CITATION: O'Brien v. Bard Canada Inc., 2015 ONSC 2470
COURT FILE NO.: CV-15-523068CP
DATE: 20150416

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:	)	
DONNA O'BRIEN and ADAM PEARCE Plaintiffs	)	*Michael J. Peerless* and *Matthew D. Baer* for the Plaintiffs
– and –	)	
BARD CANADA INC., C.R. BARD, INC. and BARD MEDICAL DIVISION Defendants	)	*Michael A. Eizenga, Gavin H. Finlayson,* and *Ashley L. Paterson* for the Defendants
Proceeding under the *Class Proceedings Act, 1992*	)	**HEARD:** March 25-26, 2015

PERELL, J.

REASONS FOR DECISION

A. INTRODUCTION

[1] Pursuant to the *Class Proceedings Act, 1992*, S.O. 1992, the Plaintiff Donna O'Brien and her spouse, the Plaintiff Adam Pearce, move for certification of a products liability class action against the Defendants Bard Canada Inc., C.R. Bard, Inc., and Bard Medical Division, (collectively "Bard"). Ms. O'Brien sues on behalf of women who were implanted with Bard branded "Pelvic Mesh Products" that were used to treat "pelvic organ prolapse" ("POP") or "stress urinary incontinence" ("SUI").

[2] The non-party Bard Davol Inc., a subsidiary of C.R. Bard, Inc., manufactures "Marlex Mesh," which was mentioned as a Pelvic Mesh Product for the first time in Ms. O'Brien's factum. No motion, however, was made to add Bard Davol Inc. as a party defendant, and it would be procedurally unfair to include it and its product, which is normally used to treat abdominal hernia, in this certification motion. Therefore, in these Reasons for Decision, save for one matter - the acquisition of Marlex® Polypropylenes from Phillips Sumika Polypropylene Company - I shall not refer to Bard Davol Inc. or to Marlex Mesh.

[3] Ms. O'Brien's proposed class action involves multiple products (19) manufactured and sold by Bard. Although the products are not identical and are different in: materials; shape; size; weight; density; weave; porosity; flexibility; configuration; fixation methodology; design

purposes; and, product warnings; and although the products' uses are dependent on the idiosyncratic factors of: patient health circumstances; different types of POP and SUI; and, idiosyncratic surgeon training, experience, judgment, and treatment preferences, all the Bard products include permanent surgical mesh as a fundamental component and all the products are designed for the treatment of POP or SUI.

[4] Ms. O'Brien and Mr. Pearce submit that the action is quintessentially appropriate for a class action.

[5] As might be expected, Bard submits that this proposed products liability class action is quintessentially unsuitable for a class action. Bard submits that none of the certification criteria are satisfied because the proposed class action is a multiple products liability action that wants for any commonality for the proposed common issues. Bard submits that Ms. O'Brien's failure to identify a singular (common) design defect across Bard's multifarious medical products designed for different ways to treat POP and SUI means that there is no basis-in-fact for the certification criteria and Ms. O'Brien's proposed class action cannot be certified.

[6] Bard submits because there is no basis-in-fact for finding that its multifarious medical products have a common design defect, a trial judge would be unable to make legally meaningful findings about the reasonableness of Bard's conduct at any point in time. Bard submits that certification would be unfair because it would impede its right to raise defences for different product systems manufactured at different times for different circumstances that have different risks and benefits.

[7] Bard also raises discrete non-commonality challenges to the cause of action, class definition, and preferable procedure criteria.

[8] While I do not agree with all of Bard's arguments, I do agree that Ms. O'Brien's proposed class action does not satisfy the test for certification. For the reasons that follow, subject to what I shall describe as an "Alternatives Motion," I dismiss Ms. O'Brien's and Mr. Pearce's certification motion.

[9] To be clear, I am dismissing the certification motion. The Alternatives Motion, which has the resources of the *Class Proceedings Act, 1992* including s. 5(4) (adjournment of certification motion), s.7 (refusal to certify: proceeding may continue in altered form), s. 12 (court may determine conduct of proceeding), s.13 (court may stay any other proceeding), s. 17(3)(4) and (5) (order respecting notice), s. 19 (notice to protect interests of affected persons), s. 29 (discontinuance, abandonment and settlement), and s. 35 (rules of court), is for the purpose of determining whether Ms. O'Brien's and Mr. Pearce's action may continue as one or more consolidated actions or one or more proposed discrete products liability class actions or in some newly devised procedure for a mass claim.

B. LEGAL, EVIDENTIARY AND FACTUAL BACKGROUND TO MS. O'BRIEN'S PROPOSED CLASS ACTION

1. Design Negligence and Duty to Warn Products Liability Actions

[10] Ms. O'Brien's action is a proposed products liability class action of a potentially dangerous medical device. In order to understand the parties' arguments about the suitability of

her action as a class proceeding, it is necessary to briefly review the law about products liability claims.

[11] For products liability claims, there are four established categories. First, manufacturers have a duty of care to consumers to see that there are no defects in manufacture that are likely to give rise to injury in the ordinary course of use: *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.). Second, manufacturers have a duty of care to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge: *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 20; *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569 at p. 574; *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1997] 3 S.C.R. 1210. Third, manufacturers have a duty of care in designing the product to avoid safety risks and to make the product reasonably safe for its intended purposes: *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (S.C.J.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.). Fourth, there is a pure economic loss claim in negligence because manufacturers have a duty of care to compensate consumers for the cost of repairing a dangerous product that presents a real and substantial danger to the public: *Winnipeg Condominium Corporation No. 36 v. Bird Construction Co. Ltd.*, [1995] 1 S.C.R. 85.

[12] All of these established categories are premised on the product causing harm or having the potential of causing harm to persons or property. The case at bar is about design negligence and the failure to warn about the dangers of using the medical devices.

[13] The underlying argument in a design negligence action is that a manufacturer has a duty of care not to design a product negligently because the manufacturer should and can fairly be held responsible for the choices it makes that affect the safety of the product. The manufacturer has a duty to make reasonable efforts to reduce any risk to life and limb that may be inherent in its design: *Gallant v. Beitz* (1983), 42 O.R. (2d) 86 (H.C.J.) at p. 90; *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, *supra*.

[14] In the case of negligence in designing a product, the defendant is blameworthy for not designing its product in a safer manner. In *Nicholson v. John Deere Ltd.* (1986), 58 O.R. (2d) 53 at p. 60, Justice Smith noted that a manufacturer does not have the right to manufacture an inherently dangerous article when a method exists of manufacturing the same article without risk of harm. In this category of duty of care, whether a manufacturer breaches its duty is determined by a risk-utility analysis that measures whether the utility of the chosen design outweighs the foreseeable risks associated with the chosen design. See: *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), *supra*; *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, *supra*.

[15] In negligent design cases, the determination of whether a manufacturer breaches its duty of care in designing a product depends upon a risk-utility analysis that measures whether the utility of the chosen design outweighs the foreseeable risks associated with the chosen design: *Goodridge v. Pfizer Canada Inc.*, 2010 ONSC 1095. This risk-utility analysis requires weighing any foreseeable risk against the foreseeable utility of the product based on the information available to the manufacturer at the time of distribution or implantation and without the benefit of hindsight: *Andersen v. St. Jude Medical Inc.*, 2012 ONSC 3660 at para. 61. Manufacturers are required to weigh the likelihood of both the benefit and the risk offered by a product as well as the value of the potential benefit and the seriousness of the potential risks: *Andersen v. St. Jude Medical Inc.*, *supra* at para. 62.

[16] In *Rentway v. Laidlaw*, *supra*, Justice Granger compiled a list of factors to consider when balancing the risks inherent in the product, as designed, against its utility and cost, namely, (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product - that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread around any costs related to improving the safety of the design.

2. The Parties

[17] C.R. Bard, Inc. ("Bard U.S.") is an American corporation incorporated in the State of New Jersey with its head office in Murray Hill, New Jersey. Its products are distributed worldwide, but Bard U.S. does not itself carry on business in Canada.

[18] Bard U.S.'s medical division, Bard Medical Division, which is not an incorporated entity, is located in Covington, Georgia, where Bard U.S. researches, develops, and manufactures medical products and medical product systems, including Pelvic Mesh Product systems.

[19] Bard Canada Inc. ("Bard Canada") is a Canadian corporation with a head office in Oakville, Ontario. It is a subsidiary of Bard U.S. It is the sole distributor of Bard U.S.'s products in Canada. Bard Canada is not involved in the research, development, or manufacturing of Bard's Pelvic Mesh Products.

[20] Ms. Donna O'Brien is a resident of the City of Cambridge, Ontario. She suffers from SUI, and on December 2, 2010, she was implanted with an Align Urethral Support System manufactured by Bard as a treatment for SUI.

[21] After her surgery, Ms. O'Brien suffered from multiple side effects including erosion of the mesh, vaginal infections, vaginal drainage, vaginal pain, dyspareunia (pain during intercourse), scarring, pelvic pain, urinary problems, bleeding, lower backache, and chronic pain from the waist down. She has also suffered significant emotional distress. She required corrective surgery on March 12, 2011 to remove pieces of the mesh that were extruding from her vagina.

[22] Mr. Pearce is Ms. O'Brien's spouse, and pursuant to s. 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, he advances a claim for loss of care, guidance, and companionship as well as for expenses and special damages.

[23] The proposed Class Counsel are McKenzie Lake Lawyers LLP, Ms. O'Brien's counsel.

[24] I cannot resist noting that Mr. Peerless, Ms. O'Brien's counsel, and Mr. Eizenga, Bard's counsel, were the class action pioneers acting along with Scott Ritchie as Class Counsel for Ms. Bendall in *Bendall v. McGhan Medical Corp.* (1993), 14 O.R. (3d) 734 (Gen. Div.), leave to appeal ref'd [1993] O.J. No. 4210 (Div. Ct.), discussed below, the first action certified as a class action in Ontario and the first products liability claim class action under the *Class Proceedings Act, 1992*. Nothing, however, turns on this tidbit of legal history or courtroom irony.

3. The Ontario Proposed Class Action

[25] On August 24, 2012, Ms. O'Brien and Mr. Pearce commenced their proposed class in the Ontario Superior Court of Justice in London, Ontario. The action was subsequently transferred to the Toronto Region of the Court.

[26] Ms. O'Brien pleads each defendant operated its business so that it was inextricably interwoven with that of the other; and that the defendants were each the agent of the other for the purposes of designing, manufacturing, developing, preparing, processing, inspecting, testing packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, the Pelvic Mesh Products in Canada.

[27] Ms. O'Brien advances claims of negligence and waiver of tort. She alleges that Bard knew or ought to have known of serious health-related complications associated with using its Pelvic Mesh Products, and that Bard's marketing and labeling practices were inconsistent with its knowledge of serious health-related complications and was a breach of its duty to warn. She alleges that Bard failed to provide patients and their physicians with adequate warning of the "injuries, conditions, and complications" associated with using its Pelvic Mesh Products.

[28] The long list of injuries, conditions, and complications are set out in the Statement of Claim. Ms. O'Brien alleges that Bard's Pelvic Mesh Products have a high failure, injury and complication rate, fail to perform as intended, require frequent and debilitating re-operations, and have caused severe and irreversible injuries, conditions and damages, including, but not limited to: mesh erosion; mesh contraction; mesh hardening or shrinking; extrusion of the mesh; vaginal erosion, urethral erosion; infection; fistula; inflammation; vaginal scarring; vaginal pain; organ perforation; dyspareunia; blood loss; neuropathic and other acute and chronic nerve damage and pain; pudenda nerve damage; neuromuscular problems; pelvic floor damage; pelvic pain, granuloma formation; urinary and fecal incontinence; prolapse of organs, and psychological damage.

[29] Ms. O'Brien pleads pecuniary and special damages of $500,000 for each person implanted with one of Bard's Pelvic Mesh Products plus non-pecuniary damages in an amount to be assessed for each person who was implanted with one of the products.

[30] Ms. O'Brien pleads that Bard was negligent in the design of Pelvic Mesh Products in that they failed to ensure they were not dangerous to the recipients during the course of their use and that they were fit for their intended purpose. She pleads that Bard was negligent in the testing of its Pelvic Mesh Products and failed to conduct meaningful tests or studies fully disclosing the risks associated with their use. Ms. O'Brien pleads that Bard was negligent in the distribution, marketing, and sale of its Pelvic Mesh Products. (I note here that the allegations of negligence in distribution, marketing, and sale are, in effect, emanations of her failure to warn allegations.)

[31] As noted above, Ms. O'Brien alleges a failure to warn. She alleges that Bard failed to adequately warn physicians and consumers of the increased risk of suffering adverse events as compared to other available products or procedures and that but for these failures she would not have suffered her injuries.

4. Class Size

[32] Bard lists 8,363 product units distributed in Canada for its Pelvic Mesh Products as of May 31, 2014.

5. Parallel Litigation

[33] Six individual lawsuits have been filed in total in Ontario and Manitoba with respect to Bard's Pelvic Mesh Products.

[34] Class actions against Bard have been commenced in Quebec, Alberta, and Saskatchewan. Counsel for the plaintiffs in those proceedings are working cooperatively with McKenzie Lake. These actions are currently stayed and subject to its right to challenge certification, Bard has agreed not to oppose a national class out of Ontario.

[35] In the United States, there is a class action against Bard. The Bard Multidistrict Litigation is proceeding in the U.S. District Court for the Southern District of West Virginia (MDL 2187), before Hon. Joseph R. Goodwin. McKenzie Lake is working cooperatively with the U.S. lawyers involved in the American litigation.

[36] There are also individual lawsuits in the United States against Bard involving some of its Pelvic Mesh Products.

6. The Witnesses for the Certification Motion

[37] Ms. O'Brien supported her motion for certification with the following evidence:

- Her affidavit sworn on March 27, 2014. She was cross-examined.
- The affidavit of Mr. Pearce, sworn March 27, 2014.
- The affidavits of Sabrina Lombardi, associate lawyer at McKenzie Lake, sworn March 28, 2014 and August 22, 2014. Exhibits to her affidavits include studies and articles from medical journals, newspaper articles, online articles, and documents from U.S. court proceedings involving unrelated device manufacturers. Ms. Lombardi was cross-examined.
- The affidavits of Dr. Harold P. Drutz sworn March 26, 2014 and August 21, 2014. Dr. Drutz is a physician and surgeon. His specialty is urogynecology, also known as female pelvic medicine and reconstructive surgery. He is a Fellow of the Royal College of Physicians and Surgeons of Canada, a professor at the Faculty of Medicine at the University of Toronto and the Head of Urogynecology at Mount Sinai Hospital and the Baycrest Geriatric Centre. Dr. Drutz was retained to opine about the safety, effectiveness, and reliability of Bard's Pelvic Mesh Products. Dr. Drutz was cross-examined.

[38] Bard responded to the motion for certification with the following evidence:

- The affidavit of Laura Bigby, sworn July 31, 2014. Ms. Bigby is an employee at Bard Medial Division who manages the product labelling group and who has been involved in the development of Bard's products for the treatment of POP and SUI.

- The affidavit of Dr. Maureen Reitman, sworn July 31, 2014. Dr. Reitman is a materials and engineering expert retained to opine on Bard's pelvic repair product systems. She is the Director of the Polymer Science and Materials Chemistry Practice at Exponent, the largest engineering firm in the U.S. She has a doctorate in materials science and engineering from MIT and over 20 years of experience in this field.
- The affidavit of Dr. Douglas Van Drie sworn July 29, 2014. Dr. Van Drie is the Director of the Female Pelvic Medicine and Urogynecology Institute of Michigan in Grand Rapids, Michigan, a centre for female urogynecologic disorders. He is the Chairman of the Department of Obstetrics and Gynecology at Spectrum Health in Grand Rapids and a clinical professor of Obstetrics and Gynecology at Michigan State University School of Medicine.
- The affidavit of Dr. Michael Kennelly sworn July 31, 2014. Dr. Kennelly is Professor, Division of Urology and Professor, Division of Obstetrics and Gynecology, Department of Surgery and Medical Director of the Charlotte Continence Centre at Carolinas Medical Center. He is the Director of Urology at Carolinas Rehabilitation Hospital, and Co-Director of the Women's Centre for Pelvic Health. He is also a Clinical Professor in the Department of Surgery, Division of Urology at University of North Carolina – Chapel Hill, North Carolina, USA.
- The affidavits of Kelly McPhie. Ms. McPhie is a law clerk at Bennett Jones, LLP, counsel to Bard. She produced Ms. O'Brien's medical records and information about individual court actions against other manufacturers of Pelvic Mesh Products.

7. Pelvic Organ Prolapse, Stress Urinary Incontinence, and Pelvic Mesh Products

(a) Pelvic Organ Prolapse

[39] In the 1950s, surgeons began using surgical mesh to repair abdominal hernias, and in the 1970s, some gynecologists began using these products for abdominal repair of pelvic organ prolapse ("POP").

[40] POP is the downward descent of female pelvic organs, including the bladder, the small or large bowel, and uterus or post-hysterectomy vaginal cuff, resulting in protrusion of the vagina, uterus or both. POP occurs because, over time, it is common for pelvic floor muscles to weaken and to lose their ability to offer support with the result that the pelvic organs drop.

[41] POP is estimated to occur to some degree in 50% of women. POP can be a very serious and debilitating condition. It is progressively disabling, and many women are forced to limit their exercise and daily activities. POP can have serious adverse physical and psychological health effects.

[42] There are many predisposing factors that put women at risk for developing POP, including childbearing, physical activity including heavy lifting, chronic straining with constipation, chronic cough, menopause, and inherited or acquired connective tissue weakness. The most common cause for POP is damage to the pelvic floor muscles from childbirth.

[43] Each POP case is unique in its area of damage and the extent of damage. Each POP patient must be individually assessed and treated on an individual basis having regard to, among other things, the tissue strength of the patient and the severity of the damage.

[44] Treatment options for POP include preventative therapy (such as strengthening pelvic floor muscles through kegel exercises), non-surgical treatments (such as the use of pessaries), and surgical treatments such as native tissue repair, which is repairing the defect using the patient's own tissue and sutures or some sort of mesh-assisted repair, using either a transvaginal or abdominal approach. For most women with POP, surgical treatment is not an elective choice but a medical necessity.

[45] There are serious risks associated with any POP repair surgery. These risks include infections, fistula formation, pain, dyspareunia, injury to the nervous system, perforation of organs, scar formation, vaginal bleeding, shortening and/or deviation of the vagina, difficulty with bowel or bladder function, and the recurrence of prolapse.

(b) **Stress Urinary Incontinence**

[46] Ihe 1990s, gynecologists began using surgical mesh for treatment of stress urinary incontinence ("SUI"), which is the loss of urine with increases in intrabdominal pressure through an intact lower urinary tract caused by urethral hypermobility or intrinsic sphincter deficiency or a combination of both. SUI is the involuntary leakage of urine on effort or exertion, such as sneezing or coughing. The leakage may be as little as a drop or two, but may be as severe as an uncontrolled stream of urine that empties the bladder. SUI affects 10% to 15% of all women and 30% to 60% of women after menopause.

[47] There are numerous potential factors that put women at risk for developing SUI, including age, pregnancy, body mass index, obesity, diabetes, previous pelvic surgical history, smoking and genetics. SUI can range in severity from a minor, embarrassing and occasional inconvenience to a serious interference with lifestyle.

[48] Treatments for SUI include lifestyle interventions, pharmacotherapy, and surgical treatment.

(c) **The Surgical Treatment of POP and SUI**

[49] Bard untiringly and frequently points out in its responding record and in its factum the obvious facts that POP and SUI are medically distinct phenomena with a broad range of severity and that patients diagnosed with these conditions will have idiosyncratic symptoms, side effects, and responses to treatment and that a patient's consent to surgical treatment for POP and SUI and the choice of the type of surgical intervention will be guided by patient-specific factors, surgeon-specific factors, as well as factors related to the mechanical and functional design and intended use of the various products available for surgical intervention.

[50] For POP and SUI surgical treatments, surgeons cut the mesh to the desired shape and then place the mesh in the patient's body through an incision. Surgical mesh products have "kits" that include tools to aid the surgeon in the placement and insertion of the mesh. There are a variety of mesh products designed for different patient circumstances and surgeons' treatment decisions.

[51] Around 2002, Bard began marketing and selling kits to treat POP and SUI, and as described immediately below, Bard has a variety of Pelvic Mesh Products with different designs and intended surgical uses. The products have different materials, sizes, and shapes, designs, warnings, etc. The products are designed to provide different approaches to the treatment of POP and SUI respectively.

[52] Bard's Pelvic Mesh Products are marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by minimally invasive surgical techniques for the treatment of POP and SUI.

[53] On October 20, 2008, the U.S. Food and Drug Administration issued a Public Health Notification describing over 1,000 complaints about complications from the use of surgical mesh for POP and SUI over a three-year period.

[54] In February 2010, Health Canada issued a Notice to Hospitals advising of its concern about international reports of various intraoperative and postoperative complications associated with the use of transvaginal surgical mesh for treatment of POP and SUI. Health Canada recommended: (i) the review of the labelling (particularly the warnings), (ii) that patients be informed during pre-surgical consultations of potential adverse events and the possible need for additional surgical procedures, (iii) that physicians be observant for signs of complications associated with placement of the mesh, and (iv) that physicians get training on proper case selection, initial implantation procedure, and management of complications.

[55] In February 2011, the Society of Obstetricians and Gynecologists of Canada issued an update to the profession, with the following recommendations: (i) patients should be counselled that transvaginal mesh procedures are novel; (ii) patients should be informed of the range of success rates, until stronger evidence of superiority is published; (iii) training specific to transvaginal mesh procedures should be undertaken before performing procedures; (iv) patients should undergo thorough preoperative counselling regarding potential serious adverse sequelae of mesh repair and the limited data available comparing mesh systems with traditional POP repairs or traditional use of graft material; and (v) until appropriate supportive data are available, new trocarless kits should be considered investigative.

[56] On July 13, 2011 the U.S. Food and Drug Administration issued a second Public Health Notification that it had received an additional 2,864 complaints about complications with surgical mesh. The 2011 Notification states that mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair without evidence of added benefit.

8. Bard's Mesh Products for Pelvic Repairs

[57] As noted, Bard offers a variety of products for the treatment of POP and SUI.

[58] I shall discuss the evidence about Bard's Pelvic Mesh Products here and again later in the discussion of the certification criteria, the some-basis-in-fact test for the certification criteria, and most particularly in my discussion throughout of commonality. As will appear, commonality (and preferable procedure) is a very contentious matter in the case at bar.

[59] Before Bard's products were marketed and sold in Canada, it carried out the testing required by Health Canada. It applied for and obtained Medical Device Licences (MDL) for each product system as regulated by the Therapeutic Products Directorate, Health Canada.

[60] Bard's Pelvic Mesh Products differ in shape, size, weight, density, weave, porosity, flexibility, configuration, fixation methodology, design details, and product warnings.

[61] All the products use surgical mesh, but there are distinct design features. For example, porcine collagen, which is known to improve tissue incorporation, is used in cases of recurrent POP where patients have thin vaginal tissue. Bard says that product systems without porcine collagen are better suited to large prolapses in patients with stronger tissue quality. Bard says that product systems that combine porcine collagen and polypropylene were created by Bard in response to demand by surgeons, who were creating their own combined-product systems by suturing biologic materials and polypropylene materials together to create a layer between the polypropylene and the vaginal tissues that would assist the healing process and lower the rate of exposure.

[62] Bard offers the following product lines and product systems for the treatment of POP and SUI.

	Product Line	Product System	Material	Functional Design Properties
1	Align	Urethral Support System	polypropylene	Treatment of SUI - retropubic placement - suprapubic placement
2		TO Urethral Support System	polypropylene	Treatment of SUI - transobturator placement
3	Avaulta Anterior BioSynthetic	Anterior BioSynthetic Support System	polypropylene monofilament fibre and porcine collagen	Treatment of POP (bladder) - anterior vagina placement
4	Avaulta Posterior BioSynthetic	Avaulta Posterior BioSynthetic Support System	polypropylene monofilament fibre and porcine collagen	Treatment of POP (rectal or urethral) - posterior vagina placement
5	Avaulta Plus Anterior BioSynthetic	Avaulta Plus Anterior BioSynthetic Support System	polypropylene and crosslinked acellular collagen	Treatment of POP (thin vaginal tissue) -anterior vagina placement
6	Avaulta Plus Posterior BioSynthetic	Avaulta Plus Posterior BioSynthetic Support System	polypropylene and crosslinked acellular collagen.	Treatment of POP -posterior vagina placement
7	Avaulta Solo Anterior	Avaulta Solo Anterior Synthetic Support System	polypropylene	Treatment of POP (bladder) -anterior vagina placement
8	Avaulta Solo Posterior	Avauluta Solo Posterior Synthetic Support System	polypropylene	Treatment of POP -posterior vagina placement
9	Pelvilace and Innerlace (manufactured by Tissue Science Laboratories and distributed by Bard pursuant to a licensing agreement)	Pelvilace and Innerlace Support Systems	collagen and elastin	Treatment of SUI - retropubic placement -suprapubic placement -transobturator placement
10	Pelvicol	Pelvicol	biocompatible porcine dermal collagen	Treatment of POP
11	Pelvisoft	Pelvisoft	collagen and elastin	Treatment of POP
12	Uretex	Uretex SUP	polypropylene	Treatment of SUI -suprapubic placement

13		Uretex TO	polypropylene	Treatment of SUI Transobturator placement
14		Uretex TO2	polypropylene	Treatment of SUI Transobturator placement
15		Uretex T03	polypropylene	Treatment of SUI -transobturator placement
16	Pelvitex		polypropylene and resorbable collagen	Treatment of POP -transobturator placement
17	Alyte	Alyte Y-Mesh Graft	polypropylene	Treatment of POP (bladder, rectal, bowel) - anterior and posterior placement -robotic, laparoscopic, or open sacrocolposuspension
18	Ajust	Ajust Single-Incision	polypropylene	Treatment of SUI (urethral hypermobility and/or intrinsic sphincter deficiency) -transvaginal and transobturator
19		Ajust Single-Incision	polypropylene	Treatment of SUI (urethral hypermobility and/or intrinsic sphincter deficiency) -transvaginal and transobturator

[63] Bard withdrew the Avaulta line of Pelvic Mesh Products from the U.S. in 2012. Bard withdrew the Avaulta line of Pelvic Mesh Products from Canada on May 13, 2014.

[64] Dr. Reitman's opinion was that the Bard Pelvic Mesh Products differed in: (a) application – i.e., the particular type of POP or SUI indicated for the mesh system; (b) approach – i.e., the particular surgical technique for the system; (c) implant geometry; i.e., shape of the graft; (d) material; (e) fixation method; i.e., how system surgically affixed to patient; (f) length; and, (g) pore size and geometry – defined by the knit pattern in polypropylene systems.

[65] Dr. Reitman deposed that the choice of a particular pelvic mesh product would depend upon product specific factors, i.e., its design specifications and upon patient-specific factors and physician-specific factors. Patient-specific factors include: age, size, weight, obesity, anatomy, health, diabetes, smoking, medications, tissue quality, healing ability, presence of chronic cough, chronic levator muscle strength or chronic constipation, the nature of the ailment, prior surgeries, prior infections, and whether the patient has experienced childbirth. Surgeon-specific factors include: training, experience, skill, judgment, technique, and surgical options and alternatives.

[66] It was Dr. Reitman's opinion that it is not scientifically reasonable to generically link adverse outcomes in Bard's multifarious system products. Her opinion was that one cannot generalize or extrapolate from an adverse outcome suffered by one patient using a particular product system to other product systems used in other patients. She opined that due to the clinically relevant differences in geometry, material, and intended surgical application between the products, one cannot generically link all the named products to adverse outcomes that differ

from known and reported outcomes of any repair implant. Her opinion was each product must be evaluated independently based on its design, construction, and intended use.

[67] Similarly, it was Dr. Van Drie's opinion that the differences in design are clinically relevant and impact patient outcomes. He noted, for example, that porcine collagen is known to improve tissue incorporation, and is, therefore, often used in cases of recurrent POP where patients have thin vaginal tissue. By contrast, product systems without porcine collagen are better suited to large prolapses in patients with stronger tissue quality. It was his opinion that every case of POP requires individual evaluation and individual treatment choices, including the choice of various surgical techniques and products each with unique characteristics.

[68] It was Dr. Kennelly's evidence that surgical treatments for the various types of SUI are varied and the choice of intervention is guided by surgeon factors and the physical characteristics of the patient and coexisting medical conditions. It was his opinion that patient, surgeon, and device factors should be taken into consideration in deciding whether surgical intervention is necessary, and, if so, what particular product system should be used.

9. Bard Davol Inc. and Marlex Mesh

[69] Ms. Lombardi attached to her affidavit the Memorandum Opinion and Order of the Honourable Joseph R. Goodwin, United States District Judge in *Cisson v. C.R. Bard*, an action in the U.S. District Court of Southern District Phillips.

[70] In the Memorandum Opinion and Order, Judge Goodwin dismissed Bard's motion, made after a jury verdict, for a directed verdict against the Cissons (the plaintiffs) as a matter of law. In the jury trial, the Cissons had sued Bard for design defect and failure to warn relating to Avaulta Plus. The Cissons alleged that Avaulta Plus had three design defects; namely: (1) the arms contained in the device; (2) the small pore size used in the mesh; and (3) the use of polypropolene to create the device. Bard Davol Inc.'s defence was unsuccessful.

[71] Ms. Lombardi attached to her affidavit Exhibits 1 and 2 from the trial.

[72] Exhibit 1 is a Material Safety Data Sheet prepared by Phillips Sumika Polypropylene Company of West Virginia. The data sheet is for Marlex® Polypropylene. The data sheet is divided into 16 sections. Section 1 bears the title Product and Company Identification and contains the following medical application caution:

> MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.
>
> Do not use this Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use.
>
> Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.

[73] Exhibit 2 is an e-mail chain of correspondence that occurred on March 25 and 26, 2004. It begins with Roger Darois of Davol (a Bard company) receiving an inquiry from a third party,

Thiemo Blank, asking for advice about a polypropylene polymer for a research project for treatment of vascular arteries. Mr. Darois responds that he will pass on Mr. Blank's request to one of Davol's engineers, but he cautions that "suppliers will likely not be interested in a medical application due to product liability concerns." The engineer from Davol, William Graham, responds to Mr. Blank that Davol has two suppliers. Mr. Graham attaches the procurement specifications. These contain the medical application caution found in Exhibit 1, noted above. Mr. Blank sends his thanks to Mr. Darois and to Mr. Graham. Mr. Graham then offers to help Mr. Blank further by obtaining a sample of the product, and Mr. Graham ends his e-mail message with the following comment:

> Once again we need to be certain that we don't contact the resin supplier due to the sensitivity of our implant application. Possibly you could ask your injection moulding source to request other resin samples for you. Let me know if I can be of further help.

[74] For the reasons expressed below, I find this evidence to be inadmissible. However, assuming it is admissible, then, in my opinion, it is not helpful to Ms. O'Brien and, indeed, is perhaps helpful to Bard.

[75] At best, for Ms. O'Brien, assuming that the non-joined Bard Davol Inc.'s knowledge can be attributed to Bard, it shows that Bard was aware that polypropylene manufacturers and raw material suppliers were protecting themselves from liability from the use of their mesh for permanent medical implantation and would not authorize their product's use for temporary medical implantation (i.e., what I take to be implementation followed by a prompt extraction), unless the mesh was supplied under an agreement that acknowledged the contemplated temporary use.

[76] This evidence would be relevant to what Bard knew about the risks associated with its raw materials, but the evidence is not necessarily determinative of the merits of Ms. O'Brien's negligence claim because a great deal more would have to be known about the circumstances of what Bard knew about the safe use of raw materials and whether that use could be made safe. The views of the raw materials suppliers are relevant but not determinative of the responsible uses that can be made of their products.

[77] In this regard it is to be noted that in his evidence, Dr. Drutz did not go so far as to submit that permanent surgical mesh products should never be used. In counsel's letter of instructions to Dr. Drutz it was acknowledged that transvaginal mesh can be effective in treating certain conditions, and in his second report, Dr. Drutz acknowledged that there is a role for device-assisted pelvic repair surgeries. Dr. Drutz does not have the expertise to opine whether design changes could be made to Pelvic Mesh Products to make them safe or safer.

[78] In any event, the ultimate merits of the design negligence and failure to warn claims is not an issue on the certification motion. For the purposes of the certification motion, for this hearsay evidence about what occurred in a U.S. trial about what a Bard subsidiary knew or ought to have known and what it did or did not do to be helpful to Ms. O'Brien, the evidence needs to provide some-basis-in-fact for the certification criteria in her Canadian action. But the evidence is not helpful in this regard. Indeed, for the purposes of the certification motion, the evidence is possibly harmful to Ms. O'Brien because it does not provide evidence that there is a common design defect across Bard's 19 Pelvic Mesh Products. In *Cisson v. C.R. Bard,* the design defects of Avaulta Plus are specified.

[79] In other words, it might have been a design defect to use polypropylene for the design purposes of Avaulta Plus, but that does not necessarily extrapolate to Bard's other products. At best, the evidence indicates that there might be some-basis-in-fact for a class action by a class of Avaulta Plus users. (But that class would require a different representative plaintiff from Ms. O'Brien, who was implanted with an Align Urethral Support System.)

[80] In any event, for the reasons discussed below, I do not find this evidence admissible, and if it is admissible, I also do not find it helpful. I have mentioned this evidence largely because Ms. O'Brien submitted that it was evidence of a cover up and because the parties spent some time debating its significance during the oral argument of the certification motion.

[81] I shall move on to discuss the other evidence for or against the satisfaction of the certification criteria.

10. Some-basis-in-fact and the Admissibility of the Evidence of Ms. Lombardi, Dr. Drutz and Ms. O'Brien

(a) Introduction

[82] Bard forcefully, indeed ferociously, challenged the admissibility and the utility of the evidence proffered for Ms. O'Brien by Ms. Lombardi and Dr. Drutz. It also challenged the utility of Ms. O'Brien's personal experience evidence.

[83] In this part of my Reasons for Decision, I shall discuss the merits of Bard's arguments about the admissibility and the utility of Ms. Lombardi's, Dr. Drutz's, and Ms. O'Brien's evidence and make my findings about their evidence.

[84] First, I shall discuss the law associated with the some basis-in-fact test that is a major component of Bard's attack against the evidence. Then, I shall describe Bard's argument, which in the main goes to the commonality requirement of the common issues criterion for certification. Next, in the light of the legal and evidentiary principles, I shall consider Bard's challenge to the evidence of Ms. Lombardi, Dr. Drutz, and Ms. O'Brien respectively. I shall describe some of their evidence that survives Bard's attack and consider what the evidence establishes for the purposes of this certification motion.

(b) The Some-Basis-in-Fact Test

[85] The representative plaintiff must come forward with sufficient evidence to support certification, and the opposing party may respond with evidence of its own to challenge certification: *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 22.

[86] The purpose of a certification motion is to determine how the litigation is to proceed and not to address the merits of the plaintiff's claim; there is to be no preliminary review of the merits of the claim: *Hollick v. Toronto (City)*, *supra* at paras. 28 and 29. However, the plaintiff must show "some-basis-in-fact" for each of the certification criteria other than the requirement that the pleadings disclose a cause of action: *Hollick v. Toronto (City)*, *supra* at paras. 16-26.

[87] In particular, there must be a basis in the evidence before the court to establish the existence of common issues: *Dumoulin v. Ontario*, [2005] O.J. No. 3961 at para. 25 (S.C.J.); *Fresco v. Canadian Imperial Bank of Commerce*, [2009] O.J. No. 2531 at para. 21 (S.C.J.);

Singer v. Schering-Plough Canada Inc., 2010 ONSC 42 at para. 140. In order to establish commonality, evidence that the alleged misconduct actually occurred is not required; rather, the necessary evidence goes only to establishing whether the questions are common to all the class members: *Pro-Sys Consultants v. Microsoft*, 2013 SCC 57 at para. 110.

[88] Certification will be denied if there is an insufficient evidentiary basis for the facts on which the claims of the class members depend: *Williams v. Canon Canada Inc.*, 2011 ONSC 6571; *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd [2003] S.C.C.A. No. 106; *Ernewein v. General Motors of Canada Ltd.*, [2005] B.C.J. No. 2370 (C.A.), leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 545; *Taub v. Manufacturers Life Insurance Co.* (1998), 40 O.R. (3d) 379 (Gen. Div.), aff'd (1999), 42 O.R. (3d) 576 (Div. Ct.).

[89] On a certification motion, evidence directed at the merits may be admissible if it also bears on the requirements for certification but, in such cases, the issues are not decided on the basis of a balance of probabilities but rather on that of the much less stringent test of "some-basis-in-fact": *Hollick v. Toronto (City)*, *supra* at paras. 16-26; *Cloud v. Canada*, [2004] O.J. No. 4924 (C.A.), at para. 50.

[90] The some-basis-in-fact test sets a low evidentiary standard for plaintiffs, and a court should not resolve conflicting facts and evidence at the certification stage or opine on the strengths of the plaintiff's case; the focus at certification is whether the action can appropriately go forward as a class proceeding: *Pro-Sys Consultants v. Microsoft, supra*; *McCracken v. CNR Co.*, 2012 ONCA 445.

[91] The evidence on a motion for certification must meet the usual standards for admissibility: *Martin v. Astrazeneca Pharmaceuticals PLC,* 2012 ONSC 2744, aff'd 2013 ONSC 1169 (Div. Ct.); *Williams v. Canon Canada Inc., supra*; *Ernewein v. General Motors of Canada Ltd., supra*; *Schick v. Boehringer Ingelheim (Canada) Ltd.,* 2011 ONSC 63 at para.13. While evidence on a certification motion must meet the usual standards for admissibility, the weighing and testing of the evidence is not meant to be extensive and if the expert evidence is admissible the scrutiny of it is modest: *Griffin v. Dell Canada Inc.*, [2009] O.J. No. 418 at para. 76 (S.C.J.). In a class proceeding, the close scrutiny of the evidence of experts should be reserved for the trial judge: *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057, aff'd 2012 BCCA 260.

[92] In a point that will become important below, Bard submitted that the law about satisfying the evidentiary standard for the certification criteria for product liability cases has changed from the approach used in the original and seminal products liability class action, a case and its progeny upon which Ms. O'Brien relies. Ontario's *Class Proceeding Act, 1992*, came into force on January 1, 1993, and on August 26, 1993, *Bendall v. McGhan Medical Corp., supra* became the first action to be certified as a class proceeding. *Bendall* was an action brought on behalf of women who had received breast implants of multifarious types made with silicone gel. The women alleged that they had sustained injuries to their breasts and suffered chronic fatigue, infection, immune system dysfunction, and emotional consequences. In *Bendall*, the certification criteria were satisfied based just on the pleadings and without an evidentiary foundation. *Bendall* was, however, decided before *Taub v. Manufacturers Life Insurance Co., supra,* and *Hollick v. Toronto (City), supra.*

[93] For the case at bar, Bard submits that unlike the situation in *Bendall v. McGhan Medical Corp., supra*, for Ms. O'Brien's proposed class action to be certified, there must some admissible

evidence to establish some-basis-in-fact that there is a singular impugned design feature common to all the Pelvic Mesh Products.

(c) **Bard's Attack on the Evidence of Ms. Lombardi and Dr. Drutz**

[94] Bard argues that in a products liability claim based on a design defect or based on a failure to warn, whether the defendant's acts or omissions were negligent (breached the standard of care) will be determined based on the reasonableness of the defendant's conduct in making design choices or in disseminating information about its product. These determinations of reasonableness will include an assessment of what the defendant knew or ought to have known and what it did or ought to have done in balancing the risks and benefits of the product.

[95] From Bard's submission about the nature of a products liability negligent-design case, it argues that in a multiple product class action, for the court to make a common issues standard-of-care analysis, the plaintiff must show some-basis-in-fact for the existence of a common design defect so that a utility-risk assessment can be made. Bard submits that demonstrating a singular design defect is necessary so that the defendant's knowledge and the reasonableness of its conduct at the time when the product was introduced into the marketplace can be measured having regard to the risks and benefits of the design of the product.

[96] The culmination of Bard's argument is that it submits that in the case at bar, Ms. O'Brien has not presented admissible evidence through her own evidence and through the evidence of Ms. Lombardi and Dr. Drutz to establish some-basis-in-fact for concluding that there is a common design defect in Bard's products, and, in contrast, Bard submits that, its own evidence demonstrates that there is not and could not be a common design defect in its very different products.

[97] Put shortly, Bard submits that Ms. Lombardi's and Dr. Drutz's evidence is not admissible and, thus, there is no evidence to satisfy the some-basis-in-fact test for certification and, therefore, Ms. O'Brien's action is unsuitable for and cannot be certified as a class action. Alternatively, Bard submits that to the extent that Ms. Lombardi's and Dr. Drutz's evidence is admissible, it does not establish some-basis-in-fact for a singular design defect in the Pelvic Mesh Products and once again Ms. O'Brien's action is unsuitable for and cannot be certified as a class action.

[98] Commonality or the absence of it is the major point of controversy in this proposed class action.

(d) **Ms. Lombardi's Evidence**

[99] Ms. Lombardi's evidence was documentary. She is not a putative Class Member, and for documentary evidence to be admissible through a solicitor's affidavit, it must be probative of a material fact in issue and that probative value must outweigh any prejudice to admitting the evidence: *Gray v. ICBC,* 2010 BCCA 459; *Patzer v. Hastings Entertainment Inc.*, 2011 BCCA 60 at paras. 19-21.

[100] Evidence may be excluded if its probative value is overborne by its prejudicial effect, including the tendencies: to yield irrational conclusions; to confuse, mislead, or distract the trier of fact's attention from the main issues; to unduly occupy the trier of fact's time; and to surprise

the opponent unfairly and to impair a fair hearing: *R. v. Mohan*, [1994] 2 S.C.R. 9; *R. v. Seaboyer*, [1991] 2 S.C.R. 577; *R. v. Potvin*, [1989] 1 S.C.R. 525.

[101] Bard submits that Ms. Lombardi's evidence should be disregarded. Bard submitted that very little of Ms. Lombardi's evidence was admissible. It submitted her evidence was hearsay, unreliable, or unqualified opinion evidence and that most of the material she filed did not specifically address Bard's products. Further, Bard submits that the material filed by Ms. Lombardi did not provide any rationale for assessing Bard's products in common on any meaningful legal basis and rather, if anything, her evidence showed that such an assessment would not be possible.

[102] Bard submits that notwithstanding Ms. O'Brien's avowed purpose of introducing the academic "journal articles" attached to Ms. Lombardi's affidavits for a limited purpose - i.e., to demonstrate that the state of knowledge of the benefits and risks of Pelvic Mesh Products, including those distributed by Bard, is an ongoing matter of research - the exhibits were, in truth, unreliable and irrelevant hearsay improperly being used to prove the truth of their contents and, therefore, the documentary evidence was not admissible.

[103] Exhaustively, Bard submitted in paragraphs 162 to 186 of its factum, that Ms. Lombardi's evidence should be disregarded for the following reasons: (a) exhibits to the Lombardi Affidavits are irrelevant and are not probative of any issue on the certification motion; (b) exhibits to the Lombardi Affidavits are unqualified opinion evidence such as academic articles and newspaper articles; (c) exhibits to the Lombardi Affidavits are mischaracterized and do not stand for the factual propositions for which they are tendered; (d) exhibits to the Lombardi Affidavits are tendered to shore up conclusions not actually made by Dr. Drutz; and (e) exhibits to the Lombardi Affidavits are unreliable hearsay evidence.

[104] While I do not agree with all of the elaborations of the deficiencies in Ms. Lombardi's evidence that are set out in paragraphs 162 to 186 of Bard's factum, I do agree that with three exceptions, Ms. Lombardi's evidence should be disregarded because it is inadmissible hearsay or inadmissible opinion evidence or inadmissible as irrelevant to the issues on the certification motion. Her hearsay evidence is also prejudicial and likely to mislead the court on the certification motion.

[105] The exceptions, where her evidence is admissible, are: (1) common knowledge or matters for which the court could take judicial notice, including the notifications issued by regulatory authorities; (2) evidence accepted or admitted to be true by Bard's witnesses; and (3) opinion evidence properly adopted by Dr. Drutz. Otherwise, I disregard Ms. Lombardi's evidence, and subject to these three exceptions, her evidence is not an operative factor in my decision on this certification motion.

[106] By way of some elaboration, I do not agree with Ms. O'Brien's submission that Ms. Lombardi's evidence was profferred for a limited acceptable purpose and as such the evidence was admissible. I regard that explanation as pretence for the real purposes of the affidavit which were to: (a) show that there is merit to Ms. O'Brien's complaints of design negligence and a failure to warn; and (b) establish some-basis-in-fact for a common design defect across Bard's line of Pelvic Mesh Products. But the evidence is not admissible for these purposes because it is multiple levels of hearsay just proffered to impugn Bard's use of surgical mesh generally.

[107] Save for the three exceptions noted above, there is no hearsay exception that applies to this hearsay evidence and no reliability or necessity grounded exception exists to make Ms. Lombardi's evidence admissible.

[108] Ms. O'Brien relied on *Schwoob v. Bayer Inc.*, 2013 ONSC 2207, leave to appeal denied, September 5, 2013 (Div. Ct.) in support of the admission of Ms. Lombardi's evidence. In that class action against a drug manufacturer, a solicitor's affidavit, containing academic articles was proffered and found admissible for the limited purpose of demonstrating that the drug industry's knowledge about the product being impugned, including the product distributed by the defendants, was not a closed subject and that research was ongoing with respect to the product's health effects.

[109] In the case at bar, I do not see how evidence that academic and clinical studies about the use of surgical mesh are evolving and that the state of scientific knowledge is in flux is particularly helpful to Ms. O'Brien in achieving certification, but, in any event, I do not accept that illuminating the state of the medical device industry's knowledge about surgical mesh was the true reason her evidence was proffered. My view is that the true reason was to attempt to prove the merits of Ms. O'Brien's claim, and if that was the true reason, then, with certain exceptions, Ms. Lombardi's evidence should not be admitted. I conclude that save for the three exceptions noted above, Ms. Lombardi's evidence is not admissible.

(e) **Dr. Drutz's Evidence**

[110] I turn now to Dr. Drutz's evidence.

[111] It was Dr. Drutz's opinion based, in part, on the scientific literature found in Ms. Lombardi's affidavit and referenced as sources in his own report, that there are very serious issues regarding the safety of Pelvic Mesh Products. He thought that there was insufficient Level I research before the products were released for use in reconstructive vaginal surgery. It was his view that the warnings and information provided to surgeons, patients and the general public of the dangers of using the products were inadequate.

[112] At paragraph 10 of his Reply Report, Dr. Drutz concludes that while there are certainly differences amongst Bard's Pelvic Mesh Products, it is the similarities that allow him to speak about them collectively. It was his opinion that while there are individual factors that impact a surgeon's choice of medical devices and a patient's outcome, those factors were not relevant to the fitness for purpose of Pelvic Mesh Products and whether adequate warnings of the types of serious complications were being provided.

[113] Bard criticizes Dr. Drutz's qualifications, methodology, and his conclusions. Further, his evidence was challenged as outside the scope of his expertise, irrelevant, inadequate, and unsuccessful in establishing a singular design defect in Bard's Pelvic Mesh Products. Bard submitted that Dr. Drutz's evidence should be disregarded because: (a) his opinions were concerned with the "industry" and the activities of surgeons and not based on facts that relate to the knowledge and conduct of Bard in particular; (b) his opinions do not assert any common design feature or provide any basis-in-fact for a common design feature in Bard's product systems; (c) he offered inadmissible fact evidence; and (d) he did not apply independent analysis to Bard's products based on his own expertise.

[114] To assess Dr. Drutz's evidence I begin by saying that I accept that he was properly qualified as an expert. He has very impressive credentials and expertise. I also accept that he was honouring his undertaking as an expert witness to provide non-partisan expertise.

[115] At the outset, I also say that some of the criticisms of Dr. Drutz's methodology and his conclusions went well beyond the fair scrutiny of his opinion that is permissible on a certification motion.

[116] However, there was merit to some of the criticisms made about the admissibility and the utility of Dr. Drutz's evidence.

[117] For instance, I find as a fact that Bard's own evidence establishes that each of its products is differently designed and has different design purposes. I further find that Dr. Drutz's evidence does not establish the contrary. Dr. Drutz admitted that he had no expertise in engineering, materials science, or the physical properties of polymers.

[118] Further, I agree with Bard that some of Dr. Drutz's evidence was inadequately supported or beyond his area of expertise. For instance, I agree that no weight can be given to Dr. Drutz's reliance on allegations about Bard's mesh products that he found on the webpage of a plaintiff's law firm in the U.S. that is suing Bard. And, I agree that the information contained in a Bloomberg news article is useless for the purposes of the certification motion. This reliance diminishes, but, in my opinion, it did not disqualify, Dr. Drutz as an independent expert witness under an obligation to provide non-partisan evidence to assist the court.

[119] I further agree that without having reviewed the documents in which Bard provides warnings, or without having attended training sessions, or without knowing what warnings were given during training sessions, Dr. Drutz does not have the factual basis to provide evidence as to whether the warnings provided by Bard were adequate.

[120] Bard criticized Dr. Drutz's reference to journal articles and studies. It submitted that unless he confirmed and adopted them they were not admissible evidence. It submitted that an expert must provide some independent review and analysis of the material and reach conclusions by applying personal expertise and skill and draw his or her own conclusion, which, it submits, Dr. Drutz did not do. Moreover, Bard submits that there was no indication in the Drutz Reports whether or not the articles and studies he cites considered any of Bard's pelvic repair product systems in their data sets. There is some merit to this criticism, although a review of Dr. Drutz's cross-examination reveals that Bard's counsel was astute to not provide Dr. Drutz with any opportunity to adopt the studies and to apply his expertise directly to Bard's products, which he might have been able to do and may actually have done without saying so apart from noting the sources in his report.

[121] Thus, there are, without doubt, limits to what use can properly be made of Dr. Drutz's evidence even with the submissive and easy-going scrutiny of the some-basis-in-fact standard. The question that emerges is whether Dr. Drutz has been absolutely discredited in providing evidence for there being some-basis-in-fact for Ms. O'Brien's proposed class action. In this regard, I conclude that he was not totally discredited.

[122] Very little of Dr. Drutz's evidence was directed at Bard in particular, and it is true as submitted by Bard that Dr. Drutz was retained by Ms. O'Brien counsel as an expert to provide background information on the "industry" of medical suppliers who distribute pelvic mesh products. Indeed, Dr. Drutz has been retained for several separate class actions against other

medical device manufacturers. However, Bard was undoubtedly a member of this medical device industry manufacturing and selling competing medical devices using surgical mesh, and I do not think it was inappropriate in the circumstances of this case for Dr. Drutz to have regard to what Bard knew or ought to have known having regard to its participation in the medical device industry.

[123] With one possible exception, which I will describe below, I agree with Bard that as a unified group of products, its Pelvic Mesh Products do not have a unified common defective design feature. Further, with the same one possible exception, I agree with Bard that each of its products has a different risk-to-benefit profile. Further still, once again - with the same one possible exception - I also agree with Bard's submission that Ms. O'Brien's expert witness, Dr. Drutz, and its non-expert witness, Ms. Lombardi, have not provided admissible evidence to show a singular or common design defect in Bard's Pelvic Mesh Products. The one possible exception – and it is crucial to the certification of this proposed class action - is that all of Bard's Pelvic Mesh Products include permanently implanted surgical mesh.

[124] As Ms. O'Brien's counsel simply put it: "this proposed class action is all about the mesh." In my opinion, Dr. Drutz was qualified to express an opinion about the use of surgical mesh in the treatment of POP and SUI and that he gave an independent and professional opinion in this regard. Unfortunately, however, for the fate of Ms. O'Brien's class action, in my opinion, a class action all about the mesh does not answer Bard's ultimate objection or the ultimate obstacle or roadblock to the certification of this class action as structured by Ms. O'Brien and her counsel.

[125] As structured, the case at bar wants for the fundamental ingredient of commonality. There is no common issue that spans this proposed class action for 19 medical devices, of which ten are for the treatment of POP and nine are for the treatment of SUI. The ten devices for the treatment of POP are each different one from the other and the nine for the treatment of SUI are different one from the other. In my opinion, Dr. Drutz's evidence about the use of mesh products in the medical device industry to treat POP and SUI does not connect the dots, so to speak, to establish that there is a some-basis-in-fact for a common issue about the use of surgical mesh in Bard's 19 products. The fact that all the 19 products include surgical mesh does not produce a commonality any more than the fact that all 19 products are medical devices sold by Bard.

[126] The commonality of surgical mesh in the 19 products conveys only a false impression of commonality, because the evidence on the certification motion shows that the 19 medical devices for the treatment of two very different medical ailments are different in materials; shape; size; weight; density; weave; porosity; flexibility; configuration; fixation methodology; design purposes; and, product warnings.

[127] Here, it should be recalled that: Dr. Drutz does not have the expertise to opine whether design changes could be made to Pelvic Mesh Products to make them safe or safer; he did not go so far as to submit that permanent surgical mesh products should never be used; and in his second report, he acknowledged that there is a role for device-assisted pelvic repair surgeries. Here, it should also be recalled that none of the U.S. Food and Drug Administration, Health Canada, and the Society of Obstetricians and Gynecologists of Canada have suggested that permanent surgical mesh products should never be used or that it would be impossible to manufacture a safely designed medical device that used surgical mesh.

[128] There is no demonstrated basis-in-fact to support the prospect that there could be a class-wide determination that there was a breach of the standard of care in designing the products for POP and SUI, and, as I shall explain again later, there is no demonstrated basis-in-fact for a determination of general causation. Simply put, Ms. O'Brien has not shown that any significant element of her claim is capable of proof on a class-wide basis: *McCracken v. Canadian National Railway*, *supra* at para. 128.

[129] The problem is not that Bard's conduct cannot be measured by its participation in the medical device industry using surgical mesh. If the case is all about the mesh as Ms. O'Brien would have it, then Bard is a part of the industry whose members, including Bard, made the decision to offer surgical mesh products to POP and SUI patients and that participation is relevant. The problem is that Bard and its competitors made separate design decisions and different decisions about warnings on a product-by-product basis.

[130] It remains to be seen whether all the separate design decisions made by medical device manufacturers were negligent, but if that turned out to be the case and it was negligent to use surgical mesh in all the products, then that would be a coincidental determination of design negligence not a common one, because in accordance with the law of design negligence, one must evaluate the risks and benefits of the design decisions made for each different product.

[131] In its submissions that Ms. O'Brien's class action wants for commonality, Bard relies on numerous idiosyncratic factors about the Class Members and their physicians. By and large, those differences among the Class Members would not defeat a finding of commonality. The commonality problem for Ms. O'Brien's class action is on the defendant's side of the forensic ledger, where a decision about one product, even about its use of surgical mesh, does not produce a class-wide decision because of significant levels of difference among Bard's products.

(f) **Ms. O'Brien's Evidence**

[132] Ms. O'Brien's own evidence also does not provide the some-basis-in-fact for a common issue for Bard's 19 products. Ms. O'Brien's evidence is directed more at the general causation issue of whether surgical mesh is a potential cause of the long list of adverse conditions described in the Statement of Claim, some of which, sadly, have afflicted Ms. O'Brien. I will return to the issue of the commonality of general causation later in these Reasons for Decision.

[133] Ms. O'Brien's evidence is undoubtedly relevant, and she is a brave and noble person to have committed herself to act as a representative plaintiff. She used a Bard product for treatment of SUI. Since her surgery, she has suffered greatly. Although individual causation and the role of her own doctors will be contested issues, she believes that the mesh is the problem that caused her conditions. She testified that had she been aware of the actual rate of side effects and the actual potential magnitude of side effects associated with the defendant's Pelvic Mesh Products she would not have had surgery that employed surgical mesh. There are apparently others like Ms. O'Brien.

[134] Here, it should be noted that Ms. O'Brien pleads Bard's Pelvic Mesh Products have a high failure, injury and complication rate, fail to perform as intended, require frequent and debilitating re-operations, and have caused severe and irreversible injuries, conditions and damages. Ms. O'Brien pleads that Bard failed to ensure its Pelvic Mesh Products were safe for

use or, in the alternative, for providing an adequate warning of the actual rate of side effects and potential magnitude of side effects associated with them.

[135] The problem, however, is that Ms. O'Brien has no basis-in-fact to pluralize her allegations beyond her own experience.

[136] Ms. O'Brien's allegations are about Bard designing a medical product to treat POP and SUI that uses permanent mesh, be it fashioned from polypropylene, *mono*filament propylene, collagen, or elastin or some combination or permutation of those materials. Ms. O'Brien's class action is indeed about the mesh, but the problem persists that 19 separate design decisions are made about the mesh.

[137] Visualize, if the use of permanent surgical mesh in the Align Urethral Support System to treat Ms. O'Brien's SUI is found to be a design defect or if the use of mesh is shown to make the Align Urethral Support System unfit for the purpose for which it was intended; i.e., as a treatment or cure for SUI, that finding could not be extrapolated to other Class Members treated by different Bard Pelvic Mesh Products for different kinds of SUI and for different kinds of POP.

[138] If there was inadequate warning about the possible consequences of using permanent surgical mesh in an Align Urethral Support System to treat Ms. O'Brien's SUI, that finding could not be extrapolated across the class to Class Members who were treated with different products and who received different warnings.

[139] Similarly, if it were determined that Bard made negligent design decisions about using mesh for the treatment of a POP bladder condition, it would not be determinative of whether it made a negligent design decision about the use of mesh for the treatment of Ms. O'Brien's SUI.

[140] For the above reasons and for the reasons described later under the heading of the Common Issues Criterion, I conclude that it is not the case that there is some-basis-in-fact for the commonality criterion that is critical to the certification of a class action.

C. DISCUSSION AND ANALYSIS

1. Introduction

[141] The conclusion just reached that there is no basis-in-fact for commonality in the common issues for Ms. O'Brien's class action is fatal to her class action, and accordingly, I dismiss the Plaintiffs' certification motion.

[142] However, there may be an appeal, and, I should also add that there are other class actions concerning the use of surgical mesh for medical devices for the treatment of POP and SUI pending before the court. These Reasons for Decision may influence the argument of the certification motions in those pending cases. Therefore, I shall complete an analysis of whether Ms. O'Brien's proposed class action satisfies the criteria for certification under the *Class Proceedings Act, 1992*.

[143] In the discussion that follows, I will add to my analysis of the commonality problem and the implications of that problem. I shall also have something to say about waiver of tort claims in personal injury product liability class actions.

[144] I should add that I have not had regard to any material filed in the other class actions and carefully avoided doing so in preparing for Ms. O'Brien's certification motion and in writing these Reasons for Decision.

2. Introduction to Certification

[145] Pursuant to s. 5(1) of the *Class Proceedings Act, 1992*, the court shall certify a proceeding as a class proceeding if: (1) the pleadings disclose a cause of action; (2) there is an identifiable class; (3) the claims of the class members raise common issues of fact or law; (4) a class proceeding would be the preferable procedure; and (5) there is a representative plaintiff who would adequately represent the interests of the class without conflict of interest and who has produced a workable litigation plan.

[146] For an action to be certified as a class proceeding, there must be a cause of action shared by an identifiable class from which common issues arise that can be resolved in a fair, efficient, and manageable way that will advance the proceeding and achieve access to justice, judicial economy, and the modification of behaviour of wrongdoers: *Sauer v. Canada (Attorney General)*, [2008] O.J. No. 3419 (S.C.J.) at para. 14, leave to appeal to Div. Ct. refused, [2009] O.J. No. 402 (Div. Ct.).

[147] On a certification motion, the question is not whether the plaintiff's claims are likely to succeed on the merits, but whether the claims can appropriately be prosecuted as a class proceeding: *Hollick v. Toronto (City)*, *supra* at para. 16.

[148] The test for certification is to be applied in a purposive and generous manner, to give effect to the important goals of class actions -- providing access to justice for litigants; promoting the efficient use of judicial resources; and sanctioning wrongdoers to encourage behaviour modification: *Western Canadian Shopping Centres Inc. v. Dutton*, [2001] 2 S.C.R. 534 at paras. 26 to 29; *Hollick v. Toronto (City)*, *supra* at paras. 15 and 16.

3. Cause of Action Criterion

(a) General Principles

[149] The first criterion for certification is that the plaintiff's pleading discloses a cause of action. The "plain and obvious" test for disclosing a cause of action from *Hunt v. Carey Canada,* [1990] 2 S.C.R. 959 is used to determine whether a proposed class proceeding discloses a cause of action for the purposes of s. 5(1)(a) of the *Class Proceedings Act, 1992*.

[150] Thus, to satisfy the first criterion for certification, a claim will be satisfactory, unless it has a radical defect or it is plain and obvious that it could not succeed: *Anderson v. Wilson* (1999), 44 O.R. (3d) 673 (C.A.) at p. 679, leave to appeal to S.C.C. ref'd, [1999] S.C.C.A. No. 476; *176560 Ontario Ltd. v. Great Atlantic & Pacific Co. of Canada Ltd.* (2002), 62 O.R. (3d) 535 (S.C.J.) at para. 19, leave to appeal granted, 64 O.R. (3d) 42 (S.C.J.), aff'd (2004), 70 O.R. (3d) 182 (Div. Ct.).

[151] In a proposed class proceeding, in determining whether the pleading discloses a cause of action, no evidence is admissible, and the material facts pleaded are accepted as true, unless patently ridiculous or incapable of proof. The pleading is read generously and it will be

unsatisfactory only if it is plain, obvious, and beyond a reasonable doubt that the plaintiff cannot succeed: *Hollick v. Toronto (City)*, *supra* at para. 25; *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) at para. 41, leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50 , rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.); *Abdool v. Anaheim Management Ltd.* (1995), 21 O.R. (3d) 453 (Div. Ct.) at p. 469.

(b) **The Products Liability Claims**

[152] Relying on Justice Horkins' judgment in *Martin v. AstraZeneca Pharmaceuticals PLC*, *supra*, Bard argues that insofar as Ms. O'Brien's claim is against the collective of C.B. Bard, Inc., Bard Canada Inc. and Bard Medical Division, it is an un-particularized and improperly or inadequately pleaded claim of enterprise liability that does not allow the defendants to know the case they must meet. Bard submits that Ms. O'Brien has not satisfied the requirement to properly plead a cause of action against each defendant with specificity. And, therefore, to the extent their claims are based in enterprise liability the claims must fail and thus Ms. O'Brien's proposed class action does not satisfy the first criterion for certification.

[153] Here, Bard's argument is without merit. Save for her pleading of waiver of tort, Ms. O'Brien's Statement of Claim is adequate for the purposes of satisfying the first criterion of certification.

[154] Bard criticizes Ms. O'Brien's lumping together of the Defendants. This criticism is fallacious. In this regard, I begin with the observation that Bard Medical Division does not exist as a legal entity independent from Bard U.S. Perhaps Bard was misled by Ms. O'Brien pleading as if Bard Medical Division was a different legal entity from Bard U.S., but as a legal matter, Bard Medical Division is already together with Bard U.S. Although I would not use the word lumped, from a legal perspective, Bard Medical Division is as much a part of Bard as an arm is a body part not a separate body.

[155] From a legal perspective, Bard Canada, as a subsidiary is indeed a separate legal entity, but Bard is just feigning ignorance in submitting that it does not understand why Bard Canada is being sued and Bard, the collective, such as it is, has fair and adequate notice of the causes of action being alleged. The pleading in the case at bar does not suffer from the numerous problems that plagued the pleading in *Martin v. AstraZeneca Pharmaceuticals PLC*, *supra.*

[156] Excepting the Waiver of Tort Claim, discussed next, I conclude that Ms. O'Brien and Mr. Pearce have satisfied the first criterion for certification.

(c) **The Waiver of Tort Claim**

[157] In *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, *supra* at para. 97, the Supreme Court of Canada held that the questions about the consequences of identifying waiver of tort as an independent cause of action involve matters of policy that should not be determined at the pleadings stage. In light of the *Pro-Sys Consultants Ltd.* decision, Bard did not challenge waiver of tort as a cause of action, save to say that it did not agree that it was a cause of action and that the plea suffered from the same defects as the product liability claim.

[158] *Pro-Sys Consultants Ltd.* was a competition law action. The case at bar is a products liability tort case. For decades, going at least as far back as *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.), and continuing to this day, courts have determined matters of policy in tort claims at

the pleadings stage and if it were necessary to do so I would decide whether waiver of tort is a cause of action and, if it is a cause of action I would decide whether it is a viable cause of action for a products liability proposed class action so as to satisfy the cause of action criterion of certification.

[159] For the purposes of this proposed class action, it is, however, not necessary to decide whether waiver of tort is a discrete cause of action. In light of Bard's concession, I will assume that waiver of tort is a discrete cause of action. However, even with that assumption, in my opinion, waiver of tort is not a certifiable cause of action in the circumstances of the case at bar.

[160] In the case at bar, it is inconceivable that Ms. O'Brien as Representative Plaintiff or the individual Class Members would ever waive their tort claims and make a claim in restitution against Bard for it to disgorge the profits it made from distributing negligently manufactured Pelvic Mesh Products.

[161] It may have made sense in *Serhan v. Johnson & Johnson* (2004), 72 O.R. (3d) 296 (S.C.J.), leave to appeal granted [2004] O.J. No. 4580 (S.C.J.), aff'd (2006), 85 O.R. (3d) 665 (Div. Ct.), leave to appeal to C.A. ref'd Oct. 16, 2006, leave to appeal to S.C.C. ref'd [2006] S.C.C.A. No. 494 to waive the tort damages claim (there were, in fact, no damages) but it makes no sense and would be irresponsible to the point of absurdity to waive individual tort damage claims which in the aggregate are pleaded to be worth billions of dollars.

[162] In *Serhan v. Johnson & Johnson*, which is the case that started the debate about the nature of waiver of tort, there were zero monetary damages for the tort claim and waiver of tort was the route to access to justice and behaviour modification. In the case at bar, assuming Bard were negligent, a waiver of tort cause of action would not provide access to justice to class members or any meaningful behaviour modification. It would be reprehensible for Class Counsel to take a contingent fee based on an award calculated on the disgorgement of profits. A judgment or a settlement based on waiver of tort would create enormous conflicts between Class Members as to how the disgorged funds should be distributed. It would be a waste of the court's and the parties' litigation resources to expend discovery and trial time calculating what profits, if any, Bard made from its Pelvic Mesh Products, when assuming liability, everybody should be spending their litigation resources calculating compensatory damages.

[163] In my opinion, in these circumstances, regardless of whether waiver of tort is a reasonable cause of action, it would not be reasonable to prosecute it as a class action. Even if the pleading of waiver of tort satisfied the cause of action criteria, the class definition, and the common issues criteria, in my opinion, the waiver of tort claim in the circumstances of the case at bar would not satisfy the preferable procedure and the representative plaintiff criteria.

[164] In these circumstances, I conclude that the waiver of tort claim in the case at bar does not satisfy the cause of action criterion for a class action.

[165] I would not certify the waiver of tort claim.

4. Identifiable Class Criterion

[166] I turn now to the second criterion for certification of a class action, the identifiable class criterion.

[167] The definition of an identifiable class serves three purposes: (1) it identifies the persons who have a potential claim against the defendant; (2) it defines the parameters of the lawsuit so as to identify those persons bound by the result of the action; and (3) it describes who is entitled to notice: *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 (Gen. Div.).

[168] In defining Class Membership, there must be a rational relationship between the class, the causes of action, and the common issues, and the class must not be unnecessarily broad or over-inclusive: *Pearson v. Inco Ltd.* (2006), 78 O.R. (3d) 641 (C.A.) at para. 57, rev'g [2004] O.J. No. 317 (Div. Ct.), which had aff'd [2002] O.J. No. 2764 (S.C.J.).

[169] The plaintiffs propose the following Class Member definition and Family Class Member definition:

> All persons resident in Canada who were implanted with Pelvic Mesh Products at any time on or before the date of the certification order, and which was manufactured, marketed and/or sold or otherwise placed into the stream of commerce in Canada by the defendants;
>
> All persons resident in Canada, who by virtue of a personal relationship to any one or more of the persons described in (a) above, have standing in this action pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, or equivalent legislation in a respective jurisdiction, or the common law.

[170] Bard notes that Ms. O'Brien's Class Member definition includes all persons implanted with the defendants' "Pelvic Mesh Products," and that in the statement of claim, "Pelvic Mesh Products" is defined by reference to 21 product systems. Bard also notes that definition includes "any other as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of instruments and procedures for implantation."

[171] I agree with Bard's submission that the proposed definition creates an open, potentially expanding definition of the Class that does not satisfy the prerequisites for a proper class definition. As currently proposed, the class definition has no clear boundary and the proposed definition does not satisfy the clear definition requirement.

[172] This defect in the Class Member definition, however, is readily correctable so that the class definition: (1) identifies the persons who have a potential claim against Bard; (2) defines the parameters of the lawsuit to identify those persons bound by the result of the action; and (3) describes who is entitled to notice. I conclude that the following class definition satisfies the class definition criterion for certification:

> All persons resident in Canada who were implanted with the pelvic mesh products listed below at any time on or before the date of the certification order, and which products were manufactured, marketed and/or sold or otherwise placed into the stream of commerce in Canada by the defendants:
>
> Align - Urethral Support System
> Align - TO Urethral Support System
> Avaulta Anterior BioSynthetic
> Avaulta Posterior BioSynthetic
> Avaulta Plus Anterior BioSynthetic
> Avaulta Plus Posterior BioSynthetic
> Avaulta Solo Anterior
> Avaulta Solo Posterior
> Pelvilace and Innerlace

Pelvicol
Pelvisoft,
Uretex SUP
Uretex TO
Uretex TO2
Uretex TO3
Pelvitex
Alyte
Ajust

[173] Bard also objects to the proposed class definition, because Bard submits that there is no rational connection between any common complaint and the proposed Class Members. This objection is in its essence an argument about the submitted absence of a singular design defect in the multifarious products manufactured by Bard for the treatment of POP and SUI. It is not an argument about the technicalities of the class definition. For the reasons discussed above, and discussed briefly again below, I agree with the argument about commonality but I do not think the argument applies to the technicalities of defining of the class.

[174] I conclude, therefore, that Ms. O'Brien has or could satisfy the second criterion for certification of a class action.

5. Common Issues Criterion

(a) General Principles

[175] The third criterion for certification is the common issues criterion. For an issue to be a common issue, it must be a substantial ingredient of each Class Member's claim and its resolution must be necessary to the resolution of each Class Member's claim: *Hollick v. Toronto (City), supra* at para. 18.

[176] With regard to the common issues, "success for one member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent." The answer to a question raised by a common issue for the plaintiff must be capable of extrapolation, in the same manner, to each member of the class: *Shopping Centres Inc. v. Dutton, supra* at para. 40; *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540 at para. 32; *Merck Frosst Canada Ltd. v. Wuttunee*, 2009 SKCA 43 at paras. 145-46 and 160; *McCracken v. Canadian National Railway Co., supra,* at para. 183.

[177] In *Pro-Sys Consultants v. Microsoft, supra* at para. 106, the Supreme Court of Canada describes the commonality requirement as the central notion of a class proceeding which is that individuals who have litigation concerns in common ought to be able to resolve those common concerns in one central proceeding rather than through an inefficient multitude of repetitive proceedings.

[178] An issue is not a common issue if its resolution is dependent upon individual findings of fact that would have to be made for each Class Member: *Fehringer v. Sun Media Corp.*, [2003] O.J. No. 3918 (Div. Ct.) at paras. 3, 6. Common issues cannot be dependent upon findings which will have to be made at individual trials, nor can they be based on assumptions that circumvent the necessity for individual inquiries: *Nadolny v. Peel (Region)*, [2009] O.J. No. 4006 (S.C.J.) at paras. 50-52; *Collette v. Great Pacific Management Co.*, [2003] B.C.J. No. 529 (B.C.S.C.) at para. 51, varied on other grounds (2004) 42 B.L.R. (3d) 161 (B.C.C.A.); *McKenna v. Gammon*

Gold Inc., [2010] O.J. No. 1057 (S.C.J.) at para. 126, leave to appeal granted [2010] O.J. No. 3183 (Div. Ct.), varied 2011 ONSC 3882 (Div. Ct.).

[179] The common issue criterion presents a low bar: *Carom v. Bre-X Minerals Ltd.* (2000), 51 O.R. (3d) 236 (C.A.) at para. 42; *Cloud v. Canada (Attorney General)* (2004), O.R. (3d) 401 (C.A.) at para. 52; *203874 Ontario Ltd. v. Quiznos Canada Restaurant Corp.*, [2009] O.J. No. 1874 (Div. Ct.), aff'd [2010] O.J. No. 2683 (C.A.), leave to appeal to S.C.C. refused [2010] S.C.C.A. No. 348.

[180] An issue can be a common issue, even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution: *Cloud v. Canada (Attorney General) supra.* A common issue need not dispose of the litigation; it is sufficient if it is an issue of fact or law common to all claims and its resolution will advance the litigation for (or against) the class: *Harrington v. Dow Corning Corp.*, [1996] B.C.J. No. 734, (S.C.B.C.), aff'd 2000 BCCA 605, leave to appeal to S.C.C. ref'd [2001] S.C.C.A. No. 21.

(b) **Common Issues Analysis**

[181] Excluding the waiver of tort claim, which I would not certify for the reasons expressed earlier, Ms. O'Brien proposes the following list of common issues:

> 1. Can the defendants' Pelvic Mesh Products cause or contribute to Injuries, Conditions and Complications?
>
> 2. If the answer to (1) is yes, are the defendants' Pelvic Mesh Products thereby defective or unfit for the purpose for which they were intended as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the defendants?
>
> 3. Did one or more of the defendants breach a duty of care owed to the Class by the way in which the defendants' Pelvic Mesh Products were marketed and distributed in Canada?
>
> 4. Did one or more of the defendants knowingly, recklessly or negligently breach a duty to warn or materially misrepresent any of the risks of harm from using the defendants' Pelvic Mesh Products?
>
> 5. If one or more of the common issues (1) though (4) are answered affirmatively, are Class Members who are subsequently able to establish valid claims entitled to special damages for medical costs incurred in the screening, diagnosis and treatment of Injuries, Conditions and Complications related to use of the defendants' Pelvic Mesh Products?

[182] As I have already mentioned above in the introduction and in the discussion of the evidentiary and factual background, Bard submits that this proposed products liability class action is quintessentially inappropriate for certification because Ms. O'Brien and her expert witness, Dr. Drutz has not provided admissible evidence to satisfy the some-basis-in-fact test for the certification criteria and, in particular, Bard submits that Ms. O'Brien and her expert witness failed to identify a common design defect for the group of Bard Pelvic Mesh Products.

[183] For the reasons already expressed above, I agree. In my opinion, there is no some-basis-in-fact evidence for a class action based on a multiproduct use of surgical mesh to treat the full panoply of POP and SUI cases.

[184] In my opinion, unlike the seminal *Bendall v. McGhan Medical Corp.*, *supra*, which concerned multifarious products and breast implants of various designs, the case at bar does not have sufficient commonality to satisfy the common issues criterion. In *Bendall,* Justice Montgomery dealt with the commonality criterion in two sentences at paragraph 45 of his reasons as follows: "Common issues are raised in that part of the pleading that addresses the common problems of escape of silicone into the body of users of implants. This sufficiently covers s. 5(c)." *Bendall* was likely rightly certified, but it was certified based on the pleadings without any genuine evidentiary foundation.

[185] In the last regard, it is interesting and informative to note that in *Harrington v. Dow Corning Corp.*, 2005 BCCA 605, a silicone breast implant class action in British Columbia, a five-member panel of the British Columbia Court of Appeal (Rowles, Ryan and Huddard, JJ.A. for the majority, Esson and Finch, JJ.A. dissenting) affirmed the decision of the motions judge, Justice Mackenzie, that whether silicone gel implants were reasonably fit for their intended purpose was a common issue.

[186] Significantly, in *Harrington*, the evidence established that there was no substantial difference among the various styles of silicone implants. The Court also affirmed Justice Mackenzie's decision that the evidence did not support the allegation that issue of fitness was common to both silicone gel and saline implants. The Court ruled that the evidence supported the judge's conclusion that the fitness issue was not common to both silicone gel and saline implants, but the judge did not err in finding that the risk assessment could fairly and efficiently be undertaken at a common issues trial with respect to the various styles of silicone gel implants.

[187] In *Harrington*, the plaintiff produced epidemiological evidence that treated the multiple silicone products of multiple defendants as generic. In the Court of Appeal, Justice Huddard, stated for the majority at para. 41:

> 41. On the basis of the evidence before him, the chambers judge saw fitness as a generic issue common to all silicone gel breast implants. Fitness would advance the litigation because the trial of that issue would move the plaintiffs significantly toward establishing liability. I am not persuaded he erred in so finding.

[188] In *Harrington*, Justices Finch and Esson dissented because they were not satisfied that commonality had been established. At para. 127 of his reasons, Justice Finch stated that it was not possible to determine if the breast implant was unfit without examining the specific product in relation to specific plaintiffs and, therefore, the common issue certified was not capable of application to all members of the class.

[189] I agree with Bard's submission that not all products liability cases are appropriate for certification and that multiple product cases, in particular, may not be suitable for class actions because there may be an absence of commonality and because of complexities in the problems of proof of the applicable duty of care over a period of time with changing manufacturing techniques, developments in science and technology, and emerging knowledge about the risks of adverse outcomes and adverse side effects.

[190] No type of class action is quintessentially certifiable, even a products liability class action. Each class action of whatever genre must be individually assessed. In some, perhaps most class actions, the evidence of an expert will be required to show some-basis-in-fact for the certification criteria. In a few others, it will be obvious that there is some-basis-in-fact for the class action. The case at bar is not a case in which it is obvious that there is some-basis-in-fact

commonality of the common issues. In my opinion, in the case at bar, all the proposed questions want for commonality and that is fatal to the class action.

[191] Many products liability actions have been certified, but not all products liability class actions are certified; for example; see: *Gariepy v. Shell Oil Co*, [2002] O.J. No 2766 (S.C.J.), aff'd 2004 CarswellOnt 8813 (Div. Ct.); *Ernewein v General Motors of Canada Ltd.*, *supra*; *Poulin v. Ford Motor Co of Canada,* [2008] O.J. No. 4153 (Div. Ct.); *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42; *Perreault c. McNeil PDI Inc.*, 2010 QCCS 4310; *Williams v. Canon Canada Inc.*, *supra*; *Arora v. Whirlpool Canada LP*, 2012 ONSC 4642; *Martin v. AstraZeneca Pharmaceuticals PLC*, *supra*; *Charlton v. Abbott Laboratories Ltd.*, 2015 BCCA 26.

[192] Conceptually, the case at bar fails on the commonality issue for much the same reason that the proposed multiple products design negligence claim failed in *Ernewein v. General Motors of Canada*, *supra*. In *Ernewein*, the British Columbia Court of Appeal reversed the certification decision in an action against General Motors. The plaintiffs alleged that General Motors designed 28 models of pick-up trucks with the design defect of placing the fuel tanks outside the frame of the truck making them prone to rupture and explosion upon a collision. The plaintiff's evidence on commonality was ruled inadmissible and General Motors' evidence rebutted the existence of any common issue. Justice Newbury delivered the judgment of the court, and she stated at paragraphs 32-33 of her judgment:

> 32. Accepting, then, that Mr. Pena's report was "not evidence", no proper basis was advanced for the proposition that the location of fuel tanks outside the rails of the subject vehicles raised a question common to all the plaintiffs, the resolution of which question would significantly advance the litigation. Rather, the only evidence is that of the defendants' expert, Mr. Sinke, to the effect that because the C/K pick-ups between 1973 and 1991 incorporated "a number of unique fuel system designs", one cannot "generalize on how such vehicles will perform in particular crashes beyond stating that all the designs are reasonably safe and meet all applicable federal safety standards." The ability to generalize, or extrapolate, from one plaintiff's vehicle to another, is crucial to the existence of a common issue. .... Having provided no "evidentiary basis", the plaintiffs did not meet this requirement in this case.
>
> 33. I reach this conclusion notwithstanding the fact that product liability claims are often cited as an example of the type of action particularly suited to class action proceedings. Since earlier cases such as *Chace v. Crane Canada Inc.* (1997) 44 B.C.L.R. (3d) 264 (B.C.C.A.) and *Campbell v. Flexwatt Corp.* (1997) 44 B.C.L.R. (3d) 343 (B.C.C.A.), experience has shown that not all product liability cases lend themselves to certification. In some, the complexities inherent in problems of proof of the applicable duty of care over a long period of time, changing manufacturing techniques, or multi-party involvement in the product delivery chain, have made the formulation of a common question problematic: see *Bittner v. Louisiana-Pacific Corp.* (1997) 43 B.C.L.R. (3d) 324 (B.C.S.C.), *Caputo v. Imperial Tobacco Ltd.* (2004), 236 D.L.R. (4th) 348 (Ont. S.C.J.), and *Gariepy v. Shell Oil Co.* (2002) 23 C.P.C. (5th) 360 (Ont. Sup. Ct. J.), aff'd [2004] O.J. No. 5309 (Div. Ct.). In each instance, the question must be determined "contextually" - i.e., not on the basis of a blanket assumption regarding product liability cases but in light of all the evidence concerning the specific case before the court. In the case at bar, the plaintiffs failed to establish an evidentiary basis; i.e., to adduce admissible evidence, for the proposition that the determination of the real common issues - whether the fuel system design(s) employed by the defendants breached the applicable standard(s) of care and created an unreasonable risk of harm to the plaintiffs - would advance the litigation in a meaningful way. I conclude that the certification order must therefore be set aside.

[193] The case at bar is not like *Schroeder v. DJO Canada, Inc.*, 2010 SKQB 125, aff'd 2011 SKCA 106. In *Schroeder,* the defendants McKinley Medical LLC and McKinley Medical Corporation manufactured a pain pump that was distributed in Canada by the defendants DJO Canada Inc. and DJO LLC. The pain pump was a medical device with a special catheter designed to be implanted to infuse anaesthetic at a surgical wound site. All of the proposed plaintiffs underwent surgery by the same orthopaedic surgeon who inserted the pain pump's catheter into their synovial cavities. Each of the plaintiffs developed a condition known as chondrolysis. Each of the proposed class members claimed that the catheter ought not to have been placed in the synovial cavity. The plaintiffs brought an action for negligence against the defendants on the basis that the defendants were negligent in the design, manufacture and distribution of the pain pumps and failed to warn patients, doctors and government regulators about the serious health risks associated with the use of the product.

[194] Interestingly, in *Schroeder,* the proposed class was comprised of 17 patients who had developed chondrolyis of the shoulder and 12 patients that developed chondrolyis of the knee. Although the courts in Saskatchewan apply a somewhat different test for certification, for present purposes what is notable about *Schroeder* is that Justice Popescul revised the proposed central common issue to make it specific and precise and capable of being answered in a way that would produce a productive class action.

[195] In *Schroeder*, the proposed common issue was: "Whether the defendants' pain pump caused serious adverse effects and, if so, what are the nature and extent of those adverse effects?" Justice Popescul revised the question, and he stated at paragraphs 92 to 94 of his reasons for decision:

> 92. The defendants point out that the first proposed common issue, as submitted by the plaintiffs, is overly broad. The issue, as framed, speaks in terms of the pain pumps having "caused serious adverse effects", which could cover a variety of adverse outcomes which may, or may not, be relevant to the individual claims of potential class members.
>
> 93. I agree with the defendants' submission respecting their view that the issue as proposed is overly broad in that it alleges "serious adverse effects", which is a very expansive and nebulous assertion not amenable to designation as a common issue. For example, patients may have suffered nausea, upset stomach, infection in the insertion site, etc. These types of adverse effects are very patient-specific. The plaintiffs' claim is focused primarily on the alleged serious adverse consequence of chondrolysis. Anything beyond that consequence makes the issue too individualistic such that it would remove it from the realm of a "common issue". Furthermore, the statement of claim, as drafted, focuses on situations where the pain pump was inserted directly into the synovial cavity. This is a very specific and precise allegation and much more amenable to a common issue determination than is the overly broad question of whether the pumps caused "serious adverse effects" and, if so, "the nature and extent of those adverse effects".
>
> 94. In my view, the real issue disclosed by the pleadings and the material filed in support of, and in opposition to, the certification application is this: Does the DonJoy Pain Control Device cause chondrolysis when placed in the synovial cavity of a knee or shoulder following surgery?

[196] Unlike *Schroeder,* in the case at bar, there are no basis-in-fact for any common issues.

[197] That said, I have some additional comments about the proposed general causation common issue. In *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260, which involved whether estrogen-progestin therapy can be said to cause or contribute to breast cancer, the British Columbia Court of Appeal noted that a plaintiff's proving that a medical treatment has a causal connection with damages is unlike being hit by a car and suffering a broken bone, because in the

case of medical treatments, the plaintiff must first prove general or generic causation; i.e., that the drug or device has the potential to cause harm and then the plaintiff must prove specific or individual caution; i.e., that the potential for harm was actualized.

[198] Where a plaintiff seeks to address questions of causation on a class-wide basis as the foundation for his or her class action, there must be some evidence of a methodology that will enable the plaintiff to prove causation on a class-wide basis: *Charlton v. Abbott Laboratories Ltd.*, 2015 BCCA 26, rev'g 2013 BCSC 1712; *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 at para. 52 (C.A.), aff'g (2001), 54 O.R. (3d) 520 (Div. Ct.), leave to appeal refused, [2003] 2 S.C.R. vi. Where no such methodology is put forward by the plaintiffs, there is not sufficient evidence before the court to show that the resolution of the proposed general causation common issue will efficiently advance the claim: *Charlton v. Abbott Laboratories Ltd.*, *supra* at para. 84; *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, *supra* at para. 115; *AIC Limited v. Fischer*, 2013 SCC 69 at para.43.

[199] In *Chadha v. Bayer Inc.*, *supra*, which was a competition conspiracy action, the Court of Appeal denied certification because there was no evidence that liability could be proved on a class-wide basis and thus there was no common issue.

[200] In *Charlton*, the defendants manufactured an antidepressant that contained sibutramine. There was some-basis-in-fact that sibutramine increased blood pressure and the risk of heart attacks and strokes in persons with a pre-existing cardiovascular condition. The plaintiffs, who as individuals had suffered strokes and heart attacks after being prescribed with drugs containing sibutramine, brought a proposed class action on behalf of patients prescribed with the drug. The expert evidence at the trial established that there was no methodology to establish that sibutramine had the potential to harm other than those with a pre-existing cardiovascular condition. Reversing the motions judge, the British Columbia Court of Appeal concluded that he had erred in certifying the class action.

[201] During argument, I used the example of the distribution of thalidomide as an over-the-counter available treatment for an expectant mother's morning sickness as a case where it was obvious that there was some-basis-in-fact for a class action and general causation would provide a certifiable common issue. Had modern class action legislation been available when the thalidomide tragedy occurred, I doubt that any expert evidence would have been necessary to establish some-basis-in-fact for a viable class action for those born with deformed limbs and other birth defects.

[202] The case at bar, however, is not so simple as the thalidomide example, and it is not obvious that there is some-basis-in-fact for a common issue about the use of surgical mesh in 19 Bard products causing personal injuries. Recalling that in counsel's letter of instructions to Dr. Drutz, it was acknowledged that mesh can be effective in treating certain conditions, and recalling that he acknowledged that there is a role for device-assisted pelvic repair surgeries, it follows that a discrete product-by-product risk-benefit analysis is required in the case at bar and there is no commonality of causation just from the fact that the action as currently structured is all about the mesh.

[203] The causation issue in the case at bar lacks commonality in the same way that the causation issue in *Martin v. AstraZeneca Pharmaceuticals PLC*, *supra*, wanted for commonality. In that case, Justice Horkins stated at para. 102:

> 102. The plaintiffs have offered no evidence to show that this issue is capable of being assessed in common. It is not susceptible to a single answer at this abstract level. Asking in the abstract if Seroquel can cause weight gain and diabetes is only the beginning of the inquiry. There is a problem with a general causation question when there is no evidence that "compelling epidemiological or statistical evidence might be sufficient to establish individual causation or go a long way to doing so"...

[204] Ms. O'Brien has failed to propose any methodology to show that a finding of causation of the multitude of Injuries, Conditions and Complications from the use of mesh for POP and SUI surgery can be extrapolated across the class.

[205] The case at bar is not like *Andersen v. St. Jude Medical Inc.* (2003), 67 O.R. (3d) 136 (S.C.J.), where Justice Cullity certified a multi-product design negligence class action against the manufacturers of heart repair medical devices coated with a substance known as silizone. The use of silizone coating for the device was a common design defect and Justice Cullity concluded that there would be a productive general causation issue and that a class action was the preferable procedure notwithstanding that there were would be numerous individual issues including assessment of damages and very complicated trials about individual causation. Justice Cullity stated at para. 58:

> 58. In contrast with these cases [*Gariepy v. Shell Oil Co.* (2002), 23 C.P.C. (5th) 360 (Ont. S.C.J.) and *Pearson v. Inco Ltd.*, [2002] O.J. No. 2764 (S.C.J.)], I am here dealing with a putative class of known individuals each of whom received a heart implant, or other device, coated with the same allegedly hazardous substance. For those who are asymptomatic, a trial of common issues will determine the question of liability and remedies. For those who seek damages for injuries suffered by reason of a breach of the standard of care, the specific issues of causation that would have to be determined on an individual basis would, in my judgment, be far more narrowly focused than those that were held to detract from commonality in *Gariepy*, and from preferability in *Pearson*.

[206] The case at bar is not like *Jones v. Zimmer GMBH*, 2011 BCSC 1198, aff'd 2013 BCCA 21 where there was some-basis-in-fact that the defendant's product had specified defects. In that case, Justice Smith stated for the British Columbia Court of Appeal at para. 36:

> 36. In order to establish liability in negligence, each class member must ultimately prove that a specific defect in the Durom Cup or deficiency in the surgical instructions was a cause of the failure of his or her hip implant. However, proof of a causal connection between a defect or deficiency and an individual plaintiff's failed implant is, along with damages, the final step in a product liability action: *Harrington* at para. 46. Causation and damages are individual issues, but proof of a defect in the Cup or a deficiency in the surgical instructions is a substantial and necessary factual link in the chain of proof leading to liability for every member of the class. One or more of the respondents' allegations of defects and deficiencies must be proven before the question of individual causation can be reached. It follows that proof of a defect in the cup or a deficiency in the surgical instructions is an issue common to all plaintiffs, the resolution of which will move the litigation along significantly.

[207] In my opinion, the general causation question (Q.1) wants for commonality and I would not certify it. In my opinion each of Bard's products and Bard's conduct in relation to each of its products requires individual assessment and there is no basis-in-fact for a common issue about general causation.

[208] Finally, on the criterion of common issues, I regard the special damages question (Q.5) as an individual issues question and, in any event, I would not certify it.

[209] I conclude that the common issues criterion has not been satisfied in the case at bar.

6. Preferable Procedure Criterion

(a) General Principles

[210] The fourth criterion is the preferable procedure criterion. Preferability captures the ideas of: (a) whether a class proceeding would be an appropriate method of advancing the claims of the Class Members; and (b) whether a class proceeding would be better than other methods such as joinder, test cases, consolidation, and any other means of resolving the dispute: *Markson v. MBNA Canada Bank* (2007), 85 O.R. (3d) 321 (C.A.) at para. 69, leave to appeal to S.C.C. ref'd, [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, *supra*.

[211] Relevant to the preferable procedure analysis are the factors listed in s. 6 of the *Class Proceedings Act, 1992*, which states:

> 6. The court shall not refuse to certify a proceeding as a class proceeding solely on any of the following grounds:
>
> 1. The relief claimed includes a claim for damages that would require individual assessment after determination of the common issues.
>
> 2. The relief claimed relates to separate contracts involving different Class Members.
>
> 3. Different remedies are sought for different Class Members.
>
> 4. The number of Class Members or the identity of each Class Member is not known.
>
> 5. The class includes a subclass whose members have claims or defences that raise common issues not shared by all Class Members.

[212] For a class proceeding to be the preferable procedure for the resolution of the claims of a given class, it must represent a fair, efficient, and manageable procedure that is preferable to any alternative method of resolving the claims: *Cloud v. Canada (Attorney General) supra* at paras. 73-75, leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 50.

[213] Whether a class proceeding is the preferable procedure is judged by reference to the purposes of access to justice, behaviour modification, and judicial economy and by taking into account the importance of the common issues to the claims as a whole, including the individual issues: *Markson v. MBNA Canada Bank*, *supra* at para. 69, leave to appeal to S.C.C. ref'd, [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, *supra*.

[214] In considering the preferable procedure criterion, the court should consider: (a) the nature of the proposed common issue(s); (b) the individual issues which would remain after determination of the common issue(s); (c) the factors listed in the *Act*; (d) the complexity and manageability of the proposed action as a whole; (e) alternative procedures for dealing with the claims asserted; (f) the extent to which certification furthers the objectives underlying the *Act*; and (g) the rights of the plaintiff(s) and defendant(s): *Chadha v. Bayer Inc. supra*.

[215] The court must identify alternatives to the proposed class proceeding: *AIC Limited v. Fischer*, *supra* at para. 35; *Hollick v. Toronto (City)*, *supra* at para. 28. The proposed representative plaintiff bears the onus of showing that there is some-basis-in-fact that a class

proceeding would be preferable to any other reasonably available means of resolving the class members' claims, but if the defendant relies on a specific non-litigation alternative, the defendant has the evidentiary burden of raising the non-litigation alternative: *AIC Limited v. Fischer*, *supra* at paras. 48-49.

[216] In *AIC Limited v. Fischer*, *supra* at paras. 24 to 38, the Supreme Court of Canada reiterated that the preferability analysis must be conducted through the lens of judicial economy, behaviour modification, and access to justice. Justice Cromwell for the Court stated that access to justice has both a procedural and substantive dimension. The procedural aspect focuses on whether the claimants have a fair process to resolve their claims. The substantive aspect focuses on the results to be obtained and is concerned with whether the claimants will receive a just and effective remedy for their claims if established.

[217] In *AIC Limited v. Fischer,* Justice Cromwell pointed out that when considering alternatives to a class action, the question is whether the alternative has potential to provide effective redress for the substance of the plaintiffs' claims and to do so in a manner that accords suitable procedural rights. He said that there are five questions to be answered when considering whether alternatives to a class action will achieve access to justice: (1) Are there economic, psychological, social, or procedural barriers to access to justice in the case?; (2) What is the potential of the class proceeding to address those barriers?; (3) What are the alternatives to class proceedings?; (4) To what extent do the alternatives address the relevant barriers?; and (5) How do the two proceedings compare?

[218] In considering the preferable procedure criterion, one should consider the type or genre of class action, because in terms of access to justice, the needs of plaintiffs suffering personal injuries are different than the needs of plaintiffs suffering a purely economic loss, and the needs of those suffering economic losses are different depending upon whether the loss is a deprivation or a missed expected financial gain.

[219] The type of remedy being sought be it declaratory, compensatory, or restitutionary may also make a difference to whether a class proceeding is the preferable procedure for the resolution of the class members' claims. Providing injured parties with access to justice cannot be divorced from ensuring that the ultimate remedy provides substantive justice where warranted: *AIC Limited v. Fischer*, *supra*, at para. 24; F. Iacobucci, "What Is Access to Justice in the Context of Class Actions?" in J. Kalajdzic, ed., *Accessing Justice: Appraising Class Actions Ten Years After Dutton, Hollick & Rumley* (2011), 17 at p. 20.

[220] And one should now add to the preferable procedure factors the factor of the relationship between access to justice, which is the preeminent concern of class proceedings, and proportionality in civil procedures. The importance of proportionality to access to justice was recently expressed by the Supreme Court of Canada in *Hryniak v. Mauldin*, 2014 SCC 7 at paras. 1-2, 27, where the Court stated:

> Ensuring access to justice is the greatest challenge to the rule of law in Canada today. Trials have become increasingly expensive and protracted. Most Canadians cannot afford to sue when they are wronged or defend themselves when they are sued, and cannot afford to go to trial. ... Increasingly, there is recognition that a culture shift is required in order to create an environment promoting timely and affordable access to the civil justice system. This shift entails simplifying

> pre-trial procedures and moving the emphasis away from the conventional trial in favour of proportional procedures tailored to the needs of the particular case. The balance between procedure and access struck by our justice system must come to reflect modern reality and recognize that new models of adjudication can be fair and just.
>
> There is growing support for alternative adjudication of disputes and a developing consensus that the traditional balance struck by extensive pre-trial processes and the conventional trial no longer reflects the modern reality and needs to be re-adjusted. A proper balance requires simplified and proportionate procedures for adjudication, and impacts the role of counsel and judges. This balance must recognize that a process can be fair and just, without the expense and delay of a trial, and that alternative models of adjudication are no less legitimate than the conventional trial.

(b) **Preferable Procedure Analysis**

[221] It is axiomatic that if there is no basis-in-fact for common issues, then there is no basis-in-fact for a class action satisfying the preferable procedure criterion. In the case at bar, it follows that Ms. O'Brien's class action does not satisfy the preferable procedure criterion.

[222] Bard's arguments that even if there were common issues in the case at bar, a class action would not be the preferable procedure are, therefore, redundant. However, because the point was fully argued, because there may be an appeal, because there are other similar class actions pending, and because the issue of the preferable procedure is relevant to the discussion below about the "Alternatives Motion," I shall address Bard's arguments on their merits and with the assumption that there are common issues in the case at bar that could be productively litigated by a class action.

[223] With the assumption that there are common issues, in my opinion, Ms. O'Brien's class action would satisfy the preferable procedure criterion. With that assumption, the case at bar would become similar to *Andersen v. St. Jude Medical Inc.*, *supra* and other design negligence or failure to warn products liability class actions that have satisfied the preferable procedure criterion.

[224] In the history of class action jurisprudence and in class action literature, products liability actions are often presented as a paradigm because with numerous persons injured or potentially injured by a negligently manufactured or a negligent designed product or by a failure to warn of dangers inherent to the product, a class action typically provides access to justice, behaviour modification, and judicial economy.

[225] These advantages of a class action are most prevalent in cases where the class members' individual claims are small in monetary value. In that situation, it is fair to say that unless an entrepreneurial class counsel was willing to take on the class action, the class members would have no practical alternative and they would never pursue access to justice and the negligent manufacturer of the defective product would get away with it. In those circumstances, of small value claims, but for a class action, there would be no access to justice and no behaviour modification.

[226] The case at bar is not a matter of small monetary claims and, as noted above, before adding in pecuniary damages (and the subrogated claims of health insurers) and punitive damages, the non-pecuniary claims are valued at $500,000 per class member. Because a claim tending toward a million dollars tends to be worth litigating, Bard makes the not uncommon argument of defendants that individual actions or the joinder of claimants with similar claims is

the preferable procedure and that a class action would be unmanageable and inevitably lead to a multiplicity of individual claims that would make the class action unproductive.

[227] The likelihood of the success of this argument is much diminished in light of the Supreme Court of Canada's judgment in *AIC Limited v. Fischer*, *supra* because (a) assuming there is even one worthwhile common issue, it is quite easy for a class action to be preferable in comparison to the alternatives even when the class members' individual claims are monetarily substantial; (b) assuming there is even one worthwhile common issue it is very difficult to convince a court that the class action would be unmanageable; and (c) assuming there is even one worthwhile common issue, then the dice are loaded so to speak in favour of answering Justice Cromwell's five questions in favour of a class proceeding being the preferable procedure.

[228] Put somewhat differently, and asking a rhetorical question, assuming that there was a worthwhile common issue and a representative plaintiff supported by a class counsel willing to take on the risk of litigating the common issue, why would or should a court decline to achieve the access to justice and the economies for the parties and the administration of justice available from prosecuting a class proceeding as far as it can be taken?

[229] Assuming that there is a meaningful common issue and recalling that s. 6 of the *Act* already directs that the court shall not refuse to certify a proceeding as a class proceeding solely on the ground that the relief claimed includes a claim for damages that would require individual assessment after determination of the common issues, the answer to this rhetorical question is that preferable procedure criterion is another low hurdle for a plaintiff seeking to certify his or her action as a class proceeding.

[230] This truth about the preferable procedure criterion is augmented by the further truth that with a few exceptions, plaintiffs' counsel in the class action bar have shown no eagerness to develop alternatives to class actions as a means to litigate mass wrongs and rather as demonstrated by *Schroeder v. DJO Canada, Inc.*, *supra* have tended to rely on class actions as the only means to pursue mass claims.

[231] For *Schroeder*, one wonders why a cumbersome class action, with its drag of a certification motion that was inevitably appealed, was necessary to litigate the personal injury claims of 29 claimants that could have, more easily, been litigated to a judgment including individual assessments of damages in two separate actions or one consolidated action.

[232] (A rare example of an exception to relying only on class actions for access to justice for mass claims is the Dr. Austin litigation; i.e. *Hudson v. Austin*, 2010 ONSC 2789, *Oakley & Oakley Professional Corp. v. Aitken*, 2011 ONSC 5613 and *Jaikaran v. Austin*, 2011 ONSC 6336.)

[233] Returning to the particular circumstances of the case at bar but making an assumption that there are one or more common issues, then, in my opinion, Ms. O'Brien's class action would satisfy the preferable procedure criterion. Not making the assumption, I conclude that the preferable procedure criterion has not been satisfied.

7. Representative Plaintiff Criterion

[234] The fifth and final criterion for certification as a class action is that there is a representative plaintiff who would adequately represent the interests of the class without conflict of interest and who has produced a workable litigation plan.

[235] The representative plaintiff must be a member of the class asserting claims against the defendant, which is to say that the representative plaintiff must have a claim that is a genuine representation of the claims of the members of the class to be represented or that the representative plaintiff must be capable of asserting a claim on behalf of all of the class members as against the defendant: *Drady v. Canada (Minister of Health)*, [2007] O.J. No. 2812 (S.C.J.) at paras. 36-45; *Attis v. Canada (Minister of Health)*, [2003] O.J. No. 344 (S.C.J.) at para. 40, aff'd [2003] O.J. No. 4708 (C.A.).

[236] Provided that the representative plaintiff has his or her own cause of action, the representative plaintiff can assert a cause of action against a defendant on behalf of other class members that he or she does not assert personally, provided that the causes of action all share a common issue of law or of fact: *Boulanger v. Johnson & Johnson Corp.*, [2002] O.J. No. 1075 (S.C.J.) at para. 22, leave to appeal granted, [2002] O.J. No. 2135 (S.C.J.), varied (2003), 64 O.R. (3d) 208 (Div. Ct.) at paras. 41, 48, varied [2003] O.J. No. 2218 (C.A.); *Matoni v. C.B.S. Interactive Multimedia Inc.*, [2008] O.J. No. 197 (S.C.J.), at paras. 71-77; *Voutour v. Pfizer Canada Inc.*, [2008] O.J. No. 3070 (S.C.J.); *LeFrancois v. Guidant Corp.*, [2008] O.J. No. 1397 (S.C.J.) at para. 55.

[237] Whether the representative plaintiff can provide adequate representation depends on such factors as: his or her motivation to prosecute the claim; his or her ability to bear the costs of the litigation; and the competence of his or her counsel to prosecute the claim: *Western Canadian Shopping Centres Inc. v. Dutton*, *supra* at para. 41.

[238] Treating the representative plaintiff criterion detached from the other criteria, my conclusion is that Ms. O'Brien and Mr. Pearce would satisfy the representative plaintiff criterion.

8. Conclusion on the Certification Criteria

[239] For the above reasons, I conclude that Ms. O'Brien and Mr. Pearce proposed class action is not an appropriate case for certification. Although they did or could satisfy the cause of action, identifiable class, and representative plaintiff criteria, their class action does not satisfy the commonality and preferable procedure criteria.

[240] I, therefore, dismiss the certification motion.

D. ALTERNATIVES MOTION

[241] As noted at the outset in the Introduction, I am dismissing the certification motion subject to an "Alternatives Motion," which has the resources of ss. 5(4), 7, 12, 13, 17(3),(4) and (5), 19, 29, and 35 of the *Class Proceedings Act, 1992*. These provisions of the *Act* state:

> *Adjournments*
>
> 5.(4) The court may adjourn the motion for certification to permit the parties to amend their materials or pleadings or to permit further evidence.
>
> ...

Refusal to certify: proceeding may continue in altered form

7. Where the court refuses to certify a proceeding as a class proceeding, the court may permit the proceeding to continue as one or more proceedings between different parties and, for the purpose, the court may,

(a) order the addition, deletion or substitution of parties;

(b) order the amendment of the pleadings or notice of application; and

(c) make any further order that it considers appropriate.

...

Court may determine conduct of proceeding

12. The court, on the motion of a party or class member, may make any order it considers appropriate respecting the conduct of a class proceeding to ensure its fair and expeditious determination and, for the purpose, may impose such terms on the parties as it considers appropriate. 1992, c. 6, s. 12.

Court may stay any other proceeding

13. The court, on its own initiative or on the motion of a party or class member, may stay any proceeding related to the class proceeding before it, on such terms as it considers appropriate.

....

Order respecting notice

17.(3) The court shall make an order setting out when and by what means notice shall be given under this section and in so doing shall have regard to,

(a) the cost of giving notice;

(b) the nature of the relief sought;

(c) the size of the individual claims of the class members;

(d) the number of class members;

(e) the places of residence of class members; and

(f) any other relevant matter.

Idem

(4) The court may order that notice be given,

(a) personally or by mail;

(b) by posting, advertising, publishing or leafleting;

(c) by individual notice to a sample group within the class; or

(d) by any means or combination of means that the court considers appropriate.

Idem

(5) The court may order that notice be given to different class members by different means.

...

Notice to protect interests of affected persons

19. (1) At any time in a class proceeding, the court may order any party to give such notice as it considers necessary to protect the interests of any class member or party or to ensure the fair conduct of the proceeding.

Idem

(2) Subsections 17 (3) to (5) apply with necessary modifications to notice given under this section.

....

Discontinuance, abandonment and settlement

29. (1) A proceeding commenced under this Act and a proceeding certified as a class proceeding under this Act may be discontinued or abandoned only with the approval of the court, on such terms as the court considers appropriate.

...

Notice: dismissal, discontinuance, abandonment or settlement

(4) In dismissing a proceeding for delay or in approving a discontinuance, abandonment or settlement, the court shall consider whether notice should be given under section 19 and whether any notice should include,

(a) an account of the conduct of the proceeding; ...

....

Rules of court

35. The rules of court apply to class proceedings.

[242] For the reasons discussed above, I have refused to certify Ms. O'Brien's action, and pursuant to s. 7 of the *Class Proceedings Act, 1992,* in these circumstances, the court may permit the proceeding to continue as one or more proceedings between different parties.

[243] Having regard to the reasons discussed above, I require argument about whether and how the court should exercise its jurisdiction under s. 7 to permit the proceeding to continue in altered form.

[244] Using the resources noted above, there may be several alternatives available to Ms. O'Brien.

[245] During the course of the oral argument and again when writing these Reasons for Decision, I had the thought that there are several different ways that the putative Class Members in the case at bar might obtain access to justice, including individual claims or the possibility that there might be up to 19 separate class actions or joined claims against Bard, one for each of its products.

[246] In other words, while Ms. O'Brien has failed to show that there is a common issue to be resolved for all 19 Bard products, it remains to be determined whether she might be able to demonstrate some-basis-in-fact for a common issue for a class of persons implanted with an Align Urethral Support System for the treatment of SUI.

[247] Another putative Class Member might be able to show that there was some-basis-in-fact for a design defect in a different Bard product that would support a class action for that product.

[248] I note here that I had the jurisdiction under s. 5(4) of the *Act* to adjourn Ms. O'Brien's motion for certification to permit her to amend her materials or pleadings or to permit further evidence. I believe that pursuant to s. 7 of the *Act*, I can now afford her the opportunity to attempt to certify a smaller proposed class action.

[249] Alternatively, Ms. O'Brien might be permitted to give notice of her individual claim and have similarly situated putative Class Members apply to join her as co-plaintiffs. In this last regard, I have the authority under s. 7 to order the addition of parties, the amendment of the pleadings, and to make any further order that I consider appropriate to facilitate the continuance of her action in altered form.

[250] It strikes me that the court under s. 7 might be able to fashion an "opt-in" type of mass claim.

[251] It is at least conceivable that other putative representative plaintiffs might come forward to represent putative Class Members that had been implanted with other Bard products.

[252] Here, I harken back to the insights gained from *Schroeder v. DJO Canada, Inc.*, *supra*. In that case, there was a small class action but the alternative of joinders of claims might have been available. The same might be said of the case at bar.

[253] There may be other alternatives as to how Ms. O'Brien's action might continue and in my opinion, the court should give her an opportunity to consider her options and then bring an "Alternatives Motion."

[254] In fairness to Bard, there should be a time limit for bringing an Alternatives Motion, but in the meantime, it is necessary to suspend the dismissal of the certification motion. The suspension is necessary so that the limitation periods suspended by s. 28 of the *Act* do not begin to run to the prejudice of persons that might wish to participate in the alternative procedure.

[255] Accordingly, I dismiss the certification motion but on the following terms:

- Ms. O'Brien and Mr. Pearce shall have 30 days to deliver a written request for a case conference to schedule an Alternatives Motion.
- In the event that a Request for an Alternatives Motion is made, the dismissal of the certification motion is suspended until the determination of the Alternatives Motion.
- In the event that a Request for an Alternatives Motion is not made: (a) the certification motion will be dismissed 30 days after notice is given to the putative Class Members that the certification motion has been dismissed; and (b) Ms. O'Brien and Mr. Pearce may deliver an amended Statement of Claim advancing her individual claim and his claim under the *Family Law Act*.

E. CONCLUSION

[256] For the above reasons I dismiss the certification motion, subject to an "Alternatives Motion," as described above.

[257] If the parties cannot agree about the matter of costs, they may make submissions in writing beginning with Bard's submissions followed by Ms. O'Brien's and Mr. Pearce's submissions within a further 20 days.

Perell, J.

Released: April 16, 2015

CITATION: O'Brien v. Bard Canada Inc., 2015 ONSC 2470
COURT FILE NO.: CV-15-523068CP
DATE: 20150416

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

DONNA O'BRIEN and ADAM PEARCE

Plaintiffs

– and –

BARD CANADA INC., C.R. BARD, INC. and BARD MEDICAL DIVISION

Defendants

REASONS FOR DECISION

PERELL J.

Released: April 16, 2015