IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: Miller v. Merck Frosst Canada Ltd.,

2013 BCSC 544

Date: 20130328 Docket: S110437 Registry: Vancouver

Between:

Michael Miller

Plaintiff

And

Merck Frosst Canada Ltd., Merck Frosst Canada & Co. Merck & Co., Inc., Merck Sharpe & Dohme Corp.

Defendants

Before: The Honourable Mr. Justice R. Punnett

Reasons for Judgment

Counsel for the Plaintiff: D.A. Klein

N.C. Hartigan

(D.J. Lennox, Ontario)

Counsel for the Defendants: J.M. Sullivan

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(C. Beagan-Flood, Ontario)

Place and Date of Hearing: Vancouver, B.C.

June 11-14, 2012

Supplementary submissions of the

plaintiff received

September 27, 2012

Supplementary submissions of the

defendant received

September 24, 2012

Place and Date of Judgment: Vancouver, B.C.

March 28, 2013

- [1] The plaintiff, Michael Miller, applies to certify this action as a class proceeding pursuant to s.4 of the *Class Proceedings Act*, R.S.B.C. 1996, c.50 (the "*CPA*") and to be appointed as representative plaintiff pursuant to s. 2 of the *CPA*. The defendants oppose certification. In doing so they raise numerous challenges to the plaintiff's application.
- [2] The action concerns the prescription drugs marketed under the trade names Propecia and Proscar. The active drug in each is finasteride. The defendants are the drug's inventors and also manufacture, market and distribute it. Proscar is sold for the treatment of prostate problems including benign prostatic hyperplasia and the prevention of urologic events. Propecia is sold for the treatment of male pattern baldness, also known as androgenic alopecia.
- [3] The plaintiff alleges that the defendants were negligent in failing to warn Canadian men of the risk that sexual dysfunction may persist after discontinuation of treatment with either Propecia or Proscar.
- [4] The plaintiff also alleges the defendants are in breach of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2 (the "*BPCPA*") for failing to "disclose that some men may experience persistent and serious symptoms of sexual dysfunction, and in making statements that any side effects experienced would go away after discontinuing use …".
- [5] Although the two products are approved for and marketed for specific and quite different purposes, in May 2008 the 25-year-old plaintiff Michael Miller obtained from his physician a prescription for Proscar for treatment of hair loss. That is, Proscar, the drug for treatment of prostate problems, was prescribed by his physician for male pattern baldness because it was cheaper for the plaintiff to purchase the 5 mg Proscar tablet and then use a drug splitter to divide it into four 1.25 mg pieces than it was to purchase the 1 mg Propecia tablets for hair loss.

[6] The defendants were required to publish a product monograph with respect to each of Proscar and Propecia. Such monographs are approved by Health Canada. The product monographs provide information respecting the drugs and their use. As new information becomes available they are updated.

Proscar

[7] The Proscar product monograph approved by Health Canada on April 27, 2007 was the product monograph in effect between May 21, 2008 and January 31, 2009, the period during which the plaintiff alleges he used Proscar. The April 2007 product monograph for Proscar expressly references erectile dysfunction, decreased libido and ejaculation disorder. In part it reads as follows:

35.

Clinical Trial Adverse Drug Reactions

In PLESS, 1524 patients treated with PROSCAR® 5 mg daily and 1516 patients treated with placebo were evaluated for safety over a period of 4 years. 4.9% (74 patients) were discontinued from treatment due to side effects associated with PROSCAR® compared with 3.3% (50 patients) treated with placebo. 3.7% (57 patients) treated with PROSCAR® and 2.1% (32 patients) treated with placebo discontinued therapy as a result of side effects related to sexual function, which were the most frequently reported side effects.

Table 1 presents the only clinical adverse reactions considered possibly, probably or definitely drug related by the investigator, for which the incidence on PROSCAR® was > 1% and greater than placebo over the 4 years of the study. In years 2-4 of the study, there was no significant difference between treatment groups in the incidences of impotence, decreased libido and ejaculation disorder.

[Emphasis added]

[8] Health Canada also approved the wording of the "Consumer Information" package insert for Proscar. The package insert in the form approved in April 2007 for the product monograph says this:

36. ..

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

PROSCAR® is generally well tolerated in men.

You should discuss side effects with your physician before taking PROSCAR® and any time you think you are having a side effect.

Like any medicine, PROSCAR® may have unintended or undesirable effects, so-called side effects. These are uncommon and do not affect most men. Side effects due to PROSCAR® may include impotence (an inability to have an erection) or less desire to have sex. Some men may have changes or problems with ejaculation, such as a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to interfere with normal sexual function. In some cases, these side effects disappeared while the patient continued to take PROSCAR®. If symptoms persisted, they usually resolved on discontinuing PROSCAR®.

In addition, some men may have breast swelling and/or tenderness. Some men have also reported allergic reactions such as rash, itching, hives and swelling of the lips and face; and testicular pain. You should promptly report to your physician any changes in your breasts such as lumps, pain or nipple discharge.

Notify your physician about any illness which may develop during your treatment with PROSCAR® and about any new prescription or non-prescription medication you may take. If you require medical help for other reasons, inform the attending physician that you are taking PROSCAR®. [Emphasis added.]

. . .

- [9] The Proscar product monograph and consumer information insert therefore warned of a risk of sexual dysfunction that "usually" (i.e. not always) resolved upon discontinuing use.
- [10] Approximately one month after using Proscar the plaintiff alleges he experienced a diminished sex-drive. Over the ensuing months, he became completely disinterested in sexual activity and was unable to maintain an erection. On January 31, 2009 the plaintiff stopped taking Proscar expecting that these alleged side effects would disappear. To date, the plaintiff continues to experience symptoms of sexual dysfunction.

[11] The certification as a class action in this instance however is not limited to the uses of Proscar, the medication used by the plaintiff. The plaintiff seeks as well to represent those who took Propecia, the medication actually marketed for treatment of male pattern baldness.

Propecia

- [12] As Propecia is marketed as a different prescription medication from Proscar its approval by Health Canada and its monographs and consumer information inserts are specific to it and differ from those for Proscar.
- [13] It was approved for sale in Canada in 1998. The package insert approved by Health Canada as of July 2006, which was the version in effect during the period of time that the plaintiff alleges he used Proscar, says this:
 - 48. ...

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medicine, PROPECIA® may have unintended or undesirable effects, so-called side effects. These are uncommon and do not affect most men.

Only a small number of men may experience less desire to have sex and/or difficulty in achieving an erection. An even smaller number may have a decrease in the amount of semen released during sex (this does not appear to interfere with normal sexual function). In clinical studies, these side effects disappeared in men who stopped taking PROPECIA® and in most men (58%) who continued treatment.

In general use, the following have been reported infrequently: allergic reactions including rash, itching, hives, and swelling of the lips and face; <u>problems with ejaculation</u>; breast tenderness and enlargement; and testicular pain.

Tell your physician or pharmacist promptly about these or any other unusual symptoms. ... [Emphasis added]

. . .

[14] The plaintiff asserts that the defendants were aware of the long-term side effects and that the warnings given in Canada were inadequate. He refers to

product monographs and warnings given in other countries in support of his position.

- [15] In April 2007 the Swedish Medical Products Agency requested that Merck include a warning in the Swedish version of the Propecia product monograph regarding the possibility of persistent erectile dysfunction continuing after discontinuation of use of the drug. In 2008 Merck agreed to do so and included the following language in the "Undesirable Effects" section of the Swedish product monograph:
 - 3. ...

 Persistence of erectile dysfunction after discontinuation of treatment with PROPECIA has been reported in postmarketing use.
- [16] Similar changes were then made to the Propecia product monographs in a number of European countries and the United States.
- [17] Until November 18, 2011, the Canadian product monograph for Propecia included warnings in respect of decreased libido, erectile dysfunction, and ejaculation disorder. The product monograph also stated "[r]esolution of these adverse reactions occurred in men who discontinued therapy with Propecia and in most who continued therapy." It was not until November 18, 2011 that the product monograph for Propecia was updated in Canada to warn of the possibility that sexual dysfunction could persist after discontinuation of treatment.
- [18] The plaintiff treats Proscar and Propecia as the same medication: finasteride. It is not disputed that finasteride is the active ingredient in both Proscar and Propecia. What differs however, in addition to their respective dosages, are the approval process for each, the testing of each, the product monographs for each and the purpose of each.
- [19] The plaintiff in treating Proscar and Propecia as simply variants in quantity of finasteride argues that they are the same drug. While that is true I

am not satisfied that the situation is necessarily that simple as it ignores that they were manufactured, approved and marketed as two separate drugs. The plaintiff submits that even the defendants have treated the two as one and the same given they provided data respecting Proscar to Health Canada in support of their application concerning Propecia.

[20] As the defendants point out the users of the drug include those who take 5 mg for prostate issues, users who take 1 mg Propecia for male pattern baldness and others who take Proscar and divide it.

<u>Plaintiff's Evidence</u>

- In his affidavit filed in support of the certification application the plaintiff [21] states that he took Proscar and divided it into four pieces because it was cheaper than purchasing Propecia. He states that he had reviewed Merck's website respecting the use of Propecia before taking the Proscar and that after about a month of taking the drug he felt different, specifically that he became completely disinterested in sexual activity. The symptoms of sexual dysfunction increased over the following months. He adverted to various sexual difficulties as well as feelings of anxiety and upset. He asserts that he believed that these changes were due to the side effects of the Proscar and he again reviewed the Merck website respecting Propecia in order to obtain information respecting the drug's side effects. As the website stated sexual side effects would resolve either with continued use or after cessation of taking the drug he continued to take the drug. He then became aware of websites where users alleged sexual dysfunction did not go away after use of Propecia and he as a result ceased taking Proscar.
- [22] He does not say that he reviewed the Proscar website or the Proscar product monographs or inserts despite the fact that it was Proscar that he consumed.
- [23] The plaintiff also filed an affidavit from Alicyn Cumming, an administrative assistant at his counsel's office, sworn on July 12, 2011. Ms. Cumming

appended to her affidavit various product monographs and articles. She also swore that she had been advised by a lawyer in the plaintiff's law firm that the lawyer had been contacted by 170 Canadian men who had advised that they wished to participate in a claim for damages arising from personal injury due to the use of Propecia and/or Proscar. Thirty-nine of them are from B.C.

- [24] An affidavit of Ms. Wong, a paralegal in the plaintiff counsel's firm, sworn October 14, 2011, was also filed. Ms. Wong attached searches of Health Canada's Drug Product Database and swore that the number of men in B.C. who had contacted the plaintiff's law firm had grown to 44 all except for one of whom had started taking "the drug" before February 1, 2010 (the date generic finasteride became available); 32 of the 44 reported having stopped taking the drug before that date. She does not give the source of this information nor which drug the men referred to.
- [25] The second affidavit of Ms. Wong, sworn March 16, 2012, asserts 281 men in Canada of whom 55 are from B.C. had now contacted the plaintiff's counsel's law firm. Again, no source is given nor which drug is referred to.
- [26] In Ms. Wong's final affidavit, sworn May 11, 2012, she clarifies that those men who called had asserted that they suffered from personal injury from ingesting finasteride; specifically, that they suffered from sexual dysfunction as alleged in para. 2 of the amended notice of claim. She then confirms that of the 55 men from B.C., 40 of them reported one or more side effects of sexual dysfunction that persisted after discontinuation of Propecia or Proscar. She also attached a copy of the Propecia product monograph for the US that was revised in April 2012 to refer to sexual dysfunction and depression continuing after discontinuation of treatment.
- [27] Dr. Wright, a Professor in the Department of Anaesthesiology, Pharmacology & Therapeutics and the Department of Medicine, at the University of British Columbia, filed two affidavits on behalf of the plaintiff, sworn July 11, 2011 and March 16, 2012, respectively.

- [28] In his July 11, 2011 affidavit Dr. Wright attaches as exhibits his written report as well as copies of the documents he refers to in that report. He states that other than the higher dose of finasteride in Proscar that Proscar and Propecia are identical and have the same contraindications and the same mechanism of action. He also states that the adverse reactions are the same for both drugs.
- [29] He describes the mechanism of action of finasteride as follows:
 - 9. Propecia is a Type II alpha-reductase inhibitor. It acts by competitively inhibiting Type II alpha-reductase, an intracellular enzyme that converts testosterone to dihydrotestosterone (DHT) and results in significant decreases in serum and tissue DHT concentrations. DHT has an androgenic potency that is about 5 times as much as testosterone.
- [30] His report then addresses issues of adverse reactions to the drugs and comments about the lack of long term-controlled trials of finasteride. It also comments on Merck's knowledge and failure to warn. The admissibility of these latter assertions are challenged by the defendants. I will address them later in these reasons.
- [31] Dr. Wright's March 16 affidavit responds to the affidavits filed by the defendants. The most significant comment of Dr. Wright relates to his opinion respecting biological plausibility:
 - ... In fact given the mechanism of action of finasteride to inhibit the production of dihydrotestosterone, it is not only biologically plausible but expected that sexual side effects would occur. Given the complexity and vulnerability of sexual function in man, including libido, erections and ejaculation, it is, in my opinion, biologically plausible that in some of the men who experience sexual dysfunction while taking finasteride, the sexual dysfunction would be persistent. ... [Emphasis added]
- [32] I will address this affidavit, as well as the other affidavits filed by both parties, later in these reasons. Generally the defendants challenge the affidavits of Dr. Wright, Alicyn Cumming and Deborah Wong as containing inadmissible hearsay. Their admissibility will be addressed as the requirements of s. 4 of the *CPA* are considered.

Defendants' Evidence

- [33] The defendants rely on affidavit material from: Mohamed Shakeel Bhatti, a pharmacist; Dr. Stacy Elliott, a physician and the Medical Manager of the B.C. Centre for Sexual Medicine; Dr. Sheldon L. Goldenberg C.M., O.B.C., M.D., F.R.C.S.(C) Professor and Head, Department of Urologic Sciences, University of British Columbia; Dr. Keith D. Kaufman, M.D., the Vice president, Project Leadership and Management, Diabetes and Endocrinology for Merck, Sharpe, and Dohme Corp; Dr. Lynn Stothers, M.D., Professor of Urological Sciences, University of British Columbia and Sandra Lee Wainwright, the Director of Regulatory Affairs at Merck Canada Inc.
- [34] Mr. Bhatti provides evidence on the information provided by pharmacies to their customers and addresses the need for pharmacological information concerning the plaintiff.
- [35] Dr. Elliott addresses sexual function, the myriad of causes of male dysfunction and the high level of complexity of any assessment of the causes of sexual dysfunction.
- [36] Dr. Kaufman was the lead scientist responsible for the clinical development of Propecia and states he is familiar as well with the clinical development and post-marketing experience of Proscar. He addresses the approval process for any new drug including clinical studies and meeting the requirements of the U.S. Food and Drug Administration ("USFDA"). He confirms that the active ingredient of both Proscar and Propecia is finasteride and that the side effects reported by users of Propecia include decreased libido, erectile dysfunction and ejaculation disorder. He states: "[r]esolution of these drug-related adverse experiences occurred in men who discontinued therapy with Propecia® and in most who continued therapy." He qualifies this statement however by noting that the side effects reported cannot be taken to confirm that a causal relationship exists. This is because the USFDA does not require proof of a causal relationship between a product and an adverse event.

- [37] Dr. Goldenberg addresses what a plausible biological mechanism of action is and how it would be proven by the expert medical community, the mechanism of action of finasteride, whether a plausible biological mechanism of action has been identified linking persistent sexual dysfunction with the use of finasteride, and finally whether the expert material relied on by Dr. Wright identifies such a mechanism.
- [38] Dr. Stothers addresses the issue of causation in medical science and factors contributing to it and whether the materials relied on by Dr. Wright identify a plausible biological mechanism of action linking persistent sexual dysfunction with the use of finasteride.
- [39] Sandra Wainwright provides in her affidavit detailed information respecting the approval process for the drugs, the testing done and the results of the drug study process.

Requirements for Certification

- [40] Part 2(4) CPA addresses the requirements for 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.
- [41] The plaintiff bears the onus of establishing that the action satisfies the requirements set out in s. 4 (*Hollick v. Toronto (City)*, [2001], 3 S.C.R. 158). Section 4(1) is mandatory. If the case meets the requirements set out in subparagraphs (a) through (e), then it *must* be certified as a class proceeding (*Wakelam v. Johnson & Johnson*, 2011 BCSC 1765 at para. 41).

Gatekeeper Function of the Court

[42] In B.C., an action cannot move forward as a class proceeding until it is certified for class treatment by the court. Although the evidentiary threshold for meeting the statutory criteria of s. 4 is low, the court must exercise a gatekeeper function.

- [43] Certification is a procedural step. The issue at the certification stage is whether the proceeding is appropriately prosecuted as a class proceeding. It is not a preliminary merits test (*Hollick*).
- [44] The purpose of evidence on a certification motion has been described in a number of ways. In *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744, Horkins J. states at para. 21 that "[e]vidence explains the background to the action. A certification motion is not the time "to resolve conflicts in the evidence or to engage in finely calibrated assessments of evidentiary weight": *Cloud v. Canada (Attorney General)*, [2004] O.J. No. 4924 at para. 50 (C.A.) ("Cloud")."
- [45] The burden on the plaintiff is only to adduce evidence to show some "basis in fact" to meet the requirements of s. 4(1) of the *CPA*. Evidence introduced by the defendant is relevant only to show that there is <u>no basis in fact</u> for the plaintiff's assertions. It is only to that extent that it is to be used to assess the merits of the claim (*Lambert v. Guidant Corporation* (2009) 72 C.P.C. (6th) 120 (Ont. S.C.J.)). As explained by Cullity J. in *Heward v. Eli Lilly & Co.* (2007), 39 C.P.C. (6th) 153, 154 A.C.W.S. (3d) 1020 (Ont. S.C.J.) at para. 13:
 - [13] ... All of this evidence is directly relevant to the merits of the litigation, and, of course, it is admissible on this motion -- and has been considered -- only to the limited extent that it may serve to rebut the plaintiffs' attempts to demonstrate the minimal basis of fact required to establish each of the requirements in section 5(1)(b) through 5(1)(e) of the CPA. I have found it ... helpful to the extent that it bears on the commonality, or lack of commonality, of the proposed common issues; the extent to which any issues that are common would advance the proceedings; the extent to which a class proceeding would be manageable and efficient; and, generally, whether such a proceeding would accord with, and advance, the objectives of the CPA and be preferable to other methods of resolving the plaintiffs' claims. [Emphasis added]
- [46] The requirement to show "some basis in fact" for the certification requirements has been explained in a number of decisions. It is a step beyond establishing the existence of a cause of action based on the pleadings alone.

- [47] In *Dow Chemical Company v. Ring, Sr.*, 2010 NLCA 20, the Newfoundland and Labrador Court of Appeal described it as follows:
 - [14] When, in **Hollick**, the Supreme Court established "some basis in fact" as the evidentiary threshold it was signalling a lesser standard of proof than that required for the determination of the merits of the claim. This position is consistent with the fact that at the certification stage the court is dealing with procedural issues, not substantive ones: **Bisaillon v. Concordia University**, 2006 SCC 19, [2006] 1 S.C.R. 666, para. 17. The fact that opposing parties may also provide evidence does not lead to the conclusion that the standard of proof must be the balance of probabilities. The Trial Division judge was correct when he stated that the evidentiary threshold for certification applications was "some basis in fact."
- [48] In *Tiboni v. Merck Frost Canada Ltd.* (2008), 295 D.L.R. (4th) 32, 60 C.P.C. (6th) 65 (Ont. S.C.J.), Cullity J. said this:
 - [50] In the six volumes that constitute the defendants' responding motion record, an enormous amount of information and medical and scientific literature is provided. ...
 - [51] All of this evidence is helpful for the purpose of explaining the factors that will bear on the issues at a trial and, to that extent, it provides context for the issues that arise on certification. Although defendants' counsel took care, and exercised some skill, in relating the evidence to the issues on certification, inevitably its relevance to the merits of the plaintiff's claims -- irrelevant at this stage -- was not entirely absent from their submissions. In particular, I note that, in determining whether there are common issues for the purpose of certification, the inquiry is not the same as that into the existence of genuine issues for trial as required on motions for summary judgment. Such motions test the merits of a plaintiff's case.
 - [52] It was established in *Hollick v. City of Toronto*, [2001] 3 S.C.R. 158 that only a minimum factual basis needs to be established by evidence for the existence of common issues. Once provided, the question whether the defendants could obtain summary judgment by providing additional conflicting evidence that demonstrates that there are no genuine issues for trial will not arise and evidence directed at the question is irrelevant and inadmissible. If this were not correct, every opposed certification motion would be likely to involve, in effect, the same test of the merits as on a motion for summary judgment, and the evidential burden on plaintiffs would be increased enormously.
 - [53] It follows that, when, as here, the defendants' deliver affidavit evidence that is relevant only to the merits of the plaintiffs' claims -- as, for example, expert opinion that Merck's scientific study and testing of Vioxx was "rigorous", that Merck did everything a responsible company

could be expected to do, and that, given the benefits of the drug, the risks involved in its use are tolerable -- the plaintiffs have no obligation to challenge the accuracy of such opinion on this motion. Statements by defendants' counsel that such evidence is "undisputed" may be literally correct for the present purposes. They are also of no significance.

- [49] As noted by Cullity J., notwithstanding the procedural nature of a certification application it has become common for the parties, and defendants in particular, to file voluminous materials that, while ostensibly addressing procedural issues, invariably involve the merits of the claim. This case is no exception.
- [50] In interpreting the *CPA*, the court is to keep in mind the significant advantages that a class action offers as a procedural tool. In *Hollick*, the Court formulated those advantages as follows: enhancement of judicial efficiency by avoiding unnecessary duplication in fact-finding and legal analysis, improved access to justice for those claims that might not otherwise be asserted, and modification of the behaviour of actual and potential wrongdoers (para.15).
- [51] At the certification stage of the class proceeding, the court should apply a liberal and purposive analysis and construe the provisions of the *CPA* generously (*Hollick*, para. 15).
- [52] I turn now to the requirements of the CPA.

Do the Pleadings Disclose a Cause of Action?

[53] The plaintiff says that the pleadings disclose a cause of action under the *BPCPA* and in negligence. The defendants submit that the statutory claims advanced pursuant to the *BPCPA* are not sustainable in law and that only a limited cause of action for a failure to warn of persistent sexual dysfunction has been adequately pleaded in negligence. They rely on *Koubi v. Mazda Canada Inc.*, 2012 BCCA 310, in support of their argument that at certification the court must determine if the claim is viable. In this case they submit that even if the facts alleged in the pleadings are true there is only a limited cause of action in

tort and no cause of action at all pursuant to the *BPCPA*. Therefore the plaintiff has no hope of success and it does not benefit the parties or the court to permit the claim to proceed.

- [54] In considering whether the pleadings disclose a cause of action, no evidence is admissible. The court must assume that the facts pleaded in the statement of claim can be proved. The test is whether it is plain and obvious that the plaintiff's claim cannot succeed. The threshold is a very low one (*Brogaard v. AG Canada*, 2002 BCSC 1149).
- [55] The "plain and obvious test" used to ascertain whether a cause of action has been properly pleaded was explained by the Supreme Court of Canada in *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 at para. 33:
 - ... [A]ssuming that the facts as stated in the statement of claim can be proved, is it "plain and obvious" that the plaintiff's statement of claim discloses no reasonable cause of action? As in England, if there is a chance that the plaintiff might succeed, then the plaintiff should not be "driven from the judgment seat". Neither the length and complexity of the issues, the novelty of the cause of action, nor the potential for the defendant to present a strong defence should prevent the plaintiff from proceeding with his or her case. ...
- [56] While no evidence is permitted on this issue and the court must assume the material facts pleaded are true, the defendants submit that the court does not need to assume that evidence improperly pleaded in the amended notice of civil claim is true. A pleading is to plead facts (Rule 3-1 Supreme Court Civil Rules). They note the amended notice of civil claim includes quotes from doctors that are expert opinion, not material facts.

Negligence

[57] The plaintiff alleges that by introducing the drug and marketing it as Propecia and Proscar in Canada, and in knowing of its adverse effects, that the defendants were in a close and proximate relationship to the plaintiff and class members such that they owed them a duty of care. The plaintiff further alleges

the defendants were negligent in designing, testing, manufacturing, marketing, labeling, promoting, distributing, importing and selling Propecia and Proscar and that they knew or ought to have known that defects in the medication would cause foreseeable injury to the plaintiff and his fellow class members. Finally the plaintiff alleges that the defendants failed to provide adequate and timely disclosure of the potential long-term effects of ingesting Propecia or Proscar and failed to implement an appropriate post-market surveillance system to monitor and quickly identify adverse risks.

- [58] The particulars of negligence alleged in the amended notice of civil claim are:
 - [42] ...
 - (a) failing to test Propecia and Proscar properly and thoroughly before releasing the drug to the market;
 - (b) failing to adequately disclose the serious side effects of Propecia and Proscar;
 - (c) failing to conduct an adequate and timely analysis of adverse event reports;
 - (d) failing to instruct their employees to accurately and candidly disclose consumer complaints and serious side effects of Proscar and Propecia to Health Canada in a timely manner, or at all;
 - (e) employing inadequately trained personnel;
 - failing to provide adequate warnings of the potential long term effects of ingesting Propecia and Proscar on the package inserts and labels;
 - (g) marketing Propecia and Proscar in such a way as to give the plaintiff and class members no reason to suspect that Propecia and Proscar had potentially harmful and serious adverse effects;
 - failing to design and implement an appropriate post marketing surveillance system to monitor and quickly identify adverse risks;
 - (i) placing Propecia and Proscar on the market when they knew or ought to have known the potential risks of these drugs outweighed their potential benefits:

- [59] The defendants submit that the allegations made by the plaintiff in the certification hearing are not consistent with the pleadings themselves because the amended notice of civil claim does not allege particulars with regard to the allegations of negligent design, manufacture and the importing of the drugs.
- [60] They submit as well that the plaintiff has failed to plead the material facts required to support some of the allegations made in the pleadings. They note that Rule 3-7(9) of the *Supreme Court Civil Rules* provides that "[c]onclusions of law must not be pleaded unless the material facts supporting them are pleaded". They argue that the plaintiff must particularize facts that, if proven, would constitute breaches of a duty of care. They state that bare allegations that the defendants were negligent with respect to their pre-market testing and post-market surveillance and disclosure of adverse events are not sufficient to support a cause of action. They rely on *Ross v. British Columbia (Public Safety)*, 2009 BCSC 1811 at paras. 19-20; *Victoria Grey Metro Co. v. Fort Gary Trust Co.* (1982), 30 B.C.L.R. (2d) 45 at para. 8 (S.C.).
- [61] The defendants then submit that the plaintiff must satisfy the court that the "class has an apparently authentic cause or causes of action based on the material facts pled and the applicable law." In doing so they rely on *Hoffman v. Monsanto Canada Inc.*, 2007 SKCA 47, 283 D.L.R. (4th) 190, where the Saskatchewan Court of Appeal said in considering the court's screening function, at para. 45:
 - [45] ... This is consistent with the purposes of the *Act*, which lie in improved access to justice, litigation efficiency, and modification of behaviour by wrongdoers. None of these purposes is served by allowing an action to proceed as a class action unless the class appears to have a genuine cause or causes of action. ...
- [62] This submission raises the often vexing distinction between material facts, particulars and the evidence required to prove them.
- [63] The defendants also submit that the pleadings reveal only a limited cause of action in negligence: they assert that the cause of action, as asserted at

certification is too broad in that the pleadings only allege harm with respect to sexual dysfunction, not other side effects. Further, as noted above, they alleged the particulars only disclose an action with respect to a duty to warn. They state that given the particular nature of pharmaceuticals, which all carry the potential risk of a myriad of side effects, an overly broad claim is fatal, as was the case in *Wuttunee v. Merck Frosst Canada Ltd.*, 2009 SKCA 43.

- [64] However, it is my view that the pleadings in the case at bar address the deficiencies found in *Wuttenee*. I reject the submission that the claim is overly broad and find that the plaintiff's pleadings clearly indicate a cause of action limited to a duty to warn with respect to the side effect of sexual dysfunction, not side effects generally. The allegations pleaded particularize facts sufficient to disclose a cause of action with respect to a duty to warn of sexual dysfunction, including post-market surveillance and pre-market testing, and the plaintiff's allegations with respect to negligent design, manufacture and importing the drug fall within that duty to warn.
- [65] The defendants also submit that approval by Health Canada, that is, regulatory compliance, is relevant. Such approval however is "not dispositive of liability" (*Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057 at para. 47(a)).
- [66] The defendants further assert that the warnings with respect to both Proscar and Propecia were adequate. The plaintiff submits that the common law imposes heavy obligations on drug and medical device manufacturers to warn consumers. The plaintiff relies on *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 23 and *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 54 O.R. (2d) 92 (C.A.) at para. 55.
- [67] I find that the adequacy of the warning of the risks of Propecia and Proscar is a matter for trial. The adequacy of the warning is much in issue and such an issue can form the basis for a cause of action in negligence (*Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057). The defendants have a duty to adequately test and to warn (*Hollis* at paras 38-42 and *Buchan* at paras. 54-55).

- [68] I noted earlier that the defendants rely on *Koubi* in support of their argument that where a claim has no hope of success it should not be certified. *Koubi* however was addressing a question of statutory interpretation. It does not change the test that a cause of action must be disclosed by the pleadings.
- [69] I am satisfied the plaintiff's amended notice of civil claim provides particulars of a claim in negligence based on the defendants' duty to warn of the side effect of sexual dysfunction. In my view it is not plain and obvious that the claims against the defendants as pleaded cannot succeed.
- [70] I shall next address whether the *BPCPA* is properly pleaded and then the issue of waiver of tort will be considered.

Plaintiff's Position Respecting the BPCPA

- [71] The amended notice of civil claim alleges that the defendant's "solicitations, offers, advertisements, promotions, sales and supply of Propecia and Proscar for personal use by the plaintiff and by class members were "consumer transactions" within the meaning of the [BPCPA]". The plaintiff says that as such, the defendants' conduct is governed by the BPCPA. The plaintiff contends that those solicitations and offers had the capability, tendency or effect of deceiving or misleading consumers as to the safety of Propecia and Proscar, and were therefore deceptive acts and practices contrary to s. 4 of the BPCPA. In particular, the plaintiff alleges that the defendants failed to disclose the material fact that the side-effect of sexual dysfunction may continue after disuse of the drug, and that this failure to disclose was a deceptive practice within the meaning of the BPCPA. The plaintiff seeks:
 - 48. ... injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss. 171 and 172 of the BPCPA on his own behalf and on behalf of class members who purchased Propecia or Proscar in British Columbia. Such relief includes the disgorgement of the profits or revenues received by the defendants from the sale of Propecia and Proscar in British Columbia.
 - 49. The declaratory and injunctive relief sought by the plaintiff in this case includes an order under s.172 of the BPCPA that the defendants

advertise any judgment against them and that they properly inform consumers and their physicians of the risks of persistent side effects of sexual dysfunction associated with the product which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

[72] The plaintiff further notes that:

- 50. It is not necessary for the plaintiff and class members to establish reliance on the defendants' deceptive acts or practices in order to establish breach of the BPCPA and a remedy for that breach. In the alternative, if reliance is required to establish statutory breach and/or remedy, such reliance may be assumed or inferred on the facts of this case. In the further alternative, there was actual reliance by the plaintiff and class members on the defendants' deceptive acts and practices.
- [73] In relation to this claim, the plaintiff's submission on certification notes that the *BPCPA* goes beyond the common law, including shifting the burden to the manufacturer, and added remedies, such as disgorgement of revenue or profits. (para. 71). The plaintiff states that its claim is articulated in a manner consistent with the wording and the applicable case law:
 - [74] As set out in the Amended Notice of Claim, the Propecia Product Monograph, with respect to side effects of sexual dysfunction, states: "Resolution of these adverse reactions occurred in men who discontinued therapy with PROPECIA and in most who continued therapy." This is an affirmative statement that is deceptive and misleading. There are men who continue to have adverse sexual side effects after discontinuing the drug. Additionally, the Product Monograph failed to accurately disclose the true risks of the product by omitting to include information about persistent sexual side effects after discontinuation of use.

...

. . .

[78] In sum, the Plaintiff pleads that the Defendants have breached their obligations under the *Consumer Protection Act* and asserts a legally plausible cause of action under the statute. He has asserted a claim recognized in other product liability suits. This is a reasonable pleading which satisfies the test under s.4(1)(a) of the *CPA*.

. . .

Defendant's Position Respecting the BPCPA

[74] The defendants argue that they are not "supplier[s]" to which the statute applies. While they acknowledge that privity of contract is not necessary under

the *BPCPA* they submit that there is no "consumer transaction" between the defendants and a patient prescribed Propecia or Proscar because a learned intermediary is required (a doctor to prescribe the medication). Therefore there is a "lack of immediacy" in the relationship between supplier and consumer. They also claim because of this lack of immediacy the defendants are not suppliers under the *BPCPA* as they are not "soliciting" in respect of a "consumer transaction" because a consumer's choice to use the medicine is a decision between him and his doctor, not through advertisement. They submit that the product labelling is not primarily used to solicit, promote or advertise the medicine but rather is intended to provide information regarding risks and benefits of medicines to prescribing physicians. Accordingly, the defendants allege there is no statutory cause of action.

- [75] The defendants summarize their submission on this issue as follows:
 - 95. All of the circumstances surrounding the disclosure of information, prescription, dispensing and purchase of a prescription medicine, including the involvement of learned intermediaries and the approval of all labelling by Health Canada under federal law remove it from the scope of the *Consumer Protection Act*.
 - 96. The plaintiff asserts that the type of claim he is advancing has been recognized in other product liability cases. However, the argument that there is no "consumer transaction" between the manufacturer of a prescription drug and the patient and that a manufacturer of a prescription medicine is not a "supplier" within the meaning of the Act was not raised in the certification decisions cited by the plaintiff.
- [76] The defendants also submit that the plaintiff has pleaded "wavier of tort", a claim they allege is not supportable in law.
- [77] In response, the plaintiff submits that whether there is a cause of action is determined on the pleadings alone. Based on the language used by the plaintiff in the pleadings, the plaintiff argues the defendants fit into the definition of "supplier" under the *BCPCA*. The plaintiff says the question of whether a medical products company is a "supplier" under the *BPCPA* has been previously certified as a common issue (see *Chalmers v. AMO Canada Co.*, 2009 BCSC 689; *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057; *Logan v. Dermatech*,

Intradermal Distribution Inc., 2011 BCSC 1097; Wakelam v. Johnson & Johnson, 2011 BCSC 1765).

[78] In regard to the defendants' "lack of immediacy" argument, the plaintiff argues that there is no case law to support that proposition and it is contrary to a plain reading of the statute. The plaintiff also denies pleading "waiver of tort".

Is the Defendant a Supplier?

- [79] The purpose of the *BPCPA* is to protect consumers. It is to be broadly construed to carry out that purpose and is to be interpreted generously in favour of consumers (*Seidel v. TELUS Communications Inc.*, [2011] 1 S.C.R. 531 at para. 37; *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260 at paras. 78 and 79).
- [80] The BPCPA defines "consumer transaction" as follows:

"consumer transaction" means

- a supply of goods or services or real property by a supplier to a consumer for purposes that are primarily personal, family or household, or
- (b) a solicitation, offer, advertisement or promotion by a supplier with respect to a transaction referred to in paragraph (a),

and, except in Parts 4 and 5, includes a solicitation of a consumer by a supplier for a contribution of money or other property by the consumer;

[81] A "supplier" is defined as follows:

"supplier" means a person, whether in British Columbia or not, who in the course of business participates in a consumer transaction by

- (a) supplying goods or services or real property to a consumer, or
- (b) soliciting, offering, advertising or promoting with respect to a transaction referred to in paragraph(a) of the definition of "consumer transaction",

. . .

[82] Judicial interpretation of "consumer transaction" has been favourable to consumers. In *Nanaimo Shipyard Ltd. v. Keith*, 2008 BCSC 1150, a commercial

shipyard that normally provided repairs to commercial vessels provided repairs to a boat that was used by the owner for personal purposes. The court held that the definition of "consumer transaction" does not depend on the nature of the services, but rather what the consumer uses those services for, saying at para. 57:

- [57] ... It is not whether the provider of services is a commercial operation. It is whether the purchaser is an individual purchasing for primarily personal, family or household purposes. ...
- [83] This emphasis on the consumer's use of the goods, services or real property in defining what is a "consumer transaction" is also found in *Bodnar v. The Cash Store Inc.*, 2006 BCCA 260 and *Kilroy v. A OK Payday Loans Inc.*, 2006 BCSC 1213. A transaction still meets the definition even where the service has a commercial element so long as the dominant purpose is for personal use. Similarly, in *De Graaf et al. v. Brar and Sorongon*, 2002 BCSC 1239, in referring to the former *Consumer Protection Act*, the court adopted a liberal interpretation of the definition of "mortgage transaction" to ensure that the protection of consumers was effected. In *Watson v. Cull*, 1992 CanLII 939 (B.C.S.C.), the British Columbia Supreme Court said this concerning the former *Trade Practice Act*, R.S.B.C. 1996, c. 457:

A. A Consumer Transaction

In order to bring this action within the purview of the Act the plaintiff has alleged that by providing members of the public with abortion services, the defendant Clinics have engaged in consumer transactions within the meaning of the Act. Can this be so?

As defined by the Act, to be a "consumer", one need only participate in the transaction; to be a "supplier", one need only advertise or promote the transaction; and, it seems, if a transaction is a "disposition or supply" of "personal property" in the form of "services", and is "for purposes that are primarily personal, family or household", it falls within the scope of the Act. There does not seem to be a need for consideration to pass from the "consumer" to the "supplier".

The Act is very broadly drafted, and it seems as if the Legislature intended that virtually every transaction entered into by an individual for a purpose that is primarily personal, family or household in nature, would fall within its embrace. That being so, it would be wrong, on an application of this nature, to decide whether or not the Act does indeed

- apply to the provision of abortion services. Accordingly, it becomes necessary to consider the allegations of unconscionable and deceptive acts or practices. [Emphasis added]
- [84] Given the liberal approach by the courts and the focus on the use of the goods, I note that Proscar and Propecia are clearly designed and marketed for personal use and that the plaintiff used the former for personal use.
- [85] Turning to the issue of the interpretation of the definition of "supplier" in the *BPCPA*, the Supreme Court of Canada recently considered this definition in *R. v. Imperial Tobacco Canada Ltd.*, [2011] 3 S.C.R. 45. The Court held that the phrase "in the course of business" in the *BPCPA* means that the person is engaged in a "commercial purpose". Therefore to be a supplier the person or business must have a "commercial purpose". I note that the defendants in marketing Proscar and Propecia clearly had a commercial purpose.
- [86] As the transactions at bar ostensibly fit within the definitions set out in the case law, the question then becomes whether the lack of immediacy between the plaintiff and the defendants somehow takes them outside the scope of the *BPCPA*.
- [87] The *BPCPA* states that a supplier is someone who "participates in a consumer transaction by supplying goods to a consumer" or by soliciting "with respect to" a consumer transaction. On a plain reading "with respect to" does not require direct solicitations to a consumer, it merely requires that the solicitations be about or related to the consumer transaction.
- [88] In support of their submission the defendants rely on *Holmes v. United Furniture Warehouse LP*, 2009 BCSC 1805 paras. 28-31, where the allegations were that directors personally participated in a consumer transaction and therefore were liable. The court states, "that a director or officer of a corporation cannot be a supplier under the *BPCPA* simply because of his or her position". The argument of the defendants is that this supports their proposition that there must be "immediacy" in the relationship between the supplier and consumer.

- [89] In my view that is not a proposition that can be derived from *Holmes*. In *Holmes* the issue was whether directors could be personally liable as directors. Normally the corporate veil would not be pierced. However, in certain circumstances it can be, such as where there is personal conduct by them. I do not take from the facts in *Holmes* a general proposition that there must be immediacy between a supplier and consumer. Rather the principle that emerges is that where there is immediacy directors may be liable. The court did not consider whether immediacy is a requirement for a finding that there is a relationship between the supplier and the consumer.
- [90] The defendants also refer to *VanBeek v. Dodd*, 2010 BCSC 1639 at para. 83. In *VanBeek* on a sale of real estate the court held that the transaction was a consumer transaction under the *BPCPA* and since the defendant builder was actively involved in the transaction he was a "supplier" within the meaning of the act. Again, as in *Holmes*, while immediacy was present for the finding that the defendant was a supplier, the court did not consider whether immediacy was an essential requirement.
- [91] Some support for the defendants' position is found in *Tracy v. Instaloans Financial Solution Centres (B.C.) Ltd.,* 2008 BCSC 669. In *Tracy,* the defendant had divided its business into two groups: companies operating storefront operations and the head office that provided staff and management to those companies. The storefront offices held a contract of service with the 'head office'. The storefront group collected revenue and paid fees to the head office over time. The trial judge held that *only the storefront companies were liable under the BPCPA*. It was only those companies who were providing the 'instaloan contracts' and were therefore participating in the consumer transaction. The British Columbia Court of Appeal did not directly address this issue on the appeal.
- [92] While *Tracy* may suggest there should be some immediacy between supplier and consumer to bring the transaction with the meaning of the *BPCPA*

in my view it is distinguishable as was the case in *Holmes*, as it addresses separate legal entities, not the "learned intermediary" issue raised here. The defendants in the case at bar are still the corporate sellers and are the parties holding out the promotions and advertisements albeit to the intermediaries rather than the consumers themselves. I also note that with the broad availability of such information on the internet and through US advertising it is arguable that the end consumer is in fact now placed directly in receipt of such information.

- [93] Further, returning to the decision in *Holmes*, the following comments made by the British Columbia Court of Appeal in upholding the trial judge's decision (*Holmes v. United Furniture Warehouse Limited Partnership*, 2012 BCCA 226), suggest judicial intention to broaden the scope of the *BPCPA*, not narrow it. Donald J.A. speaking for the court, says:
 - [26] I would add that the key phrase in the definition of supplier as a person "who in the course of business <u>participates</u> in a consumer transaction" [emphasis added] <u>may be open to a sufficiently wide interpretation to embrace the kind of participation alleged in para. 83 of the proposed consolidated statement of claim:</u>
 - 83. Further, the Defendant Directors personally developed and directed...and directed, authorized, permitted and acquiesced in the deceptive practices ...
- [94] As such in my opinion the word "participates" is to be given a wide interpretation under the *BPCPA*. I find support for this view in *Robson v*. *DaimlerChrysler Corp.*, 2002 BCCA 354, where on appeal of the chambers judge's decision that the former *Trade Practice Act* did not include an American manufacturer the British Columbia Court of Appeal said that in introducing cars into the Canadian stream of commerce the US defendants ought to have known that they would be sold to consumers in Canada and that as a result there was an arguable case that they were suppliers under the *Trade Practice Act*. To a similar effect is *Reid v. Ford Motor Company*, 2003 BCSC 1632.

- [95] If the defendants are correct in their submission that immediacy is required, the purpose and effectiveness of the *BPCPA* would be thwarted. I conclude that a liberal construction must be applied to the "consumer transaction" at issue and that such a transaction includes one where a learned intermediary is involved. In addition, I am satisfied that the defendants are "suppliers' under the *BPCPA*. I note that recently in *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260, the British Columbia Court of Appeal certified a class action involving a prescription drug. The court was clearly alive to the learned intermediary issue in doing so, although its effect on the *BPCPA* was not addressed.
- [96] The defendants also suggest that the fact that prescriptions are federally regulated under the *Food and Drugs Act*, R.S.C., 1985, c. F-27, makes the *BPCPA* inapplicable. They do not however challenge the constitutionality of the *BPCPA*. Had they done so *Unlu v. Air Canada*, 2012 BCSC 60, and *Wakelam v Johnson & John*son, 2011 BCSC 1765, indicate that the *BPCPA* still applies despite federal regulation of the businesses in question. I note both of those decisions are apparently under appeal. Given the defendants did not directly challenge the constitutionality of the *BPCPA* and in light of the existing authorities I need not address this issue further.
- [97] As a result I reject the submission of the defendants that they are not suppliers and that the transaction is not a consumer transaction and am satisfied that the plaintiff has a cause of action pursuant to the *BPCPA*. The amended notice of civil claim alleges that the defendants engaged in a deceptive act or practice, pursuant to s. 4, in failing to disclose Propecia and Proscar's product defects, namely persistent sexual side effects after discontinuation of use.
- [98] In *Chalmers v. AMO Canada Company*, 2010 BCCA 560, the British Columbia Court of Appeal considered pleadings containing similar allegations, including the failure to disclose a particular risk, and was satisfied

that the claim under the *Consumer Protection Act* met the requirements of s. 4. Justice Tysoe held the following at para.18:

[18] ... [I]t is my opinion that the amended statement of claim clearly gives particulars of the claim under the *Consumer Protection Act*. 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* 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.

Wavier of Tort

[99] As noted the defendants submit the plaintiff has pleaded "Wavier of tort". The plaintiff denies that he has done so.

[100] Waiver of tort is a restitutionary action or remedy that allows a plaintiff to forego the usual cause of action and the normal remedy attached and seek disgorgement of profits in its place.

[101] In an ordinary tort action the court attempts to provide the sum of money that will put the injured party in the same position they would have been but for the wrong done. That is, "restitution *in integrum*". However, in certain instances the defendant's gain from committing the tort is much greater than the damages suffered by the plaintiff.

[102] As noted above, the plaintiff's amended notice of civil claim seeks disgorgement of or profits or revenues received by the defendants from the sale of Propecia and Proscar in B.C., claiming that this remedy is available under ss. 171 and 172 of the *BPCPA*.

[103] Section 171(1)(a) sets out the right of a consumer to recover for pecuniary loss arising from a deceptive act. The relevant portions of s. 171(1)(a) read as follows:

171(1) Subject to subsection (2), if a person, other than a person referred to in paragraphs (a) to (e), has suffered damage or loss due to a

contravention of this Act or the regulations, the person who suffered damage or loss may bring an action against a

(a) supplier,

..

[104] Section 172 provides a basis for a consumer or other interested person to seek a remedy for breach of the *BPCPA*. The relevant sections are:

172(1) The director or a person other than a supplier, whether or not the person bringing the action has a special interest or any interest under this Act or is affected by a consumer transaction that gives rise to the action, may bring an action in Supreme Court for one or both of the following:

- (a) a declaration that an act or practice engaged in or about to be engaged in by a supplier in respect of a consumer transaction contravenes this Act or the regulations;
- (b) an interim or permanent injunction restraining a supplier from contravening this Act or the regulations.

..

- (3) If the court grants relief under subsection (1), the court may order one or more of the following:
 - (a) that the supplier restore to any person any money or other property or thing, in which the person has an interest, that may have been acquired because of a contravention of this Act or the regulations:
 - (b) if the action is brought by the director, that the supplier pay to the director the actual costs, or a reasonable proportion of the costs, of the inspection of the supplier conducted under this Act;
 - (c) that the supplier advertise to the public in a manner that will assure prompt and reasonable communication to consumers, and on terms or conditions that the court considers reasonable, particulars of any judgment, declaration, order or injunction granted against the supplier under this section.

. . .

[105] The most recent consideration of waiver of tort is found in *Koubi*. The plaintiff submits his cause of action pleaded under the *BPCPA* is not a "waiver of

tort" claim, as he is not attempting to use the *BPCPA* to "create a new, parasitical common law claim" as was the case in *Koubi*. He therefore says that *Koubi* has no relevance to the claim. In part his justification for this statement is that the claim "is properly pleaded, entirely consistent with the established case law and falls within the express language of the statute".

[106] In *Koubi* the court held that a claim for restitutionary damages and disgorgement of profits arising from waiver of tort premised on breaches of the *BPCPA* and *Sale of Goods Act*, R.S.B.C. 1996, c. 410 did not disclose a cause of action. The British Columbia Court of Appeal held that the *BPCPA* was an "exhaustive code regulating consumer transactions …" (para. 63). As a result the plaintiff in *Koubi* was "restricted to the remedies provided by the Act". The court held that the plaintiff's claim "for restitutionary damages and disgorgement of profits arising from waiver of tort [did] not disclose a cause of action." (para. 65).

[107] In light of *Koubi* ss. 171 and 172 of the *BPCPA* limit recovery for pecuniary loss to the consumer's own damage or loss. The *BPCPA* does not provide the basis for a claim based on waiver of tort and restitutionary damages.

[108] The final sentence of para. 48 of the amended notice of civil claim is therefore struck.

[109] Certain portions of the amended notice of civil claim are assertions of opinion and commentary and not statements of fact and as a result have not formed part of my assessment of the disclosure of causes of action by the pleadings. They are not relevant to the requirements for pleading a cause of action.

[110] Accordingly, as amended by these reasons, the amended notice of civil claim discloses causes of action in negligence and under the *BPCPA*.

Is There an Identifiable Class of Two or More Persons?

[111] The plaintiff's initial proposed class definition was: "All persons who were prescribed Propecia and/or Proscar in British Columbia for hair loss and experienced side effects which continued after ceasing to take these drugs."

[112] The defendants argue that:

[107] The plaintiff's proposed class definition fails to meet the requirements of section 4(1)(b) for three reasons: (a) it is unsupported by any evidence; (b) it is not rationally connected to the causes of action pleaded in the Amended Notice of Civil Claim; and (c) it is vague and ambiguous, violating the requirement that class members be determinable by objective criteria.

[113] Specifically, the defendants allege that there is no evidence that anyone in B.C., other than the plaintiff, is seeking to advance a claim that he has suffered permanent sexual dysfunction as a result of using Proscar or Propecia. The defendants allege that the affidavits submitted by plaintiff's counsel's staff claiming they have been contacted by upwards of 50 potential class members are inadmissible hearsay, as are the attached reports.

[114] The defendants also argue that the proposed class definition is not rationally connected to the cause of action pleaded because the amended notice of civil claim only pleads a cause of action with respect to the side effect of persistent sexual dysfunction, not "side effects" more generally, as suggested in the proposed definition. Accordingly, the defendants submit putative class members do not have a potential or colourable claim to recover damages against the defendants for personal injury on the basis of a failure to warn.

[115] The defendants further submit that the definition proposed by the plaintiff does not permit a potential class member to determine his membership in the class based on objective criteria on the basis that: the term "side-effects" implies that potential class members have suffered adverse reactions due to the use of Propecia or Proscar which ultimately creates a merit-based definition; the term "side-effects" is too broad; "which continued" is ambiguous as to how long side

effects would have to continue after taking the drug in order to join the class; the definition includes persons who were prescribed the drug in B.C. and it is unclear as to whether those persons must still reside in the province; there is no objective way to determine whether persons were prescribed the drug specifically for hair loss.

[116] The plaintiff, in reply, amended the proposed class definition. It now reads: "All persons who were prescribed Propecia and/or Proscar for hair loss in British Columbia."

[117] The plaintiff argues that this modified definition is appropriate. He asserts that he does not need to specify whether potential class members must reside in the province as the necessity for a sub-class only arises when there is a conflict between the class and subclass. The plaintiff is not anticipating conflict between potential class members that reside outside the province and those that have remained in the province.

[118] The requirements of s.4 (1)(b) are discussed by the Supreme Court of Canada in *Western Canadian Shopping Centres Inc. v. Dutton*, [2001] 2 S.C.R. 534, at para. 38:

While there are differences between the tests, four conditions emerge as necessary to a class action. 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: ...

[119] On the requirement of objective criteria to determine whether a person is "in or out" of the class, McLachlin C.J.C.in *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158, stated at para.17:

- 17 ... The first question, therefore, is whether there is an identifiable class. In my view, there is. The appellant has defined the class by reference to objective criteria; a person is a member of the class if he or she owned or occupied property inside a specified area within a specified period of time. Whether a given person is a member of the class can be determined without reference to the merits of the action. While the appellant has not named every member of the class, it is clear that the class is bounded (that is, not unlimited). There is, therefore, an identifiable class within the meaning of s. 5(1)(b): ...
- [120] The defendants initially submitted that no admissible evidence had been provided that anyone other than Mr. Miller is seeking to advance a claim that they have suffered permanent sexual dysfunction as a result of the use of Proscar or Propecia. I say initially because, as was noted at the outset of these reasons, the evidence filed with the application in support of there being an identifiable class of two or more persons consisted of affidavits from employees of the plaintiff's law firm.
- [121] The basis for the objection is that all of these statements are inadmissible hearsay or double hearsay given the affiants are simply repeating information provided from someone else in the plaintiff's law firm which information was itself provided by another person to that person. The primary objection is that the information is being tendered for the truth of its contents.
- [122] The parties have agreed with respect to Ms. Wong's affidavit #3 that:

The Defendants do not object to admissibility of the affidavit of Deborah Wong #3, sworn May 11, 2012 for the limited purpose of providing the Plaintiff's best information of the numbers of the members of the purported class for the purpose of s. 5(5)(c) of the *Class Proceedings Act.*

- [123] The issue is whether the plaintiff can rely on hearsay to establish the existence of an identifiable class.
- [124] In Fresco v. Canadian Imperial Bank of Commerce (2009), 71 C.P.C. (6th) 97, 84 C.C.E.L. (3d) 161 (Ont. S.C.J.), the motions judge addressed this issue as follows at para. 8:

- [8] The plaintiff also tendered an affidavit from Charlene Wiseman. one of Ms. Fresco's lawyers in this case, which purports to be evidence of CIBC's overtime practices based on a self-selected survey sample of potential class members registered on plaintiff's counsel's website. Prior to the motion, Ms. Fresco's counsel provided CIBC's counsel with an unsworn copy of the affidavit so that CIBC could advise whether it consented to the admission of that evidence or whether a motion would be required. CIBC objected to the affidavit as inadmissible hearsay. The affidavit was nonetheless filed as evidence on this motion without bringing a motion or seeking the court's direction. Ms. Fresco's response is that this is the best available survey evidence of CIBC's unpaid overtime practices, given that CIBC rejected both the plaintiffs request to provide her with information on the class members to allow the plaintiff to conduct its own random sample and the plaintiffs proposal to conduct a ioint random survey of the putative class. This is not a compelling answer. The evidence constitutes hearsay and does not meet either the test of necessity or of reliability: R. v Smith, [1992] 2 S.C.R. 915 at 933-934; R. v Khan, [1990] 2 S.C.R. 531 at 541. As the evidence is not properly before the court and constitutes inadmissible hearsay, I have not considered Ms. Wiseman's affidavit.
- [125] Turning to whether or not the affidavits of Ms. Cumming and Ms. Wong should be admitted to establish the existence of an identifiable class of two or more persons it was held in *Hollick* at para. 25 that "the representative of the asserted class must show some basis in fact to support the certification order. As the court in *Taub* held, that is not to say that there must be affidavits from members of the class or that there should be any assessment of the merits of the claims of other class members."
- [126] As noted by Lax J., in *Glover v. Toronto (City)* (2009), 70 C.P.C. (6th) 303 (Ont. S.C.J.), the term "[s]ome basis in fact is an elastic concept and its application can be vexing" (para.15). What is certain is the Court's pronouncement in *Hollick* that some basis in fact is a "low threshold" or a "minimum evidential burden" and the courts should refrain from imposing technical requirements on the plaintiffs at the certification stage (see also: *LeFrancois v. Guidant Corporation* (2009), 178 A.C.W.S. (3d) 34 (Ont. S.C.J.))
- [127] However in *Chalmers v. AMO Canada Company*, 2009 BCSC 689, Butler J. held that where a legal assistant in the plaintiff's firm swore that he was informed by one of the firm's lawyers that the firm had been contacted by six

individuals in B.C. who claimed to have used the solution in question and to have been diagnosed with AK (Acanthamoeba Keratitis), that notwithstanding the hearsay nature of that information such evidence was admissible, saying at para. 62:

- [62] The other evidence Ms. Chalmers relies on to provide some indication of class size is also admissible. The parties are required under s. 5(5)(c) of the *Act* to provide the "best information" regarding the number of members in the class. Such evidence will almost always be in the form of hearsay. While the evidence does not prove class size, it is relevant to considering the procedural issues that this Court must consider on a certification application.
- [128] I agree with Butler J. that the evidence does not prove class size however, given that the issue on certification is whether there is an identifiable class of two or more persons, proof of class size is not required. That said, the information respecting potential size may still be considered.
- [129] In any event, and presumably in response to the defendants' challenge to such evidence, plaintiff's counsel presented at the conclusion of the certification hearing an additional affidavit from another potential member of the class. That individual requested anonymity because of the private nature of the allegations. Defence counsel objected to the court receiving the affidavit as new evidence late in the certification process and due to certain inadmissible portions. The affidavit was sealed. The parties agreed that the court was only to consider paras. 1-3 and 8 of the affidavit and their admissibility.
- [130] The affidavit states that the individual was prescribed, purchased and ingested Proscar for hair loss and that he took the drug between November 2004 and October 2005. Like Mr. Miller he used a pill splitter to divide the drug into 4 portions. He asserts that he "experienced reduced sexual desire, an inability to maintain erections, and depression all of which persisted after he ceased taking the Proscar with the depression eventually resolving but the sexual dysfunction problems having continued." He states that he is

interested in participating in the lawsuit but for privacy reasons prefers not to have his name disclosed.

- [131] Given the nature of the alleged effects of the drugs it is understandable that potential plaintiffs are reluctant to have their names publicized. It would also explain in part the lateness of the filing of the affidavit.
- [132] In *Chalmers v. AMO Canada Company*, 2009 BCSC 689, Butler J. considered the introduction of fresh evidence and determined that the test for the admission of fresh evidence on an interlocutory matter is more relaxed (para. 50). He concluded at para. 51:
 - [51] In exercising my discretion to allow the new evidence, I took into account s. 5 of the *Act*. It requires parties to file affidavits containing information relevant to certification. Pursuant to s. 5(5)(c) an affiant is required to "provide the person's best information on the number of members in the proposed class." That issue is relevant to both class size and notice.
- [133] As a result he permitted the introduction of the fresh evidence.
- [134] In my view similar considerations apply here. The application as well occurred during the course of the certification hearing not after. As a result the affidavit of D.E. will be admitted.
- [135] The admission of the affidavit of D.E., a second proposed member of the class, addresses in part the argument that there was only evidence of one plaintiff. I also order additional affidavits be produced from the solicitors who were contacted by prospective class members in order to address the deficiencies of the staff members' affidavits.
- [136] On the issue of D.E.'s request for anonymity, I was provided with minimal information respecting his circumstances and concerns. Given this is an interlocutory application and the affidavit of D.E. is filed at this time to show only that there is more than one class member, and the fact that he is not a party to

the proceeding, his affidavit will remain sealed until further submissions and evidence is provided on justification for the requested anonymity to continue.

[137] I agree with the defendants that the plaintiff's proposed class definition is overbroad. The class definition must therefore be modified and will read: "All male persons who were prescribed Propecia and/or Proscar for male pattern hair loss in British Columbia prior to November 18, 2011."

[138] This definition confines the potential class members to particular factual allegations enabling the court to determine whether any person coming forward is or is not a class member. I reject the defendants' contention that the criterion of being prescribed the drug for male pattern hair loss is in some way subjective or unascertainable, do not see any need to restrict the definition to B.C. residents, and note that the defendants' other concerns are allayed by the removal of the merits based portion of the definition.

[139] I am satisfied, based on the aforementioned case law, and subject to the filing of supplementary affidavits from the solicitors contacted by putative class members that there is some basis in fact that there exists over 50 putative class members in B.C., that the modified definition is sufficiently clear so as to allow those potential members to decide whether to join the class.

Do the Claims of the Class Members Raise Common Issues?

[140] "Common issues" are defined in s. 1 of the CPA to mean:

"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;

- [141] The approach to a determination of common issues was described in *Endean v. Canadian Red Cross Society* (1997), 148 D.L.R. (4th) 158, 36 B.C.L.R. (3d) 350 (S.C.) as follows at para. 35:
 - [35] ... A common issue is sufficient if it is an issue of fact or law common to all claims, and that its resolution in favour of the plaintiffs will advance the interests of the class, leaving individual issues to be litigated later in separate trials, if necessary: *Harrington v. Dow Corning Corp.* (1996), 22 B.C.L.R. (3d) 97 at 015, 110 (S.C.). As well the court should not attempt to weigh the ultimate merits of the proposed common questions, but should merely ascertain whether they raise triable issues: *Campbell v. Flexwatt Corp.* (1996), 25 B.C.L.R. (3d) 329 at 343 (S.C.).
- [142] Also as noted by Cumming J.A. in *Campbell v. Flexwatt Corp*. (1997), 44 B.C.L.R. (3d) 343, 6 W.W.R. 275 (C.A.) at para. 53:
 - [53] When examining the existence of common issues it is important to understand that the common issues do not have to be issues which are determinative of liability; they need only be issues of fact or law that move the litigation forward. The resolution of a common issue does not have to be, in and of itself, sufficient to support relief. To require every common issue to be determinative of liability for every plaintiff and every defendant would make class proceedings with more than one defendant virtually impossible.
- [143] When certifying the action, the court has the discretion to redefine the common issues proposed by the representative plaintiff. Goudge J.A. in *Cloud,* stated: "[a]s the class action proceeds, the judge managing it may well determine that the common issues should be restated with greater particularity in light of his or her experience with the class proceeding. To permit that process to unfold with flexibility, at this stage, I would state the common issues in general terms, ..." (para. 72).
- [144] In what follows, I will list the plaintiff's proposed common issues and the nature of the defendant's argument respecting each issue followed by any necessary redefinition.

(1) Can ingesting Propecia or Proscar cause side effects that continue after ceasing to take Propecia or Proscar?

[145] The defendant argues that this issue is "hopelessly overbroad and extends beyond the scope of any reasonable cause of action." Whether the drug can cause side effects that persist after discontinuation of use is said not to be a single question but a myriad of questions susceptible to different answers in relation to each possible side effect.

[146] The defendants further submit that the plaintiff has not established any evidentiary basis for this common issue, specifically an evidentiary basis for the claim that Proscar or Propecia can cause persistent sexual dysfunction.

[147] The defendants also object to certain portions of the plaintiff's evidence on the basis that it is hearsay or speculative and lacking any factual foundation. They submit the evidence must meet the usual requirements for admissibility. (*Martin* at para. 25). Prior to considering the evidentiary basis for a common issue I turn first to the admissibility of the evidence presented.

[148] The burden is on the plaintiff to provide admissible evidence supporting the application for certification. In *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540, the British Columbia Court of Appeal stated at para: 31:

[31] ... Despite the robust approach taken by Canadian courts to class actions, I know of no authority that would support the admissibility, for purposes of a certification hearing, of information that does not meet the usual criteria for the admissibility of evidence. A relaxation of the usual rules would not seem consonant with the policy implicit in the Act that some judicial scrutiny of certification applications is desirable, presumably in view of the special features of class actions and the potential for abuse by both plaintiffs and defendants: see the discussion at paras. 31-52 of *Epstein v. First Marathon Inc.* (2000) 41 C.P.C. (4th) 159 (Ont. Sup. Ct. J.).

[149] As a result an affidavit filed in support of a certification application must comply with the *Supreme Court Civil Rules* Rule 22-2(12-13). The applicable provisions read as follows:

- (12) Subject to subrule (13), an affidavit must state only what a person swearing or affirming the affidavit would be permitted to state in evidence at a trial.
- (13) An affidavit may contain statements as to information and belief of the person swearing or affirming the affidavit, if
 - (a) the source of the information and belief is given, and
 - (b) the affidavit is made
 - (i) in respect of an application that does not seek a final order or,
 - (ii) by leave of the court under Rule 12-5 (71) (a) or 22-1 (4) (e).

...

[150] The defendants firstly object to Mr. Miller's affidavit #1 with respect to paras. 6, 8 and 9 which state:

- 6. ... I believed that these changes to my behaviour were side effects caused by the drug ...
- 8. ... The side effects that I was experiencing ...
- 9. The drug has had a significant impact on the quality of my day-to-day life ...

[151] The defendants submit that Mr. Miller's statement that he believes his sexual dysfunction is due to Proscar is inadmissible opinion evidence that he is not qualified to give. As a result they submit there is no admissible evidence to establish that Proscar is the cause of the plaintiff's sexual dysfunction. They note that the plaintiff has not provided an opinion from any treating physician or qualified medical expert respecting the probable cause of *his* sexual dysfunction.

[152] I accept that the statements of Mr. Miller above in so far as they are opinion evidence are not admissible. What Mr. Miller's evidence does establish is that he suffers from persistent sexual dysfunction and that it arose after he commenced using the Proscar. It does not establish causation. However given

the following expert evidence, I do find it is a sufficient basis in fact for the purposes of certification.

- [153] The only expert evidence lead by the plaintiff on the issue of causation is that of Dr. Wright. Dr. Wright is not a treating physician nor does he offer an opinion as to the cause of the plaintiffs claimed persistent sexual dysfunction. He does however state that sexual dysfunction due to the drugs is biologically plausible.
- [154] The defendants also challenge Dr. Wright's July 8, 2011 affidavit at paras. 12 and 20 which state:
 - 12. Long-term adverse effects of finasteride remain mostly unknown as long-term trials to assess these effects have not been conducted.
 - 20. The potential for non-reversibility of the sexual adverse effects of finasteride with long-term therapy should have been a concern for Merck & Co. Inc. as they knew that long-term controlled trials of finasteride had not been conducted and they knew that permanent irreversible adverse effects had been well documented for other drugs. ...
- [155] The basis for their objection to these paragraphs is that they are speculative, argumentative and contain statements of opinion without sufficient foundation. Similar objections are made to other portions of Dr. Wright's evidence.
- [156] In my opinion these criticisms are well founded. For the purposes of this application I have disregarded such speculative, argumentative and unsupported statements of opinion.
- [157] They also object to affidavit #2 of Dr. Wright at Exhibit A page 2 of his rebuttal report in which he states that given the mechanism of action of finasteride, it is biologically plausible that it could cause sexual dysfunction in men taking the drug.
- [158] The objection is that he only states that a connection is biologically plausible but does not give an opinion that the evidence shows that the drug

does cause persistent sexual dysfunction in some men. While that may be true that is not the issue the court must address on this application. It is an issue for trial. On a certification application the plaintiff need only show some evidence. Indeed, it is reasonable to infer that much of the relevant evidence is in the hands of the defendants and until disclosed the plaintiff is left with a limited ability to show greater evidence. In my view the evidence of Dr. Wright that a connection is biologically plausible while unproven is some evidence. It is also an issue the resolution of which will advance the litigation for all class members.

- [159] The defendants also object to Exhibit A page 3 where Dr. Wright states:
 - ... Dr. Goldenberg does not provide any rationale to refute the plausible biological mechanism of action linking persistent sexual dysfunction to the use of finasteride". ...
- [160] Again however, this goes to the merits and is a matter for trial.
- [161] Finally, they submit that Dr. Wright has referred to clinical trials that have shown that "both Propecia and Proscar caused decreased libido and erectile dysfunction in some men taking the drug" but that the articles and studies affixed to his report are not properly admissible as evidence of their contents and cannot be relied on by the court. They note as well that one of the studies of Irwig et al states that it "does not prove that finasteride caused persistent sexual side effect". They rely on Dr. Goldenberg who opines "there is no evidence to suggest a causal relationship between 5-ARIs [finasteride] and persistent/permanent sexual dysfunction in men".
- [162] The defendants' request that the court prefer the evidence of the defendants' experts in this regard and submit that it is appropriate for the court to weigh competing scientific and medical evidence when determining if the certification requirements are met (*Dumoulin v. Ontario* (2005), 19 C.P.C. (6th) 234 (Ont. S.C.J.), para. 27).
- [163] They also submit that the plaintiff has failed to establish that there is a plausible methodology for proving causation on common evidence at trial.

Indeed in their submission the plaintiff has not even set out a theory as to how that could be accomplished.

[164] In support they rely on *Pro-Sys Consultants Ltd. v. Infineon Technologies AG*, 2009 BCCA 503. In *Pro-Sys Consultants Ltd.*, the plaintiff sued electronics manufacturers for unlawful overcharges. The chambers judge found that the aggregate monetary claim could not be tried as a common issue as a methodology was not shown to be capable of proving that the wrongful conduct caused a wrongful gain arising from overcharging of purchasers. The British Columbia Court of Appeal however allowed the appeal and said this at para. 68:

The appellant was required to show only a credible or plausible [68] methodology. It was common ground that statistical regression analysis is in theory capable of providing reasonable estimates of gain or aggregate harm and the extent of pass-through in price-fixing cases. Ms. Sanderson gave evidence that aggregate harm had been estimated by two experts in the U.S. litigation. As well, it appears from the U.S. plea agreements that the Department of Justice was prepared to prove that the agreed fines were justified as representing twice the gross gain or the gross loss resulting from the price-fixing conspiracy. The dispute here is over whether total gain or loss can be determined as a practical matter on the particular facts of this case. Those facts have not yet been fully developed and it was therefore premature of the chambers judge to reject Dr. Ross' opinion. The close examination to which he subjected it should have been left for the trial judge, whose task it will be to evaluate the conflicting expert opinions and to decide what weight to give them. In my view, Dr. Ross' evidence met the low threshold required to establish for purposes of certification that gain and its counterpart, damage, can be shown on common evidence.

[165] In my view para. 68 must be read in the context of the judgment in *Pro-Sys Consultants Ltd.*, as a whole. It is clear that the court was addressing the issue of some evidence or basis in fact and that expert opinion evidence adduced at a certification hearing is not subjected to the scrutiny it would be at trial (paras. 63-66). As well in *Pro-Sys Consultants Ltd.*, the concern was whether a specific statistical approach could be successfully applied.

[166] I do not accept that the reference to a "credible or plausible methodology" necessarily requires that the plaintiff as suggested by the defendants establish a

plausible methodology for establishing causation. That is methodology in the sense of a defined plan. Rather, all that is required is there is some evidence that there is a plausible claim that is capable of being pursued and in this instance that is found in the opinion of Dr. Wright that it is "biologically plausible" that sexual side effects would occur and that some would persist. While not proof of causation the complaints of persistent side effects and the resulting change in the warnings provide relevant circumstantial evidence in support as well.

[167] Given the drugs were invented by the defendants the pursuit of the claim will necessarily involve a full investigation including oral and documentary discovery. It is only at that stage that a determination of how the claim can be proven and the method for doing so can be ascertained. Then at trial, competing expert evidence will be properly weighed and considered.

[168] A response to their objection to the admissibility of the referenced reports is found in *Jones v. Zimmer GMBH*, 2013 BCCA 21, where the court said this at paras. 45-48:

- [45] The appellants' second evidentiary objection is that the certification judge erred in admitting and relying on the opinion of Dr. Mahomed because it was based on hearsay statements taken from the article by Long et al and was therefore inadmissible.
- The appellants rely for this contention on *Ernewein v. General* Motors of Canada Ltd., 2005 BCCA 540, 46 B.C.L.R. (4th) 234. Mr. Ernewein claimed that certain vehicles manufactured by the defendant had been negligently designed such that they created a risk of harm to consumers in the event of side-impact collisions. In support of his application to certify the action as a class proceeding, Mr. Ernewein filed an affidavit of a lawyer to which was exhibited a report prepared by an agency of the U.S. government following an investigation of the safety of the vehicles in side-impact collisions. The report supported Mr. Ernewein's case and the certification judge relied on it in certifying the action. However, the report was offered in evidence as proof of its contents without any authentication or any attempt to prove by admissible evidence that the statements in the report were true or the conclusions were reliable. This Court observed on appeal that information that does not meet the usual criteria for admissibility of evidence is not admissible for purposes of a certification hearing (at

- para. 31). Thus, the report was adjudged hearsay and inadmissible as evidence of the truth of its contents.
- [47] In this case, however, the evidence on which the respondents relied was the expert opinion of Dr. Mahomed. The Long article merely provided one of the bases of Dr. Mahomed's opinion. It was not offered as proof in itself of the truth of its contents. Accordingly, *Ernewein* is materially different on its facts and is of no assistance to the appellants.
- [48] The criteria for admissibility of expert opinion evidence are that the expert must be properly qualified, the opinion must be relevant to a fact in issue, the opinion must be necessary to assist the trier of fact to draw a correct inference when the subject matter is likely outside the knowledge and experience of the trier of fact, and the opinion must not otherwise be excluded by an exclusionary rule of evidence: *R. v. Mohan*, [1994] 2 S.C.R. 9 at 20-25. Dr. Mahomed's opinion satisfied these criteria and was therefore admissible.
- [169] The defendants further submit that even if the common issue is restricted to persistent sexual dysfunction and found to be a common issue, such a finding as to "general causation" will not advance the litigation. Is that the case?
- [170] They submit "[a] finding that Propecia® or Proscar® *can* cause persistent sexual dysfunction in some men does little to establish that it *did* in any particular class member.", given "[p]ersistent sexual dysfunction can occur for many reasons, ..."
- [171] As a result they submit that "even if the plaintiff were able to show at a common issues trial that use of Propecia® or Proscar® "can" at a general level cause persistent sexual dysfunction ... the most that theoretically would be established at the level of general causation is that treatment with Propecia® and/or Proscar® *increases* the risk of persistent sexual dysfunction in men, above the background risk of persistent sexual dysfunction in men who do not ingest Propecia® and/or Proscar®." As a result they submit the litigation would not be advanced. They further argue that each class member would have to show on a balance of probabilities that his persistent sexual dysfunction was due to the medication and not another cause and hence the finding on general causation would be of no assistance.

- [172] The answer to this submission is found in *Heward* where the proposed common issue #1 was: "Can Zyprexa cause diabetes and/or other metabolic disturbances as well as secondary injuries flowing therefrom?" Cullity J. said this:
 - [82] The word "other" should, I believe, be replaced with "related" to conform with the pleading but otherwise this issue is acceptable. Its existence as an issue is amply supported by the conflicting expert evidence in the record. In effect, it asks whether the use of Zyprexa carries with it a risk of harmful side-effects of specific kinds. The question is fundamental to the claims of all the class members. The existence and nature of any such consequences can be identified at trial largely on the basis of expert evidence. As MacInnes J. stated in *Walls v. Bayer Inc.*, [2005] M.J. No.4 (Man Q.B.) (at para. 51):

A factual enquiry as to the nature of the problems caused by an allegedly defective drug is an appropriate common issue ... This issue is one which can be determined at a common issues hearing and which will turn essentially on the evidence of expert witnesses. It will not require the evidence of plaintiffs or members of the class. As well, a determination of this issue will advance the litigation.

- [83] The question whether the class members experienced such consequences will have to be determined individually but this does not detract from the commonality of the issues formulated. The significance of the individual issues in relation to the common issues is most appropriately determined after all the issues on which the defendants' liability will depend have been identified and placed in one category or the other.
- [173] I am satisfied that the plaintiff has provided sufficient evidence to establish a rational relationship between the proposed class definition in the sense that the response to the question raised by this common issue can be extrapolated to each potential class member to at least some extent. It is an issue that is relevant to the claims of all class members.
- [174] Accordingly, this common issue assists in avoiding duplication of fact-finding or legal analysis and moves the litigation forward. In my view establishing that treatment with Propecia and/or Proscar increases the risk of persistent sexual dysfunction in men would resolve a fundamental aspect of the issue of liability.

[175] I do however agree with the defendants that the question as posed by the plaintiff is susceptible to different answers. This issue must be narrowed to read: "Can ingesting Propecia or Proscar cause sexual dysfunction which persists after ceasing to take Propecia or Proscar?".

(2) Did any or all of the defendants owe a duty of care to the class members?

[176] The defendant argues that this question has previously been answered in the affirmative and is essentially trite law.

[177] Although a duty of care has been found to exist in analogous circumstances in other proceedings, it does not preclude certification of a duty of care issue (*Endean*).

[178] However, given that this issue is conceded by the defendants and is not under appeal in any other court, the resolution of this issue will not contribute to the objectives of efficiency and behaviour modification sought by class action litigation. As noted in *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057 at para. 50, "[t]his question is one of law. It is unnecessary to certify this question as a common issue."

- (3) What was the nature of the duty of care?
- (4) Did all or any of the defendants breach this duty and if so when?

[179] The defendants argue that the duty of care and its alleged breach are not distinct but interdependent, that they are not an essential ingredient of each class member's claim and that the proposed common issue is not sufficiently narrow in its scope.

[180] The defendants state that an alleged breach of the duty to warn of drugrelated adverse reactions related to persistent sexual dysfunction is the only breach of the duty of care that is rationally connected to the plaintiff's claim.

- [181] The defendants also argue that the plaintiff has not adduced any evidence to support a claim that Merck knew or ought to have known of a causal link between the drug and sexual dysfunction prior to 2008. They state that the reports of adverse events are not sufficient evidence to establish a causal link and cannot be deemed evidence of Merck's knowledge, as other causes are "just as likely".
- [182] Again, such evidence in all probability, if it exists, is in the hands of the defendants.
- [183] As I canvassed earlier in these reasons, on an application for certification the plaintiff need only show evidence of 'some basis in fact' for each element of certification (*Hollick*, para. 25).
- [184] The plaintiff's evidence regarding the demand by other jurisdictions that the defendant provide a more detailed and comprehensive adverse event report concerning persistent sexual dysfunction in men shows some basis in fact that the defendants knew or ought to have known of the potential causal link between persistent sexual dysfunction and the use of Propecia and Proscar prior to 2008.
- [185] However, I agree with the defendants that the full breadth of the scope of the defendants' duty of care is not in issue. The only breach of the duty of care that is rationally connected to the plaintiff's claim is a breach of the duty to warn of drug-related adverse reactions related to persistent sexual dysfunction.
- [186] The defendants' final argument is that the scope of the duty to warn is too individualized to be a common issue. The defendants note that since the drugs were approved in the 1990s, the product monographs and package inserts have changed more than once. They also say that sometimes the role of learned intermediaries, or even the particular knowledge of the plaintiff, will absolve liability. Because of this, the issue of breach of a duty to warn is very case specific and is therefore not a 'common issue.'

[187] I do not accept this argument. With respect to the role of learned intermediaries or the knowledge of a particular plaintiff, I note that these are issues with respect to reliance, not the defendants' overarching duty to warn and the standard against which it should be measured. Given the size of the defendants' potential market, the information the defendants' provide to the public and to doctors is standardized, not individualized. A breach of a duty to warn can be determined on the defendants' conduct alone, and can be applied commonly to class members. Reliance by any particular class member will be an individual issue. As for the varying monographs and package inserts, over the years, and between the two different products, these are still common issues, though a determination will need to be made with respect to each particular version of theme.

[188] I turn now to the claim for punitive damages, a claim that raises two common issues that are best addressed together.

- (5) 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?
- (6) If the answer to common issue 5 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?

[189] The plaintiff advances this claim on the basis that their negligence claim is against the group as a whole as opposed to conduct directed specifically to any one plaintiff. As such it focuses on whether the defendants' conduct was morally culpable. The plaintiff pleads that the defendants acted with reckless disregard and chose to value profits over public safety by ignoring labelling changes outside of Canada and by continuing to market the drugs in Canada without adequate warnings.

[190] The defendants' principle argument against punitive damages as a common issue is that these issues only arise if the defendant is first found liable in negligence. While that is correct, should that finding be made the issue of punitive damages will then have to be addressed. Where it can be addressed as a common issue when the issue of negligence is determined a higher degree of efficiency will be achieved instead of leaving the issue outstanding for subsequent adjudication.

[191] In Chalmers v. AMO Canada Company, 2010 BCCA 560, the court held 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 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.

[192] The comments of the British Columbia Court of Appeal are applicable to the case at bar.

[193] I am satisfied, based on based on the facts of this case and the aforementioned case law, that the plaintiff's claim for punitive damages should be certified as a common issue on the terms requested.

[194] I now turn to the common issues proposed that relate to the *BPCPA* claim.

- (7) Did the defendants' solicitations, offers, advertisements, promotions, sales and supply of Propecia or Proscar for personal, family or household use by class members fall within the meaning of "consumer transactions" under the Consumer Protection Act?
- (8) Are the defendants "suppliers" as defined by the Consumer Protection Act?
- (9) Are the class members "consumers" as defined by the Consumer Protection Act?
- (10) Did the defendants, or any of them, engage in conduct that constituted deceptive acts or practices contrary to the Consumer Protection Act?
- [195] The defendants' principle argument regarding the common issues relating to the *BPCPA* is that the plaintiff has not established a sufficient basis in fact to certify these common issues.
- [196] The plaintiff responds and I agree, that *Wakelam v. Johnson & Johnson*, 2009 BCSC 839, provides support for their position despite it relating to an application for particulars:
 - [39] ... The plaintiff is relying on specialized consumer protection statutes which focus the inquiry on the impact of the representation on the public at large. The question of whether a representation is deceptive or misleading does not, therefore depend on an individual inquiry. The question of deception or no deception is something that can be litigated without reference to the circumstances of the plaintiff or individual class members: ...
- [197] The common issues listed relating to the *BPCPA* are substantial ingredients of each potential class members' claim. At this stage, it is not for the court to attempt to weigh the merits of the common issue, but to only ascertain whether they raise a triable issue.
- [198] I am satisfied that the common issues related to the *BPCPA* claim are appropriately formulated.
- [199] In summary, I am satisfied that the modified common issues will assist the court in avoiding duplication of fact-finding or legal analysis, have a rational

relationship to the proposed class definition, and are capable of extrapolation to each potential class member. The proceedings will be advanced by a resolution of the common issues and as a result the objectives of the legislation as well, those being access to justice, judicial economy and behavioural modification.

Is Mr. Miller an Appropriate Representative Plaintiff?

[200] As part of the requirements for certification, s. 4(1)(e) of the *CPA* requires that that there is a representative plaintiff who would fairly and adequately represent the interests of the class, has produced a workable plan for the proceeding, including a plan for notifying class members of the proceeding, and does not have, on the common issues, an interest in conflict with the other class members.

[201] In *Western Canadian Shopping Centres*, McLachlin C.J.C. at para. 41 clarified the requirements for the adequacy of the representative plaintiff:

41 ... [T]he class representative must adequately represent the class. In assessing whether the proposed representative is adequate, the court may look to the motivation of the representative, the competence of the representative's counsel, and the capacity of the representative to bear any costs that may be incurred by the representative in particular (as opposed to by counsel or by the class members generally). The proposed representative need not be "typical" of the class, nor the "best" possible representative. The court should be satisfied, however, that the proposed representative will vigorously and capably prosecute the interests of the class: ...

[202] The claims of the representative plaintiff may include causes of action that extend beyond his personal claims. (*MacKinnon v. Instaloans Financial Solution Centres (Kelowna) Ltd.*, 2004 BCCA 472 at paras. 33-52). See also *Bellan v. Curtis et al.*, 2007 MBQB 221 at para. 46 and *Microcell Communications Inc. v. Frey*, 2008 SKQB 79).

[203] The plaintiff submits that Mr. Miller has no conflict in representing the entire class, has developed a reasonable plan for litigating the action, and that he further meets all the requirements of adequately representing the class in these proceedings.

[204] The defendants argue that Mr. Miller has no cause of action against the defendants. The defendants say that Mr. Miller received a package insert warning of impotence that usually resolves after discontinuation of use of Proscar. Thus, even if it were true that Proscar was responsible for permanent sexual dysfunction, it was a risk that Mr. Miller was aware of.

[205] Second, the defendants argue that Mr. Miller has no personal claim in relation to persistent sexual dysfunction as a result of ingesting Propecia. He did not take Propecia. Mr. Miller was prescribed Proscar and received a different warning. They also argue that because the plaintiff has not adduced any evidence as to the circumstances of other class members, that a determination that Mr. Miller is not in conflict with other class members is impossible.

[206] Third, the defendants argue that Mr. Miller has failed to produce a workable litigation plan. The defendants say that the proposed litigation plan is rudimentary, vague and boilerplate as evidenced by its failure to address significant issues such as how causation will be determined and the extent of expert opinions that may be required to prove the proposed common issues.

[207] The defendants' submission as to the plaintiff having received a warning goes to the merits of the claim. The adequacy of the warning is in issue. That is not for determination on this application. I reject this submission.

[208] The defendants' submission that Mr. Miller lacks a personal claim respecting the drug Propecia assumes a finding that Proscar and Propecia must be addressed separately. While that may be correct with respect to the adequacy of the warnings given as well as other possible issues such as dosage it ignores the common element that the active drug was finasteride. In my view Mr. Miller is capable of asserting a claim on behalf of users of both Proscar and Propecia given they share the same active ingredient. He need not share every characteristic of all putative class members nor must his circumstances be the same. (Western Canadian Shopping Centres Inc.;

- 1176560 Ontario Ltd. v. Great Atlantic & Pacific Co. of Canada Ltd. (2002), 62 O.R. (3d) 535 (S.C.J.)).
- [209] Turning to the defendants' final argument, the plaintiff asserts he has proposed a reasonable litigation plan that addresses how the action may proceed to resolution. He submits that the plan as proposed is based on litigation plans that have been approved by this Court in other certified class actions. The proposed litigation plan is Appendix A to these reasons.
- [210] As noted earlier, the defendants submit that the proposed litigation plan fails to meet the requirements of the *CPA*, describing it as "rudimentary, vague and boilerplate".

Law on Litigation Plans

- [211] Paragraph 4(1)(e)(ii) of the *CPA* requires that the plaintiff have a suitable plan for advancing the proceeding on behalf of the class. This is important as it assists the court in determining if the litigation is manageable and as a result provides insight into whether a class proceeding is the preferred procedure. (*Carom v. Bre-X Minerals Ltd.* (1999), 44 O.R. (3d) 173 (S.C.J.) at 203).
- [212] The level of detail of the litigation plan must correspond with the complexity of the litigation: *Carom* at 203; *Price v. Panasonic Canada Inc.* [2002] O.T.C. 426 (S.C.J.); *Public Service Alliance of Canada Pension Plan Members v. Public Service Alliance of Canada* (2005), C.P.C. (6th) 391 (S.C.J.).
- [213] A representative plaintiff "is not required to prepare a plan detailing every step, and it is anticipated that the plan will have to be amended as the action proceeds and the exigencies of the litigation become known" (*Koubi* at para.195).
- [214] There must be sufficient detail of how the plaintiff and his counsel will ensure that the common issues are properly pursued. (*Bellaire v. Independent Order of Foresters* (2004), 5 C.P.C. (6th) 68 (Ont. S.C.J.)).

[215] In Caputo v. Imperial Tobacco Ltd. (2004) 236 D.L.R. (4th) 348, 44 C.P.C. (5th) 350 (Ont. S.C.J.), Winkler J. addressed the need for a litigation plan to address how individual issues were to be approached after the common issues were resolved as follows:

[76] Here the plaintiffs have tailored the proposed class proceeding in such a way as to attempt to remove the overburden of individual issues. They have endeavoured to achieve this through the use of aggregate assessments combined with an argument that the common issues trial judge should bear the burden of both determining whether individual issues exist and fashioning a method for their resolution. This approach is unacceptable. It is apparent that individual issues exist and that they must be dealt with in order for the class members to obtain relief even if a common issues trial were to be decided in their favour. Consequently, by neglecting to address the presence of individual issues and an acceptable method for dealing with them, the plaintiffs have a proposed litigation plan, such as it is, that is "unworkable".

[216] In Wheadon v. Bayer Inc., 2004 NLSCTD 72, the defendants emphasized that each claim would have to be examined in light of the state of knowledge of the defendant at various times and, as well, that the individual issues were not limited to causation and damages. Rather, they involved issues concerning communications to and by learned intermediaries and issues of reliance of individual claimants. In addition resolution would depend on a number of individual factors. They argued that the result would be that the proceeding would degenerate in multiple actions, each to be tried separately. The defendants listed examples of the types of individual inquiries that would require resolution. In finding that the plaintiff had produced a workable litigation plan, Barry J. stated that the "litigation plan need only provide at the certification stage a reasonable framework for the issues which are reasonably expected to arise as the case proceeds" (para. 159). In addition litigation plans are something of a work in progress and may be amended during the course of the proceedings (Cloud).

[217] That said, the plan must still be workable and to be workable it must address not only resolution of the common issues but the individual issues as well.

Discussion and Analysis of Litigation Plan

[218] The defendants emphasize that a litigation plan must be fair to the defendants and must not create or abrogate substantive rights (*Ragoonanan v. Imperial Tobacco Canada Ltd.* (2005), 78 O.R. (3d) 98 (S.C.J.) at para. 71).

[219] The defendants take particular exception to certain alleged deficiencies in the litigation plan noting that the litigation plan limits its discussion of proposed common issues to a statement that "[t]he Class will be informed of the results of the common issues trial by publication of notice..." and fails to address the expert opinions that may be required to prove the common issues stating merely that the expert reports will be delivered in accordance with Rule 11-6. They note that the plan does not address how issues such as causation will be determined. They submit that the plan should address how the proposed experts are going to be identified and retained.

[220] This is of some concern in this case given the limited expert evidence produced on the certification hearing. It is clear that the common issue of causation is going to turn on fulsome expert and scientific evidence. The litigation plan should provide some assurance as to how those issues will be addressed in order that the court can be satisfied that the common issues will be effectively and efficiently pursued if the action is certified (*Bellaire* at para. 53). The current statement in the plan is, as was noted in *Bellaire*, "largely a recitation of the steps that would occur in any piece of litigation" (para. 52). In *Bellaire* the judge suggested at para. 53 that where experts are going to be retained there should be an indication in the plan of how those experts are going to be identified and retained. Certification of this action is therefore subject to this deficiency in the litigation plan being remedied. In requiring this I am not assessing the merits of the claim but simply recognizing the obligation of the court to insure that the proceedings proceed efficiently.

[221] The defendants also challenge what they say is a lack of specific procedures by which individual issues will be addressed. They note the plan

merely refers to "mini-trials" without defining their characteristics. They submit this is not sufficient.

[222] The defendants further submit that a reasonable litigation plan would acknowledge that full individual trials will be required. This argument however must be balanced against the resolution of common issues such that the litigation would be advanced. In my view there are efficiencies to be gained by certification.

Is a Class Proceeding the Preferable Procedure?

- [223] I will now consider whether a class proceeding is a preferable procedure. In doing so I will consider those factors listed under s. 4(2), as noted earlier in these reasons.
- [224] In Hollick at para. 27 McLachlin C.J. for the court stated:
 - 27 ... The parties agree that, in the absence of legislative guidance, the preferability inquiry should be conducted through the lens of the three principal advantages of class actions -- judicial economy, access to justice and behavioural modification: ...
- [225] It should also be emphasized that s. 4(2) is not exhaustive as the court is obliged to consider "other relevant matters" aside from the factors enumerated. The term "other relevant matters" was described in *Nanaimo Immigrant*Settlement Society v. British Columbia, 2001 BCCA 75, at para. 20 as follows:
 - [20] ... [T]he question is not whether the class action is necessary -- i.e., whether there are other alternatives -- but whether it is the "preferable procedure" for resolving the plaintiffs' claims. Section 4(2) of the *Act* states that that question involves a consideration of "all relevant matters" -- a phrase that includes the practical realities of this method of resolving the claims in comparison to other methods. In the plaintiffs' submission, what makes a class action preferable in this case are the practical advantages provided by the *Act* for the actual litigation process. Some of these advantages accrue only to the plaintiffs: as Mr. Branch noted, if the claims are aggregated, contingency fee arrangements are likely to be available for the plaintiffs. The claims can be pursued by one counsel or a few counsel rather than by many. A formal notification procedure is available. ... the assignment to the action of one case-

management judge, and the attendant elimination of lengthy Chambers proceedings before different judges. ...

- [226] The plaintiffs say that the three objectives of class action legislation would be achieved by the certification of this case: judicial economy is advanced by avoiding the need for multiple proceedings, in this case potentially 55 or more; access to justice is enhanced by enabling the fixed costs of this litigation to be shared among class members, and behaviour modification is advanced by way of a tort claim to encourage product safety.
- [227] Throughout his submissions, the plaintiff cites a number of case authorities to show that the vast majority of medical products class actions brought in Canada have been certified. He submits that this reflects a strong judicial consensus that certification is the best way to manage this type of litigation. Given each case must rest on its own I fail to see how such a submission is of assistance.
- [228] The defendants submit the preferable procedure in this case is a form of collective case management, which they allege would better serve the aims of access to justice and judicial economy than a class proceeding. They submit that class proceedings are not generally a quick or prompt means to adjudicate the claims of class members. Instead they suggest a model based on US multi-district litigation regarding product liability cases.
- [229] They suggest under that model the use of case management conferences, the managing of discovery orders, a single list of documents, a single examination for discovery of each defendant made available to each plaintiff, individual discovery of the plaintiffs and trials of individual plaintiffs.
- [230] The proposed manner of proceeding suggested by the defendants is very general and is likely to be fraught with delays and interim motions. It appears to be an attempt to design a management structure in place of class proceeding legislation. There is no assurance that it would be, as suggested by the defendants, more efficient and proceed through the court system more

expeditiously. Indeed, the 170 pages of submissions of counsel and the over 130 authorities included by the parties in their certification briefs along with binders of reports and documents do not bode well for expeditious resolution of these proceedings whether by case management or class action although the latter at least provides a structure and tools more likely to achieve the goals referred to by the defendants.

[231] The advantages of a class proceeding in my view outweigh the proposal of the defendants particularly where general causation and whether there has been a breach of the duty of care will require complex scientific and expert evidence likely beyond the means of individual plaintiffs against a well funded adversary.

[232] Class proceedings are case managed and the *CPA* provides the tools to address the reason class actions exist. As stated in *Hollick* at para 15:

15 ... class 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. ...

[233] It is clear that the common issues of causation and negligence are complex and will require extensive expert and scientific evidence. Resolution of those issues would materially advance the litigation as they are fundamental issues to each putative plaintiff's claim. They will avoid "duplication of fact-finding or legal analysis" (Western Canadian Shopping Centres Inc. at para. 39).

[234] I conclude that a class action is the preferable procedure with which to resolve the claims.

Conclusion

[235] Certification is dependent upon the plaintiff filing an affidavit of the lawyer setting out the information respecting potential class members in contact with plaintiff counsel's firm.

[236] With respect to the litigation plan in my view the proposed plan in so far as it addresses expert reports is insufficient. I invite counsel to provide submissions on what arrangements are being made respecting expert reports and when they will be produced in order that realistic orders can be made respecting their production.

[237] Subject to these two matters being addressed the application to certify this proceeding as a class proceeding is granted with Mr. Miller as the representative plaintiff. The class definition and common issues are as noted in these reasons.

"Punnett J."

APPENDIX A

Court File No. S-110437 Vancouver Registry

In the Supreme Court of British Columbia

Between

Michael Miller

Plaintiff

And

Merck Frosst Canada Ltd., Merck Frosst Canada & Co. Merck & Co., Inc., Merck Sharpe & Dohme Corp.

Defendants

Brought under the Class Proceedings Act, R.S.B.C. 1996, c.50

LITIGATION PLAN

I. NOTICE OF CERTIFICATION

- 1. If certification is granted, notice will issue pursuant to section 19 of the *Class Proceedings Act.*
- 2. Class counsel will post the notice of certification on its website www.kleinlyons.com and send a copy of the notice to every class member who has provided an address to class counsel for that purpose.
- 3. Notice of certification may also be published in appropriate newspapers to be agreed to by the parties or settled by the court.
- 4. A hearing will be held within 30 days of the issuance of the certification order to settle the terms and manner of notice. The form, content, manner and terms of the notice will be approved by the court.

- 5. The plaintiff will ask the court for an order that the defendants pay the costs of notice described in paragraph 2 and paragraph 3 pursuant to section 24 of the *Class Proceedings Act*.
- 6. The court will be asked approve an opt-in form for class members not residing in British Columbia wishing to participate in the class proceeding and an opt-out form for class members residing in British Columbia who do not wish to participate in the class proceeding. The court will be asked to set a date by when the opt-in and opt-out forms are to be delivered to class counsel.

II. DOCUMENTARY PRODUCTION

7. To assist the parties and the court in efficiently managing the production of documents, the parties will exchange documents in accordance with protocols established in the July 1, 2006 Practice Direction -- Re: Electronic Evidence.

III. EXAMINATIONS FOR DISCOVERY

- 8. The parties shall make themselves available for examination for discovery within 180 days of the issuance of the certification order or on such dates as may be agreed by the parties.
- 9. The plaintiff anticipates that given the nature of the matters at issue in the class proceeding it is not reasonably practical to complete the examination for discovery of each party in less than seven hours. The court will be asked to specify the duration of each examination for discovery pursuant to Rule 7-2(2) of the *Supreme Court Civil Rules*.
- 10. The plaintiff may ask the court for an order allowing them to examine multiple representatives of the defendants, if necessary.

IV. EXAMINATION OF NON-PARTIES

11. Any party wishing to examine a non-party shall comply with the *Class Proceedings Act* and the *Supreme Court Civil Rules*.

V. EXPERT OPINIONS

12. Expert opinions shall be delivered to each party pursuant to Rule 11-6 of the *Supreme Court Civil Rules*.

VI. REFINEMENT OF THE COMMON ISSUES

13. Following certification, examinations for discovery and the exchange of expert opinions and before the trial of the common issues, the plaintiff may ask the court for an order to amend or further refine the common issues, if required.

VII. DISPUTE RESOLUTION

14. The plaintiff is willing to participate in mediation or non-binding alternative dispute resolution efforts if the defendants are prepared to do so.

VIII. READINESS FOR TRIAL

- 15. At least 28 days before the trial date the parties arrange a trial management conference.
- 16. Within 28 days before trial, the parties will file a trial certificate.

IX. DETERMINATION OF THE COMMON ISSUES AT TRIAL

- 17. The class will be informed of the results of the common issues trial by publication of notice pursuant to section 20 of the *Class Proceedings Act*.
- 18. If the defendants are wholly successful on the common issues then, subject to any appeals, the litigation shall be at a close.
- 19. If the plaintiff is wholly or partially successful on the common issues then it is anticipated that further proceedings, as described in Part X below, will be needed to resolve any outstanding individual issues.

X. INDIVIDUAL ISSUES DETERMINATION

- 20. If any or all of the common issues are resolved in favour of the class, the plaintiff proposes that a case management hearing be held as soon as possible following judgment. At that hearing, both parties will be at liberty to make submissions regarding the methodology for resolving the remaining issues. Potential methods include references, mini-trials, mediation, arbitration or other means approved by the court pursuant to section 27 of the *Class Proceedings Act*. At this time, the plaintiffs intend to propose a method of resolving outstanding individual issues as set out below.
- 21. The court will be asked to specify procedures and deadlines by which class members shall identify themselves as claimants wishing to make claims for individual compensation.
- 22. The plaintiff anticipates that given the nature of the injuries suffered by class members, adjudication of the claims would best be resolved through minitrials with expert reports and discovery and guided by the *Supreme Court Civil Rules* for trial procedure to determine the issues of individual causation and damages.

XII. REVIEW OF THE PLAINTIFF'S LITIGATION PLAN

23. The plaintiffs litigation plan may be reviewed or modified as deemed necessary by the parties or the case management judge during case management.

XIII. CASE MANAGEMENT

24. During the litigation, regular case planning conferences and any interlocutory motions will be scheduled, as required.