Court of King's Bench of Alberta

Citation: Todd v Bayer Inc, 2025 ABKB 314

Date: 20250707
Docket: 1301 07814
Registry: Calgary

Between:

Elizabeth Todd, as Representative Plaintiff

Applicant

- and -

Bayer Inc.

Respondent

Corrected judgment: A corrigendum was issued on July 7, 2025; the corrections have been made to the text and the corrigendum is appended to this judgment.

Reasons for Decision
of the
Honourable Justice Colin C.J. Feasby

Table of Contents

I. Introduction

[1] The Mirena intrauterine contraceptive device, manufactured by Bayer Inc ("Bayer"), is one of the most widely used forms of contraception in Canada. Mirena was approved for sale by Health Canada and the evidence before the Court shows that it is safe and effective enough to be prescribed by healthcare professionals to patients. This case is not about whether Mirena is safe; it is about whether Bayer disclosed all the risks associated with Mirena in the product monographs used from the time it was first sold in Canada in the early 2000s until 2014 when different wording was adopted in the product monograph to describe the risk of migration of the Mirena device outside the uterus.

[2] Ms. Todd, who I will refer to by her name or as the Proposed Representative Plaintiff, submits that Bayer had a duty to warn prospective users of the Mirena device and their doctors of the potential risk of migration. She says that Bayer failed to do this when it should have known better. Ms. Todd relies on, among other things, the wording of the Mirena product monograph used in the US from 2008 onwards which identified migration as a risk associated with the Mirena device.

[3] The question for this application is whether this matter should be certified as a class proceeding. Bayer submits that it is not appropriate to certify the claim as a class proceeding for many reasons, including that Ms. Todd has failed to properly plead causes of action, the proposed class definition is too broad, individual issues predominate over common issues, and Ms. Todd is not an appropriate plaintiff. Ms. Todd submits that Bayer had a duty to warn of the risk of migration and failed to do so, the class definition can be narrowed if it is too broad, the common issue of the failure of a duty to warn is common to all class members and would significantly assist in the resolution of individual claims, and she is well-suited to be the representative plaintiff.

II. Background

[4] Mirena is a device inserted into the uterus that releases a synthetic form of the female hormone progesterone called levonorgesterel. The Mirena product monograph indicates that it may be used for "contraception control for a maximum up to 5 years" and for "treatment of idiopathic menorrhagia" (*i.e.* heavy menstrual bleeding).

[5] Health Canada regulates drugs and medical devices. Though Mirena has some characteristics of a medical device, Mirena is classified by Health Canada as a drug, not a device, because it releases synthetic hormone.

[6] Before a drug may be sold in Canada, a sponsor (*i.e.* a manufacturer or distributor) must make a "New Drug Submission" to Health Canada's Therapeutic Products Directorate ("TPD"). The submission must contain data about the drug's safety, effectiveness, and quality. Health Canada's fact sheet titled "How Drugs are Reviewed in Canada" explains that a New Drug Submission "includes the results of the preclinical and clinical studies, details regarding the production of the drug, packaging and labelling details, and information regarding therapeutic claims and side effects."

[7] Health Canada's fact sheet explains that upon receipt of a New Drug Submission:

- The TPD performs a thorough review of the submitted information, sometimes using external consultants and advisory committees.
- The TPD evaluates the safety, efficacy and quality data to assess the potential benefits and risks of the drug.
- The TPD reviews the information that the sponsor proposes to provide to health care practitioners and consumers about the drug (e.g. the label, product brochure).
- If, at the completion of the review, the conclusion is that the benefits outweigh the risk and the risk can be mitigated, the drug is issued a Notice of Compliance (NOC), as well as a Drug Identification Number (DIN) which permits the sponsor to market the drug in Canada and indicates the drug's official approval in Canada.

[8] Each New Drug Submission must include a product monograph. Health Canada states that "[a] product monograph is a factual, scientific document on a drug product that describes the properties, claims, indications, and conditions for use of a drug. A product monograph also contains information that may be required for optimal, safe, and effective use of the drug, but should be devoid of promotional material." A product monograph must also include, among other things, disclosure of "warnings, precautions, [and] adverse reactions...." Health Canada further explains that "the aim of a product monograph is to provide essential information for health care professionals, patients, and consumers that may be required for the safe and effective use of a drug."

[9] Product monographs are submitted by sponsors to Health Canada for approval. The Mirena product monographs in issue in this case were all prepared by Bayer and approved by Health Canada. Bayer's position is that "Health Canada ... could only have made these approvals [of the Mirena product monographs] between 2000 and 2014 if Health Canada was satisfied with the clarity and efficacy of risk warnings contained in the Product Monographs."

[10] The Proposed Representative Plaintiff submits that the Mirena product monograph in use in Canada prior to the wording change in 2014 failed to adequately disclose the risk of the Mirena device migrating from the uterus. When a Mirena device migrates from the uterus, it can cause damage to organs in the abdomen and requires surgical removal. The Proposed Representative Plaintiff asserts that Bayer's failure to identify migration as a risk in the Mirena product monograph constitutes a breach of a duty to warn. The Proposed Representative Plaintiff points to the Mirena product monograph used in the US starting in 2008 which disclosed risk of migration as evidence that Bayer was aware of the risk of migration and that it was something that should be disclosed to healthcare professionals and potential users of the product.

III. Law & Analysis

a. The Test for Certification

[11] The test for certification is set out in the *Class Proceedings Act*, SA 2003, c C-16.5 ("*CPA*"), s 5(1) as follows:

> 5(1) In order for a proceeding to be certified as a class proceeding on an application made under section 2 or 3, the Court must be satisfied as to each of the following:
>
> (a) the pleadings disclose a cause of action;
>
> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the prospective class members raise a common issue, whether or not the common issue predominates over issues affecting only individual prospective class members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
>
> (e) there is a person eligible to be appointed as a representative plaintiff who, in the opinion of the Court,
>
> (i) will 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, in respect of the common issues, an interest that is in conflict with the interests of other prospective class members.

[12] The Proposed Representative Plaintiff bears the burden of establishing each element of the test for certification. Apart from the cause of action criterion, which is determined based on the pleadings, the Proposed Representative Plaintiffs must demonstrate "some basis in fact" to satisfy the certification criteria: ***Hollick v Metropolitan Toronto (Municipality)***, 2001 SCC 68 at para 25; ***Spring v Goodyear Canada Inc***, 2021 ABCA 182 at para 40.

b. Has the Plaintiff Pleaded Causes of Action?

(i) Pleading a Cause of Action

[13] A plaintiff must plead sufficient material facts to support each element of each cause of action that they seek to certify. Bare allegations and conclusory legal statements unsupported by material facts are not sufficient: ***Wright v Horizons ETFs Management (Canada) Inc***, 2020 ONCA 337 at para 58. But the test for certification is not a civil procedure exam; a class action pleading must be read fairly so that the objective of promoting access to justice that informs the *CPA* is not frustrated by pedantry. The Court of Appeal held in ***Rieger v Plains Midstream Canada ULC***, 2020 ABQB 312 at para 34:

> As Martin J. (now of the Supreme Court of Canada) held, citing authority, in ***Andriuk v Merrill Lynch Canada Inc***, 2013 ABQB 422, 578 AR 40, aff'd 2014 ABCA 177, pleadings "must be construed generously and liberally with allowances for drafting deficiencies that do not disclose radical defects" at para 68. Further, again citing authority: "a cause of action will be disclosed if the facts

> pleaded *could possibly* be considered to entitle the plaintiff to a legal remedy; conversely, if it is plain and obvious that the facts are incompatible with an entitlement to remedy, or insufficient for that purpose so that the plaintiff has no chance of success, then a cause of action will not be disclosed": ***Andriuk*** at para 68 [emphasis in original].

[14] The purpose of a Statement of Claim is to give notice and sufficient detail of the plaintiff's claim so the defendant may respond to the claim. A plaintiff should be permitted to amend a Statement of Claim or provide particulars to remedy what Justice Martin called "drafting deficiencies." Only when there are fundamental defects in the pleading should an amendment be denied and a claim be found not to satisfy *CPA* s 5(1)(a). In the present case, one of the asserted causes of action – duty to warn – suffers from drafting deficiencies that may be remedied and the other cause of action – unjust enrichment – is fundamentally flawed and cannot be saved.

(ii) Duty to Warn

[15] A failure to warn is a species of negligence. Manufacturers owe consumers and those who might foreseeably use their products a duty to warn of dangers known to the manufacturer, or dangers that the manufacturer ought to know about, inherent in the use of their products: ***Hollis v Dow Corning Corp***, [1995] 4 SCR 634 at para 20. "Because a duty to warn claim sounds in negligence, a plaintiff must plead each of the elements of a negligence claim": ***North v Bayerische Motoren Werke AG***, 2025 ONCA 340 at para 83.

[16] Bayer submits that the Proposed Representative Plaintiff's duty to warn pleading is deficient in three respects. First, Bayer states that "the Plaintiff does not plead sufficient facts to establish a duty of care." Specifically, Bayer says that no relationship of proximity is alleged. Second, Bayer says that the Proposed Representative Plaintiff failed to plead "what warnings were given, how they were inadequate, and whether or how they could have been improved": ***Martin v Astrazeneca Pharmaceuticals Plc***, 2012 ONSC 2744 at para 159. Third, Bayer asserts that "the Plaintiff's claim fails to show that the damage was caused by the alleged failure to warn." Bayer says that the Proposed Representative Plaintiff does not state that if she had been adequately warned of the risk of migration, she would not have used the product.

[17] An assessment of the sufficiency of a pleading is concerned with the facts pleaded, not the headings given to groups of facts, though headings can be useful. Likewise, relating the facts pleaded to legal concepts can be useful, but is not required. Bayer is correct, the Proposed Representative Plaintiff did not state in the Amended Statement of Claim that Bayer and the Proposed Representative Plaintiff were in a relationship of proximity in the paragraphs under the heading "Negligence – Particulars." But that does not matter. The Amended Statement of Claim, taken as a whole, outlines that Bayer manufactured Mirena and that the Proposed Representative Plaintiff and other putative class members used Mirena. Pleading that that Bayer manufactured a contraceptive product and sold it to Canadian women is sufficient to assert a relationship of proximity.

[18] Paragraphs 23-26 of the Amended Statement of Claim plead that the Mirena product monograph prior to 2014 disclosed a risk of uterine perforation, not migration of the Mirena device outside the uterus. The Amended Statement of Claim contrasts the lack of a warning of migration in the Canadian product monograph with the warning of migration found in the US product monograph starting in 2008. This, in effect, tells Bayer how the Proposed

Representative Plaintiff thinks the warning was inadequate and could have been improved. The pleading is more than sufficient to communicate to Bayer the case that it must meet which, of course, is the function of a pleading. Indeed, Bayer's comprehensive response to certification shows that it understands the Proposed Representative Plaintiff's position well.

[19] Bayer correctly notes that the Proposed Representative Plaintiff failed to plead that if she had been warned of the risk of migration, she would not have used Mirena. Though this is something that should have been pleaded explicitly, I think that such an assertion would be implicitly understood by an objective reader. Nevertheless, Bayer has not been misled or otherwise prejudiced by the pleading because, for among other reasons, on cross-examination, Ms. Todd testified that, "[i]f I knew it could have migrated and I would have to have surgery to remove it, th[en] I would have chose[n] against it."

[20] To address the drafting deficiency identified by Bayer, the Proposed Representative Plaintiff requests leave to amend the Amended Statement of Claim to plead that if she had been warned of the risk of migration, she would not have used Mirena. Leave to amend a pleading may be granted in class proceedings to remedy defects identified by a defendant: ***Fernandez Leon v Bayer Inc***, 2023 ONCA 629 at para 5. The Alberta Court of Appeal recently described the threshold for granting a pleadings amendment as a "low bar": ***Stackard (Estate) v 1256009 Alberta Ltd***, 2025 ABCA 171 at para 10. I grant the Proposed Representative Plaintiff permission to amend the Amended Statement of Claim as requested. The amendment shall be filed within 30 days of the release of these Reasons.

(iii) Unjust Enrichment

[21] The Proposed Representative Plaintiff asks the Court to declare a remedial constructive trust over Bayer's "proceeds" from the sale of Mirena to members of the putative class. This pleading appears to have been made on the understanding that the putative class is comprised of all persons in Canada who used Mirena during the claim period. Understood in this way, it is a claim for all of Bayer's revenue from the sale of Mirena during the claim period.

[22] The Proposed Representative Plaintiff says that a constructive trust is an appropriate remedy because Bayer has been unjustly enriched by its wrongdoing in respect of the putative class. Unjust enrichment is an equitable cause of action. To plead unjust enrichment, a plaintiff must assert: (1) that the defendant was enriched; (2) the plaintiff suffered a corresponding deprivation; and (3) there is no juristic reason for the enrichment: ***Moore v Sweet***, 2018 SCC 52 at para 37. The Proposed Representative Plaintiff submits that "[t]his cause of action has been frequently certified by Canadian courts in pharmaceutical class actions."

[23] The Proposed Representative Plaintiff pleads unjust enrichment concurrently with the tort claim for breach of the duty to warn. I note that the pleading is concurrent because prior to ***Atlantic Lottery Corp Inc v Babstock***, 2020 SCC 19, a common practice in class proceedings was for plaintiffs to plead waiver of tort. Waiver of tort involved the plaintiff class waiving its claim to damages and instead pursuing the gain-based remedy of disgorgement. Under the former waiver of tort approach, damages and disgorgement were alternatives that could not be pursued in tandem. The use of constructive trust in the present case is a claim to Bayer's profits just like disgorgement but it is being pursued concurrently with the damages claim in tort. The case as pleaded requires the putative class to establish the elements of unjust enrichment and the concurrently pleaded tort of breach of the duty to warn.

[24] For present purposes, I accept that the Amended Statement of Claim pleads an enrichment of Bayer and a corresponding deprivation of the members of the putative class. The critical issue that must be considered to determine whether the unjust enrichment cause of action is viable is whether there is a plausible juristic reason for the enrichment and deprivation. The majority in ***Atlantic Lottery*** at para 71 found that the contract between the lottery company and video lottery terminal users was a "juristic reason" for the lottery company to retain its profits and, thus, "the plaintiffs' unjust enrichment claim has no reasonable chance of success." Likewise, in ***Spring*** at paras 42-52 the Court of Appeal found that there was a juristic reason for the enrichment of Goodyear; namely, that consumers received tires. ***Atlantic Lottery*** and ***Spring*** stand for the principle that a contract between manufacturer and consumer or a chain of contracts beginning with the manufacturer and ending with a consumer may be a juristic reason for enrichment and corresponding deprivation.

[25] The logic of ***Atlantic Lottery*** and ***Spring*** applies with equal force in the context of pharmaceutical product liability claims despite the Proposed Representative Plaintiff's assertion that the cause of action of unjust enrichment is often certified in such cases. When a consumer purchases a product (*e.g.* Mirena), value flows from the consumer and/or the consumer's health benefits provider, possibly through intermediaries, to the manufacturer. The juristic reason for the manufacturer's enrichment and the consumer's corresponding deprivation is the provision of the product. The provision of the product is also what gives rise to the manufacturer's duty of care in tort, including the duty to warn.

[26] The Proposed Representative Plaintiff's theory seems to involve the alleged breach of the duty to warn negating the existence of the juristic reason for enrichment. The reasoning is analogous to how the torts of negligent misrepresentation and deceit function. A consumer asserting negligent misrepresentation or deceit may, in some circumstances elect to rescind the purchase induced by the tortious words. But in doing so, the consumer makes a choice between damages and rescission; there is no ability to pursue the remedies in tandem. The duty to warn does not work like negligent misrepresentation and deceit but, even if it did, a plaintiff could not claim both damages for loss and the wrongdoer's profits.

[27] The Proposed Representative Plaintiff's unjust enrichment claim cannot succeed. There is a juristic reason for Bayer's enrichment and the putative class's deprivation. Moreover, the juristic reason for Bayer's enrichment and the putative class's deprivation – the sale of the product – is the foundation for the duty to warn claim. The unjust enrichment claim, even if it were not doomed to fail by the existence of a juristic reason for the enrichment, could not co-exist with the tort claim for breach of a duty to warn. The unjust enrichment pleading suffers from what Justice Martin calls a "radical defect" and cannot be certified.

(iv) Other Causes of Action

[28] The Amended Statement of Claim pleads waiver of tort but counsel for the Proposed Representative Plaintiff advised that this pleading was made prior to ***Atlantic Lottery*** and is no longer relied upon.

[29] The Amended Statement of Claim asserts breaches of the following statutes: *Fair Trading Act*, RSA 2000, c F-2, *Sale of Goods Act*, RSA 2000, *Competition Act*, RSC 1985, c C-34, and *Food and Drugs Act*, RSC 1985, c F-27. However, the Proposed Representative Plaintiff did not address the breach of any of these statutes in written or oral submissions nor are any of the common issues identified by the Proposed Representative Plaintiff relevant to the alleged

statutory breaches. I find that these causes of action have been abandoned and cannot be certified.

c. Is There an Identifiable Class?

[30] *CPA* s 5(1)(b) requires that the Proposed Representative Plaintiff identify the class on behalf of whom the case will be advanced. The class definition allows both the parties and the potential class members to know who is included, entitled to receive notice, and bound by the result of the class action: ***Sun-Rype Products Ltd v Archer Daniels Midland Company***, 2013 SCC 58 at para 57.

[31] The Proposed Representative Plaintiff defines the proposed class as follows:

> All women throughout Canada who used Mirena during the Class Period and who claim damages as a result as well as their estates, administrators or other legal representatives.

[32] Bayer submits that this class definition is too broad because it captures all women in Canada who used Mirena during the Class Period who claim damages. The reason why the putative class members claim damages is not specified. The class definition, according to Bayer, must be "rationally connected to the focus of the claim, which is a failure to warn about migration." Bayer further submitted that "limiting the class to those who suffered injury as a result of migration does not reference the merits of the action and is still objective." I agree.

[33] During oral argument, counsel for the Proposed Representative Plaintiff indicated that an amendment to the proposed class definition to include a reference to migration was acceptable. Accordingly, the class definition shall be as follows with underlining to highlight the added text:

> All women throughout Canada who used Mirena during the Class Period and <u>who experienced migration and</u> claim damages as a result as well as their estates, administrators or other legal representatives.

[34] Bayer objected to the use of the defined term "Class Period" in the class definition. Bayer says that the Class Period should only be from 2008 when the US Mirena product monograph was changed to address the risk of migration until 2014 when the Canadian Mirena product monograph was changed to address the risk of migration.

[35] The logic for defining the class as starting in 2008 assumes that disclosure of the risk of migration in the US Mirena product monograph was the time when similar disclosure should have been made in Canada. The risk of migration existed prior to 2008 but the legally salient question is when Bayer knew of that risk and had an obligation to warn consumers. The US Mirena product monograph is just one piece of evidence concerning Bayer's knowledge and should not be given undue weight in determining the temporal definition of the class. There may be other evidence that indicates that disclosure of the risk of migration could have and should have been made earlier than 2008. What Bayer knew about the risk of migration and when Bayer knew that information is entirely within the control of Bayer and could not be known to members of the class. Foreclosing inquiry into the period prior to 2008 by adopting a narrow temporal definition of the class prior to the class obtaining record disclosure from Bayer and conducting questioning is not appropriate.

d. Are There Common Issues?

[36] *CPA* s 5(1)(c) requires a Proposed Representative Plaintiff to identify common issues for determination on a class-wide basis. The Proposed Representative Plaintiff must show that there is some basis in fact that (a) the proposed common issue exists; and (b) the proposed issue can be answered in common across the entire class: ***Batten v Boehringer Ingelheim (Canada) Ltd,*** 2017 ONSC 6098 at para 14.

[37] Before I proceed to analyze the common issues identified by the Proposed Representative Plaintiff, I emphasize that a tort claim related to a product that is distributed widely to consumers accompanied by a standardized risk disclosure document like the product monograph mandated by Health Canada is a paradigm example of the type of claim for which the *CPA* was enacted. Of course, that does not mean that such claims must always be certified or that the certification test is applied differently. But I approach the analysis of the common issues with the perspective that the proposed class members used the same product, from the same manufacturer, and were provided the same risk disclosure and, as such, have much in common.

[38] The Proposed Representative Plaintiff has identified the following common issues in their written submission:

(1) Is Mirena prone to migrate outside the uterine cavity?

(2) Was the defendant aware that the Mirena devices migrated outside the uterine cavity?

(3) Did the defendant owe a duty of care to the class members? If so, what was the standard of care? Did the defendant breach the standard of care? If so, who, when and why?

(4) Did the defendant have a duty to warn the class members of the risks of harm from Mirena? If so, did it fail to adequately warn in a timely manner? If so, who, when and how?

(5) Are class members entitled to special damages such as for medical costs incurred in the treatment of health complications related to having used Mirena?

(6) (a) Is the defendant liable for damages resulting from the purchase and use of Mirena?

(7) (b) If the defendant is found liable for damages, does such liability include damages for pregnancies, miscarriages, and ectopic pregnancies that occur when the Mirena device was migrated?

(8) Is the defendant liable for the subrogated health care costs of class members incurred in the treatment of conditions related to using Mirena?

(9) To account to any of the Class, including the provincial insurers, with subrogated or direct claims, for any part of the proceeds of the sale of Mirena? Or in the alternative,

(10) Such that a constructive trust is to be imposed on the proceeds of the sales of Mirena for the benefit of the Class, including provincial health insurers with subrogated or direct claims.

(11) Following a determination of any compensation owed by the defendant to class members, should the defendant pay punitive damages? Should punitive damages be assessed in aggregate? If so, in what amount and how should punitive damages be distributed?

(12) Has Bayer been unjustly enriched?

(13) If Bayer has been unjustly enriched does the class have a constructive trust over the proceeds received by Bayer from the sale of Mirena during the Class Period?

(14) [Did] Bayer breach a duty of care in marketing Mirena in Canada or in failing to provide an adequate warning that Mirena could migrate?

(15) Does the intentional manner in which Bayer failed or refused to adequately warn that the Mirena device could migrate justify an award of punitive damages?

[39] Proposed common issues 9, 10, 12, and 13 concern the cause of action of unjust enrichment and/or the remedy of constructive trust. These common issues cannot be certified because I found earlier in these Reasons at paras 21-27 that the cause of action of unjust enrichment is not viable. The Proposed Representative Plaintiff did not argue that constructive trust is an available remedy for breach of a duty to warn.

[40] The common questions in this case are whether Bayer has a duty to warn class members of the risks of Mirena and, if so, whether that duty was breached by its failure to expressly state the risk of migration in the Mirena product monograph prior to 2014. The essence of these questions is housed within the proposed common issues even though the proposed common issues are not stated as crisply as they could be.

[41] Bayer objects to common issue 1 on the grounds that it asks whether the product can cause harm not whether the product caused harm. Bayer goes on to assert that causation of harm is an individual issue because there are individual factors that must be considered to determine why migration occurred in any given case. Bayer's argument misses the point. Common issue 1 addresses a foundational question in the duty to warn analysis which is whether the product poses a risk: ***Price v H. Lundbreck A/S***, 2020 ONSC 913 at paras 29-30 and ***Singh v Glaxosmithkline***, 2022 ABKB 762 at paras 38-40. Without risk, there can be no duty to warn. A determination that a product poses a risk to all users is a different question than whether the product caused harm to a specific user and an affirmative conclusion on the existence of general risk does not necessarily have any bearing on the question of individual causation.

[42] Common issue 2 flows naturally from common issue 1. Common issue 2 concerns whether Bayer was aware of the risk of migration. A manufacturer's knowledge of the existence of a risk is also an essential part of the duty to warn analysis.

[43] Common issue 1 and 2 are arguably duplicative of common issue 4 which asks if Bayer had a duty to warn and whether Bayer breached its duty. Though common issues 1 and 2 may be understood to be subsumed within the broader dimensions of common issue 4, I do not think there is any harm and there is possibly some benefit in letting the issues remain standing on their own. The focus that common issues 1 and 2 bring to the questions of the existence of risk and Bayer's knowledge of risk is useful for helping to define the scope of record production and questioning.

[44] Bayer submits that common issues 3 and 14 are irrelevant because the Proposed Representative Plaintiff advances a duty to warn claim, not a general negligence claim. Bayer says that "questions relating to a general duty and standard of care would not advance the class members' claim of duty to warn." I suspect that common issues 3 and 14 were included because duty to warn is a species of negligence and there is case law that says that each element of negligence must be pleaded: see, for example, ***North*** at para 83. Nevertheless, I agree with Bayer that common issues 3 and 14 are redundant if common issue 4, which speaks directly to the question of duty to warn, is allowed. Common issue 4 will be dealt with below in a separate section of these Reasons.

[45] Common issue 5 concerns whether class members are entitled to special damages. Special damages is an individual question that is not appropriate to certify: ***Parker v Pfizer Canada Inc***, 2012 ONSC 3681 at para 100.

[46] Common issue 6 asks whether Bayer is liable for damages and common issue 7 asks whether Bayer is liable for damages for specific kinds of injuries. The purpose of tort damages is "to put the injured person in the same position as he or she would have been in had the tort not been committed, in so far as money can do so": ***Raytch v Bloomer***, [1990] 1 SCR 940 at 962. Causation – the "but for" question – is something that must precede an assessment of damages and can only be determined on an individual basis. Lewis N. Klar and Cameron S.G. Jeffries, *Tort Law*, 7th ed, (Toronto: Thomson Reuters, 2023) at 478 explain causation in a duty to warn case as follows:

> [W]here a duty to inform of risks has been breached, the plaintiff must prove that had the information been given, the injury would have been avoided.... Where the defendant has a duty to inform users of a product of the risks posed by the product, the plaintiff has to prove that had these risks been known, the plaintiff would have avoided the accident.

[47] Because causation and, by extension, damages, are questions specific to each individual class member, I agree with Justice Perell in ***Parker*** where he held at para 102 that "damages cannot be determined until after individual issues trials." Accordingly, common issues 6 and 7 cannot be certified.

[48] Common issues 8 and 9 concern subrogated health care costs. The proposed class is national in scope and the question of whether the defendant is liable for subrogated health care costs must be determined on a province-by-province basis having regard to the different statutes governing recovery of health care costs in each province. Further, I am not persuaded that deciding such an issue on a class-wide basis would be of much assistance to the parties. I also note that Perell J declined to certify the issue of subrogation in ***Parker*** at para 104.

[49] Common issues 11 and 15 concerning punitive damages will be dealt with under a separate heading below.

e. Common Issue 4 – Duty to Warn

[50] Common issue 4 concerns whether Bayer had a duty to warn and, if so, whether Bayer satisfied its duty. Bayer and the Proposed Representative Plaintiff agree that the central question with respect to the existence of the duty to warn turns on whether the wording of the Mirena product monograph during the relevant period was adequate. Bayer, however, submits that common issue 4 "has no basis in fact and cannot be answered on a class-wide basis." Bayer

offers three reasons to support its position. First, Bayer says that there is no basis in fact for the duty to warn because its expert, Dr. Waddington, testified that "any healthcare professional would understand that perforation can include the movement of the device outside the uterus." Second, Bayer contends that it is not responsible for the choice of wording because Health Canada "has the final say on the contents of the Product Monograph." Third, Bayer says that "whether the warning was adequate will vary according to each prescriber and each purported class member's interpretation of the monograph."

(i) Is Bayer's Expert Evidence Dispositive?

[51] The Proposed Representative Plaintiff relies on expert evidence from Dr. Katia Betito who holds a doctorate in pharmacology and provides advice to pharmaceutical companies engaged in the Canadian drug regulatory approval process. She has considerable experience with all aspects of the Canadian drug regulatory process including the development and revision of product monographs. Dr. Betito opined that Bayer's use of the word "perforation" in the Canadian product monograph was insufficient to disclose the risk of migration. She concluded:

> [B]y using only the words "perforation", and not "migration", the Product Monograph did not, until October 2014, fully or properly make clear the possibility that the IUD might actually leave the uterus. By restricting the use of those words in reference to the uterus only, the Product Monograph said nothing about the possibility of migration.

[52] Bayer's expert, Dr. Waddington, is an obstetrician/gynecologist who works at the Kingston Health Sciences Centre and is an Assistant Professor at Queen's University. Bayer submits that Dr. Waddington is qualified to give evidence as to how healthcare professionals understand the words in the Mirena product monograph because she is a healthcare professional and works among healthcare professionals whereas Dr. Betito lacks that qualification and experience. Dr. Waddington states that "[t]he concern raised in the Plaintiff's Motion is that had the word 'migration' been used, physicians would have been better able to describe this potential risk to patients. I do not think that this concern is justified." She went on to conclude, "Canadian healthcare providers are, and have been, entirely capable of understanding the potential risk of perforation, and its potential sequelae, both before and after the changes to the Mirena® product monograph in 2014."

[53] I reject Bayer's position that only Dr. Waddington may testify as to how healthcare professionals would understand the meaning of the contents of a product monograph. The job of people who prepare product monographs includes understanding the audience for product monographs. Neither doctors nor those who prepare product monographs have a monopoly over how product monographs are to be read and understood. As I said to counsel during the oral hearing, the interpretation of the product monograph and what language was required to communicate risk to healthcare professionals seems to me to be a quintessential issue for trial.

[54] Even if I agreed with Bayer that Dr. Waddington is the only expert qualified to opine on how the wording of the Canadian product monograph would be understood by healthcare professionals, I would not be required to accept her evidence. As I explained in ***O'Kane v Lillqvist***, 2022 ABKB 661 at para 87:

> The Court of Appeal has said that "[a] trial judge is not obligated to accept the evidence of any expert": ***Robinson v Williams Estate***, 2007 ABCA 19 at para 18.

> Rather, the "trier of fact is entitled to reject uncontradicted expert opinion evidence if there is a rational foundation for doing so": ***Ganges Kangro Properties Ltd v Shepard***, 2015 BCCA 522 at para 50, citing ***R v Molodowic***, 2000 SCC 16 at para 8. This includes instances where the expert is the sole expert: for example, see ***GTA Structural Steel Ltd v 20 Ashtonbee Holdings Ltd and Hady Construction (Toronto) Inc***, 2012 ONSC 7158 at paras 43-49, ***Christakos v De Caires***, 2016 ONSC 702 at paras 56-57 and, in the arbitration context, ***Spadacini-Kelava v Kelava***, 2020 ONSC 7907 at para 176.

[55] A certification hearing conducted on a paper record is a poor way to evaluate expert evidence. The approach to determining the admissibility of expert evidence set out in ***White Burgess Langille Inman v Abbott and Haliburton Co***, 2015 SCC 23 at paras 16-25 was not addressed by either party in their initial written submissions. The issue of admissibility of expert evidence only arose in the Proposed Representative Plaintiff's reply submission where she pointed out that Dr. Waddington had done work for and received honoraria from Bayer. Likewise, in oral argument the ***White Burgess*** framework was an afterthought. The battle over admissibility and any potential battle of the experts is best fought out at trial where the parties can properly brief and argue the matter.

[56] The critical point at the certification stage is that the Proposed Representative Plaintiff must only adduce some basis in fact to support the common issue. As to whether the warning in the product monograph was sufficient, the Proposed Representative Plaintiff did enough by pointing out the different language used in the product monographs for Canada and the US. The word "perforation" in the Canadian product monograph in general usage means a tear in the uterus and does not necessarily imply "migration" of the device. That is some basis in fact. Dr. Waddington may prove right at the end of the day that Canadian healthcare professionals understand that a risk of "perforation" also means a risk of "migration" but that is a matter for trial.

(ii) Does Health Canada's Regulatory Role Relieve Bayer of its Duty to Warn?

[57] Bayer's argument that Health Canada's regulatory role with respect to Mirena and the product monograph absolves it of responsibility for the content of the product monograph is wrong in law. Canadian courts have repeatedly held that Health Canada compliance or approval is relevant to, but not determinative of, liability at common law: ***Miller v Merck Frosst Canada Ltd***, 2013 BCSC 544 at paras 65-67; ***Stanway v Wyeth Canada Inc***, 2011 BCSC 1057 at para 47; ***Heward v Eli Lilly & Company***, (2008) 295 DLR (4th) 175 at para 35; ***Brousseau c Laboratories Abbott limitée***, 2019 QCCA 801 at para 158; ***British Columbia v Apotex Inc***, 2025 BCSC 92 at para 509.

[58] There is conflicting expert evidence before the Court concerning the Health Canada process and the extent to which Health Canada has input into the content of product monographs and the extent to which it "approves" product monographs. Again, as noted above, a certification hearing conducted on a paper record is not the best place to determine which expert is to be preferred. The extent of Health Canada input into the product monograph and changes to the product monograph and the effect of Health Canada "approval" of the product monographs and changes to the product monographs on the existence and content of Bayer's duty to warn are matters for trial.

(iii) Can the Sufficiency of the Warning Be Determined on a Class-wide Basis?

[59] Bayer's position is that the sufficiency of the duty to warn depends on each healthcare professional and each patient's interpretation of the product monograph; therefore, the sufficiency of the warning cannot be determined on a class-wide basis. If this position was accepted, it would mean that a pharmaceutical duty to warn class action based on an allegedly insufficient product monograph could never be certified. Of course, many pharmaceutical duty to warn class actions based on product monographs have been certified over the years: see, for example, ***Singh***; ***Parker***; ***Dembrowski v Bayer***, 2015 SKQB 286; ***Tluchak (Estate) v Bayer Inc***, 2018 SKQB 311 leave to appeal denied 2019 SKCA 64; ***Kirsh v Bristol-Myers Squibb***, 2020 ONSC 1499.

[60] The duty to warn does not vary depending on the individual being warned. Justice Robins, writing for the Court in ***Buchan v Ortho Pharmaceutical (Canada) Ltd.***, (1986) 54 OR (2d) 92 at 107 held, "[t]he duty to warn clearly necessitates a warning comprehensible to the average consumer which conveys the nature and extent of the danger to the mind of a reasonably prudent person." This indicates that the content of a warning to consumers is held to an objective standard that does not vary based on the subjective qualities of the individual receiving the warning. This, of course, makes sense because the manufacturer giving the warning cannot be expected to know the subjective qualities of each person receiving the warning.

[61] The Court in ***Buchan*** discussing the standard for a warning given to learned intermediaries prescribing oral contraceptives did not articulate something like a reasonable doctor standard. Instead, the Court explained at 113 that, "[t]he extent of the warning and the steps to be taken to bring the warning home to physicians should be commensurate with the potential danger -- the graver the danger, the higher the duty." This is a different kind of objective standard than applied to warnings to lay persons. Nevertheless, it is a single standard based on the nature of the risk, not a variable standard based on the subjective qualities of the doctor receiving the warning.

[62] Justice La Forest in ***Hollis*** confirmed that a manufacturer may discharge its duty to warn a consumer by providing a warning to a learned intermediary such as a doctor in the case of pharmaceutical products. But, La Forest J went on to explain at para 29, "[t]o allow manufacturers to claim the benefit of the [learned intermediary] rule where they have not fully warned the physician would undermine the policy rationale for the duty to warn, which is to ensure that the consumer is fully informed of all risks." The law requires the manufacturer to provide a "full" warning, not a warning that varies depending on the knowledge and experience of the doctor. La Forest J concluded that because "the manufacturer is in the best position to know the risks attendant upon the use of its product and is also in the best position to ensure that the product is safe for normal use, the primary duty to give a clear, complete, and current warning must fall on its shoulders" [emphasis added]. This is an objective standard that has nothing to do with each doctor or each patient's knowledge, experience, or idiosyncratic interpretation of a product monograph.

[63] The sufficiency of Bayer's warning to doctors and prospective users of Mirena in the product monograph must be measured according to an objective standard that applies uniformly to the whole class. The Mirena product monograph is either good enough to discharge Bayer's

duty to warn or it is not. Whether Bayer satisfied its duty to warn consumers and learned intermediaries can be assessed on a class-wide basis.

[64] The knowledge or experience of a person using Mirena will be relevant if Bayer raises the defence of *volenti non fit injuria*: ***Bow Valley Husky (Bermuda) Ltd v Saint John Shipbuilding Ltd***, [1997] 3 SCR 1210 *per* Justice McLachlin, as she then was, dissenting but not on this point at para 22. Voluntary acceptance of risk is a separate question from the existence and scope of a duty to warn. In addition, Bayer has not yet filed a statement of defence, so it is not known what defences will be pleaded. If Bayer pleads such a defence, the question of whether a person using Mirena has voluntarily accepted the risk of using the device will be a matter for individual assessment.

f. Common Issues 11 & 15 – Aggregate Punitive Damages

[65] Bayer submits that punitive damages cannot be certified because there is no basis in fact that there was a "marked departure from ordinary standards of decent behaviour": ***Whiten v Pilot***, 2002 SCC 18 at para 36. Bayer also relies on Justice Slatter's concurring reasons in ***Flesch v Apache Corporation***, 2022 ABCA 374 where he observed at para 88:

> Also undesirable is the almost mechanical addition of a claim for "punitive damages" to any class proceeding just because a bare pleading to that effect has been made. Unless there is some plausible basis for the claim for punitive damages, a class proceeding is not the most appropriate procedure to pursue it. If during the litigation process it becomes apparent that there are facts to support a claim for punitive damages, the appropriate approach is to amend the certified common issues before trial under s. 9(4).

[66] I agree with Justice Slatter. The routine pleading of punitive damages is obnoxious and often undermines the "purpose and intention" of the *Rules of Court* which is to resolve cases in a timely and cost-effective way: Rule 1.2. A gratuitous pleading of punitive damages unnecessarily raises the temperature of litigation, causes parties to become entrenched in their positions, and undermines the prospects for settlement. The reflexive pleading of punitive damages should be discouraged and, where appropriate, penalized with costs.

[67] The Proposed Representative Plaintiff says that the punitive damages pleading in the present case is not boilerplate and has a basis in fact. The Proposed Representative Plaintiff states that the basis in fact for the claim for punitive damages is that for a period of more than five years, Bayer sold Mirena with an express warning about migration in the US product monograph while no such warning was in the Canadian product monograph. The explanation for the difference in the wording in the US and Canadian monographs may be benign or it may be sinister. The Proposed Representative Plaintiff argues that the reason for using different risk disclosure language in the US and Canada is only known to Bayer and placing too high an evidentiary burden on the Proposed Representative Plaintiff at the certification stage of the proceedings, prior to record production and questioning, is unfair.

[68] Justice Slatter's concurring reasons in ***Flesch*** indicate that punitive damages should not be certified as a common issue in the absence of supporting facts and that if supporting facts are discovered during the litigation process, the appropriate course of action is to seek amendment of the certified common issues. This approach is often sound, but it can be problematic where a defendant can frustrate the discovery of facts to support a punitive damages claim by taking a

hard line in record production and questioning. In such circumstances, the refusal to certify punitive damages effectively means that punitive damages cannot be claimed because no facts to support an application to amend the certified common issues will ever come to light.

[69] In the present case, for example, the issue of punitive damages may turn on why there was no express disclosure of the risk of migration in the Canadian product monograph. The question of why there was no express disclosure of the risk of migration in the Canadian product monograph is arguably a different question than whether Bayer had a duty to warn and if that duty to warn was breached. To the extent that there are records of internal Bayer deliberations as to why a warning was not given, Bayer could plausibly take the position that such records are not relevant and not required to be disclosed. Bayer could take the same approach in objecting to questions.

[70] The Proposed Representative Plaintiff has adduced all the evidence that she can to support the punitive damages pleading. She has demonstrated that Bayer did one thing in Canada and another in the US and that the reason for the different choices is reasonably presumed to be exclusively within Bayer's knowledge. I am satisfied that this amounts to some basis in fact which is sufficient to permit the Proposed Representative Plaintiff to explore Bayer's motives and reasoning for not including express mention of the risk of migration in the Canadian product monograph.

[71] I also find that punitive damages in the present case may be assessed on a class-wide basis: ***Ross v Canada (Attorney General)***, 2018 SKCA 12 at paras 90-91. The action that is alleged to constitute a "marked departure from ordinary standards of decent behaviour" is the failure to expressly warn of the risk of migration in the Canadian product monograph which is a standardized document that was provided to all members of the proposed class or their health care providers. If there was a breach of the duty to warn and the reason for failing to warn is found to be worthy of condemnation by way of punitive damages, that is something common to the whole class.

[72] Common issues 11 and 15 concerning punitive damages shall be certified.

g. Is a Class Proceeding the Preferable Procedure?

[73] Bayer submits that "[t]he preferability of a class proceeding must be assessed through the lens of access to justice, behaviour modification and judicial economy." I agree. In my view, the determination of the common issues that I have found to be certifiable would be an efficient way to proceed and determination of the key questions surrounding Bayer's duty to warn would promote access to justice and judicial economy by simplifying the remaining individual issues trials.

[74] An important question to consider when assessing whether a class proceeding is the preferable procedure is whether the resolution of the common issues will efficiently advance the determination of individual claims. Chief Justice McLachlin explained in ***Hollick*** at para 30 that "[t]he question of preferability ... must take into account the importance of the common issues in relation to the claims as a whole." She further observed that "class actions will be allowable even where there are substantial individual issues."

[75] Bayer argues that even after determination of the common issues many individual issues will remain. The significance of the remaining individual issues, according to Bayer, renders the determination of the common issues of little value. Bayer cites ***Fisher v Richardson GMP***

Limited, 2022 ABCA 123 where it was held at para 71, "[t]he number of individual issues requiring resolution quite clearly undermines any judicial economy gained by the determination of the relatively straightforward and in some cases, conceded common issues."

[76] The circumstances in ***Fisher*** are different from the present case because the claims of the putative class members in that case turned on their personal interactions and relationships with investment advisors. The claims of the proposed class in the present case are founded on what is alleged to be deficient wording in a standardized disclosure document – the Mirena product monograph – which is alleged to be a breach of Bayer's duty to warn. The questions of the interpretation and sufficiency of the product monograph are common to all class members. Both the Proposed Representative Plaintiff and Bayer approach the question of whether the wording in the Mirena product monograph is sufficient to meet Bayer's duty to warn as a matter that requires expert evidence. It is not realistic to expect that if members of the proposed class were left to bring individual claims that they would be able to marshal the expert evidence required.

[77] The Alberta Court of Appeal recently addressed how courts should determine whether a class action is the preferable procedure when individual issues will remain after common issues are decided in ***VLM v Dominey Estate***, 2023 ABCA 261 and ***Reilly v Alberta***, 2024 ABCA 270. The majority in ***Reilly*** held at para 21:

> The legislation recognizes that there may be instances where individual issues require assessment following determination of common issues: *Class Proceedings Act*, ss 28-29. And as this Court noted in *VLM* at para 29: "The test is whether the resolution of the common issues would advance the action, even if other individual issues must be resolved later" [emphasis added]. In our view the appellant's argument places undue emphasis on the prospect of the class proceeding resulting in a final resolution of damages and liability. As stated in *VLM* at para 37, "…the resolution of the common issues does not have to be determinative of liability, as long as resolution of the common issues has some 'practical utility', and the action will be advanced [citations omitted]."

[78] The principal individual issues that will remain after the common issues are decided in the present case are individual causation (*i.e.* would the individual class member have used Mirena if the risk had been disclosed?) and damages. These individual issues are significant but, in my opinion, do not undermine the utility of determining the common duty to warn issues on a class-wide basis. The resolution of the common issues in the present case would advance the action even though individual issues will remain to be determined.

[79] Bayer submits that certifying this matter as a class proceeding would not promote behaviour modification because Bayer has already modified the wording of the product monograph. The Proposed Representative Plaintiff points out that the Health Canada records concerning the 2014 change to the Mirena product monograph wording to expressly identify the risk of migration note the existence of a "national class-action lawsuit against Bayer Inc." A reasonable inference is that the filing of this case or the other similar Mirena IUD class actions in other provinces, some of which have been stayed (see, for example, ***Babin v Bayer Inc***, 2017 ONSC 3200), prompted Bayer to change the wording of the Mirena product monograph. The fact that the litigation has already achieved a measure of behaviour modification just by being commenced cannot be a reason why a class proceeding is not the preferable mode of proceeding.

[80] I find that a class action is the preferable mode for determination of the common issues.

h. Is Ms. Todd an Appropriate Representative Plaintiff

[81] Bayer says that Ms. Todd is not an appropriate representative plaintiff for two reasons. First, Bayer submits that Ms. Todd cannot represent the class because she cannot prove causation because she did not read the Mirena product monograph prior to insertion. Second, Bayer submits that Ms. Todd has not discharged her responsibility to the proposed class because she has not read other affidavits filed in this case and has instead relied on information provided by counsel. Bayer says that this shows that she is "little more than a bystander" in the litigation: ***Horseman v Canada***, 2015 FC 1149 at para 88 aff'd 2016 FCA 238 at para 10.

[82] Bayer's first objection is contrary to the learned intermediary rule. The learned intermediary rule allows manufacturers to satisfy their duty to warn to consumers "by warning the learned intermediary of the risks inherent in the use of the product": ***Hollis*** at para 28. Doctors who prescribe drugs are the best example of a learned intermediary. Justice La Forest in ***Hollis*** at para 27 quoted the articulation of the learned intermediary rule in the context of prescription drugs from ***Reyes v Wyeth Laboratories***, 498 F.2d 1264 (5th Cir. 1974) at 1276, cert. denied 419 US 1096 (1974) as follows:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

[83] Ms. Todd's evidence is that she relied on her doctor to advise her of the risks of Mirena. This is exactly what I would expect. The fact that she did not read the Mirena product monograph prior to insertion of the device is consistent with the rationale of the learned intermediary rule.

[84] Bayer's suggestion that Ms. Todd was not diligent for having failed to read the Mirena product monograph prior to insertion of the device cannot be allowed to pass unremarked. The Mirena product monograph is provided to consumers enclosed in a sealed box with the Mirena device. Ms. Todd's evidence is that she picked up the Mirena device from a pharmacy, did not open the box (presumably consistent with her doctor's instructions), and brought the unopened box to her doctor for insertion. I accept Ms. Todd's evidence because it was not contradicted and makes sense. I expect that doctors do not want patients opening the packaging for an intrauterine device because it is important not to inadvertently damage the device or expose it to contaminants. And anyone who has been in a busy doctor's office in Canada knows that there is no time during an appointment to read a long and detailed product monograph and contemplate its warnings. No doubt Bayer understands this too. I expect that almost all women who use the Mirena device did not read the product monograph prior to insertion. If anything, failing to read the Mirena product monograph prior to insertion makes Ms. Todd a more appropriate representative plaintiff.

[85] Counsel for Bayer also asked Ms. Todd if she had read an online version of the Mirena product monograph prior to attending at her doctor's office to have the device inserted. Making the product monograph available online is a good thing, but unless a prospective patient is given directions to the product monograph and told to read it by a pharmacist or physician prior to insertion of the device, the average person would not seek out the product monograph. I find that the fact that Ms. Todd did not read the Mirena product monograph in hard copy or online is not indicative of a lack of diligence that makes her in unsuitable to be the representative plaintiff.

[86] Bayer's second objection to Ms. Todd as a representative plaintiff is that, based on her failure to read affidavits, she will not "vigorously and capably prosecute the interests of the class": ***Western Canadian Shopping Centres Inc v Dutton***, 2001 SCC 46 para 41. This submission must be put in proper perspective. Bayer did not attack Ms. Todd because it wants a better representative plaintiff for the proposed class; rather, it wants the action to come to an end for lack of a representative plaintiff.

[87] Despite Chief Justice McLachlin's use of the words "vigorous and capable" in ***Dutton***, the Alberta legislature chose to use the words "fairly and adequately" when the *CPA* was adopted two years later. As I put it in ***Ingram v Alberta***, 2024 ABKB 631 at para 115, "[t]he *CPA* requires that the representative plaintiff be adequate, not perfect." The question for the court is not whether Ms. Todd could be a better representative plaintiff, it is whether she is good enough.

[88] Bayer, quoting ***Sondhi v Deloitte Management Services LP***, 2018 ONSC 271 at para 44 submits that, "[i]t is crucial that the proposed representative plaintiff have a 'real role to play' and is not a "string-puppet" or 'placeholder plaintiff recruited to cater to the entrepreneurial interests of class counsel.'" Bayer also cites ***Sullivan v Golden Intercapital (GIC) Investments Corp***, 2014 ABQB 212 where Justice Thomas at para 54 criticized class actions for being "lawyer-driven." Bayer states that "Ms. Todd has failed to show that she is an active and appropriate representative plaintiff" and implies that this is because she is nothing more than a vehicle for her counsel to bring this case.

[89] Though it is important that a representative plaintiff be able to instruct counsel and make decisions about the litigation, Courts must approach the question of the adequacy of the representative plaintiff with a certain amount of realism. A representative plaintiff, like Ms. Todd, is in the position of being representative plaintiff because she has been injured not because she trained for the role or has litigation management experience. Representative plaintiffs, more often than not, do not have any legal training or experience and they may not have post-secondary education. The fact that Ms. Todd did not read the Mirena product monograph, a long technical document, or the expert reports and other affidavits filed in this case is not surprising. She has counsel who can summarize and interpret these materials for her; sometimes that is the role of counsel.

[90] The insinuation that Ms. Todd is merely a placeholder plaintiff who serves the entrepreneurial interests of class counsel is unfair and maintains the fiction that class proceedings should not be driven by entrepreneurial interests. Courts should not be naïve to the true nature of class actions. Members of the public who have suffered losses – possible representative plaintiffs – often do not understand their rights or the potential for a class claim without a lawyer first identifying the opportunity. Likewise, representative plaintiffs rarely have the financial wherewithal to pay for lawyers, experts, and other costs or, if they do, funding the litigation may

not be an economically rational choice. This is often the situation in cases where individual losses are small compared to the cost of litigation. So, litigation costs are typically fronted by counsel and, as such, it is counsel who often have the most "skin in the game." In my opinion, there is nothing wrong with entrepreneurial members of the bar identifying potential cases, seeking out representative plaintiffs, and financing the litigation; indeed, the *CPA* would not function as intended or achieve its objective of promoting access to justice if lawyers were passive actors who waited for potential class plaintiffs with ample funding to walk through the front doors of their offices. For more on the economics of class proceedings and the role of plaintiffs' counsel, see generally John C. Coffee, Jr, "Understanding the Plaintiff's Attorney: The Implications of Economic Theory for Private Enforcement of Law Through Class and Derivative Actions" (1986) 86 Columbia Law Review 669 and Myriam Gilles & Gary B. Friedman, "Exploding the Class Action Agency Costs Myth: The Social Utility of Entrepreneurial Lawyers" (2006) 155 University of Pennsylvania Law Review 103.

[91] Ms. Todd is not the most active or involved representative plaintiff, but neither is she a mere placeholder or figurehead. She has not read the case materials herself, but she has been informed of their contents by counsel and has discussed the case with counsel. I am satisfied that she will fairly and adequately represent the interests of the class as representative plaintiff. Since I find that this class proceeding should otherwise be certified, had I not been satisfied that Ms. Todd was an adequate representative plaintiff, I would have permitted her to be replaced: ***Harrison v Afexa Life Sciences Inc***, 2018 BCCA 165 at para 60. In that situation, if no suitable class member could be found to serve as representative plaintiff, her replacement could have been a person who is not a member of the class: *CPA* s 2(4).

i. Litigation Plan

[92] The Proposed Representative Plaintiff's "litigation plan" is not a plan; it is barely even a plan to make a plan. The proposed litigation plan does not include a single deadline for any pre-trial task. The proposed litigation plan explains that "[f]ollowing certification, the Parties will seek to work out a schedule for the following events...." The list of following events includes the main pre-trial steps. So, the proposed litigation plan is for the parties to come up with a schedule. And the proposed litigation plan does not even set a deadline for coming up with the schedule. That is not good enough.

[93] This certification application was heard nearly twelve years after the case was commenced. Even allowing for jockeying over which case in which province would go ahead and the COVID-19 pandemic, the delay in getting this case to a certification hearing is disgraceful. The main insight that I take away from the way that this case has progressed to date is that the parties are not capable of moving the matter forward without strict supervision.

[94] The case that has been certified is straightforward and significant work has already been done on the common issues for trial. The parties have already engaged experts who have produced reports though I recognize that additional experts may be retained, and different reports may be produced for trial. The main pre-trial tasks for the parties will be record production and questioning. The burden of record production falls mostly on Bayer but, given that it has been aware of this case and similar cases in other provinces for nearly 12 years, the records that must be produced should have been identified, preserved, and vetted long ago. I also note that Bayer is a large company and not a stranger to litigation, so it should have some experience with and expertise in record production. There is no reason why the parties cannot get this case ready for

trial in 24 months. Accordingly, the litigation plan for this case shall set deadlines for all pre-trial steps to be completed within 24 months of the issuance of these Reasons.

[95] I direct that the parties prepare and exchange litigation plans within 14 days of the issuance of these Reasons. Thereafter, the parties shall have 14 days to negotiate an agreed litigation plan. If the parties cannot agree on a litigation plan within 28 days of the issuance of these Reasons, they are to each provide me with a litigation plan and I will choose between them. I explained why this approach to litigation plans is sometimes necessary in ***Moman v Bradley,*** 2024 ABKB 416 at paras 2-6. I reserve the right to impose my own litigation plan if neither party provides a litigation plan that will have this case trial-ready in 24 months.

[96] The parties shall provide their agreed litigation plan or battling litigation plans in the form of a court order. The deadlines in the litigation plan will be peremptory once I sign the order. Any party seeking to vary a deadline in the litigation plan will be required to make an application to the Court supported by evidence.

IV. Conclusion

[97] This proceeding is certified as a class action according to the parameters set out in these Reasons.

Heard on the 30th day of April, 2025 and the 1st day of May, 2025.
Dated at the City of Calgary, Alberta this 23rd day of May, 2025.

Colin C.J. Feasby
J.C.K.B.A.

Appearances:

Bryan C. McPhadden, McPhadden Samac Tuovi LLP
Clint G. Docken, KC, Napoli Shkolnik Canada
for the Applicant

William McNamara, Irfan Kara, and Natasha Williams, Torys LLP
for the Respondent

Corrigendum of the Reasons for Decision
of
The Honourable Justice Colin C.J. Feasby

The following counsel has been removed from the appearance section:

David Assor, Lex Group Inc