. 109-110.

[11] In *Pro-Sys Consultants Ltd. v. Infineon Technologies AG*, 2009 BCCA 503, leave to appeal ref'd [2010] S.C.C.A. No. 32, the court explained the proper assessment of expert opinion evidence in the context of certification of a class action at para. 67:

> [67] The chambers judge subjected the evidence of Dr. Ross to rigorous scrutiny. He weighed it against the respondents' evidence and against Ms. Sanderson's evidence in particular. In so doing, he failed to take into account that the factual evidence upon which Ms. Sanderson's opinion was based came in part from the respondents and was untested. Further, he failed to adequately consider that Dr. Ross' opinion was necessarily preliminary since the appellant has not yet had access to the information Dr. Ross needs to perform his analysis. In my view, this approach was fundamentally unfair at this stage of the proceeding, when the appellant has not had discoveries and an adequate opportunity to marshal the evidence required by Dr. Ross for his analysis.

Plaintiff's Evidence

[12] Ms. Stanway filed an affidavit seeking to be appointed as the representative plaintiff. There are two other affiants, Judy Midgley and Kathryn Willis.

[13] The plaintiff relies upon the medical reports of Dr. Victoria Kirsh. She is an epidemiologist employed by Cancer Care Ontario in its research unit on population studies and surveillance.

[14] The plaintiff asserts that the reports of Dr. Kirsh show there is "some basis in fact" to the allegations in the statement of claim. Specifically, the plaintiff asserts (all quotations are from Dr. Kirsh's reports):

1. Evidence supports the implication of estrogen and progestin in the etiology of breast cancer. Breast tissue is estrogen dependent and responds to the hormone's growth simulating effects. There is evidence of a role for estrogen metabolites in breast cancer. Progestin increases cell proliferation in breast tissue and "therefore an association with breast cancer is not unexpected."

2. The Women's Health Initiative (WHI) study was initiated in 1991. It was a randomized controlled trial, referred to as a level 1 study. One arm of the study was designed to measure the risks and benefits of estrogen-progestin HT. This portion of the clinical trial commenced in 1997. In 2002, WHI researchers concluded that the risks associated with estrogen plus progestin for use among healthy post menopausal women outweighed the benefits: after five years of follow up, estrogen plus progestin increased the risk of breast cancer.

3. A causal connection between estrogen-progestin therapy and an increased risk of breast cancer was established in the WHI study and these "findings were corroborated by results from recent prospective cohort studies; the increased risk appears to be particularly pronounced with longer durations of use."

4. News of the results of the WHI study caused a significant reduction in the number of prescriptions of HT. The decline in hormone therapy use in North America was followed by a decline in breast cancer rates.

5. Studies in international population trends show the same patterns in the years following the WHI trial results.

Defendants' Evidence

[15] The defendants rely on various expert reports, including that of Dr. John Collins, a retired specialist in obstetrics and gynecology with a sub-speciality in reproductive endocrinology and infertility and Dr. Robert Reid, a specialist in obstetrics and gynecology who is the chair of the division of reproductive endocrinology and infertility at Queen's University and an author of medical reports on menopause and other conditions related to aging. Dr. Reid also has a clinical practice where he provides advice and treatment to women presenting with menopausal symptoms. The defendants also rely on the report of Dr. Jan Sedgeworth, currently vice president of regulatory affairs with a consulting firm for the pharmaceutical and biotechnology industries, upon the affidavits of Marie Berry,

a lawyer and pharmacist and Terry Davidson, a former district manager employed by Wyeth Canada from 1979 to 2006.

[16] Based upon the evidence they have provided, the defendants assert:

1. Dr. Collins addresses epidemiological issues in his affidavit, particularly the different types and corresponding levels of scientific evidence used in epidemiological research. He explains in his report the development of breast cancer and the numerous factors relating to genetics, family and personal history and life choices. The risk of each woman for breast cancer based on these various factors is different. Dr. Collins explains the hormone therapy which preceded the WHI study and the significance of the WHI study. Despite an association between HT and breast cancer, causation of breast cancer remains unknown, both generally and in specific cases.

2. Dr. Reid addresses a perspective on HT from his practice related experience. He addresses the pre-WHI study attitudes on HT and explains how the WHI study, and additional research, continued to change perceptions about the role of HT in treating menopausal symptoms. Dr. Reid reviews the sources of information and drug products for physicians over the period of HT. He also describes a typical encounter with a menopausal patient and the discussion which would occur between a doctor and his or her patient forming part of the informed consent for treatment, the individualized nature of the decision to use HT and the factors that each patient and physician must consider in determining whether HT use is appropriate.

3. Dr. Sedgeworth describes the regulatory framework in which Canadian drug manufacturers develop, test, manufacture, label and market their products. She discusses the role that Health Canada has played in considering use of HT in patients and that a consultative panel was struck to consider the relationship between HT and breast cancer.

Health Canada regulates the contents of the pharmaceutical product labels and the packaging inserts and imposes stringent restrictions regarding consumer advertising.

4. Marie Berry describes the interchangeability of pharmaceutical products. A pharmacist may dispense another congregated estrogen instead of a branded estrogen product like Premarin. She also addresses the interaction between a pharmacist and a patient concerning the risks associated with HT, including breast cancer and the benefits.

5. Terry Davidson's affidavit attaches extensive communications and informal documents from Wyeth Canada and from the public domain regarding menopause, conditions associated with aging and HT. The materials appended to Mr. Davidson's affidavit describe the ongoing debate about whether HT is a risk factor for breast cancer and the evaluation and risk benefit analysis to be undertaken by a physician before prescribing HT. The material also demonstrates that Health Canada approved the product labelling. There was limited direct to consumer advertising undertaken and Wyeth Canada's sales representatives did not provide marketing material or information directly to patients, only to physicians and pharmacists.

CLASS CERTIFICATION

1. Cause of Action

[17] The requirement of disclosing a cause of action has a low threshold and the plaintiff will fail only if the claim is "certain to fail" or if it is "plain and obvious" that the statement of claim discloses no reasonable cause of action: *Koubi v. Mazda Canada Inc.,* 2010 BCSC 650 at paras. 42-43. No evidence is admissible, and the material facts pleaded are accepted as true, unless patently ridiculous or incapable of proof: *Hollick* at para. 25.

[18] The plaintiff asserts that both its claim in negligence and under the provisions of the *BPCPA* disclose a cause of action.

[19] In respect of a cause of action in negligence, the plaintiff says that the common law imposes a heavy obligation on manufacturers of medical products to provide adequate warnings to doctors and patients: *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 23. *Hollis* also notes that the heavy obligation to provide adequate warning is related to the dependence that both the patient and the physician have on the manufacturers to provide clear and current information concerning the inherent dangers of the use of their product. It also goes to the issue of informed consent (at para. 24).

[20] The plaintiff also asserts that the manufacturer's duty to warn cannot be delegated to the physician: *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, 54 O.R. (2d) 92, 25 D.L.R. (4th) 658 at para. 74.

[21] In respect of the particulars of negligence, the plaintiff argues that while the defendants appeared to be attuned to the potential issue of a connection between breast cancer and HT, they were not forthcoming, nor clear and complete in their warnings. She refers to the label having gone through many changes between 1992 and December 2003, which express a "qualitative difference" in warnings. The plaintiff asserts that if the defendants had done appropriate research, the warning label which appears in December 2003 would have been issued years or perhaps decades before.

[22] The December 1, 2003 warning label was contained in a box entitled "warning." It refers to the WHI study and mentions an increased risk of invasive breast cancer and a significant risk of osteoporosis. It recommends the lowest effective dose for the shortest period as possible.

[23] In respect of her consumer protection claim under the *BPCPA*, the plaintiff argues that the defendants, as "supplier," as defined in s. 1, engaged in deceptive

acts or practices contrary to s. 4. Section 5(2) places the burden of proof on the supplier, and thus makes this claim more suited for a class action.

[24] The plaintiff suggests that the deceptive acts described under s. 4(3) do not represent an exhaustive list. She also suggests that the provisions which are relevant are s. 4(3)(a)(i) because the defendants claim benefits which the product does not have; s. 4(3)(b)(vi) in that the defendants exaggerated or failed to state a material fact, specifically, the inadequacy of the warning label in expressing that the risk of breast cancer was a material fact; and s. 4(3)(b)(viii) may apply if scientific reports were prepared to promote and sell the product.

[25] The defendants do not take issue with the plaintiff having a cause of action in negligence, although they challenge the plaintiff's assertion that the evidence establishes that Premarin in combination with progestin and Premplus are capable of causing breast cancer. The defendants challenge the plaintiff's assertion that she has a cause of action under the *BPCPA*.

[26] The defendants argue that there is no cause of action relating to the defendants' alleged failure to disclose all material facts relating to the efficacy and safety of Premarin and Premplus, or lack thereof (para. 17 of the amended statement of claim). The defendants assert that the *BPCPA* does not include a "failure to disclose a deceptive act or practice, as its predecessor, the *Trade Practices Act* did." The court noted in *Blackman v. Fedex Trade Networks Transport & Brokerage (Canada), Inc.*, 2009 BCSC 201, that a claim for "failure to disclose" could not be advanced. The plaintiff's pleadings do not particularize the nature of the deceptive acts and practices but simply makes bald allegations relating to alleged breaches. This is fatal to a product liability case based on the consumer protection legislation: *Griffin v. Dell Canada Inc.*, 72 C.P.C. (6th) 158 (Ont. S.C.J.) at para. 65, leave to appeal ref'd, 180 A.C.W.S. (3d) 584 (Ont. Div.Ct.).

[27] The defendants assert that the representations which were made to the plaintiff and the potential class members were numerous; they were not the same for all potential plaintiffs nor consistent. There were representations made over a

significant period to physicians and to potential purchasers. One cannot amalgamate all the statements made by the defendants over 26 years to support a claim under the *BPCPA*. The proceeding would be unmanageable and unwieldy: the analysis of the alleged deception must be done individually.

[28] There is no dispute that the plaintiff has a cause of action against the defendants in negligence. I find that she also has a cause of action under the *BPCPA.* Failure to disclose appears to remain a deceptive act or practice despite its omission from the *BPCPA*. In *Chalmers v. AMO Canada Company,* 2010 BCCA 560, Tysoe J.A. stated:

> [18] Whatever deficiencies may have existed in the statement of claim at the time of the certification hearing, it is my opinion that the amended statement of claim clearly gives particulars of the claim under the *Consumer Protection Act* [*BPCPA*]. The amended statement of claim gives particulars of two specific representations allegedly made by the defendants, and asserts they were untrue. It also asserts that the defendants breached the *Consumer Protection Act* [*BPCPA*] by failing to disclose the risk that the lens solution would not prevent the eye infection and by misrepresenting that the lens solution was safe, comfortable and effective at preventing infection.

[29] The failure to disclose allegation was found to constitute a deceptive practice in *Bouchanskaia v. Bayer Inc.*, 2003 BCSC 1306.

[30] The lack of particulars referred to in *Griffin* was fatal to the plaintiff's claim under the *Competition Act*, R.S.C. 1985, c. C-34, ss. 36(1) and 52, but the court granted the plaintiff's leave to amend their pleadings to particularize their claim.

[31] The plaintiff's claim in respect of breach under the *BPCPA* is addressed in paras. 16-21 of the amended statement of claim. They are described in para. 17 as follows:

> The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Premarin and Premplus, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the efficacy and safety of Premarin and Premplus. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Premarin and Premplus were deceptive acts and practices contrary to … s. 4 of the BPCPA *.* The Defendants' deceptive acts and practices included the Defendants' failure to properly disclose all material

> facts regarding the efficacy and safety of Premarin and Premplus, or lack thereof.

[32] I am satisfied that the amended statement of claim is sufficiently particular to determine that the plaintiff has a cause of action under the *BPCPA.*

[33] The defendants' objections that the claims under the *BPCPA* are by their nature individual and therefore unwieldy in a class action are more appropriately considered in the context of the other criteria for certification.

2. Identifiable Class

[34] The Supreme Court of Canada defines the requirement for identifiable class in *Dutton* at para. 38.

> … First, the class must be capable of clear definition. Class definition is critical because it identifies the individuals entitled to notice, entitled to relief (if relief is awarded), and bound by the judgment. It is essential, therefore, that the class be defined clearly at the outset of the litigation. The definition should state objective criteria by which members of the class can be identified. While the criteria should bear a rational relationship to the common issues asserted by all class members, the criteria should not depend on the outcome of the litigation. It is not necessary that every class member be named or known. It is necessary, however, that any particular person's claim to membership in the class be determinable by stated, objective criteria [citations omitted].

[35] The plaintiff asserts that the class is identifiable and meets the requirements of s. 4(1)(b) of the *CPA*. The plaintiff asserts that the class is sufficiently numerous, objective and not tied to the merits. It is also sufficiently clear that class members can choose whether to opt in or out of this proceeding. Class members will know whether they have had HT and whether they have had breast cancer.

[36] A non-resident sub-class of individuals who are not residents of British Columbia and, therefore, not entitled to pursue the remedy under the *BPCPA* will be represented by Kathryn Willis, who is a Manitoba resident and is willing to represent the non-resident sub-class. Section 16(2) of the *CPA* expressly permits participation of non-residents of class actions in British Columbia.

[37] The defendant concedes that there is an identifiable class period but they assert that a 26-year period presents a moving target. The court will have to consider the evolution of medical science from throughout the period to determine whether there is general causation and general breach. The defendants also point out that the state of knowledge of medical science is reflected in the evolution of the product monograph: both in the label and in the Compendium of Pharmaceuticals Specialties published by the Canadian Pharmacists Association (CPA).

[38] I am satisfied that there is an identifiable class, including a non-resident class. The requirements of s. 4(1)(b) of the *CPA* is satisfied.

3. Common Issues

[39] Section 4(1)(c) of the *CPA* requires the representative plaintiff to raise common issues. "Common issues" is defined in s. 1 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;

[40] The Supreme Court of Canada explains the fundamental question behind whether the claims of the potential class members raise common issues at para. 18 in *Hollick*:

> [T]he 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" *Dutton* (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.

[41] The focus is not on how many individual issues there might be, but whether there are any issues which necessarily resolve each class member's claim or a substantial ingredient of each member's claim: *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at para. 55. Mr. Justice Strathy provided a non-exhaustive list of general propositions in respect of common issues at para. 140 of *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42:

[140] The following general propositions, which are by no means exhaustive, are supported by the authorities:

A: The underlying foundation of a common issue is whether its resolution will avoid duplication of fact-finding or legal analysis: *Western Canadian Shopping Centres Inc. v. Dutton*, above, at para. 39.

B: The common issue criterion is not a high legal hurdle, and an issue can be a common issue even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution: *Cloud v. Canada (Attorney General)*, above, at para. 53.

C: There must be a basis in the evidence before the court to establish the existence of common issues: *Dumoulin v. Ontario*, [2005] O.J. No. 3961 (S.C.J.) at para. 25; *Fresco v. Canadian Imperial Bank of Commerce*, above, at para. 21. As Cullity J. stated in *Dumoulin v. Ontario*, at para. 27, the plaintiff is required to establish "a sufficient evidential basis for the existence of the common issues" in the sense that there is some factual basis for the claims made by the plaintiff and to which the common issues relate.

D: In considering whether there are common issues, the court must have in mind the proposed identifiable class. There must be a rational relationship between the class identified by the Plaintiff and the proposed common issues: *Cloud v. Canada (Attorney General)*, above at para. 48.

E: The proposed common issue must be a substantial ingredient of each class member's claim and its resolution must be necessary to the resolution of that claim: *Hollick v. Toronto (City)*, above, at para. 18.

F: A common issue need not dispose of the litigation; it is sufficient if it is an issue of fact or law common to all claims and its resolution will advance the litigation for (or against) the class: *Harrington v. Dow Corning Corp*., [1996] B.C.J. No. 734, 48 C.P.C. (3d) 28 (S.C.), aff'd 2000 BCCA 605, [2000] B.C.J. No. 2237, leave to appeal to S.C.C. ref'd [2001] S.C.C.A. No. 21.

G: With regard to the common issues, "success for one member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent." That is, the answer to a question raised by a common issue for the plaintiff must be capable of extrapolation, in the same manner, to each member of the class: *Western Canadian Shopping Centres Inc. v. Dutton*, above, at para. 4, *Ernewein v. General Motors of Canada Ltd.*, above, at para. 32; *Merck Frosst Canada Ltd. v. Wuttunee*, 2009 SKCA 43, [2009] S.J. No. 179 (C.A.), at paras. 145-146 and 160.

H: A common issue cannot be dependent upon individual findings of fact that have to be made with respect to each individual claimant: *Williams v. Mutual Life Assurance Co. of Canada* (2000), 51 O.R. (3d) 54, [2000] O.J. No. 3821 (S.C.J.) at para. 39, aff'd [2001] O.J. No. 4952, 17 C.P.C. (5th) 103 (Div. Ct.), aff'd [2003] O.J. No. 1160 and 1161 (C.A.); *Fehringer v. Sun Media Corp.*, [2002] O.J. No. 4110, 27 C.P.C. (5th) 155, (S.C.J.), aff'd [2003] O.J. No. 3918, 39 C.P.C. (5th) 151 (Div. Ct.).

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

[42] There are additional principles which have application here. While only a minimum evidentiary basis is required, the plaintiff must demonstrate that there is some evidence showing that the issue exists and that there is a basis in fact for accepting that the common issue is a triable issue: *Campbell v. Flexwatt Corp.* (1996), 25 B.C.L.R. (3d) 329 (S.C.) at para. 51. The assessment of whether an issue is a common issue involves a discretionary component. The Chambers Judge must determine whether the proposed issue is "significant" or a "substantial ingredient" of the claim: *Lam v. University of British Columbia*, 2010 BCCA 325 at para. 48.

[43] Whether the defendants' conduct could cause a particular type of harm may constitute a common issue: *Boulanger v. Johnson & Johnson Corp.* (2007), 40 C.P.C. (6th) 170 at para. 25. A product liability case may be particularly amenable to a class action: *Harrington v. Dow Corning Corp.*, 2000 BCCA 605 at para. 48.

[44] In *Pro-Sys Consultants*, the court cautioned against "exacting scrutiny" of expert opinion evidence adduced during a certification hearing in respect of the question of whether there are common issues (at para. 66).

[45] In *Wilson v. Servier Canada Inc.* (2000), 50 O.R. (3d) 219 (Ont. S.C.J.), and *Walls v. Bayer* Inc., 2005 MBQB 3, the courts expressed the view that an inquiry into whether a drug was defective or unfit is ideally suited for class certification.

[46] The plaintiff identifies five common issues based on a claim in negligence and four common issues based on the *BPCPA*. I will go through each of the issues identified by the plaintiff, shown at para. 7 above, in turn.

Part I. Common Issues Based on a Claim in Negligence

i. General Causation

[47] The defendants' position requires that I engage in "exacting scrutiny" of the expert opinions. While I appreciate that the experts hold differing views concerning whether there is a causal connection between the use of the defendants' products and breast cancer, I cannot at this stage of the proceedings compare or weigh the opinions. Such an approach is not consistent with the provisions of the *CPA*, which is to be construed generously in order to achieve its objects, as the jurisprudence consistently emphasises. I am not to assess the merits of the claim but rather, whether the form of the action can be heard as a class proceeding.

(a) The defendants have emphasized that the cases where certification has been granted have the three factors: a limited time period on the market, a more apparent nexus between the product and the harm, and the product was withdrawn voluntarily or at the direction of Health Canada. The drug Neurontin was still on the market when the class action was certified in *Goodridge v. Pfizer Canada Inc.,* 2010 ONSC 1095*.* I agree with the plaintiff that whether the drug is removed from the market or sold with a revised warning is immaterial: *Heward v. Eli Lilly & Co.* (2007), 39 C.P.C. (6th) 153 (Ont. S.C.J.), aff'd (2008) 91 O.R. (3d) 691 (Div. Ct.). The allegation is whether the defendants failed to provide a timely warning. In regard to the defendants' assertion that other cases were certified where there was more apparent nexus between the product and the harm, I repeat that it is not appropriate at this stage to subject the opinion evidence to vigorous scrutiny. Finally, in respect of whether the drug was voluntarily withdrawn from the market or by the direction of Health Canada does not preclude a certification in a class proceeding. Whether the drug

was approved and reviewed from time to time by Health Canada is not dispositive of liability.

(b) I find that the causal connection issue is a "substantial ingredient" of each of the class member's claims.

ii. Duty of Care

[48] The plaintiff suggests that this is a threshold legal question which should be decided once and is therefore an appropriate common issue. The defendants say that it should not be certified as a common issue as its resolution would not advance the litigation. The defendants assert that it is a "self-evident proposition of law that manufacturers owe a duty of care to consumers of those products."

[49] The defendants refer to *Bouchanskaia* where the Supreme Court of British Columbia refused to certify this as a common issue. The court held at paras. 99-100:

> [99] Bayer effectively conceded that this is a common question, but argued that it is a self-evident proposition of law, and its resolution would not advance the case. Plaintiff's counsel argued that Bayer's concession that it owed a duty of care would not be binding as against any other members of the proposed class unless the case were certified.
>
> [100] The question of whether Bayer owed a duty to persons who ingested a drug that it distributed is common, but is a question which must be answered affirmatively as a question of law. Answering this question alone would not advance this litigation and, accordingly, I did not certify that question.

[50] I agree with the defendants. This question is one of law. It is unnecessary to certify this question as a common issue.

iii. Breach of Duty

[51] The plaintiff asserts that this "core common issue" focuses on the defendants' knowledge and conduct toward the class. She suggests that the defendants were negligent in over-promoting the long-term and widespread use of the drugs; and in marketing them with insufficient research as to their efficacy and safety.

[52] The defendants assert that the duty of care must be evaluated over the entire class period of 26 years. There was an evolving state of medical knowledge, including an evolution of the “product monograph,” which included the label and the CPA entries. The issue of whether there was breach of duty will have to focus on each of these issues over a 26-year period: what did the defendants know at the beginning and before each change to the product monograph?

[53] The defendants also assert that the breach of duty issue is complicated by the involvement of healthcare professionals. The manufacturer’s duty to warn consumers is discharged if the manufacturer provides prescribing physicians, rather than consumers, with an adequate warning of potential dangers associated with a drug: *Goodridge* at para. 85.

[54] I find that this common issue should be certified as such despite the defendants’ reliance on having provided an adequate warning to a “learned intermediary." The defendants continue to have an obligation to provide accurate product labels throughout the class period. If they failed to do so, it remains the manufacturer’s responsibility. The learned intermediary’s considerations are irrelevant if the defendants failed to provide accurate product labels or did not fairly state the risk of the drugs. In *Tiboni v. Merck Frosst Canada Ltd.* (2008), 295 D.L.R. (4th) 32 (Ont. S.C.J.), aff’d (2009) 95 O.R. (3d) 269 (Div. Ct.), the court stated at para. 88:

> Merck accepts that the information it is to provide to physicians, and the manner in which this is to be done, is prescribed by regulation. If it has failed to provide such information in the prescribed manner, it may well be found to breach a duty, and a standard of care, whether or not a patient or a physician has obtained information from other sources, and whether the physician has passed on all appropriate information and warnings to the patient.

[55] The plaintiff also asserts that the defendants have actively engaged in misleading sales tactics. *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 54 O.R. (2d) 92 (C.A.), considered the promotional materials which the defendant provided to doctors and statements of the defendant’s sales agents who minimized the risk of harm at para. 66:

> This, patently, is not a case in which the intervening doctor proceeded solely onindependently acquired information. Ortho's failure to give physicians a warning commensurate with its actual knowledge of the dangers inherent in its products combined with the efforts of its sales representatives to minimize those dangers and counteract reports of adverse side- effects plainly influenced the doctor's opinion as to the drug's safety and the need to inform patients of the risks. It is, therefore, not unreasonable to conclude, as I infer the trial judge did, that the doctor's failure to disclose the risk of stroke (or, for that matter, any thromboembolic risk) to the plaintiff was contributed to by the inadequacy of Ortho's warnings, devoid as they were of any reference to stroke, and the promotional tactics of its pharmaceutical salesmen. In these circumstances, I cannot agree that there was no causal link between Ortho's breach of the duty to warn and the plaintiff 's ingestion of the drug, and, it follows, the doctor's intervention cannot operate to exonerate Ortho from liability for its breach of duty.

[56] Determining whether the learned intermediary defence is established is beyond the scope of the court's role in determining whether this is a common issue in support of a certification application. I find that this is an appropriate common issue.

iv. Does the Defendants' Conduct Justify Punishment

[57] It is not the role of this court in this certification proceeding to determine whether there was a breach of the duty of care by the defendants in the first place, and thus, it is not appropriate to deal with the question of whether that breach of duty justifies punishment.

v. Punitive Damages

[58] The courts in British Columbia endorse a bifurcated approach to punitive damages as a common issue in class action proceedings. The Court of Appeal stated in *Chalmers* at para. 31:

> [31] Although the ultimate determination of the entitlement and quantification of punitive damages must be deferred until the conclusion of the individual trials, it does not follow, in my opinion, that no aspect of the claim of punitive damages should be certified as a common issue. It is my view that the question of whether the defendants' conduct was sufficiently reprehensible or high-handed to warrant punishment is capable of being determined as a common issue at the trial in this proceeding where the other common issues will be determined. The focus will be upon the defendants' conduct and there is nothing in this case that will require a consideration of the individual circumstances of the class members in order to determine

> whether the defendants' conduct is deserving of punishment. The ultimate decision of whether punitive damages should be awarded, and the quantification of them, can be tried as a common issue following the completion of the individual trials.

[59] At para. 35, the court formulated the questions as follows:

> ...
>
> (c) If either or both of the Defendants breached a duty of care owed to class members, was either or both of the Defendants guilty of conduct that justifies punishment?
>
> (d) If the answer to common issue 7(c) is "yes" and if the aggregate compensatory damages awarded to class members does not achieve the objectives of retribution, deterrence and denunciation in respect of such conduct, what amount of punitive damages is awarded against either or both of the Defendants?

[60] I am satisfied, based on the court's comments in *Chalmers*, that the plaintiff's claim for punitive damages should be certified as a common issue.

Part II. Common Issues Based on the *BPCPA*

[61] The plaintiff asserts a statutory claim under the *BPCPA*. The *BPCPA* concerns conduct and representations which a supplier directs to the "world at large" in the marketing of its products as opposed to specific interactions between a supplier and an individual customer. The question of whether a representation is deceptive or misleading does not require an individual enquiry: *Wakelam v. Johnson & Johnson*, 2009 BCSC 839 at para. 39.

[62] The defendant reiterates its position regarding whether there is a cause of action under the *BPCPA*. In respect of whether it is an appropriate common issue, the defendants argue that alleged deceptive acts under the *BPCPA* are not common, but are an amalgamation of differing allegedly deceptive representations relating to safety, risk, efficacy, long-term use and benefits. The defendants also assert that there is no commonality amongst the issues challenged or the statements made. Remedies under the *BPCPA* will only be triggered if the transaction is considered to be a "deceptive practice." A statement made by the defendants in a particular context which may be deceptive will not advance other

class members' claims and cannot be extrapolated. Finally, the allegedly false representations were made in a variety of different documents at different times and in the context of a prescribing decision involving a physician and/or a pharmacist. Addressing these matters as a common issue is unmanageable, too broad and unfocused.

[63] I agree with the plaintiff that if I consider that the negligence allegation is a common issue, the claimant or the *BPCPA* does not make the case any more complicated. The defendants have not satisfied me that there is no commonality in respect of each individual class member which results in these claims not representing common issues.

[64] I agree with the plaintiff that the objective nature of the statutory cause of action under the *BPCPA* is suited for class treatment. The participation of individual class members is not necessary to determine whether the defendants have breached the statute.

4. Preferable Procedure

[65] Section 4(1)(d) of the *CPA* requires that a class proceeding be the preferable procedure for the fair and efficient resolution of common issues. The court, in considering whether to certify the class action, must analyze whether a class proceeding is preferable to any alternative method of resolving the claims and represents a fair, efficient and manageable way of determining common issues: *Cloud* at paras. 73-75.

[66] The factors to be considered are listed in s. 4(2) of the *CPA*.

[67] The *CPA* provides specific guidance to the court, as it was explained in *Rumley* at para. 35:

> [35] The question remains whether a class action would be the preferable procedure. Here I would begin by incorporating my discussion in Hollick as to the meaning of preferability: see Hollick, supra, at paras. 28-31. While the legislative history of the British Columbia Class Proceedings Act is of course different from that of the corresponding Ontario legislation, in my view the

> preferability inquiry is, at least in general terms, the same under each statute. The inquiry is directed at two questions: first, "whether or not the class proceeding [would be] a fair, efficient and manageable method of advancing the claim", and second, whether the class proceedings would be preferable "in the sense of preferable to other procedures" (Hollick, at para. 28). I would note one difference, however, between the British Columbia Class Proceedings Act and the corresponding Ontario legislation. Like the British Columbia legislation, the Ontario legislation requires that a class action be "the preferable procedure" for the resolution of the common issues: see Ontario Class Proceedings Act, 1992, s. 5(1)(d); British Columbia Class Proceedings Act, s.4(1)(d). Unlike the Ontario legislation, however, the British Columbia legislation provides express guidance as to how a court should approach the preferability question, listing five factors that the court must consider: see s. 4(2). I turn, now, to these factors.

[68] The advantages of a class procedure are discussed in *Bouchanskaia* at para. 150:

> [150] There are numerous advantages to class actions for plaintiffs. Mr. Branch suggested that they include the following:
>
> (a) Whatever limitation period is found to be applicable to the claim is tolled for the entire class (s. 39);
>
> (b) A formal notice program is created which will alert all interested persons to the status of the litigation (s. 19);
>
> (c) The class is able to attract counsel through the aggregation of potential damages and the availability of contingency fee arrangements (s. 38);
>
> (d) A class proceeding prevents the defendant from creating procedural obstacles and hurdles that individual litigants may not have the resources to clear;
>
> (e) Class members are given the ability to apply to participate in the litigation if desired (s. 15);
>
> (f) [omitted in the original]
>
> (g) The action is case managed by a single judge (s. 14);
>
> (h) The court is given a number of powers designed to protect the interests of absent class members (s. 12);
>
> (i) Class members are protected from any adverse cost award in relation to the common issues stage of the proceeding (s. 37);
>
> (j) In terms of the resolution of any remaining individual issues, a class proceeding directs and allows the court to create simplified structures and procedures (s. 27);
>
> (k) Through the operation of statute, any order or settlement will accrue to the benefit of the entire class, without the necessity of resorting to principles of estoppel (ss. 26 & 35).

[69] The courts have recognized that product liability suits involve significant time and expense and are best litigated once in a class action rather than many times through protracted individual litigation: *Tiboni v. Merck Frosst Canada Ltd.*, 295 D.L.R. (4th) 32; 60 C.P.C. (6th) 65 at para. 100.

Common Issues v. Individual Issues

[70] The plaintiff asserts that the common issues form an essential component of each class member's claim which favours certification. Despite their remaining individual issues of specific causation and damages, a decision on the common issues will substantially advance the litigation towards the resolution of the claims, which suggests that a class action procedure is preferable: *Tiboni* at para. 105-107. Even where individual issues substantially predominate over common issues, and the overall benefits may be slight, the plaintiff asserts that there may be some practical utility in deciding the common issues once: *T.L. v. Alberta* (*Child, Youth and Family Enhancement Act*, Director), 2009 ABCA 182 at para. 25.

[71] The defendants assert that all eight of the questions posed by the plaintiff as common issues could be decided by way of a common issues trial but, before liability can be determined for any class member, it will be necessary to consider multiple potential individual issues. These include the length of time a class member ingested the defendants' products, whether the class member took the product continuously or from time to time, whether the class member took products manufactured by the defendants or some interchangeable product, the extent to which the class member and her physician or pharmacist were aware of warnings, and to what extent the class member's physician or pharmacist heeded those warnings. The defendant says that the issues relating to individual claimants overwhelm common issues and that no purpose is served by trying the proposed common issues. This includes a consideration under *BPCPA*. Even if there is a determination of deception common to the class, every consumer transaction occurred in the presence of a learned intermediary and the court will have to consider whether the learned intermediary explained the various risk factors based on his or her clinical judgment.

[72] I find that in spite of the significant individual issues which arise, class proceeding is a preferable procedure to resolve the common issues. The common issues are not, in my view, overwhelmed or subsumed by the individual issues and in spite of there being a number of individual issues, there will be substantial benefits with respect to access to justice and judicial economy achieved through a common issues trial. As noted in *T.L. v. Alberta,* a class proceeding will be of some practical utility (at paras. 131-132). As noted in *Cloud* at para. 73-75, the preferability requirement can be met even where there are substantial individual issues and the common issues do not predominate.

[73] In specific reference to the factors referred to at s. 4(2)(b)-(e), individual litigation would not be economically viable for most of the class members and a class proceeding is the most effective means providing access to justice. There is no evidence that other proceedings in British Columbia or in other Canadian jurisdictions address this particular claim against the defendants; judicial economy is served by proceeding with this class action. There is also no reason to assume that the administration in this case would be unduly burdensome. Class proceedings have demonstrated that an appropriate and reasonable way to manage medical product claims in many cases. Finally, the defendants' position that HT and its sale in Canada is governed by a regulatory regime established by Health Canada does not, in my view, satisfy me that a class action is not the preferable procedure because behaviour modification is not a concern in this case. I appreciate that a comprehensive regulatory regime exists, but as I have stated, that is not dispositive of the plaintiff's action in negligence or under the *BPCPA*.

5. Representative Plaintiff

[74] Section 4(1)(e) of the *CPA* requires that there be a representative plaintiff who can adequately represent the class, does not have a conflict with other class members, and has developed a reasonable plan for litigating the action and providing notice to other potential class members. The test for adequacy of a proposed plaintiff is whether she will "vigorously prosecute the claim": *Campbell v. Flexwatt Corp.* (1997), 98 BCAC 22 at paras. 75 and 76.

[75] The plaintiff asserts that she meets the test and that her litigation plan is workable.

[76] The plaintiff asserts that the litigation plan is a template and is purposely general. The litigation plan provides for ongoing modification based on input from the parties or the case management judge. The litigation plan need only demonstrate that the plaintiff fully considered how the action will proceed and will be resolved: *Fakhri et al. v. Alfalfa Canada Inc. cba Capers*, 2003 BCSC 1717 at paras. 77 and 78, aff'd 2004 BCCA 549.

[77] The defendant asserts that Ms. Stanway has given an advantage to residents of British Columbia by advancing her claims under the *BPCPA* without regard to the consumer protection legislations in other provinces. While this may make the proposed class action more amenable to certification, it demonstrates the lack of adequate representation by the plaintiff whose British Columbia residency precludes her from making statutory consumer claims in other provinces or territories.

[78] The defendants also argue that the plaintiff's litigation plan is deficient: it does not address a workable methodology for determining the issues of causation on a class-wide basis. The litigation does not address the issue of how individual causation will be determined. Moreover, the medical records of Ms. Stanway, Ms. Midgley, and Ms. Willis demonstrate that each proposed representative plaintiff may have conflicts of interests with other putative class members.

[79] I find that Ms. Stanway is an appropriate class representative. She has the advantage of protection and the ability to advance a claim under the *BPCPA*, However, Ms. Willis, a resident of Manitoba, has offered to fill the role of a non-resident sub-class in accordance with s. 6(2) of the *CPA*. I have addressed the defendants' position on the substantial individual issues and have determined that proving liability against the defendants advances the proceeding for all class members. I do not find that there is a conflict of interest between Ms. Stanway as a representative plaintiff and other potential members of the class which would make

her an unsuitable representative. Conflicts may arise. I have the flexibility to amend the order to address those conflicts which actually do arise: *Tiboni* at para. 114.

CONCLUSION

[80] I grant the plaintiff's application to certify this proceeding as a class proceeding, which will include a non-resident subclass. The class definition will be that described by the plaintiff (at para 7 of these reasons).

[81] Ms. Stanway is an appropriate representative plaintiff as is Ms. Willis as the representative of the non-resident subclass. Ms. Stanway has provided a workable litigation plan.

[82] The common issues (outlined in para. 7 herein) are suitable for certification under the *CPA*, with the exception of item 1(b): Did the Defendants, or any of them, breach a duty of care to class members, and if so, when?

"Gropper J."