IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Bosco v. Mentor Worldwide LLC,*
2024 BCSC 1931

Date: 20241021
Docket: S190084
Registry: Vancouver

Between:

Denée Jesanna Bosco, Stephanie Nicole Marto and Jaime Lyn Hoolsema

Plaintiffs

And

Mentor Worldwide LLC and Johnson & Johnson Inc.

Defendants

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

Before: The Honourable Justice Douglas

Reasons for Judgment

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Place and Dates of Hearing:	Vancouver, B.C. April 29 – May 2, 2024
Place and Date of Judgment:	Vancouver, B.C. October 21, 2024

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I. OVERVIEW

[1] This partially contested proposed national class action relates to Mentor Worldwide LLC MemoryGel™ silicone gel-filled breast implants used in breast augmentation and reconstruction surgery (the "Implants").

[2] The proposed uncontested common issues relate to allegations that the Implants cause or contribute to adverse health effects in patients, including the development of specific connective tissue disorders ("CTDs") and systemic inflammatory and/or autoimmune symptoms commonly referred to as Autoimmune Syndrome Induced by Adjuvants or Breast Implant Illness (collectively, "BII"). The plaintiffs say that the defendants, Mentor Worldwide LLC and Johnson & Johnson Inc. (collectively, "Mentor"), breached the duty they owed to class members in their post-market surveillance and/or monitoring of the Implants, and that Mentor failed to warn class members and surgeons of the risk that the Implants can cause these conditions. The plaintiffs further allege that Mentor's supply of the Implants to class members breached consumer protection and competition legislation.

[3] The parties have agreed to defer some proposed common issues, including Mentor's alleged breach of consumer protection legislation in other provinces and damages issues, until after the common issues trial.

[4] The proposed contested common issues relate to Mentor's allegedly inadequate disclosure of the presence of heavy metals and volatile and extractable chemicals in the Implants (collectively referred to by the plaintiffs as the "Toxins"), and whether this failure to disclose was negligent and/or in breach of consumer protection and competition legislation. The plaintiffs assert that these alleged Toxins can diffuse through the shell of the Implants through a process called gel bleed and lead to potential adverse health effects. They say that, despite a recommendation from the US FDA in 2020 that all breast implant manufacturers disclose to patients the materials contained in their products, Mentor continues to provide surgeons with an incomplete list of the Implants' contents, followed by a conclusory statement that

the effect of gel bleed is of no clinical consequence, despite this statement being unproven and controversial.

[5] The plaintiffs argue that the contested common issues focus entirely on Mentor's allegedly wrongful conduct and its own mislabeled product. They say there is evidence that they, and more than 1,000 other class members, have had adverse health impacts from the Implants, and scientific evidence that the alleged Toxins in the Implants cause cell death and harm to organisms.

[6] The plaintiffs rely on *Kibalian v. Allergen Inc.*, 2022 ONSC 7116, which they describe as an analogous case. In *Kibalian*, the court certified common issues related to a failure to warn of three different health risks associated with silicone breast implants, namely: breast implant-associated anaplastic large-cell lymphoma ("BIA-ALCL"), premature rupture of the implants, and systemic symptoms, referred to as "ASIA/BII" throughout the certification decision. Those issues overlap with the plaintiffs' proposed uncontested common issues here. Mentor notes that *Kibalian* involved different devices, manufactured by different defendants, that were (unlike the Implants) subject to a recall.

[7] Mentor denies the plaintiffs' allegations. It disputes the validity of BII as a recognised medical condition and says that the preponderance of scientific and medical evidence supports the conclusion that the Implants are safe. Nonetheless, it does not oppose certification of the proposed uncontested common issues regarding BII, a reasonable concession given the decision in *Kibalian*, or specific CTDs.

[8] There is no dispute that the Implants, by virtue of their name alone, contain silicone, or that Mentor has disclosed the presence of silicones in the Implants. The uncontested common issues address the plaintiffs' allegations that silicones in the Implants can cause or contribute to CTDs or BII.

[9] Mentor denies there is any evidence that platinum, or any of the other alleged Toxins, are implicated in the development of the conditions that are the subject of this litigation. Mentor notes that it has disclosed the presence of platinum in the

Implants, and the fact that it can bleed through an intact implant shell, to patients and surgeons. Mentor denies there is evidence that any of the alleged Toxins are present in the Implants, or diffuse through the shell of the Implants, in quantities that would cause any adverse health effects. Mentor also denies there is any evidence that the plaintiffs (or any class member) have been diagnosed with any disease, injury, or condition caused by the presence of the alleged Toxins in the Implants. Mentor argues that the proposed statutory claims are not common and lack an evidentiary foundation since there is no evidence that any of the plaintiffs or other class member either reviewed or relied on Mentor patient brochures, online advertising, or other public documents or specific representations before having their breast implant surgery.

[10] For the reasons that follow, I conclude that the proposed uncontested common issues are certifiable but the contested common issues are not.

II. FACTUAL BACKGROUND

A. The Implants

[11] Mentor Worldwide LLC, a Delaware limited liability company, manufactures the Implants. Johnson & Johnson Inc. acquired Mentor in 2009. Johnson & Johnson Inc. was the Canadian distributor of Mentor Implants in Canada from 2009 – 2023; it has been the Canadian distributor of Mentor medical devices since 2023.

[12] The Implants are filled with a proprietary gel. They have never been subject to a recall and remain approved for sale in Canada.

B. The Regulatory Framework

[13] The Implants are Class IV medical devices which are regulated in Canada pursuant to the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the *Medical Devices Regulations*, SOR/98-282. The Implants can only be sold commercially in Canada with a licence from Health Canada. Health Canada has licensed various types, shapes, and sizes of Mentor silicone breast implants for distribution in Canada since 2006.

[14] The Implants are highly regulated and not sold directly to patients in Canada. They are provided to patients only through healthcare professionals, generally plastic or cosmetic surgeons. Mentor argues that this fact distinguishes the Implants from other products that consumers can purchase directly from retail outlets.

[15] Plaintiffs' counsel underscores that manufacturers owe a duty of accurate disclosure to consumers despite compliance with Health Canada protocols, citing *WN Pharmaceuticals Ltd. v. Krishnan*, 2023 BCCA 72 [*Krishnan BCCA*] at para. 108; *Miller v. Merck Frosst Canada Ltd.*, 2013 BCSC 544 [*Miller BCSC*] at para. 65; *Heward v. Eli Lilly & Co*., 91 O.R. (3d) 691, 2008 CanLII 32303 (Ont. S.C. Div. Ct.) at para. 35.

C. Mentor's Product Information Data Sheet and Patient Brochures

[16] Mentor Implants sold in Canada are provided with a Canada-specific Product Information Data Sheet ("PIDS"). Health Canada reviewed this document as part of Mentor's application for a medical device license.

[17] Mentor describes the PIDS as a physician-labelling document which provides directions to treating physicians and implanting surgeons. It intends this document to provide an overview of essential information for use, contraindications, warnings, precautions, important factors to discuss with patients, adverse events and other reported conditions, a summary of clinical study results, returned devices, product evaluation, and medical device reporting.

[18] Mentor currently provides its Canadian PIDS to health care professionals electronically through a website link found on the outside of the box containing the Implants. It previously provided a hard copy of this document, secured on the outside of the box containing the Implants. Mentor also provides a global PIDS inside each box containing the Implants.

[19] Various Mentor PIDS, patient brochures, and extracts from Mentor's website regarding the Implants are in evidence. The plaintiffs say Mentor has consistently represented that the Implants are safe.

[20] The dates of the PIDS in evidence range from 2011 to December 2022. Substantial sections of these PIDS remained unchanged or were minimally updated in this timeframe. They include a section with the heading "Potential Health Consequences of Gel Bleeds." The 2022 version of this section reads:

> **Potential Health Consequences of Gel Bleed**
>
> Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell. Studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture and lymphadenopathy. Evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state. In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.
>
> Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. The test method was developed to represent, as closely as possible, conditions in the body surrounding an intact implant. The results indicate that only the LMW silicones D4, D5, and D6, and platinum, bled into the serum in measurable quantities. In total, 4.7 micrograms of these three LMW silicones was detected. Platinum levels measured at 4.1 micrograms by 60 days, by which time an equilibrium level was reached and no more platinum was extracted from the device. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the **extremely low level of gel bleed is of no clinical consequence.**
>
> [Emphasis added.]

[21] Since at least 2015, Mentor has made educational brochures available to patients considering breast implant surgery. Their stated purpose is to provide information about the risks and benefits of the Implants and to assist patients in making informed decisions about breast implant surgery. These brochures expressly state that they are not intended to replace consultations with patients' surgeons.

[22] One such brochure in evidence, published in 2015 or later, stated that scientific evidence strongly supported the conclusion that there was no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants. This brochure did not reference BII explicitly but noted that scientific expert panels and literature reports had found no evidence of a consistent pattern of signs and symptoms in women with silicone gel-filled breast implants.

[23] In 2019, Mentor provided the following information on its website about platinum used in the Implants:

> Platinum is the only metal added during the manufacturing process for the silicone gel and shells of breast implants and tissue expanders. Scientific evidence supports that the extremely low level of the specific type of platinum used in breast implants that may diffuse through the shell doesn't represent a significant health risk.

[24] On the same webpage, Mentor provided a link to a US FDA "Backgrounder" publication from 2018 regarding the type of platinum used in the Implants, together with an overview of studies that Mentor stated had affirmed the safe use of this metal. Following its review of the published studies on the presence of platinum in silicone breast implants, the FDA concluded in its 2018 Backgrounder publication:

> Some studies have shown that small quantities of platinum may bleed through an intact implant shell and be present in trace amounts (parts per billion) in surrounding tissue. However, these results need to be confirmed using a larger number of subjects. Other studies have serious scientific flaws that raise concerns about the validity of their results and conclusions. Even if the analytical results of large, well-controlled studies were to show relatively high levels of platinum in biological samples, the toxicological significance would still need to be determined.
>
> Based on the existing literature, FDA believes that the platinum contained in breast implants is in the zero oxidation state, which would pose the lowest risk, and thus that the small amounts of platinum that leak through the shell do not represent a significant risk to women with silicone breast implants. FDA will continue to review and analyze the literature on the issue of platinum in breast implants, as part of its ongoing assessment of the safety of these devices.

[25] In 2020, Mentor's website referenced BII and stated, in part, that the current body of scientific evidence did not support claims that breast implants causes systemic illness.

[26] The plaintiffs deny Mentor warned consumers, health care professionals, the FDA, or Health Canada about the risk and/or alleged consequences of a significant gel bleed. They say Mentor has not fully disclosed the contents of the Implants, including the presence of the alleged Toxins. Mentor makes a distinction between the presence of silicone and platinum in the Implants (which are disclosed in its patient-facing documents) and the presence of trace metals (which are not disclosed).

D. The Plaintiffs

[27] The plaintiffs have sworn substantially similar affidavits in these proceedings. Between 2008 and 2017, they all had breast implantation surgery with the Implants. All say that they relied on Mentor's representations that the Implants were safe and that they agreed to have them implanted in their bodies based on that assumption.

1. Ms. Bosco

[28] Denée Jesanna Bosco had breast implantation surgery on April 19, 2012. She deposes in her first affidavit made October 23, 2020, that she was then 29 years old and in good health. She denies she was made aware before her breast implant surgery of the risk of developing adverse health effects, including CTDs and BII.

[29] Ms. Bosco deposes that she developed multiple health issues after her implant surgery. She says her doctors investigated these health issues but were unable to identify a cause for them. On Ms. Bosco's evidence, she began to suspect that her health symptoms were related to the Implants and that she had developed BII in about June 2018. Accordingly, she had surgery to remove the Implants on August 28, 2018. Thereafter, she says that her symptoms mostly disappeared. Ms. Bosco deposes that she would never have had breast implantation surgery with the Implants if she had been warned about the risk of developing a CTD or BII.

[30] Ms. Bosco swore a second affidavit on January 10, 2024. In it, she deposes that she was not warned that the Implants contain toxins or heavy metals, or that gel

bleed could lead to health problems. She denies she would have had surgery with the Implants if she had been aware of this information.

2. Ms. Marto

[31] Stephanie Nicole Marto had breast augmentation surgery on March 26, 2017. She deposes that she was then 21 years old and in good health.

[32] Ms. Marto deposes that before her breast implantation surgery, she reviewed a patient brochure and Mentor's website to learn about the Implants and potential associated health risks. Ms. Marto denies she was made aware before her implant surgery that she could develop CTDs or BII due to the Implants. She says that she reviewed and relied on Mentor's representations about the Implants which lead her to conclude that they were safe.

[33] Ms. Marto deposes that she developed a variety of symptoms in about April 2017, and that she began to suspect her symptoms were associated with the Implants and that she had developed BII. She denies she would have had breast augmentation surgery with the Implants if she had known of these risks. On Ms. Marto's evidence, she had planned explant surgery to remove the Implants in 2019, but cancelled this procedure because she could not afford it.

3. Ms. Hoolsema

[34] Jaime Lyn Hoolsema had breast augmentation surgery with the Implants on July 14, 2015. She deposes that she was then 32 years old and in good health. She denies she was made aware before her surgery of the risk of developing CTDs or BII.

[35] Ms. Hoolsema deposes that she developed several health issues about one year after her breast implant surgery. She says that despite extensive investigation, her doctors could not identify a cause for them. On her evidence, these health issues required her to stop working.

[36] Ms. Hoolsema deposes that she began reading about BII in about September 2018, and to suspect that she had symptoms of BII due to the Implants. She denies she would have had surgery with the Implants if she had known they could cause her to develop BII. Ms. Hoolsema had the Implants surgically removed on October 24, 2018; she says that her symptoms improved significantly thereafter.

4. Anonymous Class Member, AC

[37] Anonymous putative class member, AC, provided class counsel with reports of two analyses done on her hair: one was conducted a week before removal of her Implants; the second was conducted about six months after their removal. AC provided no affidavit evidence on this certification application. Plaintiffs' counsel seeks to rely on these test results as evidence that the level of toxic heavy metals in AC's hair decreased after surgical removal of her Implants. Mentor objects to the admissibility of this evidence.

III. THE ACTION

[38] The plaintiffs filed their original notice of civil claim on January 3, 2019; they amended it on September 15, 2021. The most current version of this pleading is the second amended notice of civil claim filed March 5, 2024 (the "Second ANOCC").

A. Negligent Failure to Warn

[39] The plaintiffs plead that Mentor's Canadian packaging does not adequately disclose the contents of the Implants or the risk of exposure to the alleged Toxins in them: Second ANOCC, paras. 52 and 90. They plead that the Implants contain volatile and extractible chemicals and heavy metals, including arsenic, antimony, platinum, barium, cobalt, mercury, nickel, copper, zinc, chromium, titanium, lead, vanadium, selenium, tin, and molybdenum (collectively, the "Toxins"): Second ANOCC, para. 86.

[40] The plaintiffs plead that Mentor did not disclose the risk of a significant gel bleed in either its "Directions for Use" or its consumer labelling of the Implants,

despite the availability of substantial evidence that this was a significant potential risk of use, even in a properly manufactured product: Second ANOCC, para. 91.

B. Claims under the *BPCPA*

[41] The plaintiffs plead that Mentor's solicitations, offers, advertisements, promotions, sales, and supply of the Implants to them and to other class members for the purposes of breast augmentation and reconstruction were "consumer transactions" within the meaning of the *Business Practices and Consumer Protection Act,* S.B.C. 2004, c. 2 [*BPCPA*], that the plaintiffs and class members who purchased them were "consumers", and that Mentor was a "supplier": Second ANOCC, para. 99.

[42] The *BPCPA* defines those terms as follows:

> "consumer" means an individual, whether in British Columbia or not, who participates in a consumer transaction, but does not include a guarantor;
>
> "consumer transaction" means
>
> (a) a supply of goods or services or real property by a supplier to a consumer for purposes that are primarily personal, family or household, or
>
> (b) a solicitation, offer, advertisement or promotion by a supplier with respect to a transaction referred to in paragraph (a),
>
> and, except in Parts 4 and 5, includes a solicitation of a consumer by a supplier for a contribution of money or other property by the consumer;
>
> "supplier" means a person, whether in British Columbia or not, who in the course of business participates in a consumer transaction by
>
> (a) supplying goods or services or real property to a consumer, or
>
> (b) soliciting, offering, advertising or promoting with respect to a transaction referred to in paragraph (a) of the definition of "consumer transaction",
>
> whether or not privity of contract exists between that person and the consumer, and includes the successor to, and assignee of, any rights or obligations of that person and, except in Parts 3 to 5 *[Rights of Assignees and Guarantors Respecting Consumer Credit; Consumer Contracts; Disclosure of the Cost of Consumer Credit]*, includes a person who solicits a consumer for a contribution of money or other property by the consumer;

[43] The plaintiffs plead that Mentor's conduct had the capability, tendency, or effect of deceiving or misleading consumers regarding the safety and efficacy of the

Implants, and constituted deceptive acts and practices contrary to s. 4 of the *BPCPA*: Second ANOCC, para. 100. They allege that Mentor's statements and omissions were unfair, deceptive, or misleading because scientific evidence suggests that the Implants cause systemic illness, including CTDs and BII, and/or contain the Toxins: Second ANOCC, para. 103.

C. Claims under the *Competition Act*

[44] The plaintiffs further allege that Mentor committed an unlawful act and breached s. 52 of the *Competition Act*, R.S.C., c. C-34 by its representations and omissions regarding the Implants: Second ANOCC, para. 114.

[45] Section 52 of the *Competition Act* provides as follows:

> 52 (1) No person shall, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever, knowingly or recklessly make a representation to the public that is false or misleading in a material respect.

D. Relief Sought

[46] The plaintiffs seek injunctive and declaratory relief, general, special, and punitive damages, statutory relief pursuant to the *BPCPA* (and similar legislation in other provinces) and the *Competition Act*, ss. 36 and 52. They allege that Mentor has been unjustly enriched and seek restitution or disgorgement of the profits gained as a result of its alleged wrongdoing against the plaintiffs and class members: Second ANOCC, paras. 120 and 122.

[47] The plaintiffs also seek to recover health care costs incurred on their behalf by the BC Ministry of Health Services pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27, and comparable legislation in other provinces and territories: Second ANOCC, para.113.

[48] Mentor has not yet filed a response to civil claim.

IV. THE CERTIFICATION APPLICATION

[49] The plaintiffs filed their certification application on November 20, 2023. They seek to certify this action as a class proceeding under the *Class Proceedings* Act, R.S.B.C. 1996, c-50 [C*PA*], and to represent a class comprising all persons who were implanted with Mentor MemoryGel™ silicone gel-filled breast implants in Canada between October 19, 2006 and the date of certification.

V. THE CERTIFICATION TEST

[50] The general principles governing certification are not controversial. The test for certification of a class proceeding is set out in s. 4(1) of the *CPA*:

> Class certification
>
> **4** (1) Subject to subsections (3) and (4), the court must certify a proceeding as a class proceeding on an application under section 2 or 3 if all of the following requirements are met:
>
> (a) the pleadings disclose a cause of action;
>
> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
>
> (e) there is a representative plaintiff who
>
> (i) would fairly and adequately represent the interests of the class,
>
> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
>
> (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[51] The provisions of s. 4(1) of the *CPA* are mandatory. To meet the criteria under s. 4(1)(a), the plaintiffs must meet the "plain and obvious" standard for pleadings, as set out under Rule 9-5(1)(a) of the *Supreme Court Civil Rules* [*SCCR*]*: Pro-Sys* at para. 63. The plaintiffs must demonstrate "some basis in fact", on admissible evidence, for each of the criteria set out in sections 4(1)(b) to (e): *Pro-*

Sys Consultants Ltd. v. Microsoft Corporation, 2013 SCC 57 [*Pro-Sys*] at paras. 99–100; *Hollick v. Toronto (City)*, 2001 SCC 68 at paras. 22, 25.

[52] The certification criteria must be construed generously in order to achieve the objectives of class proceedings, including access to justice, judicial economy, and behaviour modification: *Pro-Sys* at para. 137. Courts must be mindful not to impose unduly technical requirements on plaintiffs so as to ensure that the relevant policy goals are realized: *Knight v. Imperial Tobacco Canada Limited*, 2006 BCCA 235 at para. 20; *Miller BCSC* at paras. 42, 126, aff'd 2015 BCCA 353 [*Miller BCCA*] at para. 53; *Finkel v. Coast Capital Savings Credit Union*, 2017 BCCA 361 at paras. 13 and 15.

[53] The court must certify an action as a class proceeding where the requirements of s. 4(1) of the *CPA* are met. Although the burden is on the plaintiff, the opposing party may respond with its own evidence to challenge certification: *Tonn v. Sears Canada Inc.*, 2016 BCSC 1081 at para. 28; *Hollick* at para. 22. It is proper for the court to scrutinize the plaintiff's evidence by reference to the defendant's evidence: *Tonn* at para. 28; *Marshall v. United Furniture Warehouse Limited Partnership*, 2013 BCSC 2050 at paras. 53 – 55, aff'd 2015 BCCA 252. A judge must not weigh competing evidence on a certification application but must consider the defendants' responding evidence in assessing the certification criteria: *Pro-Sys v. Microsoft Corp*, 2010 BCSC 285 at para. 102, aff'd 2013 SCC 57.

[54] It is insufficient for the plaintiffs to meet their burden by asserting that product liability and consumer protection claims are well-suited to class proceedings. Canadian courts have refused to certify such cases, including those involving medical devices. Each case must be considered on its own facts, in light of the claims advanced and the evidence adduced: *Pro-Sys* at para. 104; *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540 at para. 33; *Hollick* at para. 37.

[55] The court has an important gatekeeper role on a certification application: *Krishnan v. Jamieson Laboratories Inc.*, 2021 BCSC 1396 [*Krishnan BCSC*] at para. 41, aff'd *Krishnan BCCA; Miller BCSC* at para. 42. The Supreme Court of Canada

has reaffirmed the importance of certification as a meaningful screening device: *Pro-Sys* at para. 103. While the standard for assessing evidence at certification does not give rise to a determination of the merits, it does not involve such a superficial level of analysis into the sufficiency of the evidence that it would amount to nothing more than symbolic scrutiny: *Pro-Sys* at para. 103.

VI. SECTION 4(1)(A): CAUSE OF ACTION

[56] Section 4(1)(a) of the *CPA* requires the plaintiffs to establish that the pleadings disclose a cause of action on the "plain and obvious" standard which applies to striking a pleading under Rule 9-5(1)(a) of the *SCCR: Pro-Sys* at para. 63. In other words, a court will only refuse to certify an action on this ground if it is plain and obvious that the plaintiff's claim is bound to fail, assuming the facts alleged in the pleading are true: *Pro-Sys* at para. 63.

[57] A plaintiff must plead a concise statement of the material facts giving rise to a claim: *SCCR*, R. 3-1(2); *R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42 at para. 22; *Kindylides v. Does*, 2020 BCCA 330 at paras. 29-30, leave to appeal to SCC ref'd, 2021 CanLII 98076 (SCC). The claim must be read generously to allow for inadequacies due to drafting frailties and the plaintiff's lack of access to key documents and discovery information; unsettled points of law must be permitted to proceed: *Krishnan BCSC* at para. 45. Courts are to consider the claims as they are, or as they may be amended: *Sharp v. Royal Mutual Funds Inc.*, 2020 BCSC 1781 at para. 22 [*Sharp BCSC*], aff'd 2021 BCCA 307 [*Sharp BCCA*]; *MacKinnon v. Pfizer Canada Inc.*, 2021 BCSC 1093 at para. 48.

A. The Claims in Negligence

[58] The constituent elements of a claim in negligence are well-established: *Mustapha v. Culligan of Canada Ltd.*, 2008 SCC 27 at para. 3; *James v. Johnson & Johnson Inc.*, 2021 BCSC 488 at para. 94, aff'd 2022 BCCA 111. In a product liability claim, a plaintiff must plead:

a) The existence of a legal duty of care;

b) A defective product;

c) The defendant failed to meet the required standard of care;

d) The defect caused the plaintiff's injuries; and

e) Damage resulted from the defendant's negligence.

[59] Manufacturers owe a specific duty to warn consumers of the dangers inherent in those uses of their products for which they have, or ought to have, knowledge; there will almost always be a heavy onus on manufacturers of medical products to provide clear, complete, and current information concerning dangers inherent in the ordinary use of their product: *Hollis v. Dow Corning Corp.,* [1995] 4 S.C.R. 643, 1995 CanLII 55 at paras. 20, 23, 26, and 29.

[60] The Supreme Court of Canada has recognised that breast implants are distinct from most manufactured goods and analogous to prescription drugs where patients place primary reliance on a physician for information: *Hollis* at para. 31. A manufacturer may discharge its duty to warn consumers regarding the risks inherent in the use of its products by directly warning a learned intermediary (i.e., the implanting surgeon): *Hollis* at paras. 27 – 31. The learned intermediary rule presumes that the intermediary is fully apprised of the risks associated with use of the product. In other words, the manufacturer can only be said to have discharged its duty to the consumer when the intermediary's knowledge approximates that of the manufacturer: *Hollis* at para. 29.

[61] A claim in negligence should plead particulars of an alleged failure to warn, including what warnings were given, how they were inadequate, and whether they could have been improved: *James* at para. 103; *Cantlie v. Canadian Heating Products Inc.*, 2017 BCSC 286 at para. 204, citing *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 at paras. 158-159.

[62] The plaintiffs allege that Mentor's written communications, including its patient brochures and PIDS, failed to disclose: 1) that the Implants contained volatile and extractable chemicals and heavy metals; and 2) the deleterious health effects of

those materials (Second ANOCC, paras. 4 and 52). The plaintiffs plead as follows in the Second ANOCC:

a) Mentor had a duty of care and a duty to warn (paras. 81 – 94);

b) Mentor breached its duty to warn (paras. 86 – 90; 94); and

c) The plaintiffs sustained injuries and damages as a result (para. 124).

[63] Mentor does not dispute, and I accept, that the plaintiffs have adequately pleaded a claim based on a negligent failure to warn in the Second ANOCC.

B. Claims under the *BPCPA*

[64] The *BPCPA* creates a statutory cause of action when a supplier commits a prohibited, deceptive, or unfair act or practice in relation to a consumer transaction, including making a false or misleading representation or branding a product in a misleading way: *Krishnan BCSC* at paras. 73 – 74. The plaintiffs submit that a defendant's failure to communicate information about risks or dangerous defects associated with a product may convert an omission into a misrepresentation by implication: *Williamson v. Johnson & Johnson*, 2020 BCSC 1746 at para. 125.

[65] The plaintiffs have pleaded consumer protection claims pursuant to the *BPCPA* in the Second ANOCC as follows:

a) The defendants engaged in consumer transactions and were suppliers of the Implants to the plaintiffs and class members who were consumers, within the meaning of the *BPCPA* (para. 99);

b) The defendants' conduct in their solicitations, offers, advertisements, promotions, sales, and supply of the Implants were deceptive acts or practices, contrary to s. 4 of the *BPCPA* (para. 100);

c) The defendants' conduct had the tendency or effect of deceiving consumers regarding the presence and effect of the alleged Toxins (para. 102);

d) The deceptive acts and practices were false and/or misleading in a material respect, namely as to the contents and risks of the Implants (para. 103);

e) The plaintiffs and class members relied on the defendants' representations (para. 104); and

f) The plaintiffs and class members have suffered loss and damages as a result of the defendants' conduct and seek to recover the cost of the product they purchased and other ancillary relief (para. 106).

[66] The plaintiffs plead in the Second ANOCC that the defendants breached the *BPCPA* by:

a) Misrepresenting the Implants as safe (paras. 87; 102);

b) Misrepresenting and omitting information about materials in the Implants, including the presence of the alleged Toxins (paras. 50–52, 86–91, 102); and

c) Misrepresenting and omitting information about the alleged Toxins' propensity to bleed into the body and the clinical consequences of exposure to them (paras. 52, 86–91, 102).

[67] The parties disagree about whether or not it is necessary to prove detrimental reliance in order to establish a claim under s. 4 of the *BPCPA*. The plaintiffs say that if the representation is deemed to be a deceptive act or practice under s. 4(3)(i), there is no need to determine whether it has the capability, tendency, or effect of deceiving or misleading a consumer under s. 4(1), citing *Krishnan BCSC* at para. 198. They submit that this case best fits the category of cases dealing with a general overarching message or "branding" displayed to the public, thereby permitting an objective assessment: *Krishnan BCSC* at para. 199.

[68] The consumer protection causes of action pleaded in the Second ANOCC include remedies which may not require reliance (s. 171) and those which do not

require reliance (s. 172). The *BPCPA* permits consumers to recover the costs of goods they purchased if suppliers have made false, misleading, or deceptive representations: *BPCPA*, s. 172.

[69] Justice Matthews rejected an argument that the plaintiff had not adequately pleaded causation in *Bowman v. Kimberly-Clark Corporation*, 2023 BCSC 1495:

> [29] In *Finkel v. Coast Capital Savings Credit Union*, 2016 BCSC 561 [*Finkel BCSC*], Justice Masuhara addressed this issue again and held that a deficient pleading of reliance was not fatal to the claim under the *BPCPA* because it was not necessary for the Plaintiffs to plead reliance as an element of the claim for causation purposes. Justice Masuhara held that a pleading linking the breach of the *BPCPA* to the class members' alleged losses was sufficient to plead causation, even though it was not a detrimental reliance pleading.

[70] In *MacKinnon* at paras. 64–65, Justice Horsman (then of this Court) found that the causation and misrepresentation by omission pleadings in that case were adequate. Mentor does not dispute and I accept that the plaintiffs have adequately pleaded consumer protection claims pursuant to the *BPCPA*.

C. The Claims under the *Competition Act*

[71] Section 52 of the *Competition Act* deems a representation that is "contained in or on anything that is sold, sent, delivered, transmitted, or made available in any other manner to a member of the public" as one that is made to the public. The general impression the representation conveys and its literal meaning shall both be considered in determining whether or not it is materially false and/or misleading: *Krishnan BCSC* at paras. 63 – 64; *Kibalian* at para. 25; *British Columbia v. Apotex Inc.*, 2022 BCSC 1 [*Apotex*] at paras. 150, 153, aff'd *Valeant Canada LP/Valeant Canada S.E.C. v. British Columbia,* 2022 BCCA 366 [*Valeant*] at para. 236.

[72] The plaintiffs plead that Mentor knowingly and recklessly breached s. 52 of the *Competition Act*, and that its representations and omissions were materially false, misleading, or deceptive: Second ANOCC at paras. 114–116. They deny they must plead reliance in order to advance a claim under s. 52, citing *Krishnan BCSC* at paras. 181–189; *Apotex* at paras. 150–151, aff'd *Valeant* at paras. 232-233.

[73] The plaintiffs have nonetheless pleaded that they would not have purchased the Implants but for Mentor's representations and omissions: Second ANOCC at para. 118. They note that a similar pleading was found to be sufficient in *Krishan BCSC* at para. 69, aff'd *Krishnan BCCA* at paras. 112 – 116. Mentor does not dispute, and I accept, that the plaintiffs have adequately pleaded claims under the *Competition Act*.

D. Conclusion

[74] I conclude that the Second ANOCC meets the requirements in s. 4(1)(a) of the *CPA*.

VII. SECTION 4(1)(B): CLASS DEFINITION

[75] Section 4(1)(b) of the *CPA* requires that there be an identifiable class of two or more persons. The class definition is intended to: 1) identify those persons who have a potential claim for relief against the defendants; 2) define the parameters of the lawsuit and those persons bound by its result; and 3) identify who is entitled to notice of the action: *Sun-Rype Products Ltd. v. Archer Daniels Midlands Company*, 2013 SCC 58 at para. 57 [*Sun-Rype*]; *Jiang v. Peoples Trust Company*, 2017 BCCA 119 at para. 82. The class must identify members by objective criteria which are rationally connected to the pleaded claims and the common issues: *Hollick* at para. 19.

[76] The plaintiffs bear the onus of demonstrating that the class could not be defined more narrowly without excluding those with a valid claim: *Hollick* at para. 21; *Sun-Rype* at para. 58. A class definition will not be overly broad even if it includes some class members who may ultimately be unsuccessful in establishing a claim: *MacKinnon* at paras. 74, 82.

[77] The parties agree on the following proposed class definition:

> All persons who were implanted with Mentor MemoryGel™ silicone gel-filled breast implants ("Mentor Silicone Breast Implants") in Canada from October 19, 2006, until the date of certification of this action (the "Class Period").

[78] The class size is currently unknown to the plaintiffs. As of October 1, 2020, approximately 1,196 people across Canada who reported issues with their Mentor Implants have contacted plaintiffs' counsel and co-counsel in Québec. Plaintiffs' counsel expects that these numbers will increase after certification.

[79] The proposed class is defined in objective terms. Membership in the class is readily ascertainable without reference to the merits. The class members all have a rational connection to the proposed common issues. I accept that this definition cannot be narrowed without excluding class members who might have a valid claim: *Hollick* at para. 21; *Sun-Rype* at para. 58. The definition need not include a requirement that members have suffered damages: *Jones v. Zimmer GMBH*, 2011 BCSC 1198 at paras. 41-42, aff'd 2013 BCCA 21.

[80] The parties agree, and I accept, that the proposed class definition meets the requirements of s. 4(1)(b) of the *CPA*.

VIII. SECTION 4(1)(C): COMMON ISSUES

[81] The proposed common issues are set out in Appendix A to these reasons.

A. Legal Principles

[82] Section 4(1)(c) of the *CPA* requires that the claims of the class members raise common issues, whether or not they predominate over issues affecting only individual members. The rationale for the commonality requirement is that individuals who have litigation concerns in common ought to be able to resolve them in one central proceeding rather than through an inefficient multitude of repetitive proceedings: *Pro-Sys* at para. 106.

[83] The Supreme Court of Canada summarised the key elements of a common issue in *Pro-Sys* at para. 108:

a) An issue will be common only when its resolution is necessary to the resolution of each class member's claim;

b) It is not essential that the class members be identically situated vis-à-vis the opposing party;

c) It is not necessary that common issues predominate over non-common issues but class members' claims must share a substantial common ingredient to justify a class action; and

d) Success for one class member must mean success for all (i.e., all members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent).

[84] If an issue is one that the court at trial could only decide by reference to the facts relating to the claim of each class member, it lacks commonality: *Price v. H. Lundbeck A/S*, 2022 ONSC 7160 at para. 82. An issue will not satisfy the common issues test if it is framed in overly broad terms: *Rumley* at para. 29. An issue stated in general terms, even if it results in a finding common to the class, will not be appropriate as a common issue to support certification if it provides only context and does not yield concrete answers to real claims that would advance the litigation in a meaningful way: *Price* at paras. 82, 89 – 92; *Rumley* at para. 29; *Charlton v. Abbott Laboratories Ltd.,* 2015 BCCA 26 at para. 85; *Pro-Sys* at para. 139; *Hollick* at para. 32.

[85] The commonality threshold is low; a triable factual or legal issue which advances the litigation when determined will be sufficient: *Finkel v. Coast Capital Savings Credit Union*, 2017 BCCA 361 at para. 22. A common issue need not be determinative of liability in order to advance the litigation for or against the class: *Kirk v. Executive Flight Centre Fuel Services Ltd.*, 2019 BCCA 111 at para. 65. The commonality inquiry is not a test of the merits: *Trotman v. Westjet Airlines Ltd.*, 2022 BCCA 22 at para. 57.

[86] Plaintiffs' counsel submits that the burden on defendants resisting certification is inversely high: to defeat certification, they must show that there is no basis in fact for the certification requirements: *Miller BCSC* at para. 45; *676083 B.C. Ltd. v.*

Revolution Resource Recovery Inc., 2019 BCSC 2007 at para. 70; *Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681 at para. 51.

[87] Commonality should be approached purposively: the question is whether class proceedings will avoid duplication of fact-finding or legal analysis: *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260 at para. 9; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 39. There must be evidence to establish some basis in fact for each of the proposed common issues that the plaintiffs seek to have certified (i.e., evidence and some basis in reality to show that an issue exists and that a judge would be able to assess it in common): *Williams* at paras. 257–258. Each of the proposed common issues must be considered separately*: Sandhu v. HSBC Finance Mortgages*, 2016 BCCA 301 at paras. 121 – 122.

[88] There has been a debate in recent years about whether the test for commonality requires one step (that the proposed issue can be answered on a class-wide basis) or two steps: namely, that the common issue both exists and can be answered in common. Plaintiffs' counsel describes this debate as an academic one here because, regardless of the approach taken, there is ample evidence of both the existence and commonality of the proposed common issues.

[89] I agree (as did Matthews J. in *Bowman* at para. 135) with the observations of Chief Justice Hinkson (as he then was) in *O'Connor v. Spinks*, 2023 BCSC 1371 at para. 263 that, in most cases, evidence of commonality will also be evidence of the existence of the matter the issue seeks to address. The plaintiff's burden is the same in any event: *O'Connor* at para. 261.

[90] For a claim to be certified, there must also be a method through which the common issue may plausibly be proven at trial: *Miller BCCA* at para. 29. While there is no requirement at the certification stage for rigorous assessment of conflicting expert evidence, the plaintiffs must present some type of actual, rather than theoretical, method for establishing loss on a class-wide basis; there must also be

some evidence of the availability of the data to which the method is to be applied: *Pro-Sys* at paras. 116 – 118.

B. Is there some basis in fact for the contested common issues?

[91] The Court of Appeal, citing various seminal authorities, recently explained the requirement for "some basis in fact" on certification in *Nissan Canada Inc. v. Mueller*, 2022 BCCA 338 at paras. 133 - 139:

a) The court must consider the language of the proposed common issue and whether there is some evidence to support the argument that it is a common issue across class members;

b) This is a low threshold;

c) The standard is simply to ensure that the action is suited to a class proceeding and does not entail a robust analysis of the merits of the claim;

d) The court must undertake more than superficial scrutiny of the sufficiency of the evidence;

e) This standard requires an evidentiary basis to show that the plaintiff has met the certification requirements; and

f) The requirement for "some basis in fact" is better understood in contrast to no basis in fact.

[92] The requirement that there be some basis in fact to support the proposed common issues is there to provide the certification judge with some level of confidence that certification will be of practical benefit when, in the future, the claims reach trial, as opposed to being simply a procedural complication for claims that are not truly common. It also helps the judge determine if a class proceeding is in fact a preferable procedure: *Nissan Canada Inc.* at para. 139.

1. Parties' Positions

[93] The first two proposed contested common issues relate to whether the Implants contain the alleged Toxins, and whether Mentor knew or ought to have known that the Implants contain the alleged Toxins. Plaintiffs' counsel describes the answers to both questions as necessary precursors to all other contested common issues related to an alleged negligent failure to warn and whether Mentor's omissions and representations about the Implants' contents, and their impact on gel bleed, breached the *BPCPA* and the *Competition Act*.

[94] The plaintiffs say there is some basis in fact to certify the proposed contested common issues, including evidence that:

a) The alleged Toxins are present in the Implants, a fact which has been known to the defendants for at least a decade, but probably much longer;

b) In 2019, the US FDA recommended that manufacturers provide clear and complete disclosure to patients of the presence and clinical effect of the alleged Toxins;

c) Mentor never disclosed the presence or effect of the alleged Toxins in any patient-facing documents;

d) Mentor provided incomplete, and arguably incorrect, information about the alleged Toxins and their clinical consequences to surgeons;

e) Mentor's statement that gel bleed is of no clinical consequence is highly contentious and contrary to studies showing that the alleged Toxins in the Implants are implicated in harm to human cells and organisms; and

f) There is a workable method to determine the impact of the alleged Toxins on human health.

[95] Mentor denies there is any evidentiary basis for the proposed common issues regarding the alleged Toxins.

2. Expert Evidence

[96] The plaintiffs filed expert reports from Dr. Diana Zuckerman, psychologist, health policy analyst, and patient advocate, and Dr. Jan W. Cohen Tervaert, rheumatologist. While Mentor intends to contest this evidence at the merits stage of this action, these opinions are relevant only to certification of the uncontested common issues. Accordingly, neither counsel nor I have addressed them in detail.

[97] At Mentor's request, Dr. Joseph V. Rodricks, toxicologist and chemical risk assessment consultant, prepared a report dated October 23, 2023. Based on his training, experience, and review of the references cited in this report, he concluded, with a reasonable degree of scientific certainty, that available data does not demonstrate that the Implants contain toxins or toxic compounds and, accordingly, they are not defective or unfit for use. He specifically considered silicone and platinum toxicity.

[98] Dr. Rodricks stated that the toxicity of silicone has been studied broadly in animals since the early 1940s and the results of these studies have overwhelmingly shown no adverse effects. He stated that the immunological effects of silicone fluids have also been extensively studied given their use in breast implants, and that epidemiological studies of breast implants (of which the main ingredient is silicone) have investigated the association between silicone and CTDs, rheumatic and autoimmune diseases, and breast cancer. He noted that the results of these studies have failed to show an association between human disease and silicone. Overall, he concluded that the scientific data indicate that silicone does not represent a risk to human health.

[99] Dr. Rodricks noted in his report that, due to their use as a catalyst in the manufacture of silicone gels and solids, the potential toxicity of platinum compounds has also received attention. He referenced the 1999 work of a Committee of the US Institute of Medicine ("IOM") of the National Academy of Sciences on the safety of silicone breast implants, a 2006 Health Canada report, and the 2018 FDA Backgrounder. He made the following statements in his report:

a) The IOM Committee concluded that evidence is lacking for an association between platinum in silicone breast implants and local or systemic health effects in women who have these implants;

b) Health Canada determined that:

i. Platinum levels in gel-filled breast implants are significantly lower than the standardized tolerance level and do not pose a toxicity threat; and

ii. The most convincing scientific evidence demonstrates that the platinum levels in gel-filled implants are too low to produce any ill effects and that platinum will exist primarily in an inert form in the body; and

c) The US FDA concluded that the small amounts of platinum that may leak through the implant shell do not represent a significant risk to women with silicone breast implants.

[100] In summary, Dr. Rodricks opined that:

a) The Implants are safe and not toxic; and

b) Available data do not demonstrate that Mentor breast implants contain toxins or toxic compounds, and they are not defective or unfit for use as a result.

[101] In response to Dr. Rodricks' report, the plaintiffs served the report of biochemist Dr. Ger Pruijn, dated January 11, 2024. Dr. Pruijn is a Professor of Biomolecular Chemistry with a PhD in physiological chemistry. His area of expertise is biochemistry, with a special interest in the molecular basis of autoimmune diseases. His research is focused on:

a) The identification of biomolecules that play a crucial role in the immune response associated with autoimmune diseases and their exploitation in the development of autoimmune diagnostics;

b) The biochemical processes mediated by targets of the immune system in autoimmunity; and

c) Why the immune system mounts an anti-self-response in autoimmunity.

[102] Dr. Pruijn discussed silicone toxicity and platinum-containing compounds in his report. He refers to two sets of experiments focused on the impact of low molecular weight (LMW) silicones on human cells and whole organisms, one of which he conducted, together with collaborators. Based on the data from these experiments, Dr. Pruijn concluded that LMW silicones may activate cell death pathways, leading to tissue degeneration, functional impairment, or activation of the immune system. He stated that these phenomena can each contribute to the pathophysiology of BII. In Dr. Pruijn's opinion, the statement that "overall, the scientific data indicate that silicone does not represent a risk to human health" is inaccurate.

[103] Dr. Pruijn studies silicones, including those from breast implants, in his lab. He and his colleagues published a peer-reviewed study in 2021 entitled "Low molecular weight silicones induce cell death in cultured cells". Mentor accepts that Dr. Pruijn is an expert regarding silicones. There is no dispute that he is qualified to comment on scientific studies in areas that relate to his own research (i.e., the connection between cell death induced by silicones and BII). I accept Dr. Pruijn's report as some basis in fact that silicones in the Implants can cause or contribute to the development of BII. This finding supports certification of the proposed uncontested common issues.

[104] Dr. Pruijn attaches to his report various documents that he reviewed in formulating his opinions, including an FDA Summary of Safety and Effectiveness Data regarding silicone gel-filled breast implants referred to by the trade name Memory Shape™ Breast Implants (the "FDA Summary"). Mentor submitted the FDA Summary to the US FDA and the FDA approved it on June 14, 2013.

[105] The FDA Summary indicates, in part, that the major components (i.e., the shell and gel) of Mentor's breast implants were chemically tested and "the chemical data support the biological safety of this device for its intended use because the values for concentration of low molecular weight silicones and heavy metals are well below known toxicity levels".

[106] The FDA Summary refers to the volatile extractables profile of these implants, a heavy metal analysis on them, and the total amount of heavy metals in the implants, including: antimony, arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, lead, mercury, molybdenum, nickel, platinum, selenium, silver, tin, titanium, vanadium, and zinc. This list of volatile and extractable chemicals and heavy metals overlaps with the alleged Toxins in the Second ANOCC at para. 86.

[107] The FDA Summary states that the total heavy metal results demonstrate that platinum was the only metal present in significant quantities. It notes that platinum is used as a catalyst in the manufacture of the shell and gel materials of the Implants, and that the small amounts of platinum remaining in the product may enter the body, either by diffusing through the intact shell (i.e., gel bleed) or through an implant rupture. The FDA Summary concludes:

> Based on a review of the published literature and other available data, FDA has concluded that the platinum contained in breast implants is in the zero-oxidation state, which has the lowest toxicity, and thus, does not pose a significant risk to women with silicone breast implants.

[108] The FDA Summary also references the FDA "Backgrounder" posted on its website and provides a brief summary of the key scientific studies on platinum and silicone gel-filled breast implants. I accept the FDA Summary as some basis in fact that the Implants contain the heavy metals identified in this document, and that Mentor was aware of this information by at least June 14, 2013. However, I do not accept the FDA Summary as some basis in fact that the alleged Toxins are either present or diffuse from the Implants in sufficient quantifies to cause harm.

3. Evidentiary Objections

[109] Mentor objects to some of the evidence on which the plaintiffs rely at this certification hearing, including:

a) Dr. Pruijn's qualifications and opinions regarding platinum and the information that manufacturers ought to disclose to patients about risks associated with the Implants;

b) A 2020 FDA Guidance Document; and

c) The hair element test results for AC, the anonymous class member.

[110] Mentor also argues that Ms. Bosco's evidence is neither credible nor reliable and that, taken as a whole, it deserves little to no weight.

[111] It is well-established that the normal rules of evidence and the usual criteria for admissibility apply on certification applications (except for the cause of action requirement in s. 4(1)(a)): *Ernewein* at para. 31; *O'Connor* at para. 71; *Martin* at paras. 25, 39 – 40; *Huebner Estate v. PR Seniors Housing Management Ltd.*, 2021 BCSC 837 at para. 14. The court has an important gatekeeping role in ensuring the admissibility of evidence at certification: *O'Connor* at para. 72.

[112] The "some basis in fact" test must not be conflated with the principles of admissibility: "some basis in fact" refers to the requisite standard of proof for the certification requirements which is less than a balance of probabilities; it does not reflect a lower threshold for the admissibility of evidence: *Pro-Sys* at paras. 102 – 104; *Krishnan BCSC* at para. 123, citing *Nissan Canada Inc.* at para. 142.

[113] The law regarding the admissibility of expert opinion evidence is well-established: *R. v. Mohan*, [1994] 2 S.C.R. 9; 1994 CanLII 80; *White Burgess Langille Inman v. Abbott and Haliburton Co.*, 2015 SCC 23. While expert evidence at certification is scrutinized at a lower standard than it will be at a trial, there remains a standard that must be met: *Krishnan BCSC* at para. 127. The court must be satisfied

that the expert's evidence on the issue is sufficiently reliable that it provides some basis in fact for the existence of the common issue: *Bhangu* at para. 99.

[114] I address each of Mentor's objections in turn.

a) Dr. Pruijn's Qualifications and Opinions

[115] Mentor objects to the admissibility of Dr. Pruijn's report on the basis that he opines on matters beyond the scope of his qualifications. Mentor denies Dr. Pruijn is an expert on platinum, the labelling of medical devices, or the kind of patient disclosure that manufacturers must make regarding silicone breast implants.

[116] Dr. Pruijn admits he has never conducted any research or published any scientific papers about platinum. It is generally insufficient for experts to arrive at opinions outside their particular area of expertise based only on their review of literature published by others who possess expertise on the subject: *Williamson* at para. 65. Mentor highlights Dr. Pruijn's admissions on cross-examination that:

a) He is aware of no evidence or data indicating that long-term exposure to platinum in the Implants leads to health consequences;

b) The amount of platinum, duration of exposure, and oxidation state of the platinum compounds are all relevant to an inquiry about whether platinum can cause health effects;

c) There are insufficient studies to draw conclusions about the long-term toxicity of platinum-containing compounds from breast implants; and

d) He did not review the FDA's 2018 Backgrounder publication regarding platinum in silicone breast implants before formulating his opinions, despite Dr. Rodricks expressly citing and relying on it in his report.

[117] Dr. Pruijn offers the following opinions about platinum in silicone breast implants in his report:

> In conclusion, I agree with Dr. Rodricks that at present there are insufficient studies to determine whether there is an association between platinum compounds leaking from silicone breast implants and adverse health effects. The controversial data on platinum toxicity emphasizes the need for investigation of whether or not platinum compounds from silicone implants cause health effects. In order to conclusively answer this question, long-term toxicology studies should be conducted and should at least in part be based on adverse event reports from the manufacturers. In addition, the possibility that metallic platinum is converted into the more harmful oxidation states when silicone implants reside for long periods (more than 5 years) in a human body, either in the implant or after diffusion through the shell, should be investigated.

[118] Mentor argues that, at most, Dr. Pruijn opines that there is insufficient data regarding the long-term risks of platinum to human health (an opinion Mentor describes as beyond his expertise) and that more research is warranted. Mentor denies this statement establishes some basis in fact for the existence of any issue regarding the presence of the alleged Toxins in the Implants or any adverse health consequences associated with them.

[119] Based on Dr. Pruijn's own admissions, I conclude that he is not an expert on platinum. I accept that the plaintiffs may retain a more specialised expert to testify at the common issues trial, and that I am not required to weigh competing expert opinions at this procedural stage. However, I conclude that there is no material conflict in the expert evidence regarding platinum. Dr. Pruijn agrees with Dr. Rodricks that there is currently insufficient evidence that platinum compounds that leak from silicone breast implants lead to adverse health effects. There is currently no expert evidence to support the conclusion that platinum is either present or diffuses from the Implants in sufficient quantities to cause adverse health effects.

[120] Dr. Pruijn does not comment on any of the other alleged Toxins in his report. No expert does so. I find that Dr. Pruijn's evidence is insufficient to comprise some basis in fact to support the proposed contested common issues regarding Mentor's alleged failure to warn of the presence of the alleged Toxins in the Implants, or for related breaches of consumer protection or competition legislation. I agree with Mentor that these contested common issues require some basis in fact, beyond

speculation, that the alleged Toxins are either present or diffuse from the Implants in sufficient quantities to cause harm.

[121] Dr. Pruijn also offers opinions about the information that ought to be disclosed to patients regarding the materials in silicone breast implants, including that:

a) Silicones are not biologically inert and the long-term effects of silicone bleed have not been extensively studied;

b) Studies show that silicones are more likely than not toxic to cells and organisms, which likely forms part of the explanation for BII; and

c) Although experimental data from manufacturers indicates that the amount of LMW silicones and platinum leaking from implants during relatively short periods (up to a few months) would not lead to adverse effects, this does not imply that compounds leaking from implants that stay in the body for many years cannot lead to health issues.

[122] Mentor objects to these opinions as outside the scope of Dr. Pruijn's expertise. In doing so, they rely on his admissions on cross-examination that:

a) He is not a medical doctor, toxicologist, pathologist, epidemiologist, or plastic surgeon and he does not see patients, diagnose diseases, or counsel patients about surgical procedures;

b) He does not do clinical research on humans;

c) He has never conducted risk reviews or assessments of potentially harmful substances or presented to public health agencies as part of his work;

d) He has no education or training in public health; and

e) He has no education or training regarding the Canadian regulatory approval process for medical devices or any knowledge about labelling

> requirements for medical devices in Canada, including Health Canada's approval of PIDS.

[123] Dr. Pruijn's professional career and research has focused on the structure and function of biomolecular complexes, including, in particular, those relating to intracellular processes. I accept that much of Dr. Pruijn's research is, at least indirectly, related to the study of diseases in humans and that he has done studies on human tissue cells in his lab. However, Dr. Pruijn is not a medical doctor and he neither counsels nor treats patients. Plaintiffs' counsel concedes that Dr. Pruijn is not an expert regarding the regulation of medical devices, including breast implants.

[124] I have found that Dr. Pruijn is not an expert on platinum. Based on his own admissions, I am not persuaded that Dr. Pruijn is appropriately qualified to offer expert opinion evidence about the kind of patient disclosure that manufacturers of medical devices, including the Implants, must make. I conclude that to the extent he purports to offer opinions on those matters, they are inadmissible. This evidence predominantly relates to the proposed contested common issue regarding Mentor's alleged negligent failure to warn.

b) FDA Guidance Document

[125] On September 29, 2020, the US FDA published a document entitled "Breast Implants – Certain Labelling Recommendations to Improve Patient Communication" (the "FDA Guidance Document"). It contains non-binding recommendations regarding the format and content of labelling information for all manufacturers of saline and silicone breast implants in light of new information pertaining to the risks associated with breast implants, including BII. While the FDA noted that this information was publicly available for each of the approved breast implants, it nonetheless recommended that manufacturers make detailed device description information easily accessible to patients to help ensure transparency and patient safety:

> This device description information is intended to help inform the patients of the types and quantities of chemicals and heavy metals that are detected in the breast implants. The patient should also be informed that most of these

> chemicals stay inside the shell of the implant but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

[126] Mentor does not dispute the authenticity of the FDA Guidance Document, leaving aside the fact that it is appended to the affidavit of a paralegal, in the absence of any expert evidence, but denies it is relevant to the contested common issues. Mentor describes the FDA Guidance Document as inadmissible hearsay evidence on which the plaintiffs cannot rely for its truth. Mentor denies it comprises some basis in fact that the Implants contain toxins that cause adverse health effects.

[127] The FDA Guidance Document expressly states that it establishes no legally enforceable responsibilities but rather describes the FDA's current thinking on a topic. Plaintiffs' counsel accept that the FDA Guidance Document is not binding on Health Canada regarding the sale or distribution of medical devices in Canada. The FDA Guidance Document recommended that breast implant manufacturers provide to patients:

a) A noticeable and easy to understand boxed warning to inform patients and highlight specific risks, including the association between breast implants and systemic symptoms;

b) A patient decision checklist highlighting key information about risks, including the risk of systemic symptoms;

c) A detailed description of the materials in the breast implant shell and filling, in a format understandable to the patient, including tables listing breast implant materials, chemicals which might be released from breast implants, and heavy metals present in breast implants; and

d) Context to the levels of risk/exposure to the toxins and chemicals in the breast implants, including, for example, the results of toxicity testing and risk assessments in comparison to amounts determined likely to be safe, while noting that individual results may vary and all reactions cannot be predicted.

[128] The FDA Guidance Document also recommended that manufacturers inform patients that, while most chemicals stay inside the implant shell, small quantities have been found to diffuse through the shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

[129] Mentor updated its Canadian packaging in May 2022, to include some of the recommendations in the FDA Guidance Document, including the provision of a boxed warning. Plaintiffs' counsel says that as of December 2022, Mentor's Canadian packaging for the Implants still does not adequately disclose the materials in the Implants, the risk of exposure to these chemicals, heavy metals, and the alleged Toxins, or the potential health consequences of gel bleed.

[130] The plaintiffs rely on the FDA Guidance Document as evidence that the FDA made the recommendations contained in it. They argue it is admissible as a public document, prepared by persons entrusted with a public duty and in the discharge of that duty, with the intention that it would serve as a permanent record and be made available to the public for inspection: *Pantusa v. Parkland Fuel Corporation*, 2022 BCSC 322 at para. 84. They say that whether and when Mentor ought to have disclosed information to patients and surgeons regarding the alleged Toxins, as set out in the FDA's non-binding recommendations in the FDA Guidance Document, will be a central question at the common issues trial.

[131] The plaintiffs deny that the non-binding and unenforceable nature of the FDA recommendations in the FDA Guidance Document makes them irrelevant. They say this document is evidence that the FDA recommended to breast implant manufacturers that they disclose the presence of the alleged Toxins in breast implants and that Mentor did not do so.

[132] Plaintiffs' counsel also says that the FDA Guidance Document provides a list of heavy metals found in breast implants. Appendix C to the FDA Guidance Document includes a "Materials Device Description Example" that provides a list of heavy metals found in breast implants, including: antimony, arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, lead, magnesium, mercury,

molybdenum, nickel, platinum, selenium, silver, tin, titanium, vanadium, and zinc. This document is not specific to the Implants; it expressly notes that the list of concentrations in Appendix C is for illustrative purposes only. I do not accept it as comprising some basis in fact that the Implants contain the alleged Toxins.

[133] I find that the FDA Guidance Document is admissible as some evidence that the FDA made the recommendations contained in it, and that Mentor did not follow all of them. I draw no inferences about what, if anything, Mentor ought to have done in response to these recommendations in the absence of an expert opinion on that matter. I do not agree that the FDA Guidance Document is admissible as some basis in fact that the alleged Toxins have the propensity to cause adverse health effects. These findings are relevant to the contested common issues regarding Mentor's negligent failure to warn of the presence of the alleged Toxins in the Implants, and corresponding alleged breaches of consumer protection and competition legislation.

c) Hair Element Analyses

[134] The affidavit of Cassandra Campbell, a legal assistant with class counsel's law firm, appends the test results of two hair element analyses conducted on AC's hair. Ms. Cassandra identifies AC as a person who contacted their law firm and provided the results from two hair element tests that were apparently done one week before, and six months after the removal of AC's Mentor breast implants.

[135] Ms. Cassandra deposes, based on information from plaintiffs' counsel and, presumably, based in turn on information from AC, that:

a) AC had breast reconstruction surgery with Mentor breast implants following a mastectomy;

b) AC developed BII as a result of her Mentor implants and this prompted her to have them removed;

c) AC experienced significant improvement in her symptoms after removal of her Mentor breast implants; and

d) AC has no explanation for the reduction in toxic elements between her two hair analyses, apart from the removal of her Mentor breast implants.

[136] Mentor objects to this evidence, which it describes as inadmissible, multi-level hearsay.

[137] There is no expert evidence comprising some basis in fact that the methods used to conduct AC's hair element analyses are reliable and accepted means of testing for the presence of aluminum, lead, tin, silver, titanium, or any of the other elements identified in these reports. There is no expert evidence about what, if any, inferences can be drawn from these test results.

[138] Defence counsel cite a recent study, referenced in Dr. Pruijn's report, whose authors: 1) found no statistically significant difference in platinum levels in the hair of women who had silicone breast implants compared to those who did not; and 2) did not recommend this test for clinical use: K.A. Spit et al., "Measuring Platinum Levels in Hair in Women with Silicone Breast Implants and Systemic Symptoms" (2022) 10:6 Plastic & Reconstruction Surgery Global Open 1 at 6 . Mentor underscores: 1) the tests on AC's hair were conducted by two different labs; 2) these tests may have utilized different analytical methodologies or test procedures (which could explain the different results); and 3) there is no evidence from an appropriately qualified expert to confirm that the asserted difference in AC's hair analysis test results has any significance.

[139] Plaintiffs' counsel argues that the statements in Ms. Campbell's affidavit, relaying the experience of AC, are admissible as some basis in fact for assessing the certification criteria, citing *Felker v. Teva Branded Pharmaceutical Products R,* 2022 BCSC 1813 at paras. 94 – 100. He describes Mentor's objections regarding the reliability of these hair element analyses as merits-based and irrelevant at certification.

[140] I accept that hearsay evidence is admissible on an interlocutory certification hearing which does not result in a final order: *Tietz v. Affinor Growers Inc*., 2022 BCCA 307 at para. 89; *Tippett v. Canada*, 2019 FC 869 at para. 24. Such evidence is permitted if the source of the information and belief is provided: *SCCR*, R. 22-2(13); *Araya v. Nevsun Resources Ltd.*, 2016 BCSC 1856 at para. 141, aff'd 2020 SCC 5. Ms. Campbell deposes that she was informed by plaintiffs' counsel. Notably, she says nothing about the source of plaintiffs' counsel's information regarding AC.

[141] I accept that AC's hair element analyses are admissible as some evidence that AC had those tests and received those results. However, absent evidence from an appropriately qualified expert interpreting these test results, I assign very limited weight to this evidence in establishing the "some basis in fact" test for certification of the proposed contested common issues.

d) Ms. Bosco's Evidence

[142] Mentor argues that Ms. Bosco's evidence is unreliable and lacks credibility because:

a) She has a limited recollection of her consultations with health care professionals before her cosmetic surgeries;

b) There are conflicts between her affidavit evidence and the transcript of her evidence given on cross-examination; and

c) She made incomplete disclosure of material facts in her affidavits.

[143] Plaintiffs' counsel describes these as merits-based objections, citing *Hollick* at para. 16. I am not in a position to assess Ms. Bosco's credibility or the reliability of her evidence at this procedural stage, nor am I required to weigh the evidence. For those reasons, I decline to do so.

e) Summary of Evidentiary Findings

[144] In summary, I make the following findings regarding the disputed evidence:

a) Dr. Pruijn is not appropriately qualified to offer expert opinion evidence on platinum, or the kind of information that manufacturers of medical devices, including the Implants, ought to disclose to patients and, to the extent he purports to offer such opinions, they are inadmissible;

b) The FDA Guidance Document is admissible as some evidence that the FDA made the non-binding recommendations set out in this document, and that Mentor followed some, but not all, of them; and

c) AC's hair element analyses are admissible as some evidence that AC had those tests and received those results.

4. Summary

[145] I find there is some admissible evidence on this application that:

a) Silicones are not biologically inert;

b) Low-molecular weight silicones may lead to tissue degeneration, functional impairment, activation of the immune system, and/or induce cell death; and

c) There may be an association between silicones in breast implants and BII.

These findings are relevant to the proposed uncontested common issues.

[146] I find there is some admissible evidence on this application that:

a) The Implants contain the heavy metals identified in the FDA Summary (which overlap with the alleged Toxins referenced in the Second ANOCC);

b) There are currently insufficient studies to determine whether there is an association between platinum compounds leaking from silicone breast implants and adverse health effects; and

c) There is a need for long-term toxicology studies, including investigating the possibility that metallic platinum is converted into the more harmful

oxidation states when silicone breast implants remain in the body for long periods (i.e., more than five years), in order to answer this question conclusively.

These findings are relevant to the contested common issues regarding the presence of the alleged Toxins in the Implants, Mentor's knowledge and alleged failure to warn of the presence of the alleged Toxins in the Implants, and corresponding alleged breaches of consumer protection and competition legislation.

[147] I find there is no admissible evidence on this application that:

a) Platinum is either present in, or diffuses from, the Implants in sufficient quantities to cause adverse health effects; or

b) Any of the other alleged Toxins are either present in, or diffuse from, the Implants in sufficient quantities to cause adverse health effects.

These evidentiary findings are relevant to the proposed contested common issues regarding Mentor's negligent failure to warn of the presence of the alleged Toxins in the Implants, and related alleged breaches of consumer protection and competition legislation. Before addressing the specific proposed common issues, I consider whether there is some basis in fact to support a workable method for proving general causation.

C. Is there some basis in fact for a workable methodology?

[148] The Court of Appeal reviewed the requirement for a workable methodology in *Miller BCCA* at para. 33. Reference to methodology in this context is not to be confused with a prescribed scientific or economic methodology; rather, it refers to whether there is *any* plausible way in which the plaintiff can legally establish the general causation issue embedded in their claim. 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: *Miller BCCA* at para. 44.

[149] Proving causation in the context of toxic substances puts the added burden on plaintiffs to establish general and specific causation: *Charlton* at para. 95. A plaintiff must first prove that a particular substance is capable of causing a particular illness; next, a plaintiff must prove that exposure to a particular toxic substance did, in fact, cause the plaintiff's illness: *Miller BCCA* at para. 44, citing *Charlton* at 95.

1. Expert Evidence

[150] In Dr. Pruijn's opinion, based on his own research and that of others, Mentor's statement that "overall, the scientific data indicate that silicone does not represent a risk to human health", is inaccurate. He opines that studies show that silicones are probably toxic to cells and organisms, which likely forms part of the explanation for BII.

[151] As noted, Mentor acknowledges, and I accept, that Dr. Pruijn is an expert on silicones. I have found that Dr. Pruijn is not an expert on platinum; he does not comment on any of the other alleged Toxins. Dr. Pruijn opines that Mentor's studies relating to platinum are too short in duration. He states that although experimental data from manufacturers indicates that the amount of platinum leaking from breast implants during relatively short periods (i.e., up to a few months) would not lead to adverse effects, this does not imply that compounds leaking from implants that remain in the body for many years cannot lead to health issues.

[152] Dr. Pruijn states that the long-term toxicity of silicones and platinum can be investigated by the methodologies he describes in his report, following disclosure by manufacturers of adverse events and scientific studies in their possession. He does not comment on whether these methods could be applied to any of the other alleged Toxins referenced in the Second ANOCC.

[153] Plaintiffs' counsel relies on Mentor's statement in the FDA Summary that the silicones and heavy metals contained in the Implants and identified in that document were "well below known toxicity levels":

> Chemical testing was performed on the major components (shell and gel) of Mentor's product. The chemical data support the biological safety of this

> device for its intended use because the values for concentrations of low molecular silicones and heavy metals are well below known toxicity levels.

[154] Plaintiffs' counsel argues that these statements imply Mentor has conducted tests to support these conclusions, or at the very least, that they could be conducted. He relies on Dr. Pruijn's evidence as some basis in fact that, while currently available studies are insufficient to assess the long-term health effects of the Implants, this could be investigated with a workable methodology: *Pro-Sys* at paras. 116-118; *Miller BCCA* at paras. 27-30, 38; *MacKinnon* at paras. 126-127.

[155] The plaintiffs deny they must prove that the alleged Toxins are, in fact, toxic. They say it is sufficient at this stage that there is evidence that tends to prove this allegation, a workable methodology for providing an answer at trial, and that the question can be answered in common. The plaintiffs rely on their own evidence that they suffered harm after their breast implantation surgery. Plaintiffs' counsel denies he must prove what caused those harms, or demonstrate actual harm at the certification stage, citing *Miller BCCA* at para. 50.

[156] Dr. Rodricks does not comment on whether a workable method exists for investigating possible adverse health effects associated with long-term exposure to the alleged Toxins in the Implants. Leaving aside the admissibility of Dr. Pruijn's opinions, Mentor argues that Dr. Pruijn's conclusions accord with Dr. Rodricks' opinion that there is currently no experimental evidence of an association between platinum leaking from silicone breast implants and adverse health effects. Mentor argues further that Dr. Pruijn's statement that available data indicates the amount of platinum leaking from implants during relatively short periods would not lead to adverse effects, also essentially accords with Dr. Roderick's conclusions. As noted, Dr. Pruijn does not comment on any of the other alleged Toxins in his report.

2. Conclusion

[157] The plaintiffs rely heavily on the concluding statement in Dr. Pruijn's report:

> Taken together, even when experimental data would show that the amount of low molecular weight silicones and platinum leaking from implants during a 60-day period would not lead to adverse effects, this does not imply that

> compounds leaking from implants that stay in the body for many years do not lead to health issues. Studies referenced above provide a plausible methodology to test whether the statement provided by the Defendants is accurate.

[158] Plaintiffs' counsel argues that Dr. Pruijn is qualified to opine on the potentially harmful oxidation states of platinum after long periods of implantation, and to comment on appropriate study design using the scientific method. I have found that Dr. Pruijn is not an expert on platinum. I accept that, as a biochemist, he has some expertise regarding the chemical composition of the Implants and appropriate study design using the scientific method.

[159] I accept Dr. Pruijn's report as some basis in fact that a study could be designed to determine whether long-term exposure to gel bleed of silicone or platinum from breast implants is of any clinical consequence. I am not persuaded the evidence comprises some basis in fact that the data required to conduct an actual (rather than theoretical) study currently exists: *Pro-Sys* at paras. 116 – 118.

[160] I agree with Mentor that Dr. Pruijn provides no method for showing that exposure to platinum in the Implants, or any of the other alleged Toxins, poses a risk of any specific condition, disease, or injury (i.e., a specific risk of harm). Dr. Pruijn concedes that a defined and testable syndrome is a precondition to any type of study. Based on the information in Dr. Pruijn's report, it appears that the type of study he contemplates as being necessary to investigate the long-term implications of platinum in breast implants would take at least five years.

[161] I accept that Dr. Pruijn is an expert on silicones, including those in breast implants, and that there is a workable method for proving general causation regarding the proposed uncontested common issues. However, I am not persuaded on the evidence before me that there is a workable method, based on available data, for proving general causation regarding the proposed contested common issues.

D. Are the proposed common issues certifiable?

1. Uncontested Common Issues

[162] While Mentor vigorously disputes the plaintiffs' allegations, it does not oppose certification of the proposed uncontested common issues #1 – 12 (as set out in Appendix A to these reasons). Those issues relate to whether the Implants can cause specific CTDs and/or BII and, if so, whether Mentor breached its duty to class members in its post-market surveillance and/or monitoring of the Implants with respect to those conditions, and, by extension, whether Mentor's acts or omissions were negligent or in breach of the *BPCPA* and/or *Competition Act*.

[163] A modified approach to the certification inquiry is appropriate when certification is not contested: *Kibalian v. Allergen Inc.*, 2022 ONSC 1827. Plaintiffs need only establish a *prima facie* case for certification for the uncontested proposed common issues: Branch & Good, *Class Actions in Canada*, 2nd ed. At 17.260, citing *Haney Iron Works Ltd. v. Manufacturers Life Insurance Co.*, 169 D.L.R. (4th) 565,1998 CanLII 3085 (B.C.S.C.) at para. 16; *Rezmuves v. Hohots*, 2019 ONSC 4871 at paras. 7-8; *Warner v. Google LLC*, 2020 BCSC 1108 at para. 124.

[164] In summary, I make the following findings regarding the proposed uncontested common issues:

a) The Second ANOCC adequately pleads claims in negligence and breaches of the *BPCPA* and *Competition Act*;

b) There is an identifiable class of two or more persons;

c) The proposed class is sufficiently clear and defined by objective criteria;

d) The proposed representative plaintiffs are class members; and

e) The proposed uncontested common issues are suitable common issues.

[165] I conclude that the plaintiffs have met the requirements in s. 4(1)(a) – (c) of the *CPA* for certification of proposed uncontested common issues #1 - 12.

2. Deferred Common Issues

[166] The parties have agreed to defer the proposed common issues regarding Mentor's alleged breach of consumer protection legislation in other provinces, the plaintiffs' entitlement to damages, and the quantification of damages. Accordingly, I do not address those issues.

3. Contested Common Issues

a) Negligent Failure to Warn

[167] Proposed common issues #13 – #15 concern Mentor's alleged negligent failure to warn. I address each in turn.

i. Presence of the Alleged Toxins

[168] Contested common issue #13 relates to the presence of the alleged Toxins in the Implants:

#13. Do Mentor Silicone Breast Implants contain heavy metals and/or volatile and extractible chemicals, or other toxins as may otherwise be proven at trial (the "Toxins")?

[169] The plaintiffs describe this proposed common issue as a factual inquiry which is focused on Mentor's product and not individual class members' experiences. They say this question can be answered on a class-wide basis and that the Second ANOCC appropriately incorporates by reference the FDA Guidance Document which therefore forms part of any assessment of the pleadings: *McCreight v. Canada (Attorney General)*, 2013 ONCA 483 at para. 32.

[170] As noted, the plaintiffs say this issue is a necessary precursor to questions about Mentor's alleged failure to warn of the materials contained in its product, and whether Mentor's omissions and representations regarding those contents breached the *BPCPA* and *Competition Act.* Plaintiffs' counsel argues that the evidentiary

threshold for a common issue in an alleged dangerous product liability claim does not require two distinct categories of evidence: namely, evidence that there is a common defect; and evidence that the common defect is dangerous: *Nissan Canada Inc.* at paras. 132 – 134.

[171] Mentor denies proposed common issue #13 poses a legally relevant question. It says the mere presence of platinum, heavy metals, or other chemicals in the Implants is not actionable in the absence of injury (i.e., an adverse event, disease, or medical condition). It denies there is any evidence that platinum or any of the other alleged Toxins are implicated in the development of the so-called signature health issues that are the subject of this litigation.

[172] Mentor describes the "Toxins" as a vague term which references a potentially open-ended list of substances: *Martin* at paras. 220 and 224; *Williamson* at para. 252; *Rumley* at para. 29. Defence counsel notes a discrepancy between the description of the alleged Toxins, as defined in para. 86 of the Second ANOCC, and as defined at para. 4 of the plaintiffs' written submissions on this certification hearing.

[173] There is no dispute that the Implants, by their name alone, contain silicone. The association between silicone in the Implants and the development of CTDs and BII is addressed in the proposed uncontested common issues. I accept Dr. Pruijn's report as some basis in fact to support certification of the uncontested common issues regarding whether silicones in the Implants can cause or contribute to the development of BII and CTDs.

[174] I acknowledge there is some basis in fact that the Implants contain small quantities of platinum (in zero oxidation state). Mentor has disclosed the presence of platinum in the Implants to physicians and patients. It is therefore unclear how a common issue that asks whether the Implants contain platinum would advance the plaintiffs' claims.

[175] I have found the FDA Summary comprises some basis in fact that the Implants contain the heavy metals identified in this document and described in the Second ANOCC as the Toxins, and that Mentor was aware of this information by at least June 14, 2013. I have also found that the FDA Guidance Document is some basis in fact that the FDA made the non-binding recommendations outlined in this document, and that Mentor followed some, but not all, of them. I have made no inferences about what, if anything, Mentor ought to have done in response to these recommendations in the absence of expert evidence on that matter. I do not accept the FDA Guidance Document as some basis in fact that the alleged Toxins in the Implants have the propensity to cause adverse health effects.

[176] Ultimately, I find that there is no basis in fact for certifying the proposed contested common issues relating to the alleged Toxins. I have found there is no basis in fact that the alleged Toxins are either present or diffuse from the Implants in sufficient quantities to cause harm.

[177] I accept that a factual inquiry about the materials in the Implants is a prerequisite to the plaintiffs establishing claims in negligence and statutory breaches of the *BPCPA* and *Competition Act*. However, as presently worded, common issue #13 is vague and overbroad. It refers to “other toxins as may otherwise be proven at trial” and is therefore potentially unlimited in scope. Mentor is entitled to know what alleged toxins are at issue on a common issues trial.

[178] I do not agree that incorporating by reference terminology from the FDA Guidance Document (including volatiles, extractables, heavy metals, D-Siloxones, and low molecular weight silicones) into the Second ANOCC and, by extension, the proposed common issues, adequately clarifies this proposed common issue. A common issue cannot be certified if it is not clear what it means: *Martin* at para. 227. Court orders should be clear and unambiguous and should not require resort to extrinsic sources: *Hoisington v. Johnson & Johnson Inc.*, 2016 BCSC 807 at paras. 34 – 35.

[179] I find that proposed common issue #13 is not certifiable. I do not agree that it would be appropriate to narrow this issue to silicone (as silicone is clearly present in the Implants by virtue of its name) or platinum (which Mentor has disclosed as present in the Implants).

[180] I accept that the list of other alleged Toxins in this proposed common issue could be narrowed to correspond to the heavy metals identified in the FDA Summary. However, given my finding that the evidence does not comprise some basis in fact that those heavy metals are either present in, or diffuse from, the Implants in sufficient quantities to cause adverse health effects, I conclude that doing so would not advance the plaintiffs' claim.

[181] In the result, I agree with Mentor that proposed common issue #13 poses no legally relevant question. In my view, it would yield no concrete answers to real claims in this case: *Price* at paras. 82; 89 – 92. The other contested common issues all reference the same definition of the alleged "Toxins". While I conclude that, by extension, they too are not certifiable, I address them nonetheless.

ii. Knowledge of Alleged Toxins

[182] Contested common issue #14 addresses Mentor's knowledge of the Implants' contents:

#14. Did the Defendants know or ought they to have known that Mentor Silicone Breast Implants contain the Toxins, and if so, when?

[183] Plaintiffs' counsel says that a determination of this question in favour of the class will advance the litigation for members of the proposed class because it is an element of causes of action relating to both a negligent failure to warn and breaches of consumer protection and competition legislation.

[184] Mentor argues that whether or not it was aware of the presence of the alleged Toxins is not actionable on its own, without some harm or compensable injury, citing *Dussiaume v. Sandoz Canada Inc.*, 2023 BCSC 795 at paras. 63 – 64, 70, 72. It emphasizes that none of the proposed contested common issues relate to whether

the alleged Toxins cause injury. Mentor denies an affirmative answer to common issue #14 would significantly advance a claim that Mentor had a duty to warn patients and/or surgeons of the presence of the alleged Toxins in the Implants. The plaintiffs reply that whether the alleged Toxins are actually toxic is a common issue for trial.

[185] I have found that the evidence comprises some basis in fact that Mentor was aware, by at least by 2013 (the date of the FDA Summary), that the Implants contained the heavy metals defined in the Second ANOCC as the Toxins. However, I find that proposed common issue #14 suffers from the same flaws as proposed common issue #13. As presently worded, it imports a vague and potentially open-ended list of alleged "Toxins" that cannot be narrowed in a way that meaningfully advances the plaintiffs' claims. Additionally, as noted, I have found that the evidence does not comprise some basis in fact that the alleged Toxins are either present or diffuse from the Implants in sufficient quantities to cause adverse health effects.

[186] I find that proposed common issue #14 is not certifiable.

iii. Failure to Warn of Alleged Toxins

[187] Contested common issue #15 relates to Mentor's alleged negligent failure to warn of the alleged Toxins' presence in the Implants:

#15. Did the Defendants, or any of them, fail to warn, or fail to adequately warn, Class Members and/or surgeons with respect to the presence of the Toxins in the Mentor Silicone Breast Implants, and if so, who, when and how?

[188] Plaintiffs' counsel asserts that Mentor's May 2022 PIDS, a document that references only "LMW silicones D4, D5, and D6, and platinum", is the only disclosure Mentor has ever provided of the Implants' contents. He argues that Mentor ties this incomplete disclosure to a subsequent conclusory statement that "[t]he overall body of available evidence supports that the extremely low level of gel bleed [from the Implants] is of no clinical consequence". He says this disclosure is

both incomplete and contrary to the recommendations of the US FDA in the FDA Guidance Document.

[189] Plaintiffs' counsel denies Mentor's 2022 PIDS provides any useful information to patients or surgeons about the alleged Toxins. It states:

> **DEVICE DESCRIPTION**
>
> Mentor Silicone Gel-Filled Breast Implants are devices with shells constructed from silicone elastomer. The shell is filled with MemoryGel™, Mentor's proprietary formulation of silicone gel. The shell is constructed of successive cross-linked layers of silicone elastomer, which give the prosthesis its elasticity and integrity. There are two styles of shell: smooth and textured. The devices are available in two shapes: round and countour-shaped.

[190] Plaintiffs' counsel says that contested common issue #15 focuses on the elements of the test for a negligent failure to warn, is entirely dependent on Mentor's conduct, and can therefore be answered in common. He argues that certification of this issue will significantly advance the litigation for all class members by deciding Mentor's liability on a class-wide basis and avoiding duplication of factual and legal analyses. He says this proposed common issue inherently considers both the presence of the Toxins and the risks associated with exposure to them. He argues that the evidence establishes some basis in fact that Mentor breached its duty to provide clear, complete, and current information about the contents of the Implants, including that silicones are not biologically inert. He relies on the statements in Dr. Pruijn's report that studies show silicones are probably toxic to cells and organisms, which likely forms part of the explanation for BII.

[191] The plaintiffs say that, at this preliminary stage, there is evidence that: 1) the alleged Toxins are present in the Implants; and 2) the statement that they are of "no clinical consequence" is unproven. They rely on Dr. Pruijn's statement that available research to date "does not imply that compounds leaking from implants that stay in the body for many years cannot lead to health issues". Notably, Dr. Pruijn makes this statement in reference to low molecular weight silicones and platinum. His report is silent regarding the other heavy metals identified in the list of alleged Toxins in the Second ANOCC. I have found that this statement does not comprise some basis in

fact that the alleged Toxins are either present in, or diffuse from, the Implants in sufficient quantities to cause adverse health effects.

[192] I conclude that proposed common issue #15 suffers from the same fundamental flaws as the other proposed contested common issues: it includes an unclear and potentially unlimited list of alleged Toxins that requires reference to extrinsic sources to understand.

[193] Mentor denies it has any duty to warn of the mere presence of platinum or any of the other metals or chemicals in the Implants, unless their presence poses a danger to patients. Mentor denies there is any evidence that the Implants either contain or diffuse platinum, or any of the other alleged Toxins identified in the Second ANOCC (i.e., antimony, arsenic, barium, cobalt, mercury, nickel, copper, zinc, chromium, titanium, lead, vanadium, selenium, tin, and molybdenum), in sufficient quantities that would cause adverse health effects. I agree.

[194] Mentor denies the plaintiffs assert a general causation issue linking the alleged Toxins to a particular adverse health effect: *Price* at para. 120. Rather, they say the plaintiffs ask the wrong questions and seek to go straight from common issues regarding the mere presence of the alleged Toxins in the Implants (and Mentor's knowledge of them) to a common issue regarding a negligent failure to warn, without demonstrating that any of the alleged Toxins can cause injury or harm. Mentor denies this common issue, even if answered affirmatively, would establish actionable conduct or an actionable wrong, or significantly advance the claims of class members.

[195] Plaintiffs' counsel replies that whether or not the alleged Toxins cause injury or harm is both a component of proposed common issue #15 and an issue for trial. They say the plaintiffs' evidence about their symptoms, and Mentor's implicit acknowledgment that the volatile and extractible chemicals and heavy metals in the Implants can be toxic at certain levels, comprises some basis in fact to support a common issue for a negligent failure to warn. I do not share that view.

[196] It is well-established in Canadian law that a manufacturer of a product has a duty in tort to warn consumers (subject to the learned intermediary principle) of dangers inherent in the use of its product of which it either has, or ought to have, knowledge: *Hollis* at paras. 20, 23, and 26. The conduct of a defendant is only wrong in negligence to the extent that it causes actual harm or materialized loss: *Mustapha* at para. 3; *Dussiaume* at paras. 63-64; *Atlantic Lottery Corp. Inc. v. Babstock*, 2020 SCC 19 at para. 33. Mentor denies the mere creation of risk or the potential for future injuries is actionable: *Babstock* at para. 33; *Dussiaume* at paras. 63 – 64; *1688782 Ontario Inc. v. Maple Leaf Foods Inc.*, 2020 SCC 35 at para. 44. The plaintiffs rely on their own evidence that they suffered actual injury after their breast implant surgery, and that those who had explant surgery to remove the Implants thereafter enjoyed improvement in, or resolution of, their symptoms. They deny this is a case about a future risk of harm.

[197] Plaintiffs' counsel argues that whether or not Mentor's failure to comply with the recommendations in the FDA Guidance Document (regarding disclosure of the contents of the Implants and labelling of the Implants) constitutes a breach of the duty to warn is a matter for trial. They say the presence of the alleged Toxins, their levels, and effect are all well-suited for common determination. I have found that the non-binding recommendations in the FDA Guidance Document do not comprise some basis in fact to support a common issue for a negligent failure to warn of the presence of the alleged Toxins, absent some expert evidence about what, if anything, Mentor ought to have done in response to them.

[198] A certification judge cannot perform the task of assessing a common issue if it is unclear what it means: *Martin* at para. 227. In *Martin*, the certification judge found that there must be some evidence to explain the meaning of the words, together with some evidence that the drug in question could cause related metabolic disturbances as well as secondary injuries flowing therefrom, and that this question could be assessed in common. Those comments are analogous here.

[199] The duty to warn can only arise with respect to specific risks and cannot be imposed to require a general warning of potential harm, or harm without any reference to the specific risk: *Price* at para. 150. For a risk to be material and therefore require disclosure, the cause of the injury must be known: *Price* at para. 152. The duty to warn can only arise for material risks of which a manufacturer has, or ought to have, knowledge and reasonable foreseeability is required: *Hollis* at para. 20; *Price* at para. 156.

[200] In my view, common issue #15 is not sufficiently clear to be certifiable. I accept that a manufacturer owes a duty of care to the consumers of its products: *Stanway v. Wyeth Canada Inc.,* 2011 BCSC 1057 at paras. 48–50; *James* at paras. 92-93. Warnings must be sufficiently detailed to convey a comprehensive indication of the specific dangers that can arise from use of the product: *Kirsh v. Bristol-Myers Squibb*, 2020 ONSC 1499 at para. 17; *Buchan v. Ortho Pharmaceutical (Canada) Ltd*., 25 D.L.R. (4th) 658, 1986 CanLII 114 (Ont. C.A.) at 667. The plaintiffs do not identify the specific danger they say is associated with the alleged Toxins and about which Mentor ought to have warned class members and/or surgeons.

[201] Mentor denies there is any evidence that the alleged Toxins have any adverse health impacts on recipients of the Implants. Mentor says its PIDS discloses to treating physicians, surgeons, and other healthcare professionals (i.e., the persons to whom they say a warning is required) that silicone gel, low weight molecular silicones, and/or platinum can bleed through an intact breast implant shell. Dr. Pruijn admits Mentor disclosed this information.

[202] Mentor emphasizes the highly-regulated nature of breast implants in Canada. I accept that a manufacturer's compliance with Health Canada requirements is neither determinative of the requisite standard of care, nor a defence to a product liability claim in Canada: *Heward* at para. 35; *Miller BCSC* at para. 65; *Ryan v. Victoria (City)*, 1999 CanLII 706 (SCC) at paras. 29, 39; *Krishnan BCSC* at para. 143; *Krishnan BCCA* at paras. 99-101 and 108; *Buchan* at 672. Whether compliance with Health Canada's standards means that Mentor has complied with the applicable

standard of care is a defence it can advance at a common issues trial: *MacKinnon* at para. 108.

[203] I find that proposed contested common issue #15 regarding Mentor's alleged negligent failure to warn about the presence of the alleged Toxins is not certifiable. In my view, the plaintiffs conflate Dr. Pruijn's statements about the potential adverse effects of silicones with the alleged Toxins.

[204] I find that the evidence is insufficient to comprise some basis in fact to support certification of proposed common issue #15. To the extent the plaintiffs allege a negligent failure to warn that silicones are implicated in the development of CTDs or BII, contested common issue #15 is duplicative and adds nothing to proposed uncontested common issues #5-12. The only specific risk of harm the plaintiffs plead relates to the development of CTDs and BII; proposed uncontested common issue #7 addresses that matter.

[205] I find that proposed common issue #15 is not certifiable.

b) *BPCPA* Claims

[206] Contested common issue #16 addresses the *BPCPA* claims:

#16. If the answer to #13 and/or #14 is yes, did the Defendants, or any of them, engage in conduct that constituted a "deceptive act or practice" contrary to the *BPCPA* in that regard?

[207] This question asks only whether the *BPCPA* was breached. The parties have agreed to defer issues regarding the nature and availability of remedies under the *BPCPA*.

[208] Plaintiffs' counsel describes the *BPCPA* as a separate statutory regime that is meant to be interpreted generously in favour of consumers, citing *Seidel v. Telus Communications Inc.*, 2011 SCC 15 at para. 37; *Ileman v. Rogers Communications Inc.*, 2015 BCCA 260 [*Ileman BCCA*] at para. 51. They say it is ideally suited for resolution on a class-wide basis because it focuses on the defendants' conduct.

They argue there is some basis in fact to establish that Mentor's misrepresentations were made in common to the class, that Mentor failed to disclose the presence of the alleged Toxins in the Implants, and that Mentor represented gel bleed as being of no clinical consequence. They say that Mentor nurtured a uniform narrative in its advertising and disclosure documents that would be material to any reasonable consumer: namely, that its product was safe. They reference Mentor's webpage, directed to patients, about the Implants. It states, in part, as follows:

> Are breast implants safe?
>
> Yes. Breast implants are safe and Health Canada approved. In fact, hundreds of thousands of women choose breast implants every year and report no adverse effects. But as with any medical device, breast implants carry a risk of complications. In the event any complication develops don't wait to consult your plastic surgeon. With decades of research behind our products, Mentor is committed to your safety.
>
> You can find more information on considerations and possible complications in our online brochure.

[209] The parties disagree about whether reliance is required in order to advance a consumer protection claim. Plaintiffs' counsel notes that common issue #16 relates only to Mentor's representations and omissions regarding the presence of the alleged Toxins, and whether those representations and omissions constitute deceptive acts or practices. He says that determination of whether a representation is false, misleading, or deceptive under consumer protection legislation can be made on an objective basis and does not depend on subjective factors: *Krishnan BCSC* at paras. 192-193. He says the standard is that of a reasonable consumer and not any particular consumer.

[210] Plaintiffs' counsel deny consumer protection claims require individual class members' reliance on the representations in order to establish causation: *Krishnan BCSC* at paras. 196-199, aff'd *Krishnan BCCA* at paras. 114-116; *Valeant* at paras. 232-236; *Drynan v. Bausch Health Companies Inc.*, 2021 ONSC 7423 at paras. 237-239; *Rebuck v. Ford Motor Company*, 2018 ONSC 7405 at paras. 45 and 51. They say this action fits into the category of cases where products are branded with over-arching representations made to the public: citing *Krishnan BCSC* at para. 196;

Ileman v. Rogers Communications Inc., 2014 BCSC 1002 [*Ileman BCSC*] at para. 67.

[211] In *Stanway BCCA*, a case relating to the failure to warn of the risk of breast cancer with hormone therapy, the defendant argued that the alleged deceptive acts under the *BPCPA* arose in individualized contexts and there was therefore no commonality between individual class members. Justice Gropper found that consideration of individual participation was unnecessary to determine whether Wyeth made deceptive or misleading representations. Plaintiffs' counsel here argues that intentional statements or omissions may have the capacity, tendency, or effect of misleading a consumer, as contemplated by the *BPCPA*, citing *Live Nation Entertainment, Inc. v. Gomel*, 2023 BCCA 274 [*Live Nation*] at paras. 69 - 70. He describes this as an issue for trial.

[212] Mentor argues that proposed common issue #16 is fundamentally flawed and not certifiable. It denies there is any evidence that this issue is either common to the class or could be answered without individual inquiries for each class member. It says there is no basis in fact that the plaintiffs, or any class member, reviewed or relied on any of the defendants' public representations. Defence counsel submits that whether or not Mentor's representations were material to the plaintiffs' choice of the Implants can only be answered with reference to all of the information they received before their implant surgery. They deny there is any evidence that disclosure of the presence of trace metals in the Implants would have been material to the plaintiffs. They argue that, absent evidence that the presence of trace metals in the Implants poses any risk or danger, Mentor's failure to disclose their presence in the Implants is immaterial.

[213] In response to Mentor's complaint that there is no evidence the plaintiffs or class members reviewed or relied on any of the defendants' public representations, plaintiffs' counsel highlight Ms. Bosco's evidence that the presence of the Toxins in the Implants was not disclosed to her before she had her breast implant surgery. They describe this as a common-sense proposition since Mentor did not adequately

disclose the presence of the alleged Toxins to surgeons. They rely on *N&C Transportation Ltd.* at para. 141, where the court held that evidence about how a marketing campaign and written representations are conveyed to each individual class member is not required to establish commonality where representations are made to consumers as part of a consistent, unified, written campaign.

[214] A similar objection was rejected in *Drynan* at paras. 98 and 104:

> [98] It is settled law that the test for whether a representation is an unfair practice is based on an objective consumer, not on the interpretation that each individual consumer might apply. While Drynan and the defendants disagree on the specific objective test to apply, the law is settled that the test is, at a minimum, objective and based on the reasonable person.
>
> […]
>
> [104] It is not necessary for the court on this certification motion to decide which objective standard would be used at a common issues trial to determine whether a representation was false and misleading. Regardless of whether the "reasonable person" or *Richard* test is used, there is no dispute that an objective standard is required. […]

[215] Mentor argues that given the nature of breast implants, breast implant surgery, and the individualized consultations that occur before this kind of surgery proceeds, determining whether there has been a statutory breach due to an alleged misrepresentation is impossible without first considering all the information that patients received before they decided whether to have surgery with the Implants.

[216] Mentor submits that, contrary to the plaintiffs' submissions, a claim under the *BPCPA* is dependent on proof of a causal connection between a statutory contravention and loss or damage suffered by the plaintiff: *Wakelam v. Wyeth*, 2014 BCCA 36 at para. 69; *Williamson* at para. 120; *Ileman BCCA* at paras. 50 – 51. Mentor denies the *BPCPA* creates a general duty of disclosure on manufacturers of medical devices, or usurps the learned intermediary rule.

[217] Mentor submits that neither the *BPCPA* nor the *Competition Act* contemplates strict liability. It says neither statute can provide the basis for an action or recovery unless a plaintiff received, reviewed, and relied upon the impugned representation: *Vallance v. DHL Express (Canada), Ltd.,* 2024 BCSC 140 at para. 219; *Wakelam* at

paras. 91 – 92. Mentor denies there is any evidence from the plaintiffs (or any class member) that they reviewed, much less relied on, any statement contained in its patient information brochures, company websites, or any other document. Mentor further denies there is evidence that any of the alleged Toxins are present in the Implants in dangerous quantities or cause patient harm. In the result, it says there is no basis in fact that there was any misrepresentation.

[218] Mentor distinguishes *Krishnan BCCA* on its facts and argues that highly-regulated implantable medical devices are not analogous to over-the-counter health supplements which patients can purchase directly at a retail store. Mentor denies an alleged misrepresentation in a lengthy PIDS document is comparable to product branding or a misstatement on the bottle of a health supplement.

[219] The Court of Appeal has recently reaffirmed that reliance is not always necessary to establish the required causal link pursuant to s. 171 of the *BPCPA*: *Live Nation* at para. 79; *Krishnan BCCA* at paras. 114 – 116. A deceptive act or practice pursuant to the *BPCPA* does not require actual deception: *Bowman* at para. 28, citing *Seidel* at paras. 88 – 104. The question of deception can be litigated without reference to the circumstances of the class members because the focus is on what the defendant did and the effect it was capable of having, not what effect it actually had: *Bowman* at para. 28.

[220] I am not persuaded that proof of individual reliance is required to certify the proposed *BPCPA* claims. However, this proposed common issue depends on certification of proposed common issues #13 and #14, which I have found are not certifiable. It also presumes that the alleged Toxins are present and/or diffuse from the Implants in sufficient quantities to cause adverse health effects. I have found that there is no basis in fact to support that presumption. By extension, I find common issue #16 is not certifiable.

c) *Competition Act* Claims

[221] Contested common issue #17 addresses the *Competition Act* claims:

17. If the answer to 13 and/or 14 is yes, did the Defendants, or any of them, engage in conduct which is contrary to s. 52 of the *Competition Act* in that regard?

[222] Section 52 of the *Competition Act* prohibits materially false or misleading representations to the public, which are only actionable under s. 36 of the *Act* if there is a causal connection to subsequent loss or damage: *Vallance* at para. 219.

[223] Plaintiffs' counsel argues that common issue #17 focuses on Mentor's conduct and is therefore ideally suited to resolution on a class-wide basis. He says this common question relates to whether Mentor's alleged misrepresentations regarding the alleged Toxins were false or misleading, and whether remedies are available to the class members. Mentor's arguments in response to common issue #16 parallel those it made in response to proposed common issue #15. Mentor denies s. 52 of the *Competition Act* creates a general duty of disclosure.

[224] The parties disagree about whether a claim under s. 52 of the *Competition Act* requires evidence of detrimental reliance. Plaintiffs' counsel denies such evidence is necessary, citing *Valeant* at paras. 233 – 236; *Live Nation* at paras. 110 -119. They say the *Competition Act* is concerned with representations to the public and that Mentor's advertising, patient brochures, and disclosures to surgeons were unquestionably made to the public and contain similar, if not identical, public representations. They deny any adequately discloses the presence of the alleged Toxins.

[225] A failure to disclose a non-dangerous defect cannot constitute a "representation" within the meaning of s. 52 of the *Competition Act,* the object of which is to target deceptive marketing practices, not to create liability for defective products: *Palmer* at para. 95. I am not persuaded the evidence comprises some basis in fact that the presence of the alleged Toxins in the Implants constitutes a dangerous defect. In the absence of some basis in fact that the alleged Toxins are either present or diffuse from the Implants in sufficient quantities to cause adverse health effects, I find that proposed common issue #17 is not certifiable.

4. Conclusion

[226] In summary, I conclude that while there is some basis in fact to support certification of the proposed uncontested common issues, the same cannot be said of the proposed contested common issues.

IX. SECTION 4(1)(D): PREFERABLE PROCEDURE

A. Legal Principles

[227] Section 4(1)(d) of the *CPA* requires that a class proceeding be the preferable procedure for the fair and efficient resolution of the common issues. Section 4(2) of the *CPA* outlines the non-exhaustive factors a court must consider when assessing preferability and provides as follows:

> (2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, the court must consider all relevant matters including the following:
>
> (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members;
>
> (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;
>
> (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings;
>
> (d) whether other means of resolving the claims are less practical or less efficient;
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.

[228] These are merely factors and not conditions precedent which a plaintiff must prove will be fully achieved in a class proceeding: *Bodnar v. Community Savings Credit Union*, 2015 BCCA 504 at para. 51; *Lockyer-Kash v. Workers' Compensation Board of British Columbia*, 2015 BCCA 70 at para. 54.

[229] A preferability analysis is conducted through the lens of the three principal purposes of class proceedings: judicial economy, access to justice, and behaviour modification: *Pro-Sys* at para. 137. It requires consideration of two core concepts:

(1) whether or not the class proceeding would be a fair, efficient, and manageable method of advancing the claim; and (2) whether a class proceeding is preferable to other reasonably available means of resolving the claims of class members (such as joinder, test cases, or consolidation): *Hollick* at para. 28; *Knight* at para. 24; *Finkel* at paras. 24 - 26.

B. Do questions common to class members predominate?

[230] The plaintiffs submit that the proposed common issues predominate over any individual ones which might remain after the common issues have been resolved. They say that resolution of them is essential to the recovery of each class member vis-à-vis Mentor and would thus significantly advance the claim: *Pro-Sys* at para. 140. The court must not refuse to certify a proceeding as a class proceeding merely because the relief claimed includes a claim for damages that would require individual assessment after determination of the common issues: *CPA*, s. 7(a).

[231] The plaintiffs argue that consumer protection and product liability cases generally lend themselves to class actions which do not require the court to examine evidence individual to each class member because the common issues focus on the defendants' knowledge and conduct. They say that the proposed common issues address the predominant liability issue in each class members' claim against Mentor: *Pro-Sys* at para. 140.

[232] The advantage of a class proceeding from the plaintiffs' perspective is that it does not place the burden of marshalling the resources necessary to prosecute this claim on individual plaintiffs; the advantage to the defendants is the prospect that, if the plaintiffs' case on causation is found to be lacking in merit, the claims of all class members will be disposed of in a single proceeding: *MacKinnon* at para. 162.

[233] The proposed uncontested common issues will proceed to a common issues trial. Defence counsel suggested no alternate preferable procedure for the resolution of those issues. I conclude that the general causation issues related to the proposed uncontested common issues predominate in this case and that a class action would promote judicial economy and access to justice.

C. Do individual class members have an interest in prosecuting claims?

[234] There is no evidence that any putative class member wishes to pursue their claims on an individual basis. This factor favours certification.

D. Would the class proceeding involve other claims?

[235] Plaintiffs' counsel advises that this proceeding is the only actively litigated proposed national class action concerning the Implants in Canada. The Québec class action related to overlapping subject matter has been temporarily stayed pending final judgment in this action: *Basal v. Allergan Inc.*, 2020 QCCS 3859. This factor favours certification.

E. Are there other means of resolving the claims?

[236] Plaintiffs' counsel advises that their law firm has been contacted by more than 1,000 class members to date. They say that certification would prevent a multiplicity of proceedings and promote judicial economy while offering access to justice to class members for whom individual litigation might otherwise be prohibitive.

[237] Given the complexity of the general causation issues related to the proposed uncontested common issues, I am not persuaded that there are any preferable alternatives to a class action; Mentor proposed none. This factor favours certification.

F. Would administration create comparatively greater difficulties?

[238] Section 4(2)(e) of the *CPA* requires the court to consider whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means. The plaintiffs submit that one class action is preferable to a multitude of individual claims. Absent a class proceeding, they say that hundreds to thousands of individuals would need to litigate all of the same issues independently, and that doing so would be time-consuming, prohibitively expensive, unduly strain limited judicial resources, and risk inconsistent decisions.

[239] The plaintiffs say defendants who argue that a class proceeding is not the preferable procedure must propose a realistic alternative and support it with evidence. They deny an assertion that the mere existence of alternate procedures means they are to be preferred: *Jer v. Samji*, 2013 BCSC 1671 at para. 208; aff'd *Jer v. Royal Bank of Canada*, 2014 BCCA 116.

[240] The plaintiffs argue that, if certification is denied, the likely outcome would not be multiple individual lawsuits but rather no (or very few) actions. They say that given the relatively high cost of the litigation relative to the modest value of claims, the most common barrier to pursuing such claims is (as here) an economic one: *AIC Limited v. Fischer*, 2013 SCC 69 [*Fischer*] at para. 27.

[241] Mentor denies there is evidence that any plaintiff, or other proposed class member, has experienced significant health concerns or has any economic, psychological or social barriers which impact their ability to pursue a legal claim. It denies a class proceeding would serve the objectives of judicial economy, access to justice, or behaviour modification.

[242] Ultimately, I conclude that certification of the uncontested common issues would create no greater difficulties than those likely to be experienced if relief were sought by other means.

G. What is the purpose of class proceedings?

[243] Given the allegations in the proposed uncontested common issues, I accept that a class action could advance the goals of deterrence and behaviour modification.

H. Conclusion

[244] Plaintiffs' counsel observes that Mentor advances no argument that a class proceeding is not a preferable procedure. Mentor submits that the plaintiffs bear the onus of establishing some basis in fact that a class proceeding would be the preferable procedure for the fair and efficient resolution of their claims: *Kett v. Mitsubishi Materials Corporation*, 2020 BCSC 1879 at para. 170, citing *Fischer* at

para. 48. Ultimately, having regard to the factors in s. 4(1)(d) of the *CPA*, I conclude that it would be appropriate to adjudicate the proposed uncontested common issues in common in a class proceeding.

X. SECTION 4(1)(E): REPRESENTATIVE PLAINTIFFS

[245] I next consider whether there is an adequate representative plaintiff with a proper litigation plan.

A. Adequacy of Plaintiffs

[246] To satisfy s. 4(1)(e) of the *CPA*, a proposed representative plaintiff must: (1) fairly and adequately represent the interests of the class; (2) have 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 (3) have no interest that conflicts with those of other class members on the common issues. A proposed representative plaintiff must also be a member of the defined class.

[247] A proposed representative plaintiff need not have a claim that is typical of the class, nor be the best possible representative: *Kirk* at para. 154; *Miller BCCA* at para. 75. The test for determining the adequacy of a proposed representative plaintiff is whether they have a common interest with other class members and will vigorously prosecute the action: *Miller BCCA* at para. 75; *Campbell v. Flexwatt Corp.*, 1997 CanLII 4111 (BCCA) at paras. 75 – 76.

[248] Plaintiffs' counsel say that all representative plaintiffs share a common interest with other class members and are members of the class. All had breast implantation surgery with the Implants during the proposed class period. The proposed representative plaintiffs have all sworn affidavits deposing that they are prepared to represent the interests of the class members and are aware of the duties associated with acting as representative plaintiffs in this action. None are aware of any conflicts with other class members. Plaintiffs' counsel submits that all plaintiffs clearly meet the requirements to be representative plaintiffs. He notes that a materially identical class definition was certified in *Kibalian* at paras. 31 - 32.

[249] Mentor denies the plaintiffs are appropriate representatives. It says there is no evidence that any plaintiff has a tenable claim against Mentor regarding the contested common issues relating to disclosure of the alleged Toxins. Mentor denies there is any evidence that Ms. Bosco, Ms. Marto, or Ms. Hoolsema have suffered any compensable injuries arising from the presence of platinum or any of the other alleged Toxins. I have not certified any of the proposed contested common issues.

[250] I accept that the viability of individual plaintiffs' claims is irrelevant to their qualification as representative plaintiffs: *Sweet v. Canada,* 2022 FC 1228 at para. 194. I conclude that the plaintiffs are appropriately qualified representative plaintiffs to advance the proposed uncontested common issues in this action.

B. Litigation Plan

[251] Section 4(1)(e)(ii) of the *CPA* mandates that the representative plaintiffs have a suitable plan for advancing the proceeding on behalf of the class.

[252] The purpose of the litigation plan at the certification stage is to assist the court by providing a framework within which the case may proceed and to demonstrate that the representative plaintiffs and class counsel have a clear grasp of the complexities apparent in the case at the time of certification and a plan to address them: *Koubi v. Mazda Canada Inc.*, 2010 BCSC 650 at para. 195, rev'd on other grounds 2012 BCCA 310; *Singer v. Shering-Plough Canada Inc.*, 2010 ONSC 42 at para. 223. The court need not scrutinize the plan at the certification hearing; it is expected that plans will require amendment as the case proceeds: *Fakhri et al. v. Alfalfa's Canada Inc. cba Capers*, 2003 BCSC 1717 at para. 77, aff'd 2004 BCCA 549.

[253] The plaintiffs agree with Mentor's suggestion that the parties be permitted to revisit the contents of the notice and litigation plan after certification is determined. In my view, the litigation plan is adequate at this stage.

XI. DISPOSITION

[254] In summary:

a) Proposed uncontested common issues #1 – 12 are certified; and

b) Proposed contested common issues #13 – 17 are not certified.

"Douglas J."

SCHEDULE "A"

Proposed Uncontested Common Issues

Negligence and General Causation

1. Did the Defendants, or any of them, owe a duty of care to the Class Members?

2. Is Autoimmune Syndrome Induced by Adjuvants due to silicone breast implants or Breast Implant Illness (collectively, "BII") a real disease and, if so, what are its defining characteristics?

3. If the answer to #2 above is yes, do Mentor Silicone Breast Implants have the capacity to cause the development of BII?

4. Do Mentor Silicone Breast Implants have the capacity to cause the development of the following connective tissue disorders: rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, and/or systemic sclerosis?

5. If the answer to #3 and/or #4 above is yes, did the Defendants, or any of them, breach their duty to the Class Members in their post-market surveillance and/or monitoring of the Mentor Silicone Breast Implants with respect to those conditions and if so, who, when and how?

6. If the answer to #3 and/or #4 above is yes, did the Defendants know or ought they to have known that Mentor Silicone Breast Implants have the capacity to cause the development of BII, rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, and/or systemic sclerosis, and if so, when?

7. If the answer to #3 and/or #4 above is yes, did the Defendants, or any of them, breach a duty to warn, or to adequately warn, Class Members and/or surgeons with respect to the risks of BII, rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, and/or systemic sclerosis associated with Mentor Silicone Breast Implants and if so, who, when and how?

BC Consumer Protection Claims

8. Did the Defendants' supply of Mentor Silicone Breast Implants to Class Members in British Columbia during the Class Period constitute a "consumer transaction" pursuant to the *BPCPA*?

9. With respect to the supply of Mentor Silicone Breast Implants to Class Members in British Columbia during the Class Period, are the Defendants or any of them "suppliers" pursuant to the *BPCPA*?

10. Are the Class Members "consumers" pursuant to the *BPCPA*?

11. If the answer to #3 and/or #4 above is yes, did the Defendants, or any of them, engage in conduct that constituted a "deceptive act or practice" contrary to the *BPCPA* with respect to the risks of BII, rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, and/or systemic sclerosis associated with Mentor Silicone Breast Implants?

Competition Act

12. If the answer to #3 and/or #4 above is yes, did the Defendants, or any of them, engage in conduct which is contrary to section 52 of the *Competition Act* with respect to the risks of BII, rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, and/or systemic sclerosis associated with Mentor Silicone Breast Implants?

Proposed Contested Common Issues

13. Do Mentor Silicone Breast Implants contain heavy metals and/or volatile and extractable chemicals, or other toxins as may otherwise be proven at trial (the "Toxins")?

14. Did the Defendants know or ought they to have known that Mentor Silicone Breast Implants contain the Toxins, and if so, when?

15. Did the Defendants, or any of them, fail to warn, or fail to adequately warn Class Members and/or surgeons with respect to the presence of the Toxins in the Mentor Silicone Breast Implants, and if so, who, when and how?

16. If the answer to #13 and/or #14 is yes, did the Defendants, or any of them, engage in conduct that constituted a "deceptive act or practice" contrary to the *BPCPA* in that regard?

17. If the answer to #13 and /or #14 is yes, did the Defendants, or any of them, engage in conduct which is contrary to section 52 of the *Competition Act* in that regard?

Proposed Common Issues to be deferred until after Common Issues Trial

Consumer Protection Claims for Other Provinces

18. Did the Defendants, or any of them, breach the applicable consumer protection legislation of the other (non-British Columbia) provinces and territories, including:

a) Sections 6 and 7.3 of the Alberta *CPA;*
b) Sections 6 to 8 and/or 19 (d) - (e) of the Saskatchewan *CPBPA*;
c) Sections 2 to 3 and/or 5 of the Manitoba *BPA*;
d) Sections 9(2), 14, 15 and/or 17 of the Ontario *CPA*;

e) Articles 37, 41, 53, 219 to 221 and/or 228 of the Québec *CPA*;
f) Sections 10, 11, 15 and/or 27 of the New Brunswick *CPWLA*;
g) Sections 7 to 9 of the Newfoundland and Labrador *CPBPA*;
h) Sections 2 to 3 of the PEI *BPA*;
(Together with the *BPCPA*, the "Consumer Protection Acts")?

Damages Issues

19. If the answers to #11, #12, #16 and/or #18 above is yes, do Class Members have a right to a declaration, rescission, damages, restoration, repayment of the purchase price and/or equitable relief under the Consumer Protection Acts?

20. Are Class Members "beneficiaries" who are entitled to recovery from the Defendants for health care services provided by Provincial Health Insurers ("PHIs"), for the cost of health services received by Class Members pursuant to s. 2 of the *Health Care Cost Recovery Act,* S.B.C. 2008, c. 27, including all applicable "health care services" and "future cost of health services" as defined in s. 1 and the applicable health care cost recovery legislation of the other provinces and territories?

21. Are the Defendants, or any of them, liable to pay compensatory damages to the Class Members? If so, which Defendants and in what amount?

22. If the Defendants, or any of them, breached a duty of care owed to Class Members, were the Defendants, or any of them, guilty of conduct that justifies punishment? If so, what amount of punitive damages is awarded against the Defendants, or any of them?