CITATION: Kibalian v Allergan Inc., 2022 ONSC 7116
COURT FILE NO.: CV-19-00620507-00CP
DATE: 20221221

SUPERIOR COURT OF JUSTICE - ONTARIO

RE: Takwihin Kibalian, Yeghia Kibalian, Karen Basal, and Samara Bunsko, Plaintiffs

– AND –

Allergan PLC, Allergan Limited, Allergan, Inc., Allergan USA, Inc. and Allergan Inc., Defendants

BEFORE: E.M. Morgan J.

COUNSEL: *Vincent Genova, Kate Cahill, and Anthony Leoni*, for the Plaintiffs

Peter Pliszka and Mitchell Stephenson, for the Defendants

HEARD: September 28-30, 2022

CERTIFICATION

I. Background

[1] The Plaintiffs seek certification under section 5(1) of the *Class Proceedings Act, 1992*, SO 1992, c 6 ("*CPA*").

[2] The claim alleges that the Defendants were negligent in designing, testing, marketing, labelling, distributing, and post-market surveilling of their breast implants in Canada. It further alleges that the Defendants failed to warn Canadian patients adequately about the risks of developing three different types of harms: breast implant-associated anaplastic large-cell lymphoma ("BIA-ALCL"), premature rupture of the implants, and systemic symptoms classified as Autoimmune/Inflammatory Syndrome Induced by Adjuvants ("ASIA"), sometimes known and referred to as Breast Implant Illness ("BII").

[3] In an endorsement dated March 23, 2022, I granted partial certification of this action: *Kibalian v Allergan Inc.*, 2022 ONSC 1827. That ruling arose by consent between the Plaintiff and the Defendant, Allergan Inc., in relation to those Canadians who were implanted with textured breast implants between May 31, 1999 and May 29, 2019, as well as their family members making claims in respect of their own losses due to those implants. The common issues in respect of that

partial certification are limited to those claims relating to BIA-ALCL. The balance of the Plaintiffs' claims remain to be determined here.

[4] Accordingly, the present motion focuses on certification of the claims of those who were implanted between May 31, 1999, and May 29, 2019 with any of the Defendants' breast implants in issue here, along with their family members who claim in respect of various associated harms. This includes all claims related to ASIA/BII and premature rupture and their related damages. The motion also seeks to expand the partial certification Order to ensure that the claims related to BIA-ALCL are also certified as against all Defendants.

II. Product history

[5] The present action was launched following the 2019 withdrawal from European and American markets of certain of the Defendants' breast implants. This withdrawal came in response to the increasing evidence of an association between textured breast implants and the development of BIA-ALCL. That disease is a form of cancer of the immune system that was first associated with breast implants two decades earlier, in 1997.

[6] In 1992, well before the regulatory action with respect to textured implants, all silicone-filled breast implants had been removed from the North American market due to health concerns. Other than under a Health Canada special access programme, silicone breast implants were not available for implantation in Canada until the moratorium was lifted in 2006 by Health Canada for this country and by the FDA south of the border.

[7] As a condition of being permitted to resume marketing silicone implants in North America, breast implant manufacturers – including the Defendants – were required to conduct large-scale, long-term, post-market safety studies. Any adverse events had to be regularly reported to regulators, and revised labeling had to be created which added warnings as new safety information emerged. Despite these requirements, within two years of reinstatement of silicone implants the Defendants' key 40,000-patient study had lost 40% of its participants.

[8] As for textured breast implants, the "Biocell" texturing technique was originally developed by the McGhan Corporation in the 1990s as a way of making the implants more stable and less susceptible to contraction and rupture once surgically implanted. McGhan was acquired by Allergan Inc. in 2006. The surface of a Biocell implant is textured using what is called a "salt loss" technique in which the implant is imprinted with salt crystals during manufacture which are then washed out to leave a pitted surface. McGhan (and then Allergan) marketed textured breast implants manufactured with the Biocell technique under a number of different brands and product lines.

[9] The Defendants' silicone-filled Biocell-textured implants were widely used following the lifting of the moratorium in 2006. In fact, they quickly reached the point of representing 50% of the Canadian breast implant market. Biocell implants were also available with both saline and silicone fill, and the Defendants' evidence is that approximately 49,975 Canadian patients were implanted with the textured breast implants.

III. Litigation history

[10] The Plaintiffs issued their Amended Statement of Claim on May 23, 2019. Several other proposed class actions related to Allergan breast implants were also commenced across Canada. These include a Quebec action, two different British Columbia actions, and an Alberta action. Counsel in all of the breast implant cases have reached an agreement to pursue the within Ontario action as a national class action.

[11] As indicated at the outset of these reasons, Allergan Inc. consented to certification of the proceeding as against it with respect to a more limited class of claimants than that which the Plaintiff now seeks to certify. In my Order or March 23, 2022, I certified the following classes:

> (a) All persons who, between May 31, 1999, and May 29, 2019, were implanted in Canada with one or more BIOCELL textured breast implants supplied by Allergan Inc. and enumerated in as follows:
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> > Natrelle Saline-Filled Breast Implants (Textured); Natrelle 410 Truform Silicone-Filled Breast Implants, Natrelle Silicone-Filled Breast Implants (Biocell Round), Natrelle Inspira Truform 1 (Responsive) Breast Implants (Textured Shell), and Natrelle Inspira Truform 2 (SoftTouch) Breast Implants (Textured Shell) ("Primary Class Members").
>
> and/or other silicone gel-filled breast implants supplied by the Defendants, and their estates, administrator or other legal representatives, heir or beneficiaries ("Expanded Primary Class" or "Expanded Primary Class Members"); and
>
> (b) All persons who, by virtue of a personal relationship with one or more Primary Class Member, have standing to claim damages pursuant to section 61(1) of the *Family Law Act*, RSO 1990, c. f.3, as amended, or analogous provincial legislation ("Family Class Members").

[12] At the same time, with the consent of the Plaintiff and Allergan Inc., I certified the following common issues:

> (1) Are any of the Textured Breast Implants defective in that they have the propensity to cause breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL")?
>
> (2) Did Allergan Inc. have a duty to warn the Plaintiffs and class members of a risk of developing BIA-ALCL in relation to any of the textured breast implants?
>
> (3) If so, when did that duty arise, did the content of the duty change over time between 1999 and 2019, and if so, how did it change?
>
> (4) Did Allergan Inc. fulfil that duty at the applicable times?

> (5) Did Allergan Inc.'s sale of the textured breast implants breach any of the provincial Consumer Protection Acts, and if so, when and how?
>
> (6) Does Allergan Inc.'s conduct warrant an award of punitive damages?

[13] In the motion before me now, the Plaintiffs seek certification as against all Defendants on behalf of a class that includes individuals who were implanted with textured breast implants and/or Allergan silicon gel-filled breast implants in Canada between May 31, 1999 and May 29, 2019. They do so in order to advance claims related to premature rupture of the textured breast implants and claims related to ASIA/BII for all Allergan breast implants (in addition to the already certified claims related to BIA-ALCL, including statutory misrepresentation claims under consumer protection statutes and the *Competition Act*). In other words, the Plaintiffs now seek certification of this claim in its totality as against all named Defendants.

IV. The certification test

[14] A certification motion has been called "an important screening mechanism for claims that '…are not appropriate for class actions'": *Arabi v Toronto-Dominion Bank*, [2007] OJ No 5035, at para 10 (Div Ct). That said, the focus is on whether the case is right for the *CPA* procedure, not on whether the claim is likely or not to be a winner at the end of the day.

[15] The Supreme Court of Canada has indicated that, "[t]he certification stage does not involve an assessment of the merits of the claim and is not intended to be a pronouncement on the viability or strength of the action": *Pro-Sys Consultants Ltd. v Microsoft Corporation*, [2013] 3 SCR 477, at para 102. Instead, "the certification stage focuses on the *form* of the action": *Hollick v. Toronto (City)*, [2001] 3 SCR 158, at para 16 [emphasis in original].

[16] The statutory test for certification is well-known and is set out in a step-by-step analysis in subsections 5(1)(a) through (e) of the *CPA*. That step-by-step process will be followed below.

(a) Section 5(1)(a) – causes of action

[17] The cause of action analysis under section 5(1)(a) of the *CPA* sets a very low bar for plaintiffs, and generally follows the "plain and obvious" test: *R. v. Imperial Tobacco Canada Ltd*., [2011] 3 SCR 45, at para 16. That test, which is the same as applies to pleadings motions under Rule 21 of the *Rules of Civil Procedure*, is applied on the basis of the pleadings alone, without reference to an evidentiary record: *Hollick*, at para 25. It provides that only "[i]f it is plain and obvious that the action is certain to fail because it contains some such radical defect, then the…statement of claim may properly be struck out": *Hunt v. Carey Canada Inc*., [1990] 2 SCR 959.

[18] As Plaintiffs' counsel set out in their factum, the causes of action pled here are well established. These include:

> i) Negligence in the design, testing, manufacturing, marketing, distribution and post-market surveillance of the Allergan Breast Implants, and in failing to warn of the risks of BIA-ALCL, ASIA/BII and rupture; and,

ii) Breach of the misrepresentation provisions of provincial consumer protection legislation and the federal *Competition Act* vis-à-vis the failure to warn of the risks of BIA-ALCL, ASIA/BII and rupture.

[19] Turning first to negligence, the claim asserts that the Defendants were negligent in the design, development and/or testing of the breast implant products in issue. The Plaintiffs plead that it was reasonably foreseeable that a failure by the Defendants in the design, development and/or testing of the implants would in a material way cause, contribute to, or increase the risk of harm to patients implanted with them.

[20] The Plaintiffs also allege that the Defendants breached a duty of care owed to the Plaintiffs (and to all class members) by failing to ensure their breast implants did not create a substantial likelihood of harm and by failing to adequately test their implants in a way that would reveal the nature and extent of that risk of harm. In addition, the claim alleges that the Defendants failed to implement design changes when safer and economical alternative designs existed. It also alleges that the Defendants disregarded reports of adverse symptoms from patients, and that they failed to monitor and initiate appropriately timely review of such adverse reports.

[21] The claims advanced by the Plaintiffs under Ontario's *Consumer Protection Act* and analogous legislation elsewhere in Canada, posit that the Plaintiffs and class members are entitled to damages for their loss of the "benefit of the bargain" that they anticipated when they acquired their defective breast implants. The pleading sets out that all of the class members bargained for breast implants with the safety and reliability represented by the Defendants in their product pamphlets and in materials made available to physicians. The Plaintiffs claim that class members instead received dangerously defective breast implants that were unfit for use and that were acquired as a result of the Defendants' misrepresentations.

[22] Prior cases have held that where the representations are false or misleading, a statutory cause of action is available: g. *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260, at para 80. Further, a failure to state a material fact is sufficient to ground a claim since the failure can be a misrepresentation or an unconscionable representation: *Matoni v. C.B.S. Interactive Multimedia Inc. (Canadian Business College)*, 2008 CanLII 1539 (SCJ).

[23] In fact, the cases establish that there is no difference between a misrepresentation based on a false representation and a misrepresentation based on the omission of a material fact: *Wright v. United Parcel Service Canada Ltd.*, 2014 ONSC 1008. Moreover, under consumer protection statutes the question of whether a representation is inaccurate or misleading is an objective one that is susceptible to being advanced on a class-wide basis: *Rebuck v. Ford Motor Co.*, 2018 ONSC 7405, at para 31.

[24] The Plaintiffs also put forward claims under the *Competition Act* based on the same alleged misrepresentations as described above. The misrepresentation provisions under the *Competition Act* carry with them a requirement of actual knowledge or recklessness by the Defendants; in all other respects they are otherwise similar to the provincial consumer protection legislation.

[25] Further, pursuant to section 52 of the *Competition Act*, it is not necessary to prove that a person was, in fact, misled or deceived in order to establish an actionable misrepresentation or to obtain damages: *Krishnan v. Jamieson Laboratories Inc*., 2021 BCSC 1396, at para 64. Moreover, although causation must be proven, a causal connection between the alleged breach of section 52 and the damages claimed under section 26 of the *Competition Act* can be inferred from the circumstances: *Rebuck*, at paras 33-34; *British Columbia v Apotex Inc.*, 2022 BCSC 1, at para 147.

[26] Plaintiffs' counsel submit in respect of all of these causes of action, but in particular in respect of the statutory claims, that there is a pressing and socially important interest in opening the remedies to a broader set of claim categories, allowing consumers to mitigate the costs of managing the risks posed by dangerously defective medical devices, particularly where the cost of the medical device in question is borne by the patient. I would agree. As with novel causes of action, "The fact that the case the plaintiff wishes to present may involve complex issues of fact and law or may raise a novel legal proposition should not prevent a plaintiff from proceeding with his action": *Hunt, supra*.

[27] Finally, the Plaintiffs plead the subrogated claims of the provincial and territorial health insurers pursuant to Ontario's *Health Insurance Act* and analogous provincial legislation. Under this heading, the claim for their expenses incurred in the delivery of insured services to class members arising from injuries caused by the Defendants' breast implants. The Plaintiffs also put forward claims on behalf of the family members of injured class members under Ontario's *Family Law Act* and analogous provincial legislation. There is a recognized legislative basis and ample precedent for these claims as pleaded here.

[28] All of the causes of action contained in the Plaintiffs' pleading meet the section 5(1)(a) test. They are sufficiently pleaded for certification of this action.

b) Section 5(1)(b) – identifiable class

[29] Plaintiffs' counsel has set out a class definition that expands on the definition used in my previous partial certification Order. The expanded definition is:

> (a) All persons who, between May 31, 1999 and May 29, 2019, were implanted in Canada with one or more Biocell textured breast implants enumerated as follows:
>
> > Natrelle Saline-Filled Breast Implants (Textured); Natrelle 410 Truform Silicone-Filled Breast Implants, Natrelle Silicone-Filled Breast Implants (Biocell Round), Natrelle Inspira Truform 1 (Responsive) Breast Implants (Textured Shell), and Natrelle Inspira Truform 2 (SoftTouch) Breast Implants (Textured Shell).
>
> and/or other silicone gel-filled breast implants supplied by the Defendants, and their estates, administrator or other legal representatives, heir or beneficiaries ("Expanded Primary Class Members");

and

> (b) All persons who, by virtue of a personal relationship with one or more Expanded Primary Class Members, have standing to claim damages pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c. f.3, as amended, or analogous provincial legislation ("Expanded Family Class Members").

[30] It is well established that class membership must be determinable in accordance with objective criteria that do not depend on the merits of the claim: *Western Canadian Shopping Centres Inc. v. Dutton*, [2001] 2 SCR 534, at para 38. The class membership must not be unlimited, but rather must be construed as narrowly as possible without arbitrarily excluding any person who shares an interest in the resolution of the common issues: *Hollick*, at paras 17, 20-21.

[31] Furthermore, the class members must have a rational connection to the proposed common issues, although since the merits are not at issue in certification the definition is not required to be limited to only those whose claims will succeed: *Hollick*, at para 19; *Frohlinger v. Nortel Networks Corporation*, 2007 CanLII 696, at paras. 23-28 (SCJ). Additionally, class members need not have identical claims, although the parameters of the class must be such that all members' claims would be advanced by resolution of the common issues: *Sankar v. Bell Mobility*, 2013 ONSC 5916, at para. 57.

[32] As with the class definitions previously certified for this action, the definitions put forward here by class counsel are fashioned to allow class members to identify themselves. At the same time, they provide independent and objective criteria for inclusion in the class. The definitions do not rely on the merits of the claim in determining who is in and who is out, nor do they reference the merits of any individual class member's particular claim. There is a rational connection between the class definitions and the proposed common issues as drafted and as discussed below.

[33] The expanded class definitions proposed by the Plaintiffs meet the criteria for certification contained in section 5(1)(b) of the *CPA*.

c) Section 5(1)(c) – common issues

[34] In addition to the common issues previously certified, the Plaintiffs seek the certification of the following common issues:

Negligence and Failure to Warn Issues

> (1) Did the Defendants, or any of them, owe a duty of care to the Expanded Primary Class Members, and if so, who, when and how?
>
> (2) Were the Allergan breast implants defective or unfit for their intended use due to a propensity to cause and/or materially contribute to the development of rupture and/or ASIA/BII?

(3) If the answer to question (2) is yes, did the Defendants, or any of them, know or ought they to have known that the Allergan breast implants were defective or unfit for their intended use and if so, who and when?

(4) Did the risks of BIA-ALCL, rupture and/or ASIA/BII arise due to any of the Defendants' negligent design, manufacture, testing, and/or post-market surveillance and/or monitoring of the Allergan breast implants?

(5) Did the Defendants, or any of them, breach their duty to the Expanded Primary Class Members in their design, manufacturing, testing and/or post-market surveillance of the Allergan breast implants and if so, who, when and how?

(6) Did the Defendants, or any of them, fail to warn, or fail to adequately warn, Expanded Primary Class Members and surgeons with respect to the risks of rupture, and/or ASIA/BII associated with the Allergan Breast Implants and if so, who, when and how?

Consumer Protection and Competition Act Issues

(7) Did the Defendants, or any of them, make false, misleading, deceptive, and/or unconscionable representations about the Allergan breast implants contrary to provincial consumer protection legislation, and if so, who, when and how?

(8) Did the Defendants, or any of them, make false and misleading representations and/or omissions about the risks posed by the Allergan breast implants contrary to s. 36 and s. 52 of the *Competition Act*, RSC 1985, c.34, and if so, who, when and how?

Damages Issues

(9) Are Expanded Primary Class Members "insured persons" who are entitled to recovery from the Defendants for the cost of health care services provided by Provincial Health Insurers ("PHIs"), in relation to which PHIs have a subrogated interest pursuant to s. 30(1) of the *Health Insurance Act*, RSO 1990, c. H-6, including all applicable "insured services" as defined in s. 1 therein and pursuant to the related applicable health care cost recovery legislation of the other Provinces and Territories?

(10) Do monitoring and testing procedures exist which make early detection of BIAALCL, rupture, and/or ASIA/BII associated with

> Allergan breast implants, or some of them, possible and reasonably beneficial?
>
> (11) If so, do the Expanded Primary Class Members or any of them have an increased need for medical and testing procedures for early detection of BIA-ALCL, Rupture, and/or ASIA/BII associated with the Allergan breast implants?
>
> (12) If so, and if the Defendants, or any of them, are liable for any or all of the breaches alleged by the Plaintiffs, are the Defendants, or any of them, required to fund, or otherwise compensate Expanded Primary Class Members for, the costs of operating and administrating an adequate system for health monitoring to screen for BIA-ALCL, rupture, and/or ASIA/BII associated with Allergan breast implants?
>
> (13) Are the Defendants, or any of them, liable to pay compensatory damages to the Expanded Class Members? If so, which Defendants and in what amount?
>
> (14) Can the value of any or all of the claims of the Expanded Class Members, including compensation for medical monitoring, compensation for a 'base level' of physical and/or psychological harm, compensation for removal of Allergan breast implants, and damages or refunds pursuant to the *Competition Act* and/or applicable consumer protection legislation, be assessed on an aggregate basis?
>
> (15) Is the gain-based remedy of disgorgement for wrongful conduct available to the Expanded Class Members and if so, can this be assessed on an aggregate basis?

[35] With respect to the proposed common issues dealing with negligent design, the Plaintiffs must be shown to have a "plausible methodology" capable of proving, on a class wide basis, that the impugned design is capable of causing the harms alleged by the Plaintiffs: *Vester v. Boston Scientific Ltd*., 2017 ONSC 1095, at para 64. The methodology must also be capable of establishing and that an alternative and economical design existed which would have avoided the harms alleged in the claim: *Price v Smith & Wesson Corp*. (2021), 154 O.R. (3d) 675, at para 92.

[36] To be clear, "the Plaintiffs need not prove every scientific aspect of their case at the certification stage. What they must establish is that they have a 'plausible methodology' for analyzing the issues, and expert evidence that will support that methodology": *Kirsh v. Bristol-Myers Squibb,* 2020 ONSC 1499, at para 63, citing *Pro-Sys*, *supra*, at paras 125-6.

[37] The Plaintiffs do not, however, have to demonstrate that all expert opinion is in their favour; disputes among experts are not to be resolved at this stage, but rather are to be left for trial: *Kirsh*, at paras 64-65. The Plaintiffs' evidence can even appear to be weak compared with the Defendants', but the certification test will nevertheless be passed. The Plaintiffs need to show that

there is, "literally, *some* basis in fact" to support their claim; they do not have to present a convincing basis as long as there is *something* in the evidentiary record for them to go on: *MacKinnon v. Volkswagen Group Canada Inc*., 2022 ONSC 5501, at para 43 (Div Ct).

[38] Plaintiff's expert, immunologist and internal medicine specialist Dr. Jan Willem Cohen Tervaert of University of Alberta, has opined that a causal relationship between implantation with silicone-containing breast implants and ASIA/BII is biologically plausible. In his expert report, Dr. Cohen Tervaert explains that ASIA (and the related U.S. terminology BII) is what he calls an "umbrella" syndrome describing the phenomenon of "adjuvants" – compounds foreign to the body which provoke an immune reaction – which cause systemic "autoimmune pathogenesis".

[39] Thus, the existence of ASIA in a patient suggests an underlying adjuvant-induced autoimmunity, which involves a significant foreign body cell reaction. That reaction, in turn, can prompt an enhanced immune response that ultimately becomes a systemic autoimmune disease.

[40] Dr. Cohen Tervaert goes on to observe that it is long established that silicone and silicone-containing medical devices, including breast implants, can act as adjuvants. The symptoms of this autoimmune disease generated in response to these adjuvants include chronic fatigue, myalgia, arthralgia, neurological and skin manifestations, sicca (dry eyes and mouth), cognitive impairment, and fever. Those, in turn, can evolve into well defined autoimmune diseases such as lupus, multiple sclerosis, rheumatoid arthritis, etc. Removal of the adjuvant – i.e. the breast implant – will, according to Dr. Cohen Tervaert, often resolve all symptoms, although patients with evolved diseases will generally require immune-suppressing drugs or other treatments.

[41] As for the set of symptoms known as ASIA/BII, Plaintiffs' experts are among a small minority of physicians who view this as a coherent phenomenon at all, let alone one for which causation can be identified. Evidence produced by the Defendants shows that much of the medical community considers ASIA to be an amalgam of many disparate symptoms, none of which are unique to ASIA, and for which there are overarching diagnostic criteria.

[42] Defendants' counsel point out that the U.S. Food and Drug Administration ("FDA"), for example, is of has taken the public position that ASIA/BII "is not recognized as a formal medical diagnosis and there are no specific tests or recognized criteria to define or characterize it." One of the Plaintiffs' own experts, Dr. Nicholas Carr, a Vancouver-based plastic surgeon, has conceded in cross-examination that an authoritative study by the Institute of Medicine in the U.S. showed that there is no evidence of an association between silicone breast implants and auto-immune systemic symptoms, and that these findings are the official view of the medical community.

[43] Dr. Cohen Tervaert, on the other hand, opines in his report that one can apply to the epidemiologic evidence of ASIA/BII a set of analytic focal points known as the "Bradford Hill" criteria used in this field to deduce causation. These criteria include: strength (based on a large number of case reports), consistency (demonstrated by multiple independent researchers studying distinct patient populations), specificity (specific cluster of symptoms typical of ASIA/BII), temporality (the emergence of ASIA/BII following implantation), coherence and plausibility (the response to adjuvants described above), and experiment (the "challenge-dechallenge" experience of breast implant removal described above).

[44] The Defendants argue, and in reading the literature one must concede, that all of this is exceedingly controversial. Their expert, Dr. Daniel Clauw, a Professor of anesthesiology, rheumatology, and psychiatry at the University of Michigan, explains that the existence of ASIA is itself not recognized by the mainstream medical community as anything other than a coming together of unrelated symptoms. Counsel for the Defendants goes so far as to call the ASIA/BII diagnosis "junk science". They support this label by pointing to an editorial response published by senior FDA official Binita Ashar in the journal Annals of Surgery taking issue with studies elaborating on the ASIA theory and its association with breast implants.

[45] The FDA response, however, concedes that the matter is still under ongoing study and that it remains a developing area of research and scientific debate. Dr. Ashar's editorial states, among other things, that the ASIA theory regarding the risks associated with breast implants "should be viewed with caution". She then concedes a number of points regarding the risks of breast implants with which Plaintiffs' experts concur:

> While many patients with breast implants are satisfied, there are important risks that FDA continues to communicate to the public. Patients who are considering breast implants should be aware that:
>
> - Breast implants are not lifetime devices and the longer the patient has the implants, the more likely they are to experience local complications and adverse outcomes requiring breast implant removal.
>
> - Local complications and adverse outcomes include capsular contracture, reoperation, removal, and implant rupture. Many patients also experience breast pain, wrinkling, asymmetry, scarring, and infection.
>
> - Breast implants are associated with BIA-ALCL, a cancer of the immune system. While most patients with BIA-ALCL may be treated only with breast implant removal, some patients have required radiation therapy, chemotherapy, or both, and some patients have even died from BIA-ALCL.
>
> - At the present time, there is not sufficient evidence to show an association between breast implants and rheumatological or connective tissue diseases.
>
> The FDA remains committed to thoughtful, scientific, transparent, public dialogue concerning breast implant safety and effectiveness.

[46] For the majority of the scientific community to advise that a minority of scientists' opinion on a subject should be viewed "with caution" is not to say that there is no basis in fact for the minority view. It says that the matter – much like conflicting expert reports in many contentious court cases – is one of ongoing research and debate. Indeed, Dr. Ashar says as much herself. Although she critiques the methodological shortcomings that have led to conclusions embraced by by the Plaintiffs, she prefaces her remarks by acknowledging on behalf of the FDA that, "We commend efforts to better understand the benefits and risks of breast implants."

[47] It is evident from this pronouncement and from a review of the scientific literature in the record that research on the autoimmune phenomenon that Plaintiffs' experts associate with breast implants continues apace. There is a majority view and a minority view, the former embraced by the Defendants here and the latter by the Plaintiffs. As the FDA statement indicates, even the minority view contributes to the current understanding of the benefits and risks of the products in issue.

[48] In this light, it bears repeating that, "The requirement that there be an evidentiary foundation – or some basis in fact – to support the certification criteria does not include a preliminary merits test…": *2038724 Ontario Ltd. v. Quizno's Canada Restaurant Corp.* (2009), 96 OR (3d) 252, at para 74 (Div Ct). A certification motion is simply "not the time for finely calibrated assessments of the expert opinions": *Darmar Farms Inc. v. Syngenta Canada Inc.*, 2021 ONSC 6411, at para 90. As the Divisional Court has recently put it, "[t]he issue is merely whether the experts present a plausible – indeed, even a barely plausible – methodology; not whether it will ultimately work": *MacKinnon*, *supra*, at para 35.

[49] While I acknowledge the substantial critique and debate, in my view there is sufficient evidence in the record before me to conclude that there is "some basis in fact" which justifies the common issues dealing with negligent testing and design of breast implants. There are, as Dr. Ashar's editorial highlights, significant methodological disagreements with the Plaintiffs' experts; indeed, the Defendants may have demonstrated through their own expert reports that the Plaintiffs' theory is not likely to succeed. But as already explained, potential success is not the test.

[50] The record does not show that there is nothing plausible on the Plaintiffs' side. To the contrary, the views expressed by Dr. Cohen Tervaert and other scientists with minority views on ASIA and causation are recognized as contributions even if disagreed with. That suggests a methodological approach that, while not adopted by many, is nevertheless at least plausible.

[51] The onus on the Plaintiffs at this stage is not a strenuous one, and the evidentiary threshold they must cross is not high. It demands more than a leap of faith, but can be passed with a meagre bound. With their expert evidence, which is concededly controversial among scientists, the Plaintiffs have managed to step over that threshold and satisfy the onus.

[52] Turning to the proposed common issues pertaining to the claim of failure to warn, the claim turns on how one views the strength of the advisory that appears on the "Directions for Use" of the implants in issue. The 2018 Directions, now included with the Defendants' textured implants line that is most strongly connected with autoimmune conditions, states in important part:

> There have been reports in the literature of other conditions in women with breast implants. Many of these conditions, which are listed below, have been studied to evaluate their potential association with breast implants. There is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants…
>
> Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. There have been a number of published epidemiological

> studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The most recent of these concluded that the weight of the evidence did not support causal association between implants and definite or atypical CTD. The study size needed to conclusively rule out a smaller risk of connective tissue disease would need to be very large. Published studies taken together show that breast implants are not significantly associated with a risk of developing a specific CTD. These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific CTD diagnoses and symptoms in women with silent ruptured versus intact implants, but the study was too small to rule out a small risk.

[53] Dr. Cohen Tervaert has opined that this information is inaccurate and would mislead people with respect to the true nature of the risks. In September 2020, the FDA issued updated industry guidance on breast implants recommended a "black-box" warning to accompany breast implant packaging that highlights the risks associated with implants, as follows:

> WARNING:
> • Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
>
> • Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
>
> • Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

[54] Plaintiffs' counsel note that the labelling for the breast implants produced and marketed by the Defendants that remain on the Canadian market does not include any similar language warning related to "systemic symptoms". Likewise, as Plaintiffs' expert Dr. Carr opines, there is evidence that the Defendants have never accurately reported the rates of rupture or the prematurity of those ruptures.

[55] Given that there is some basis in fact for finding that those systemic symptoms exist, there is equally some basis in fact for faulting the Defendants for not warning of them. Again, the test that the Plaintiffs must meet is not whether this basis in fact is strong or weak, but rather whether it exists at all.

[56] Turning to the common issues addressing the *Consumer Protection Act* and *Competition Act* claims, a similar analysis to the above can be applied. Under the consumer protection statutes,

breast augmentation and reconstruction patients were "consumers", their implants were acquired pursuant to "consumer agreements", and the Defendants' alleged failures to warn were, if proved, "unfair practices" giving rise to liability under s.18 of the *Consumer Protection Act* and analogous provincial statutes.

[57] Similarly, under the *Competition Act*, the alleged failures to warn would be, if proved, false and misleading in the material respect of the implants' safety. Plaintiffs allege they were made to the public to promote the Defendants' breast implant products, and were made either knowing of the risks or recklessly disregarding them.

[58] The Amended Statement of Claim specifically identifies the Defendants' representations made in the 2014, 2015 and 2018 Directions for Use documents, the 2015 and 2016 product catalogues, the 2008 and 2018 patient brochures, a 2018 patient "surgery planner", and information contained on the Defendants' website. These are alleged to reflect a failure to warn of the true extent of the risk of BIA-ALCL, ASIA/BII, and rupture posed by the Defendants' breast implants.

[59] In short, given the nature of the common law claims the statutory claims make logical sense to advance. The factual basis on which they are premised may or may not be a strong one, but some basis in fact does exist.

[60] The balance of the proposed common issues are related to damages. These are framed in a way that flows directly from the common law and statutory liability claims. If substantive claims are appropriate for answering on a common basis, so are the damages questions that are posed as a result of the substantive claims. Needless to say, damages are remedial and the questions related thereto are only relevant in the event that liability is first found to exist.

[61] The proposed common issues related to compensatory damages pose questions that all of the named class have in common; accordingly, answering them in common will serve to advance the case. As Plaintiffs' counsel point out in their submissions, the availability of an aggregate assessment of damages is one of the CPA's "means of avoiding the potentially unconscionable result of a wrong eluding an effective remedy": *Markson v. MBNA Canada Bank*, 2007 ONCA 334, at para 42.

[62] An aggregate assessment of damages such as envisioned in the proposed common issues is made available by sections 23 and 24 of the *CPA*. These provisions make clear that there must be a reasonable likelihood, that damages need not be addressed on an individualized basis: *Vezina v. Loblaw Companies Ltd*., [2005] OJ No 1974, (SCJ). That appears to be the case here with all class members making claims for similar symptoms from a common cause. That said, the ultimate decision of whether aggregate damages are awarded is, of course, left to the trial judge: *Serhan Estate v. Johnson & Johnson* (2006), 85 OR (3d) 665, at para 139 (Div Ct).

[63] The common issues proposed by the Plaintiffs also pose questions relating to subrogated claims by provincial health insurance plans, as well as claims relating to ongoing medical monitoring of class members. These are also appropriately addressed on a common basis for all class members. Thus, for example, whether the Expanded Primary Class Members are found to be "insured persons" who must seek recovery of the cost of insured services provided by provincial

insurers is a question that will be answered the same way for every member. Its answer, in turn, will advance that aspect of the claim dealing with the right of public health insurers to recover expenses incurred treating Expanded Primary Class Members for the alleged breast implant-related harms.

[64] The same holds true with respect to the cost of ongoing medical monitoring borne by health insurers. The answers to the relevant common issue questions will significantly advance the claims of the health insurers by determining whether class members are statutorily required to protect and advance them. These are appropriate common issues under the circumstances of the within claim.

d) Section 5(1)(d) – preferable procedure

[65] In order to be certified, the *CPA* requires a class proceeding to be the preferable procedure for the resolution of the claims. This entails asking whether a class proceeding would be a fair, efficient and manageable method of resolving the claim": *Shah v. LG Chem, Ltd.* (2018), 142 OR (3d) 721, at para 18 (Ont CA). Moreover, to meet the test of preferability, the Plaintiffs must show that litigation on a class-wide basis will serve the goals of access to justice, behaviour modification and judicial economy: *Hollick*, *supra*, at para 30.

[66] Numerous medical products liability cases have been certified in Ontario, with the class action mechanism contributing greatly to their resolution. In the present circumstances, it is difficult to imagine an alternative procedure that would be preferable from an access, efficiency, and fairness perspective.

[67] The Defendants themselves have not shown that they have in mind another preferable procedure; in fact, all they have managed to do in this regard is to identify a small handful of individual claims that have been filed but not advanced beyond the initial stage. Chief Justice Winkler pointed out in *1176560 Ontario Limited et al. v. The Great Atlantic & Pacific Company of Canada Limited* (2002), 62 OR (3d) 535, at para 27, that the availability of individual legal actions does not make them the preferable procedure absent concrete proposals as to how that preferability will play out.

[68] More specifically, "[a]ccess to justice is extended to persons who may have been injured by a defective product. There would be a very significant cost to any claimant pursuing an individual claim given the tremendous complexities of evidence and issues": *Wilson v. Servier Canada Inc*. (2000), 50 OR (3d) 219, at para 124 (SCJ). In the same sense, judicial economy is served by the class procedure in that it avoids the courts being clogged with hundreds of similar or identical claims.

[69] Finally, behaviour modification can be more effectively achieved by a class proceeding than by individual proceedings that may or may not go ahead depending on the individual plaintiff's means. In this respect one of the *CPA*'s most important goals is achieved by certifying the claim. That goal has been described as putting an end to "misconduct by those who might ignore their obligations to the public": *Ibid.*, at para 126.

[70] Given that the most fundamental goals of the *CPA* are satisfied by a class proceeding here, I see no reason that it is not preferable here to all other available procedures.

e) Section 5(1)(e) – representative Plaintiffs

[71] As required by section 5(1)(e) of the *CPA,* the representative Plaintiffs are motivated and imbued with "independence and loyalty to the class": *Sondhi v. Deloitte,* 2018 ONSC 271, at para. 59. There are no apparent conflicts of interest, the litigation plan submitted by them appears workable, and they have been fully engaged in instructing counsel and fashioning the case. While the claim may have a different impact on different class members, including the Representative Plaintiffs, difference is not in itself a conflict: *Elwin v. Nova Scotia Home for Colored Children*, 2013 ONSC 411, at para. 152.

[72] Under the circumstances, I see no reason to conclude anything other than that the current Plaintiffs are appropriate as representatives of the class.

V. Proper parties

[73] The Defendants contend that Allergan Inc., the Canadian operating company that distributes breast implant products in Canada, is the only proper Defendant. They submit that the other Defendants are within the same family of companies, but that they represent parent holding companies or U.S.-based operating and marketing companies that do not operate in Canada.

[74] The Plaintiffs respond to this by stating that it is the theory of their case that all of the corporate entities that make up the Defendant family were involved in researching, developing, marketing breast implants in Canada as elsewhere, and that the overall corporate strategy of this enterprise involves each of the named Defendants. They further contend that the Defendants have failed to produce evidence with respect to the functions of each of the Defendant entities, and as a result their assertions about the propriety of naming them as Defendants cannot be tested or adjudicated on at this stage.

[75] I agree with the Plaintiffs that the argument as to which of the Defendants might be improperly included in this action is premature. It may well become apparent at a later stage, on a more complete record, that one or more of the Defendants should be let out of the action. At present, prior to discovery, it is not possible to determine which of the related corporate entities is responsible for design and manufacture of the various products in issue or, as Plaintiffs' counsel put it, where one corporate Defendant's function ends and another's begins.

[76] For certification purposes, I will therefore take as a given that the Defendants act as one intertwined corporate enterprise as described by the Plaintiffs: see *Klaus v Black Diamond Equipment Ltd*., 2022 BCSC 1182, at para 36. There is simply not a sufficient record to proceed otherwise at this juncture.

VI. Disposition

[77] The action is hereby certified against all Defendants pursuant to section 5(1) of the *CPA*. The class is as set out in paragraph 29 above. The common issues are as set out in paragraph 34 above.

[78] The parties may make written submissions on costs. I would ask counsel for the Plaintiffs to send brief written submissions by email to my assistant within two weeks of the date hereof, and for counsel for the Defendants to send equally brief submissions by email to my assistant within two weeks thereafter.

Date: December 21, 2022 Morgan J.