COURT OF APPEAL FOR BRITISH COLUMBIA

Citation: *Miller v. Merck Frosst Canada Ltd.,*
2015 BCCA 353

Date: 20150806
Docket Nos: CA40832; CA41731

Between:

Michael Miller

Respondent
(Plaintiff)

And

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

Appellants
(Defendants)

Before: The Honourable Mr. Justice Donald
The Honourable Madam Justice Newbury
The Honourable Mr. Justice Savage

On appeal from: Orders of the Supreme Court of British Columbia,
dated March 28, 2013 and April 9, 2014 (*Miller v. Merck Frosst Canada Ltd.*,
2013 BCSC 544, Vancouver Registry Docket S110437).

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Place and Date of Hearing: Vancouver, British Columbia
June 24, 2015

Place and Date of Judgment: Vancouver, British Columbia
August 6, 2015

Written Reasons by:
The Honourable Mr. Justice Savage

Concurred in by:
The Honourable Mr. Justice Donald
The Honourable Madam Justice Newbury

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Summary:

This appeal from a class action certification decision concerns the prescription drugs Propecia and Proscar, which are manufactured, marketed and distributed by the appellants. At the certification proceedings, the proposed representative plaintiff Michael Miller alleged that the appellants were negligent in failing to warn of the risk that sexual dysfunction may persist after discontinuation of treatment with either drug. Eight common issues were certified, including the general causation question of whether ingesting either drug could cause sexual dysfunction which persisted even after cessation of treatment. On appeal, the appellants contended that the respondent failed to demonstrate a plausible methodology for determination of the general causation question, that causation cannot not be decided commonly on class-wide evidence, and that Mr. Miller is not an appropriate representative plaintiff.

Held: Appeal dismissed. Methodology in this context is not, and should not be, confused with a prescribed scientific or economic methodology. Instead, it refers to whether there is any plausible way in which the plaintiff can legally establish the general causation issue. Although a more detailed, explicit methodology might be preferable, what has been produced is sufficient, in light of the available data, to meet the low threshold at this early stage. There is sufficient evidence to support the "some basis in fact" threshold regarding the general causation issue, and determination of the common issue will move the litigation forward. Finally, the certification judge applied the correct legal principles in determining that Mr. Miller is an appropriate representative plaintiff, and his finding should not be disturbed.

Reasons for Judgment of the Honourable Mr. Justice Savage:

I. Introduction

[1] This action relates to prescription drugs marketed as Propecia and Proscar, which contain the active ingredient finasteride (5 mg of finasteride per Proscar tablet, and 1 mg per Propecia tablet). Proscar is sold for the treatment of prostate problems, while Propecia is sold for the treatment of male pattern baldness. The appellants ("Merck") invented, manufacture, market and distribute the drugs.

[2] Mr. Miller alleges that Merck negligently failed to warn of the risk that sexual dysfunction may persist after discontinuation of treatment with either drug. He also alleges that the failure to disclose was a deceptive act under the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 ("*BPCPA"*).

[3] In January 2011, Mr. Miller applied to have the action certified as a class proceeding pursuant to s. 4 of the *Class Proceedings Act,* R.S.B.C. 1996, c. 50 ("*CPA")*, and to be appointed as representative plaintiff. The action was certified in April 2014.

[4] This appeal primarily concerns the "methodology" requirement for establishing common issues pursuant to s. 4(1)(c) of the *CPA*. This methodology requirement has received varied treatment in Canadian courts. Other issues raised by Merck on appeal are (1) whether there is "some basis in fact" to support the position that the general causation question can be decided commonly on class-wide evidence and (2) whether there is sufficient evidence that Mr. Miller is an appropriate representative plaintiff.

[5] At the certification stage, Merck argued that Mr. Miller was required and had failed to present a plausible methodology for establishing general causation. It relied on this Court's decision in *Pro-Sys Consultants Ltd. v. Infineon Technologies AG,* 2009 BCCA 503 ("*Infineon*"), to support the position that Mr. Miller was required to show a "credible or plausible methodology" for establishing causation.

[6] On appeal, Merck submits that the Supreme Court of Canada has established that "the expert methodology must be sufficiently credible or plausible to establish some basis in fact for the commonality requirement": *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 118 ("*Microsoft")*, and that this requirement was solidified in *Charlton v. Abbott Laboratories, Ltd*., 2015 BCCA 26 ("*Charlton*").

[7] Mr. Miller submits that at the certification stage, a plaintiff is not required to establish *the* precise methodology by which general causation can be established: *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260 ("*Stanway*"). Instead, the plaintiff must demonstrate that there is some basis in fact for the commonality requirement.

[8] In response to *Charlton*, Mr. Miller argues that as a matter of law, not every common issue requires expert evidence. He also submits that the court in *Charlton*

misread *Stanway* and that it is inconsistent with Supreme Court of Canada jurisprudence. In any event, Mr. Miller argues that the methodology requirement is satisfied by the evidence that has been led in this case, or by a reasonable prospect of putting forth a methodology, as "... the Canadian approach at the certification stage does not allow for an extensive assessment of the complexities and challenges that a plaintiff may face in establishing its case at trial": *Microsoft* at para. 105.

II. Background

[9] In 2008, Mr. Miller began to take Proscar (5 mg dose) for male pattern baldness. He divided the tablets into four pieces and took one piece daily, as this was cheaper than purchasing Propecia (1 mg dose). He alleges that one month after he began to use Proscar, he experienced diminished sex drive and then became unable to maintain an erection. He alleges that on January 31, 2009 he stopped taking Proscar, and that at the time of the certification hearing he continued to experience sexual dysfunction.

[10] At the time, the Proscar monograph warned of a risk of sexual dysfunction that "usually" resolved upon discontinuing use. The Propecia monograph similarly warned of a risk of sexual dysfunction and that "resolution of these adverse reactions occurred in men who discontinued therapy with Propecia, and in most who continued therapy". On November 18, 2011, the monographs for both drugs were updated to warn of the possibility of persistent sexual dysfunction after discontinuation of treatment.

[11] It is common ground that the mechanism of action of the active ingredient finasteride in Propecia and Proscar is to inhibit the production of dihydratestosterone. In light of this, Mr. Miller's expert Dr. Wright opined that "it is not only plausible but expected that sexual side effects will occur". Merck did not dispute that general proposition. Dr. Wright opined further that it was "biologically plausible" that sexual side effects may persist in some individuals even after discontinuance. The Merck studies did not prove otherwise.

[12] In the judgments below (*Miller v. Merck Frosst Canada Ltd.*, 2013 BCSC 544, supplemental reasons at 2013 BCSC 1652) Punnett J. found that the pleadings disclosed a cause of action in negligence related to the duty to warn about sexual dysfunction side effects (paras. 57-70), and an action under ss. 171 and 172 of the *BPCPA* (paras. 71-110).

[13] The judge modified the class description to include "all male persons who were prescribed Propecia and/or Proscar for male pattern hair loss in British Columbia prior to November 18, 2011" (paras. 111-139). He was satisfied there were over 50 putative class members in B.C.

[14] The judge certified eight common issues. He found Mr. Miller was capable of asserting a claim on behalf of users of both Proscar and Propecia given they share the same active ingredient, finasteride, even though Mr. Miller did not use Propecia.

[15] At the certification stage, Merck argued that Mr. Miller was required and had failed to present a plausible methodology for establishing general causation, citing *Infineon*. In rejecting this position, Punnett J. said:

> [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.
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> [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.
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> [Emphasis added.]

[16] On the issue of whether Mr. Miller was an appropriate representative plaintiff, Punnett J. stated:

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

III. Arguments of the Parties

[17] In its factum, Merck submits that the chambers judge erred in:

> … certifying the general causation question: "Can ingesting Propecia or Proscar cause sexual dysfunction which persists after ceasing to take Propecia or Proscar?", where:

> there was no basis in fact that the issue can be resolved commonly on a class-wide basis; and
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> there was no plausible or credible methodology to answer this question or otherwise establish general causation on common class-wide evidence or otherwise; and
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> certifying the action where there is insufficient evidence that the respondent is an appropriate representative plaintiff.

[18] Merck takes issue with Dr. Wright's statement that it is "biologically plausible" that sexual dysfunction would persist based on the medication. In its submission, the fact something is "biologically plausible" does not provide a basis in fact that there is a plausible claim that is capable of being pursued.

[19] Before us, Merck's main argument is that there is no evidence of plausible or credible methodology which could lead to an answer to the causation question (Can ingesting Propecia or Proscar cause sexual dysfunction which persists after ceasing to take Propecia or Proscar?) or otherwise establish general causation on a class-wide basis. It submits that the court below should not have certified the general causation issue as there was no evidence that the question could be answered commonly for all of the various types of sexual dysfunction.

[20] Mr. Miller submits in response that the chambers judge properly exercised his discretion in determining that this action should be certified as a class proceeding, and noted that class certification is a discretionary decision entitled to substantial deference.

IV. Applicable Law

A. "Some Basis in Fact"

[21] As noted by Merck, the respondent bears the onus of satisfying the requirements for certification as set out in s. 4 of the *CPA*. The respondent must establish "some basis in fact" for each of the criteria set out in ss. 4(1)(b) to 4(1)(e) of the *CPA*. The threshold is not an onerous one, and is not to be confused with the requirement of proof on a balance of probabilities applied at trial. As stated by the Supreme Court of Canada in *Microsoft*:

> [99] The starting point in determining the standard of proof to be applied to the remaining certification requirements is the standard articulated in this Court's seminal decision in *Hollick*. In that case, McLachlin C.J. succinctly set out the standard: "... the class representative must show some basis in fact for each of the certification requirements set out in ... the Act, other than the requirement that the pleadings disclose a cause of action" (para. 25 (emphasis added)).
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> …
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> [102] I cannot agree with Microsoft's submissions on this issue. Had McLachlin C.J. intended that the standard of proof to meet the certification requirements was a "balance of probabilities", that is what she would have stated. There is nothing obscure here. The *Hollick* standard has never been judicially interpreted to require evidence on a balance of probabilities. Further, Microsoft's reliance on the U.S. law is novel and departs from the *Hollick* standard. The "some basis in fact" standard does not require that the court resolve conflicting facts and evidence at the certification stage. Rather, it reflects the fact that at the certification stage "the court is ill-equipped to resolve conflicts in the evidence or to engage in the finely calibrated assessments of evidentiary weight"…
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> [Citations omitted; emphasis added.]

[22] While the court has a "gatekeeper" function on a certification application, this function does not change the evidentiary threshold on certification. A court must assess the evidence only to the extent required to determine whether the plaintiff has established "some basis in fact" for each requirement in ss. 4(1)(b) through 4(1)(e) of the *CPA*.

[23] A review of the chambers judge's reasons reveals that he was cognizant of the evidentiary threshold and the court's "gatekeeper" function:

> [42] … Although the evidentiary threshold for meeting the statutory criteria of s. 4 is low, the court must exercise a gatekeeper function.
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> [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*).

B. Methodology

[24] The judge below held that the plaintiff was not required at the certification stage to demonstrate a plausible methodology for establishing general causation in the sense that it required the definition of a specific plan. Merck argues that in light of the Supreme Court of Canada's decision in *Microsoft* and this Court's decision in

Charlton it is evident that the certification judge erred and the certification order must be set aside.

[25] The experts do not disagree on *whether* there is a methodology that can prove general causation as it relates to the persistence of sexual side effects: as I read the opinions, the experts for both parties agree that one such method that could establish whether finasteride can cause *persistent* sexual dysfunction is a "gold standard" randomized, double blind, clinical trial involving thousands of men over a lengthy period. No such study, however, has been undertaken.

[26] The issue is whether anything less than the gold standard might provide some basis in fact to support the general causation question posed. Here, and based on divergent interpretations of the scope, detail and type of methodology that must be established at the common issues stage in certification proceedings, the parties disagree. To resolve this issue, it is necessary to review the "methodology" requirement.

i. Pro-Sys Consultants Ltd. v. Microsoft Corporation

[27] Before *Microsoft*, there was uncertainty over whether plaintiffs needed to establish a methodology for proving a common issue, or simply to meet the "some basis in fact" threshold. That question was answered in *Microsoft*: for a claim to be certified, there must be a "methodology" through which the common issue may plausibly be proven at trial.

[28] In *Microsoft*, the representative plaintiffs brought an action against Microsoft alleging that the defendant had engaged in systematic overcharging. Although the chambers judge certified common issues, this court set aside the decision on appeal. At the Supreme Court of Canada, in reinstating the decision of the chambers judge, the Court revisited the methodology requirement.

[29] The Court held that while there was no requirement at the certification stage for rigorous assessment of conflicting expert evidence, the plaintiffs were required to

present some type of actual, rather than theoretical, method for establishing loss on a class-wide basis:

> [116] The most contentious question involving the use of expert evidence is how strong the evidence must be at the certification stage to satisfy the court that there is a method by which impact can be proved on a class-wide basis. The B.C.C.A. in *Infineon* called for the plaintiff to show "only a credible or plausible methodology" and held that "[i]t 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" (para. 68). This was the standard adopted by Myers J. in the present case. Under this standard, he found the plaintiffs' methodologies to be adequate to satisfy the commonality requirement.
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> …
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> [118] In my view, the expert methodology must be sufficiently credible or plausible to establish some basis in fact for the commonality requirement. This means that the methodology must offer a realistic prospect of establishing loss on a class-wide basis so that, if the overcharge is eventually established at the trial of the common issues, there is a means by which to demonstrate that it is common to the class (i.e. that passing on has occurred). The methodology cannot be purely theoretical or hypothetical, but must be grounded in the facts of the particular case in question. There must be some evidence of the availability of the data to which the methodology is to be applied.
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> [Emphasis added.]

[30] Following *Microsoft*, the requirement for a workable methodology was applied by the Alberta Court of Appeal in *Andriuk v. Merrill Lynch Canada Inc.*, 2014 ABCA 177 ("*Andriuk*"), which involved certification for a class action in relation to a speculative stock*:*

> [10] The certification judge … correctly stated the applicable principle. Where questions relating to causation or damages are proposed as common issues, the plaintiff must demonstrate (with supporting evidence) that there is a workable methodology for determining such issues on a class-wide basis: *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 (Ont. C.A.) at para 52. The Supreme Court of Canada has recently reaffirmed the requirements [for methodology] at the certification stage.

[31] As Mr. Miller notes in his factum, *Microsoft* and many of the other cases that appear to have more onerous methodology requirements have involved claims by indirect purchasers. Indirect purchaser actions are notoriously complex, and *Microsoft* is a good illustration of that. As the Court stated at the start of its decision:

> [1] It is no simple task to assess liability and apportion damages in situations where the wrongdoer and the harmed parties are separated by a long and complex chain of distribution, involving many parties, purchasers, resellers and intermediaries. Such is the problem presented by indirect purchaser actions in which downstream individual purchasers seek recovery for alleged unlawful overcharges that were passed on to them through the successive links in the chain.
>
> [Emphasis added.]

[32] That said, the *Microsoft* decision suggests that plaintiffs are required, at the certification stage, to establish some type of method for testing the common issues.

[33] In my opinion, however, "methodology" in this context is not, and should not be, confused with a prescribed scientific or economic methodology. Instead, it refers to whether there is *any* plausible way in which the plaintiff can legally establish the general causation issue embedded in his or her claim. As noted in *Andriuk*, not every case will require expert evidence (para. 11).

[34] The methodology requirement must also be considered in light of the policy objectives of class actions: the object is to promote fair and efficient resolution of the common issues. If there is no way that the common issues could realistically be established in a class action proceeding, then these goals would not be achieved and a class action should not be certified. It is that concept which underpins the methodology requirement described in *Microsoft*.

[35] The appellants point to the Court's statement in *Microsoft* that "the expert methodology must be sufficiently credible or plausible to establish some basis in fact for the commonality requirement" (para. 118). But that statement must be read in context with the rest of the decision.

[36] *Microsoft* was not a case about one agent causing a common type of reaction in some consumers. It was about whether "indirect purchasers", namely "ultimate consumers who acquired Microsoft products from re-sellers, re-sellers who themselves purchased the products either directly from Microsoft or from other re-sellers higher up the chain of distribution" (para. 5), experienced a common type of harm or loss due to Microsoft's overcharging. The class was massive and diffuse,

and involved separate instances of wrongdoing over multiple decades with nearly 20 products. As the Court noted:

> [110] The multitude of variables involved in indirect purchaser actions may well present a significant challenge at the merits stage. …
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> …
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> [114] … In order to determine if the loss-related issues meet the "some basis in fact" standard, some assurance is required that the questions are capable of resolution on a common basis. In indirect purchaser actions, plaintiffs generally seek to satisfy this requirement through the use of expert evidence in the form of economic models and methodologies.
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> [115] The role of the expert methodology is to establish that the overcharge was passed on to the indirect purchasers, making the issue common to the class as a whole (see *Chadha*, at para. 31). The requirement at the certification stage is not that the methodology quantify the damages in question; rather, the critical element that the methodology must establish is the ability to prove "common impact" … In indirect purchaser actions, this means that the methodology must be able to establish that the overcharges have been passed on to the indirect-purchaser level in the distribution chain.
>
> [Emphasis added.]

[37] The point is not that every case requires expert testimony about the existence of an economic, medical or scientific methodology which may realistically enable plaintiffs to establish causation; the point is that every case requires plaintiffs to show how general causation of the common issue could be established. In *Microsoft*, due to the complex factual context involving indirect purchasers, expert testimony about the power of an analytical tool, multiple regression analysis, was required. That will not always be true. As observed in *Andriuk* :

> [10] … Where questions relating to causation or damages are proposed as common issues, the plaintiff must demonstrate (with supporting evidence) that there is a workable methodology for determining such issues on a class-wide basis ...
>
> [11] Here, the certification judge found that the appellants had failed to demonstrate a methodology to determine causation. The respondent's expert testified that he was unaware of any such methodology. The appellants did not adduce expert evidence on the issue. They argued on appeal that there was no need for expert evidence at the certification stage. We do not read the certification judge's reasons as insisting on expert evidence at this stage. It seems to us that the need for expert evidence would depend upon the nature of the case and the determination of the common issues. What the

> certification judge did say was that it was the appellants' burden to demonstrate a methodology and they had failed to do so.
>
> [Emphasis added.]

[38] Although a methodology may include a prescribed scientific or economic methodology, the methodology requirement as contemplated in *Microsoft* encompasses a broader category of methods: "the critical element that the methodology must establish is the ability to prove 'common impact'" (para. 115). In other words, to overcome the certification hurdle, plaintiffs are required to show how their common issue could be established at a common issues trial, remembering that the threshold, at this stage, is not an onerous one.

ii. Stanway v. Wyeth Canada Inc. and *Charlton v. Abbott Laboratories Ltd.*

[39] Although a number of cases have been decided in British Columbia dealing with methodology at the certification stage, the two most important, recent, and somewhat contrasting decisions are *Stanway* and *Charlton*. They are especially relevant as they involve medical causation rather than financial impact. While they may appear divergent on their faces, the plaintiff argues they are underpinned by the same broad principles.

[40] The general causation question at issue in *Stanway*, which was decided before *Microsoft*, involved the connection between the ingestion of hormone replacement therapy drugs and breast cancer. In support of its position, the plaintiff tendered evidence about a number of studies, including a watershed study of 17,000 women which linked the use of hormone therapy to an increased risk of breast cancer.

[41] In *Stanway*, this Court said that it was:

> [58] … not persuaded the plaintiff had to establish, at this stage of the proceedings, the methodology by which the court can determine that hormone therapy causes breast cancer. That determination will necessarily be informed by the expert evidence at trial; if no methodology is available, it is difficult to see how general causation will be established. However, there is in my view sufficient evidence to support the general causation issue posed, which deserves to be tried.
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> [Emphasis added.]

[42] In *Charlton*, however, this Court stated that "[i]f there is no methodology of addressing [a] question it ought not to have been certified" (para. 124). The Court was alive to its decision in *Stanway*, but distinguished the decision in the following manner:

> [93] Where there is some evidence by which general causation may be proven, that is sufficient; the evidence ought not to be weighed at certification. As this Court held in [*Stanway*]:
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> > [55] ... [A]s has been stated many times, on a certification hearing, the court is not to weigh the competing evidence. Here there is evidence that, if accepted at the trial of the common issues, may answer the general causation question as to whether there is a causal connection between hormone therapy and breast cancer. A positive answer would obviously move the litigation forward, although individual class members may face formidable challenges in establishing causation specific to themselves.
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> [94] The analysis in *Stanway* is particularly apposite in the case before us. The pharmaceutical manufacturer in that case, Wyeth, sought to set aside the certification of a class action brought by patients who had undergone hormone replacement therapy and were faced with addressing the general causation question: whether estrogen-progestin therapy can be said to cause or contribute to breast cancer. At the certification hearing, there was evidence hormone replacement can effect changes in breast tissue and that the risk of breast cancer is increased as a result. A causal connection between estrogen-progestin therapy and the risk of breast cancer was established in a large clinical study.
>
> [Emphasis added.]

[43] In *Charlton* there were two very different types of claimants: (1) those who had taken sibutramine and suffered cardiac events (for whom the action was grounded in negligence and required proof of damages and causation) and (2) those

who had taken sibutramine without harm, but had taken a drug with a poor risk-to-benefit ratio. In that context the Court said:

> [111] The question that ought to have been asked at the certification hearing in relation to both types of claims, is not whether the resolution of the general causation question will advance the class claims, but rather, whether there is a reasonable prospect of doing so.
>
> [112] The evidence before the certification judge was that the question whether sibutramine causes or contributes to heart attacks, strokes, and arrhythmia on a class-wide basis is incapable of resolution. There was no evidence of a methodology for establishing that the class as a whole, as opposed to those who were wrongly prescribed sibutramine despite a history of disease, was affected or put at risk by its use of sibutramine. The appellants say the trial judge did not properly exercise his gatekeeping function; he is said to have erred by failing to consider whether the class had adduced some evidence of a method of proving the claim. I agree with that submission.
>
> [113] This cannot be said to be a case like *Stanway*, where the increased risk of a certain result to the class as a whole can be quantified. While there is no dispute that those with pre-existing cardiopulmonary disease are at a statistically increased risk of adverse cardiac events, this is not a case where the experts disagree on the extent of the risk, but rather, a case where the experts are uncertain whether there is a risk to the class as a whole and cannot describe a methodology for addressing that question. Further, there is no reason to believe that the certification of the question whether sibutramine posed a risk to those with pre-existing undiagnosed cardiac disease, an undefined segment of the class, will move the litigation forward.
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> [Emphasis added.]

[44] Related jurisprudence in the context of "toxic substances" suggests that to meet the methodology requirement, the plaintiff must, at a minimum, identify the mechanism by which the impugned substance causes disease and therefore harm. In *Charlton*, this Court stated:

> [95] The Court addressed the objection to certification by referring to the judgment of this Court in *Harrington v. Dow Corning Corp.*, 2000 BCCA 605 (B.C.C.A.), and an article by Patrick Hayes entitled *Exploring the Viability of Class Actions Arising from Environmental Toxic Torts: Overcoming Barriers to Certification*, 19 J. Env. L. & Prac. 190 at 195:
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> > Proving causation in the context of toxic substances, however, puts the added burden on plaintiffs to establish two types of causation, both general and specific. This is because, unlike the causal connection between being hit by a car and suffering a broken bone, for instance, the causal connection between a toxic substance and a disease is not as easy to decipher. Thus, a plaintiff must first prove "general" or "generic" causation — that a particular substance is

> capable of causing a particular illness. The issue must be addressed, whether explicitly or implicitly, in toxic torts litigation, since it is axiomatic that "an agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general." Next, a plaintiff must prove "specific" or "individual" causation — that exposure to a particular toxic substance did, in fact, cause the plaintiff's illness.

[45] This case differs from *Charlton*. The mechanism of finasteride and its potential for causing sexual dysfunction is established and admitted. It is simply the persistent effects that are contested. Everyone in the class experienced some sort of sexual dysfunction, rather than having simply ingested the same medication with no common effect, which was the case in *Charlton*.

[46] The Supreme Court did not say in *Microsoft* that what is required is evidence of a specific type of "methodology". Instead, it required a way to test the alleged common issue at trial. That is what is needed to fulfill the "methodology" requirement. In *Stanway* it was satisfied by the existence of a robust study which established general causation. There was a realistic way to prove the common issue at trial. That is what matters.

V. Discussion and Analysis

A. Methodology

[47] Although it may have been preferable for an expert to lay out explicitly how causation could be established, in the case at bar a "methodology" for proof of general causation at trial can be inferred – the plaintiff says he will present all the circumstantial evidence he already has, such as changes made by Merck to labelling and monograph materials, a growing class of plaintiffs, and the plausible biological mechanism to support the argument that, on a balance of probabilities, finasteride can cause *persistent* sexual dysfunction. Importantly, this is not a case where there is an issue over whether the agent can cause the more general complaint: i.e., whether finasteride can cause sexual dysfunction. The mechanism of action of finasteride, which inhibits the production of dihydratestosterone, is known to have

sexual side effects which are admitted. The issue here is whether it can be proven that such side effects may persist despite discontinuation of therapy.

[48] Unsurprisingly, the type of evidence required to overcome the common issue methodology hurdle will be different in every factual scenario. In *Microsoft*, the economic context demanded expert testimony about the applicability of multiple regression analyses; in this case, there is other evidence available to suggest that there is a way the plaintiff can establish general causation at trial as I have noted.

[49] It is not necessary at this stage that there be specified a "gold standard" randomized, double blind, clinical trial involving thousands of men over a lengthy period establishing persistent sexual dysfunction. Dr. Wright did not suggest a specific scientific test − but he did not have to, nor does the adoption of the Bradford-Hill criteria (which I will discuss below) require one. In my view, to suggest otherwise is to impute an overly narrow definition of the term "methodology" as used by the Supreme Court in *Microsoft*. That proposition is reinforced by consideration of what evidence is available at the certification stage of the litigation.

[50] In *Microsoft*, the Supreme Court of Canada rejected Microsoft's submissions that "the 'credible or plausible methodology' standard adopted by [the chambers judge] was too permissive and allowed for a claim to be founded on insufficient evidence", partially because the Canadian class action regime does not have rigorous pre-certification discovery:

> [119] To hold the methodology to the robust or rigorous standard suggested by Microsoft, for instance to require the plaintiff to demonstrate actual harm, would be inappropriate at the certification stage. In Canada, unlike the U.S., pre-certification discovery does not occur as a matter of right. …

[51] In *Jones v. Zimmer GMBH*, 2011 BCSC 1198 (upheld on appeal: *Jones v. Zimmer GMBH*, 2013 BCCA 21) the Court made a similar point:

> 58 It is also important to remember that at the certification stage the injured plaintiffs have had no discovery of the defendants.
>
> 59 As the Ontario Superior Court noted in *Lambert v. Guidant Corp.* [2009 CarswellOnt 2535 (Ont. S.C.J.)], 2009 CanLII 23379 at para. 65:

> ... At this stage of the proceeding, however, the plaintiffs are, in my opinion, entitled to treat as in issue facts relating to the defendants' conduct that are exclusively within their knowledge and may bear directly on the resolution of the claims against them. Such an approach is, I believe, necessary to reconcile the rule that certification motions are not tests of the merits of a proceeding with the undoubted fact that evidence that bears on the merits can also be relevant to requirements for certification such as the existence of a class with claims that raise common issues, and the manageability of the litigation.
>
> 60 Without discovering the various aspects of the design and intended function of the Durom Cup, it is difficult to see how the plaintiffs could present any more evidence than they have done at this Chambers hearing in support of their allegation that the Durom Cup was defective. Where the product is, like the Durom Cup, a highly technical medical device, it would not be expected that without access to what is likely proprietary information of the defendants regarding that device the plaintiffs would be in a position to present evidence of a defect in the device.
>
> [Emphasis added.]

[52] Of course a defendant manufacturer has an enormous informational advantage over an injured plaintiff. At the certification stage, an injured plaintiff has no discovery as of right of the defendant and is in no position to challenge evidence that relates to matters exclusively within the defendant's specialized knowledge: *Lambert v. Guidant Corp.* (2009), 72 C.P.C. (6th) 120, 2009 CanLII 23379 at para. 71 (Ont. S.C.J.).

[53] With all this in mind − the recent guidance from the Supreme Court in *Microsoft* and the subsequent decision of this court in *Charlton*, the objectives of class proceedings, the information asymmetry embedded in this type of action, and the arguments put forth by both parties at trial and on this appeal − I find that there is a plausible way in which the plaintiff might establish, on a balance of probabilities, that finasteride caused the persistent sexual dysfunction common to the class as a whole. Although a more detailed, explicit methodology might be preferable, what has been produced is sufficient, in light of the available data to meet the low threshold at this early stage.

B. Application of the Methodology / "Some Basis in Fact" Requirements

[54] I turn now to an examination of these in more detail.

[55] In arguing that the requirement to establish some basis in fact is met for this claim the respondent referred us to the Bradford-Hill criteria which, it is accepted, form a framework of factors commonly used by epidemiologists and others in the scientific community to assess proof of causation.

[56] In this case the generally accepted factors for assessing proof of medical causation were set forth in an affidavit of Dr. Stothers, the appellants' expert, a professor of Urological Sciences at the University of British Columbia. Dr. Stothers referred to the Bradford-Hill criteria, a set of "…nine factors commonly used by epidemiologists and others in the scientific community…." She opined:

> 29. In considering issues of medical causation it is important to understand that general causation must be established first (i.e. that finasteride can cause persistent/permanent sexual dysfunction) before specific causation can be proven (i.e. that finasteride caused the persistent/permanent sexual dysfunction of the Plaintiff and other class members).

In this respect the affidavit supports the view that the question posed as the "common issue" has efficacy for the class as a whole.

[57] Dr. Stothers continued:

> 30. In order to show causation between finasteride and persistent/permanent sexual dysfunction the available medical evidence must be analyzed with the Bradford-Hill criteria, which is a framework of nine factors commonly used by epidemiologists and others in the scientific community to assess causation.
>
> 31. In 1965 Austin Bradford Hill detailed criteria for assessing evidence of causation. These guidelines are sometimes referred to as the Bradford-Hill criteria, but this makes it seem like it is some sort of checklist. For example, Phillips and Goodman (2004) note that they are often taught or referenced as a checklist for assessing causality, despite this not being Hill's intention. Hill himself said "None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required *sine qua non*":

> 1. **Strength**: A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal.
>
> 2. **Consistency**: Consistent findings observed by different persons in different places with different samples strengthen the likelihood of an effect.
>
> 3. **Specificity**: Specificity describes a specific exposure resulting in a specific event. Since causality often has multiple underlying factors and given the complexity of the human body, specificity is difficult to rely upon on its own. Some authors report that specificity is one of the weaker of the Bradford-Hill criteria.
>
> 4. **Temporality**: The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).
>
> 5. **Biological gradient**: Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence.
>
> 6. **Plausibility**: A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism is limited by current knowledge).
>
> 7. **Coherence**: Coherence between epidemiological and laboratory findings increases the likelihood of an effect.
>
> 8. **Experiment**: "Occasionally it is possible to appeal to experimental evidence".
>
> 9. **Analogy**: The effect of similar factors may be considered.
>
> [Emphasis added.]

[58] None of the Bradford-Hill criteria bring indisputable evidence for or against the cause-and-effect hypothesis and none are required *sine qua non*. Thus, although I accept that a gold standard clinical trial could establish general causation in this case, such is not necessary. The respondent argues that addressing some of those factors is sufficient, at this stage, to satisfy the certification requirements, a proposition with which the judge below agreed. To be clear, the Bradford-Hill factors are <u>not</u> a methodology. They are, however, a useful set of factors used by epidemiologists to analyse the available evidence to establish causation. Consideration of those factors can also be useful in addressing the sufficiency of the information available at the certification stage, to determine whether the plaintiff has

passed the "some basis in fact" threshold and to establish whether there is some viable, plausible way in which general causation could be proven at trial.

[59] Legal degrees of proof are not mathematical probabilities but legal or epistemic likelihoods. There are no hard and fast rules for inferring causation in any given case. Of the Bradford-Hill factors only one is, in my view, necessary (temporal precedence) and none is, of itself, sufficient to "establish" causation. In any given case evidence on some of the factors, if sufficiently persuasive, may satisfy a court as to the validity of an inference of causation.

[60] In this case the incontrovertible evidence is that Merck has altered its behaviour to warn users of the reporting in post-marketing use of persistent sexual dysfunction. Merck has various explanations for this, focusing on regulatory requirements. Nevertheless:

> (1) According to Merck's evidence, the Swedish Agency requested that Merck include in the Special Warnings and Precautions for Use section of the Summary of Product Characteristics ("SPC") for Propecia language concerning the possibility of persistent erectile dysfunction after discontinuation of treatment. The "Undesirable Effects" section of the SPC was amended in 2008 to include:
>
> > <u>Persistence of erectile dysfunction after discontinuation of treatment with Propecia has been reported in post-marketing use.</u>
>
> (2) Subsequent to the revision of the Swedish SPC, the following European countries requested a similar change: Austria, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Luxembourg, the Netherlands, Portugal and Spain.
>
> (3) The Propecia product label in the United Kingdom was updated and now has the following warning:

> In addition, the following have been reported in post-marketing use: persistence of erectile dysfunction after discontinuation of treatment with PROPECIA.

(4) In June of 2011, the Propecia product monograph for the United States was amended to include a warning of persistent erectile dysfunction after discontinuation of treatment.

(5) Although the Canadian product monograph for Propecia was revised on October 6, 2010, these revisions did not include an updated warning regarding the persistence of sexual dysfunction after discontinuation of use.

(6) It was not until August of 2011 that Merck sought the permission of Health Canada to update the Canadian product monographs for Propecia and Proscar to include a statement regarding the persistence of sexual dysfunction after discontinuation of treatment. The Canadian product monographs were updated in November of 2011.

[61] The July 2006 package insert for Propecia in Canada, which was the version in effect during the period of time that the respondent was prescribed Proscar, stated:

> 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. …
>
> [Emphasis added.]

[62] At this stage in the proceedings Merck has not been discovered on the why and wherefore of these label warning changes. In contrast, Merck's expert, Dr. Goldenberg says:

> 32. The sexual adverse effects of 5-ARI's have been shown to be transient and/or reversible. In many studies the statistical differences between treated and placebo arms progressively disappear with longer treatment times and in the longer duration prospective trials, the sexual dysfunction (at least the libido and erectile changes) tended to resolve either during prolonged therapy (3 to 7 years of therapy) or after treatment was discontinued.
>
> 33. I have treated many men over the years suffering from BPH with Proscar. In my clinical experience, the drug is well-tolerated, safe and effective. Though the drug may impact on various aspects of sexual function, it does so to a variable degree and results in very few having to stop the medication. In many instances these issues resolved with continued treatment with Proscar. I have not had any of my patients complain of persistent or permanent sexual dysfunction after discontinuation of Proscar treatment.

[63] Dr. Wright refers to a study outlined in a paper by M.S. Irwig and S. Kolukula, "*Persistent Sexual Side Effects of Finasteride for Male Pattern Hair Loss"*, *J. Sex. Med.* (2011), Vol. 8 at 1747-1753 in support of the plaintiff's position. The authors concluded that "[p]hysicians treating MPHL should discuss the potential risk of persistent sexual side effects associated with finasteride".

[64] The methodology used by the authors was critiqued by Dr. Goldenberg, although the shortcomings of the study are acknowledged by Irwig and Kolukula. Dr. Wright says that Dr. Goldenberg's critique applies equally to Dr. Goldenberg's own clinical experience. In response Dr. Wright opines:

> I also respectfully disagree with the conclusions of Dr. S. Larry Goldenberg. Dr. Goldenberg correctly identifies that the actual difference in the incidence of sexual dysfunction between the finasteride and placebo groups ranges from 2.7 to 9.5% validating that finasteride causes this problem. He then states that this problem resolves after treatment is discontinued, however, the reference he cites (Tosti et al. Arch Dermatol 2004; 140: 857-858) provides no information about the resolution of sexual dysfunction with discontinuation of finasteride therapy. Dr. Goldenberg does not provide any rationale to refute the plausible biological mechanism of action linking persistent sexual dysfunction to the use of finasteride. Experts in sexual medicine have provided a strong case for the possibility [Goldstein I. An Old Problem with a new Cause—5 Alpha Reductase and Persistent Sexual Dysfunction J. Sex Med 2011; Traish AM, Hassani J, Guay AT, Zitzmann M, and Hansen M. Adverse side effects of 5a- reductase inhibitors therapy: Persistent diminished libido and erectile dysfunction and depression in a subset of

> patients. J Sex Med 2011; 8: 872-884.] Dr. Goldenberg criticizes the clinical experience of Dr. Irwig and Kolukula in identifying 71 men with "persistent sexual side effects" as being weak evidence and then provides his own clinical experience of not having any patients complain of persistent or permanent sexual dysfunction after discontinuation of Proscar treatment as evidence that it does not occur.
>
> [Emphasis added.]

[65] Dr. Wright opines that that "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" and "biologically plausible that in some of the men who experience sexual dysfunction while taking finasteride, the sexual dysfunction would be persistent".

[66] Given that placebo-controlled randomized trials have demonstrated that finasteride as both Propecia and Proscar causes decreased libido and erectile dysfunction in some men, the other available evidence, including Dr. Wright's opinions on biological plausibility in my opinion are sufficient in this case to provide some basis in fact, grounded in the evidence in this case, in support of an affirmative answer to the general causation question posed at this stage. Taken together, I am also satisfied that the evidence, both circumstantial and directly related to the finasteride mechanism, is sufficient to meet the evidentiary threshold that there is a plausible method by which general causation could be proven at a trial of the common issues.

C. Other Arguments

[67] I turn now to Merck's other grounds of argument, that there was no evidence that general causation is a common issue and that Mr. Miller is not an appropriate representative plaintiff.

i. General Causation as a Common Issue

[68] As the discussion above makes clear, I am satisfied that there is sufficient evidence to support the "some basis in fact" threshold regarding the general causation issue. I also reject Merck's contention that the certified general causation

question cannot be answered commonly for the various types of persistent sexual dysfunction allegedly caused by both Propecia and Proscar.

[69] General causation must be established before individual causation can be proven. As this Court stated in *Harrington v. Dow Corning Corp.*, 2000 BCCA 605, leave to appeal to SCC denied, [2001] S.C.C.A. No. 21:

> [42] At the risk of oversimplifying a complex decision-path, I venture to suggest the first step in every products liability case alleging negligent design, manufacture, or marketing is the determination of whether the product is defective under ordinary use or, although non-defective, has a propensity to injure. Some American authorities refer to this step as "general causation", whether a product is capable of causing the harm alleged in its ordinary use.

[70] It is also worth emphasizing that common issues need not be determinative of liability. In upholding the trial judge's decision to certify a class action in *Jones v. Zimmer GmbH*, 2013 BCCA 21 the Court said:

> [4] To be a "common issue", an issue must be a substantial and necessary ingredient of the claim of each member of the class: *Hollick v. Metropolitan Toronto (Municipality)*, 2001 SCC 68 (S.C.C.) at para. 18, [2001] 3 S.C.R. 158 (S.C.C.). It need not be determinative of liability: rather, it will be sufficient if it is an issue of fact or law common to all claims and if its resolution will move the litigation forward…

The Court recognized that while there may need to be further individual actions to prove reliance on an allegedly defective product, focussed questions of individual liability "did not arise at the certification stage". Instead, "[a]ll that is required at this stage is a common issue the resolution of which will move the action along" (para. 57.)

[71] These comments apply to the case at bar. There are a number of common issues, including the central question of general causation − can ingesting finasteride cause persistent sexual dysfunction in some users even after discontinuation of treatment? This question is a "substantial and necessary ingredient" of every class member's claim, as noted by the defendants' expert, Dr. Stothers.

[72] There are very likely to be further issues which must be determined on individual bases based on the specific circumstances of class members. Further individual actions may become necessary to determine issues such as causation, regarding different types of sexual dysfunction, or duty of care and liability, regarding the sufficiency of warning labels. That said, I am satisfied not only that resolution of the general causation issue is possible, but that such resolution would materially advance the litigation.

ii. Mr. Miller as Representative Plaintiff

[73] I turn now to Merck's submissions that Mr. Miller is not an appropriate representative plaintiff for the purposes of s. 4(1)(e)(i) of the *CPA*. Merck submits that as Mr. Miller was prescribed and received a package insert for Proscar that warned of sexual dysfunction, he has no cause of action against Merck, and also that he did not adduce medical evidence to substantiate his claim. In any event, based on his method of ingesting finasteride (scoring Proscar tablets), he is not a suitable representative for men who took Propecia. According to Merck, as the chambers judge acknowledged, the product monographs and other issues related to dosage must be addressed separately for Proscar, Propecia and broken tablets.

[74] I do not accept this argument. Applying the relevant legal principles, Punnett J. found that Mr. Miller was an appropriate representative plaintiff. He found that Merck's submission about the adequacy of Mr. Miller's warning goes to the merits of the claim, and is not for determination at the certification stage. He also held that although there may be issues that need to be addressed separately regarding dosage and warnings, Merck's submission that Mr. Miller lacks a personal claim regarding Propecia "ignores the common element that the active drug was finasteride … Mr. Miller is capable of asserting a claim on behalf of users of both Proscar and Propecia given they share the same active ingredient" (para. 208). I see no error in this conclusion.

[75] The representative plaintiff represents the class, but need not be representative *of* the class: *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 21. He

or she need not have a claim typical of the class, or be the “best” possible representative. Instead, the court must be satisfied that “the proposed representative will vigorously and capably prosecute the interests of the class”: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 41. Punnett J. was satisfied that Mr. Miller was appropriate for this role, and I see no grounds upon which to disturb his decision.

V. Conclusion

[76] In the result, I would dismiss the appeal.

“The Honourable Mr. Justice Savage”

I agree:

“The Honourable Mr. Justice Donald”

I agree:

“The Honourable Madam Justice Newbury”