IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Jones v. Zimmer GMBH,*
2011 BCSC 1198

Date: 20110902
Docket: S095493
Registry: Vancouver

Between:

Dennis Jones and Susan Wilkinson

Plaintiffs

And

Zimmer GMBH, Zimmer Inc., and Zimmer of Canada Limited

Defendants

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

Before: The Honourable Mr. Justice Bowden

Reasons for Judgment

Counsel for the Plaintiffs:	D.A. Klein J.Z. Murray
Counsel for the Defendants:	A.D. Borrell P.J. Pliszka
Place and Date of Trial/Hearing:	Vancouver, B.C. February 7-9 and April 26, 2011
Place and Date of Judgment:	Vancouver, B.C. September 2, 2011

Introduction

[1] The plaintiffs seek an order certifying this proceeding as a class proceeding under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50 [*Act*], and appointing one of them as the representative plaintiff.

[2] The proposed class definition is:

> All persons who were implanted with the Durom acetabular hip implant in Canada.

[3] The Durom acetabular hip implant or "Durom Cup" is an artificial device used in hip replacement surgery. It is a prosthetic shell meant to be implanted into a patient's acetabulum, or hip socket, as a component of such surgery or resurfacing surgery.

[4] Both plaintiffs were implanted with Durom Cups. Mr. Jones in January 2008 and Ms. Wilkinson in April 2008.

[5] The Durom Cup is manufactured by Zimmer GMBH and imported into Canada and distributed here by Zimmer of Canada Ltd. Both of those companies are wholly-owned subsidiaries of Zimmer, Inc. It is alleged that these three defendants functioned as a joint enterprise in the promotion and sale of the Durom Cup in Canada.

Background of the Plaintiffs

[6] Dennis Jones is a 63-year-old retiree and resides in Langley, British Columbia. He underwent initial hip replacement surgery on his right hip on January 14, 2008, and received an implant of a Durom Cup.

[7] After starting to recover, Mr. Jones began experiencing pain in his right hip in September 2008. He found it difficult to get out of his car and to stand from a seated position. By December 2008, the increasing pain led him to return to using the cane that he had used immediately after the surgery. Walking with the cane was still painful for him and movement became increasingly difficult. He also experienced

pain when he tried to bend or pick up heavy objects. He slept on his left side because of the pain on his right.

[8] He visited his family doctor and was referred back to the surgeon who had implanted his Durom Cup. He waited seven weeks for an appointment with his surgeon. He was examined and advised to undergo revision surgery to replace the Durom Cup.

[9] On May 11, 2009, Mr. Jones underwent revision surgery to replace his Durom Cup. The Durom Cup had not adhered to Mr. Jones' bone and his surgeon removed the Durom Cup noting that "the cup tapped and easily removed showing no bony ingrowth in any area."

[10] Since the removal of his Durom Cup, Mr. Jones has noticed a gradual improvement in his condition. He no longer uses a cane and is able to exercise and swim without much difficulty.

[11] Susan Wilkinson is a 51-year-old nurse who resides in Osoyoos, British Columbia. She is employed by the Interior Health Region at an extended care facility in Oliver. She was implanted with a Durom Cup in her left hip on April 28, 2008.

[12] Three months after her hip replacement, Ms. Wilkinson began to experience pain in her left leg, and in August or September 2008 she began noticing more pain in her left groin and hip. She associated the pain with a feeling and sound of a clicking sensation in her left hip. She described it as feeling like her hip was going to "pop out." The pain became worse and she started using a cane in January 2009. She had difficulty sleeping and began taking narcotic pain medication every four hours to manage the pain in her hip.

[13] As a result of her pain, Ms. Wilkinson experienced considerable difficulty performing her work. Her job as a licensed practical nurse required her to spend 10 hours of her 12-hour shifts on her feet, to reposition patients, to push wheel chairs and to transport heavy boxes of medicine. On some days she would turn

down work because of the pain. She was also not able to take extra shifts that were offered by her employer.

[14] The pain and discomfort in her hip resulted in Ms. Wilkinson being unable to continue many household and leisure activities such as gardening, golfing, skiing, curling, walking or exercising.

[15] After visiting her surgeon, Ms. Wilkinson was scheduled for revision surgery to remove her Durom Cup. After encountering delays, the revision was performed on October 29, 2009.

[16] It appears that the Durom Cup had failed to adhere to Ms. Wilkinson's bone. She was awake during the surgery and remembers the Durom Cup popping out, merely with the force of her surgeon's hand.

[17] After a week in hospital, Ms. Wilkinson began to recover and has been able to return to many of the activities she enjoyed before the replacement surgery. She started a gradual return to work on March 15, 2010, and on April 15, 2010, she returned to full-time employment.

[18] In general, the plaintiffs say, the consequences of a failed hip implant are significant both in the short and long-term, causing pain and disability and affecting function. Revision surgery involves the removal of the loose or failed component. It is usually more complex, longer in duration than the initial implant operation, and is associated with greater blood loss and greater risk of complication. Often, bone loss requires implantation of a larger implant and there is the potential need for bone grafts.

General Background

[19] At least 4,941 Durom Cups have been sold in Canada since 2005. It is unclear how many of these have been implanted in Canadian residents or how many residents who received implants have experienced failure of their Durom Cup. The plaintiffs' solicitors have been contacted by at least 13 individuals who advise that

they were implanted with the Durom Cup and have since experienced pain and discomfort. Of those, at least seven have undergone revision surgery and a further three anticipate revision surgery. Thirty-three cases of revision surgeries involving the Durom Cup have been reported to the defendants. It is unclear whether all failures have been reported to the defendants. The defendants point out that the revision rate for Canadian Durom Cup patients is .67% of all Durom Cups implanted in Canada.

[20] The plaintiffs also adduced evidence that at least two residents of Ontario say that they have experienced pain and discomfort after being implanted with the Durom Cup. One of those persons, Gloria McSherry, was implanted with a Durom Cup on August 1, 2007. She continued to experience pain after that operation. Following the advice of her doctor, she underwent revision surgery to remove the Durom Cup on June 29, 2010. The related medical records indicate that “there was no ingrowth observed on the back of the Durom Cup.”

[21] The defendants say that revision surgery is a known risk of any joint replacement surgery, including hip replacement surgery. They also say that the fact that a particular patient requires hip revision surgery does not mean that the hip implant device was defective. They point to various other causes of post-operative pain such as infection, trauma, dislocation, bone fractures, metal hypersensitivity, improperly-sized components and others.

[22] Some problems with the Durom Cup became public in mid-2008 when an American orthopaedic surgeon warned his colleagues in the United States of failures and defects associated with that product. Zimmer suspended the marketing and distribution of the Durom Cup in the United States on July 22, 2008, because of increased revision rates, and determined that additional surgical technique instructions were required. An Urgent Safety Notice regarding the failures of implants followed in Europe on October 13, 2009, after reported revisions. When issuing that notice, Zimmer GMBH indicated that it had conducted “a widespread clinical investigation of the clinical experience of the Durom Acetabular Cup in

Europe and Canada." Zimmer again determined that European surgeons required more instruction and training.

[23] What is called a "Field Safety Notification" for the Durom Cup was issued on November 9, 2009, and published by Health Canada on December 7, 2009. It read as follows:

> Reasons for Recall
>
> There have been reports of revisions of Zimmer's Durom Acetabular Cup and the Metalsul LDH (Large Diameter Head) femoral head in certain European markets. As a result of these reports, Zimmer has been conducting an investigation to identify the root cause. Zimmer has been actively investigating clinical data from users regarding the performance of these devices and analyzing their performances compared to similar devices in the market.
>
> Based on the results of the investigation, the most probable root cause for the reported revisions is using a surgical technique which differs from that prescribed in the surgical technique for the Durom Acetabular Cup.

[24] This resulted in a retraining program for Canadian surgeons. No Canadian surgeon could access a Durom Cup unless the surgeon provided the defendants with written confirmation by December 24, 2009, that their retraining had been completed. A letter from Zimmer to surgeons dated November 9, 2009, contained a revised warning, namely:

> Reaming for the Durom Acetabular Component must be verified with the corresponding provisional shell performed according to the surgical technique. Failure to ream properly may lead to component loosening and persistent groin pain.

[25] The defendants say that the Durom Cup has never been recalled or changed and is still for sale and currently being used in Canada. The defendants also say that "the product has never been the subject of any action by Health Canada." I note, however, that Exhibit "S" of Alicyn Cumming's Affidavit, at Tab 6 of Volume 1 of the plaintiffs' application record, which is an excerpt from the Health Canada Medical Device Recall List from October 2009 to December 2009, refers to Recall Number 51631. This number refers to the defendants' Durom Cup and the stated "Reason for Recall" reflects the wording of the Field Safety Notification referred to above.

Statutory Requirements for Certification

[26] Section 4 of the *Act* provides:

> **4** (1) The court must certify a proceeding as a class proceeding on an application under section 2 or 3 if all of the following requirements are met:
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> (a) the pleadings disclose a cause of action;
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> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
>
> (e) there is a representative plaintiff who
>
> (i) would fairly and adequately represent the interests of the class,
>
> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
>
> (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.
>
> (2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, the court must consider all relevant matters including the following:
>
> (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members;
>
> (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;
>
> (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings;
>
> (d) whether other means of resolving the claims are less practical or less efficient;
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.

[27] Section 5(7) of the *Act* provides:

> **5** (7) An order certifying a proceeding as a class proceeding is not a determination of the merits of the proceeding.

[28] Section 7 of the *Act* provides:

> **7** The court must not refuse to certify a proceeding as a class proceeding merely because of one or more of the following:
>
> (a) the relief claimed includes a claim for damages that would require individual assessment after determination of the common issues;
>
> (b) the relief claimed relates to separate contracts involving different class members;
>
> (c) different remedies are sought for different class members;
>
> (d) the number of class members or the identity of each class member is not known;
>
> (e) the class includes a subclass whose members have claims that raise common issues not shared by all class members.

Analysis

[29] In *Hollick v. Toronto (City)*, 2001 SCC 68, [2001] 3 S.C.R. 158 at para. 16, the Supreme Court of Canada described the general nature of the certification process:

> … the certification stage is decidedly not meant to be a test of the merits of the action. … Rather, the certification stage focuses on the form of the action. The question at the certification stage is not whether the claim is likely to succeed, but whether the suit is appropriately prosecuted as a class action: … [Emphasis in original.]

Do the Pleadings Disclose a Cause of Action?

[30] The plaintiffs allege that the defendants were negligent in the research, development, testing, manufacture, distribution and sale of the Durom Cup and that they knew or ought to have known that defects in the device would cause foreseeable injury to the plaintiffs and their fellow class members. The plaintiffs also allege that the defendants owed the plaintiffs and class members a duty to use all reasonable care and skill to ensure that the Durom Cup was effective and to warn the plaintiffs, class members, health care providers and regulators of any safety problems with the Durom Cup. Further, the plaintiffs allege that the defendants failed

to properly test the Durom Cup before marketing it and failed to conduct subsequent proper post-market monitoring.

[31] The defendants do not dispute that the pleadings disclose a cause of action in negligence.

[32] The plaintiffs also say that the pleadings disclose a cause of action under the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 [*BPCPA*]. This claim is only available to class members who were implanted in British Columbia.

[33] In relation to this claim, the statement of claim provides:

> 26. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the Product [the "Durom System"] for personal use by the Plaintiffs and by class members were "consumer transactions" within the meaning of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 ("BPCPA"). With respect to those transactions, the Plaintiff and class members who were implanted with the Product in British Columbia are "consumers" and the Defendants are "suppliers" within the meaning of the BPCPA.
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> 27. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of the Product, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of the Product. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of the Product were deceptive acts and practices contrary to s.4 of the BPCPA. The Defendants' deceptive acts and practices included the Defendants' failure to properly disclose all material facts regarding the safety and efficacy of the Product.
>
> 28. Further, in their marketing brochures, promotional materials and website directed both to consumers and their physicians, the Defendants made representations concerning the efficacy of the Product, including a description of studies that suggested that the Product had a success rate of up to 99%. In reality, the Product's failure rate is unreasonably high compared to other, available implants. The Defendants knew or ought to have known that their marketing claims regarding the Product were inaccurate, incomplete or misleading, and that the Product had an unreasonably high failure rate. Such marketing claims were deceptive and had the tendency, capability or effect of misleading consumers and their physicians.
>
> 29. As a result of the Defendants' deceptive acts and practices, the Plaintiffs and class members have suffered loss and damages. The Plaintiffs seek injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss.171 and 172 of the BPCPA on their own behalf and on behalf of class members implanted with the Product in British Columbia.

[34] The plaintiffs submit that the statement of claim discloses a statutory cause of action under s. 171 of the *BPCPA*.

[35] The defendants argue that the failure to disclose information is not a basis for a claim under the *BPCPA* and rely on a decision of this court, *Blackman v. Fedex Trade Networks Transport & Brokerage (Canada), Inc*., 2009 BCSC 201. The plaintiffs say that the defendants' argument is defeated by a decision of the Court of Appeal, *Chalmers v. AMO Canada Company*, 2010 BCCA 560.

[36] The plaintiffs will satisfy the requirement in s .4(1)(a) unless it is "plain and obvious" that the statement of claim discloses no reasonable cause of action. No evidence is required at this stage to substantiate the pleading.

[37] In my view, the statement of claim provides particulars of this claim, which includes allegations of both the failure to disclose material facts and misrepresentations. It therefore discloses a reasonable cause of action. In *Chalmers v. AMO Canada Company*, the Court of Appeal considered pleadings containing similar allegations, including the failure to disclose a particular risk, and was satisfied that the claim under the *BPCPA* met the requirements of s. 4(1)(a) of the *Act*.

Is there an Identifiable Class of Two or More Persons?

[38] As noted above, the proposed class definition is: "All persons who were implanted with the Durom acetabular hip implant in Canada."

[39] The requirement of an identifiable class is discussed by the Supreme Court of Canada in *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46, [2001] 2 S.C.R. 534 at para. 38:

> [38] While there are differences between the tests, four conditions emerge as necessary to a class action. First, the class must be capable of clear definition. Class definition is critical because it identifies the individuals entitled to notice, entitled to relief (if relief is awarded), and bound by the judgment. It is essential, therefore, that the class be defined clearly at the outset of the litigation. The definition should state objective criteria by which members of the class can be identified. While the criteria should bear a

> rational relationship to the common issues asserted by all class members, the criteria should not depend on the outcome of the litigation. It is not necessary that every class member be named or known. It is necessary, however, that any particular person's claim to membership in the class be determinable by stated, objective criteria: …

[40] The defendants say that the lack of evidence adduced by the plaintiffs defeats their position on the proposed class definition. They say that the proposed class would include approximately 4,900 people who have not had a problem with the Durom Cup and the plaintiffs have failed to show a rational connection between a class of every recipient of a Durom Cup and the common issues that they propose.

[41] Only some basis in fact for the existence of a class need be established by the plaintiffs. In *LeFrancois v. Guidant Corporation*, 2008 CanLII 15770 (Ont. S.C.J.), the Ontario Superior Court said at para. 66:

> [66] The question whether any particular member of the class has suffered damage as a result of the defendants' conduct is, in cases of this kind, essentially an individual issue that, in addition, may raise questions of causation: …To require further evidence at this stage would cause the court to stray too far into the merits of the claims asserted on behalf of the class … It follows, moreover, from the prohibition of merits-based class criteria that class definitions will very often – and I think probably most often – be over-inclusive to the extent that they will include persons who cannot establish that they suffered damages.

[42] The fact that the class definition may contain persons who did not suffer any injury is an expected outcome of a class definition. As Cullity J. held in *Tiboni v. Merck Frosst Canada Ltd.,* 2008 CanLII 37911 at para. 78 (Ont S.C.J.), "this is virtually ordained by the authorities that preclude merits-based class definitions." In *Tiboni*, the rate of problems among the defined class appears to have been only .57%.

[43] In my view, the proposed definition of the class, namely, "all persons who were implanted with the Durom acetabular hip implant in Canada," satisfies the requirement under s. 4(1)(b) of the *Act*. It is sufficiently clear to meet the requirements for an identifiable class set forth by the Supreme Court of Canada in *Western Canadian Shipping Centres Inc.* Importantly, it also includes all persons

who potentially have a claim. As will be apparent from these reasons, I am also satisfied there is some basis in fact for the proposed class.

[44] The plaintiffs say that a national class is appropriate. The plaintiffs' solicitors have been contacted by one resident of Alberta and two persons who reside in Quebec who have said that they were implanted with the Durom Cup and have experienced pain and discomfort since. Two residents of Ontario have had the same experience. Of the 33 reports of the failure of the Durom Cup which Zimmer has disclosed, the reports have been submitted by physicians in British Columbia, Alberta, Ontario and Quebec. These reports indicate 22 failures in British Columbia, two in Alberta, six in Ontario and three in Quebec. Twenty-one of the failures are said to involve evidence of pain and/or loosening associated with the Durom Cup, and four reports indicate a failure of the Durom Cup to adhere to a patient's bone.

[45] If I certify these proceedings, it is not disputed by the defendants that a national class is appropriate so as to allow non-residents of British Columbia to participate.

Do the Claims of Class Members Raise Common Issues?

[46] "Common issues" are defined in s. 1 of the *Act* to mean:

> (a) common but not necessarily identical issues of fact, or
>
> (b) common but not necessarily identical issues of law that arise from common but not necessarily identical facts;

[47] In considering the proposed common issues it is helpful to consider the comments of Cumming J.A. in *Campbell v. Flexwatt Corp*. (1998), 44 B.C.L.R. (3d) 343 (C.A.) at para. 53:

> [53] When examining the existence of common issues it is important to understand that the common issues do not have to be issues which are determinative of liability; they need only be issues of fact or law that move the litigation forward. The resolution of a common issue does not have to be, in and of itself, sufficient to support relief. To require every common issue to be determinative of liability for every plaintiff and every defendant would make class proceedings with more than one defendant virtually impossible.

[48] The plaintiffs propose the following common issues:

(a) Was the Durom Cup defective and/or unfit for its intended use?

(b) Did any of the defendants breach a duty of care owed to class members and, if so, when and how?

(c) Does the defendants' conduct warrant an award of punitive damages, and, if so, to whom should they be paid and in what amount?

(d) With respect to British Columbia residents, did any of the defendants breach a statutory duty under the *BPCPA* owed to class members who received the Durom acetabular hip implant in British Columbia and, if so, when and how?

[49] The plaintiffs submit that a threshold issue in any medical products case is whether the product can cause injury to anyone. The plaintiffs' expert, Dr. Mahomed, opines that "there is clear concern about the clinical performance of the [Durom Cup] in the clinical situation" and says that reported failure rates "are quite concerning" or "far in excess of what would be expected of an average hip replacement."

[50] The defendants say, in effect, that there are a multitude of individual issues and that a determination of what necessitated Mr. Jones' and Ms. Wilkinson's revision surgery will not mean success for all class members. They say that the issue of causation must be determined on a patient-by-patient basis with a review of the evidence on each of the individualized factors identified by their expert, Dr. Belzile.

[51] The plaintiffs argue that it is not the number of individual issues alleged by the defendants but rather the relative importance of the common issues to the claim as a whole. Relying on *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.), they say that the court must make a qualitative assessment, not a quantitative one.

[52] The defendants also submit that the plaintiffs have not adduced any evidence to provide some basis in fact for the proposed common issues. In particular, they say the plaintiffs have not produced any evidence of a defect in the Durom Cup or that a common defect necessitated the revision surgeries of the plaintiffs. The defendants' expert, Dr. Belzile, says that the 33 patients who have undergone revision surgery did so for varied reasons including pain, infection, broken stem, swelling, avascular necrosis, patient request and failure to ingrow. They say the plaintiffs did not produce any records that would prove otherwise. Dr. Belzile opines that a .67% revision rate gives him no cause for concern about the use and safety of the Durom Cup in Canada. Unlike Dr. Mahomed, Dr. Belzile does not consider the revision rate to be inordinately high or alarming.

[53] I am satisfied that the evidentiary burden in relation to this issue has been satisfied by the plaintiffs in this case. It is not an onerous burden. They have shown some basis in fact for the presence of a common issue; namely, whether the Durom Cup was defective and/or unfit for its intended use. The evidence of the revision surgery required by the two plaintiffs and Ms. McSherry, among others, raises the question of the cause of the failure of the Durom Cup to attach itself to the bone or what is described as the "lack of ingrowth." The evidence is that there have been at least 33 cases of Durom Cup failure in Canada and it also appears that not all instances of Durom Cup failure in Canada have been reported to the defendants. As an example, it appears that Dennis Jones' Durom Cup failure and revision surgery were not reported to the defendants. Furthermore, the number of suspected product failures in Canada provided by the defendants does not correspond with the experience in the United States and Europe, although the clinical design and recommendations for use of the Durom Cup are materially the same in all jurisdictions. The evidence is that the defendants suspended the marketing and distribution of the Durom Cup in the United States on July 22, 2008, because of elevated revision rates and determined that additional surgical technique instructions and training were necessary. Similar events occurred in Europe, resulting in an Urgent Safety Notice regarding implant failure being issued on October 13, 2009. On

November 9, 2009, the Field Safety Notification and letter to surgeons, referred to earlier in these reasons, was issued by the defendants in Canada.

[54] In describing the reports of revision surgery, the receipt of which presumably prompted the defendants to write to the Health Product and Food Branch Inspectorate of Health Canada, Zimmer Canada said in the Urgent Safety Notice that “the most probable root cause for the reported revisions is using a surgical technique which differs from that prescribed in the surgical technique for the Durom Acetabular Cup.” Clearly this notice still leaves the actual cause to be determined. It is also clear from these notices that surgical techniques then being used needed to be reviewed as they appear to have been defective.

[55] Based on the definition of “recall” in s. 1 of the *Medical Devices Regulations*, S.O.R./98-282 (enacted pursuant to the *Food and Drugs Act*, R.S.C. 1985, c. F-27), it is apparent that Zimmer’s warning letter to surgeons amounted to a recall. I agree with the plaintiffs that there is a clear concern about the performance of the Durom Cup in clinical situations.

[56] In *Harrington v. Dow Corning Corp.*, 2000 BCCA 605 at paras. 42-46 (leave to appeal ref’d [2001] S.C.C.A. No. 21), a majority of the Court of Appeal described the steps in a products liability case as follows:

> [42] At the risk of oversimplifying a complex decision-path, I venture to suggest the first step in every products liability case alleging negligent design, manufacture, or marketing is the determination of whether the product is defective under ordinary use or, although non-defective, has a propensity to injure. Some American authorities refer to this step as "general causation", whether a product is capable of causing the harm alleged in its ordinary use.
>
> [43] The second step is the assessment of the state of the manufacturer's knowledge of the dangerousness of its product to determine whether the manufacturer's duty was not to manufacture and distribute, or to distribute only with an appropriate warning. It may be prudent to refer to this as an assessment of the state of the art; it may be that a manufacturer did not but should have known of its product's propensity for harm.
>
> [44] In my view, these two steps are the "risk assessment" Mr. Justice Mackenzie permitted to be undertaken as a part of what he saw as a multi-staged proceeding.
>
> [45] If the value of the product's use outweighed its propensity to injure such that distribution with a warning was appropriate, the third step will be an

> assessment of the reasonableness of the warning (whether direct or by a learned intermediary) given the state of the art and the extent of the risks inherent in the product's use.
>
> [46] The final step will be the determination of individual causation and damages. The difficult question will be whether the individual's knowledge of the risks would have prevented the injury. If the product should not have been manufactured or distributed, the determination of whether the product caused the injuries to the individual seeking damages and the assessment of those damages will be the last step.

[57] This so-called bifurcated process was commented upon by Thomas J. of the Alberta Court of Queen's Bench in *T.L. v. Albert (Child, Youth and Family Enhancement Act, Director)*, 2010 ABQB 203, where he said at para. 16:

> … In this case, the class proceeding is still at its first stage and as such, the relevance and materiality of the records ought to be determined by reference to the common issues. … In order to preserve the goals of access to justice and judicial economy, it is imperative to respect the bifurcated process and to not confuse the common issues at the first stage with matters that are best left to the determination of any outstanding individual issues at the second stage.

[58] It is also important to remember that at the certification stage the injured plaintiffs have had no discovery of the defendants.

[59] As the Ontario Superior Court noted in *Lambert v. Guidant Corporation*, 2009 CanLII 23379 (Ont. S.C.J.) at para. 65:

> … At this stage of the proceeding, however, the plaintiffs are, in my opinion, entitled to treat as in issue facts relating to the defendants' conduct that are exclusively within their knowledge and may bear directly on the resolution of the claims against them. Such an approach is, I believe, necessary to reconcile the rule that certification motions are not tests of the merits of a proceeding with the undoubted fact that evidence that bears on the merits can also be relevant to requirements for certification such as the existence of a class with claims that raise common issues, and the manageability of the litigation.

[60] Without discovering the various aspects of the design and intended function of the Durom Cup, it is difficult to see how the plaintiffs could present any more evidence than they have done at this Chambers hearing in support of their allegation that the Durom Cup was defective. Where the product is, like the Durom Cup, a highly technical medical device, it would not be expected that without access to what

is likely proprietary information of the defendants regarding that device the plaintiffs would be in a position to present evidence of a defect in the device.

[61] I am also concerned that in support of their position that there is an "evidentiary vacuum," the defendants have stated in their submissions that the product has never been recalled or the subject of any action by Health Canada. That assertion does not appear to be supported by the evidence before me.

[62] It appears that the action of the defendants in sending out a warning letter regarding the Durom Cup amounted to a recall under s.1 of the *Medical Devices Regulations*, and that Health Canada included a description of the problem in the publically-issued recall list referred to earlier in these reasons.

[63] Although the parties have filed conflicting expert reports, as stated by my brother, Butler J., in *Chalmers v. AMO Canada Company*, 2009 BCSC 689 at para. 17, aff'd 2010 BCCA 560, at this stage of these proceedings I do not need to resolve conflicting expert opinions because this is not a determination of the merits.

[64] As stated by the Court of Appeal in *Campbell v. Flexwatt Corp*. at para. 53, "the common issues do not have to be issues which are determinative of liability; they need only be issues of fact or law that move the litigation forward."

[65] In my view, the determination of whether the Durom Cup was defective or unfit for its intended use is common to all those Canadians who received an implant of a Durom Cup. There is evidence that at least 33 residents of Canada reported problems with the Durom Cup. Furthermore, at this stage a determination of this issue will move this litigation along.

[66] The second common issue proposed is, "Did any of the Defendants breach a duty of care owed to class members and if so, when and how?" I accept that this is a threshold question common to all class members and does not depend on the evidence of individual class members. As stated in *Wheadon v. Bayer Inc*., 2004 NLSCTD 72 at para. 133:

> 133 The issue of breach of a duty has been repeatedly certified in product liability class actions. It is an appropriate common issue because it focuses upon the Defendant's knowledge and conduct, can be resolved without the participation of class members, and, depending on its resolution, will either advance or dispose of their claims...

[67] This issue will also involve consideration of the defendants' duty to inform regarding deficiencies in the surgical technique originally recommended by them as soon as that was discovered by them.

[68] The next common issue proposed is whether the defendants' conduct warrants an award of punitive damages, and, if so, to whom should they be paid and in what amount?

[69] The plaintiffs have pleaded that the defendants acted with reckless disregard for public safety, that their conduct was reprehensible, and that their conduct departed to a marked degree from ordinary standards of decent behaviour or that their conduct was markedly worse than negligence. They say that if such allegations are proven at trial, they support a claim for punitive damages. They also say that the certification of punitive damages as a common issue is consistent with other certified class actions where claims have been advanced in relation to defective medical devices. The plaintiffs say that punitive damages can be awarded without evidence from individual class members.

[70] The plaintiffs refer to a discussion of the issue of punitive damages by Mackenzie J.A. in *Rumley v. British Columbia*, 1999 BCCA 689 at paras. 48 and 49, aff'd 2001 SCC 69, [2001] 3 S.C.R. 184 at para. 34:

> [48] ...The purpose of punitive damages is to punish a morally culpable defendant: …The plaintiffs' pleading alleges conduct that if substantiated could be characterized as morally culpable. Any award for punitive damages should reflect the overall culpability of the defendant. It does not have to be linked to the harm caused to any particular claimant and does not require individualized assessment. A global award can be assessed for the successful class members as a group, and allocated among them as the trial judge considers appropriate. The plaintiffs would be required to succeed on a common issue related to sexual abuse as well as proving moral culpability to establish a foundation for punitive damages.

> [49] As compensatory damages also punish the defendant indirectly, any award for punitive damages should take into account the quantum of compensatory damages awarded. In the context of a class proceeding, that suggests that the assessment of any award for punitive damages should be deferred until the total amount of compensatory damages has been assessed.

[71] The defendants argue that punitive damages cannot be a common issue where there is no underlying common issue in relation to the plaintiffs' substantive claims. As I have found there to be underlying common issues relating to the plaintiffs' substantive claims, I reject this argument.

[72] The defendants also say that punitive damages are not always amenable to certification as a common issue in product liability cases. They referred the Court to *Robinson v. Medtronic Inc.*, 2009 Canlii 56746 (Ont. S.C.J.), where the issue of punitive damages was not certified. Mr. Justice Perell distinguished *Rumley v. British Columbia* and held that, in the case before him, entitlement to punitive damages could only be resolved after determination of both the common issues and the individual trials on causation and damages.

[73] In *Chalmers v. AMO Canada Company*, our Court of Appeal said at para. 31:

> [31] Although the ultimate determination of the entitlement and quantification of punitive damages must be deferred until the conclusion of the individual trials, it does not follow, in my opinion, that no aspect of the claim of punitive damages should be certified as a common issue. It is my view that the question of whether the defendants' conduct was sufficiently reprehensible or high-handed to warrant punishment is capable of being determined as a common issue at the trial in this proceeding where the other common issues will be determined. The focus will be upon the defendants' conduct, and there is nothing in this case that will require a consideration of the individual circumstances of the class members in order to determine whether the defendants' conduct is deserving of punishment. The ultimate decision of whether punitive damages should be awarded, and the quantification of them, can be tried as a common issue following the completion of the individual trials.

[74] In my view, those comments of the Court of Appeal are applicable to the case at bar. In this case, I have concluded that punitive damages are an appropriate common issue.

[75] The next proposed common issue is whether any of the defendants breached a statutory duty under the *BPCPA* owed to class members who received the Durom acetabular hip implant in British Columbia and, if so, when and how.

[76] This issue arises from the statutory cause of action under the *BPCPA*. This claim is only applicable to class members who received the Durom Cup in British Columbia.

[77] The defendants say that the plaintiffs have not presented any evidence that any representations were ever made to the plaintiffs or any other potential class member regarding the Durom Cup, or that any potential class member was even aware of the alleged representations, or that anyone suffered loss or damage as a result.

[78] The plaintiffs argue that the *BPCPA* claim addresses conduct and representations directed by a supplier to the world at large in the marketing of its products, as opposed to specifically between a supplier and an individual consumer.

[79] Support for the plaintiffs' position is found in the following passage from *Wakelam v. Johnson & Johnson*, 2009 BCSC 839 at para. 39:

> … The plaintiff is relying on specialized consumer protection statutes which focus the inquiry on the impact of the representation on the public at large. The question of whether a representation is deceptive or misleading does not, therefore depend on an individual inquiry. The question of deception or no deception is something that can be litigated without reference to the circumstances of the plaintiff or individual class members: …

[80] The plaintiffs' claim under this heading is also based on the failure of the defendants to disclose a material fact. The evidence is that the defendants suspended the marketing and distribution of the Durom Cup in the United States on July 22, 2008, because of increased revision rates, and determined that additional surgical instructions were required. On October 13, 2009, an "Urgent Safety Notice" was issued by the defendants in Europe regarding the Durom Cup, again because of increased revisions. For unknown reasons, a "Field Safety Notification" for the Durom Cup was not published until December 7, 2009, with a recall start date of

November 15, 2009, based on letters to Health Canada and a list of Canadian Durom Cup users from the defendants on November 9 and 13, 2009. While it is not clear how many residents of Canada experienced a failure of an implanted Durom Cup, the defendants are aware of 33 of them and it remains to be determined how many of those who experienced such failure had undergone an initial implant after the date of the recall in the United States. In my view, a determination of the issue under the *BPCPA* is an appropriate common issue.

[81] While it is not essential at the certification stage, I am of the view that the common issues predominate over issues affecting only individual members. Certification may still be appropriate where threshold issues, such as whether the Durom Cup was defective, can be decided as common issues with common evidence. It is to be expected that there may be individual issues of specific causation and damages that will have to be decided following a determination of the common issues.

Is a Class Proceeding the Preferable Procedure?

[82] The next question, under s. 4(1)(d) of the *Act*, is whether a class proceeding is the preferable procedure for the fair and efficient resolution of the common issues. In considering that question, this Court must consider all relevant matters including the factors enumerated in s. 4(2) of the *Act*.

[83] As my sister, Dardi J., said in *Koubi v. Mazda Canada Inc.*, 2010 BCSC 650 at para. 171, citing *Hollick v. Toronto (City)* at para. 15:

> … No single factor is determinative. The “preferability” inquiry should be conducted through the lens of the three principle procedural advantages of class actions: judicial economy, access to justice and behavioural modification: ...

[84] The plaintiffs say that each of these objectives would be achieved by the certification of this case. Judicial economy is advanced by avoiding the need for multiple proceedings, in this case potentially 33 or more; access to justice is enhanced by enabling the fixed costs of this litigation to be shared among class

members, and behaviour modification is advanced by way of a tort claim to encourage product safety.

[85] The plaintiffs cite a number of case authorities to show that the vast majority of medical products class actions brought in Canada have been certified. They submit that this reflects a strong judicial consensus that certification is the best way to manage this type of litigation.

[86] The plaintiffs also refer to proceedings in the United States where the U.S. Judicial Panel on Multidistrict Litigation found that the centralization of Durom Cup litigation, a procedure which they say is similar to the trial of common issues in a class action, would "eliminate duplicative discovery, prevent inconsistent pretrial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and the judiciary": see *Re: Zimmer Durom Hip Cup Product Liability Litigation*, MDL No. 2158 (9 June 2010) U.S.J.P.M.L. at p. 2. The defendants say that the U.S. Court has since ordered the parties to mediate their claims on a case-by-case basis.

[87] The defendants also say that the substantial individual elements of the causes of action would yield a proceeding that is too unwieldy to manage fairly and efficiently. Referring to *Abdool v. Anaheim Management Ltd*. (1993), 15 O.R. (3d) 39 at 49 and 51 (G.D.), they say that a scrupulous and effective screening of class proceedings is imperative so that the quest for cost effectiveness does not sacrifice the ultimate goal of a just determination to the altar of expediency.

[88] The defendants argue that the individual issues predominate over common issues, that resolution of the common issues would not end the cases, and that the circumstances of each patient would have to be considered to determine why they each required revision surgery. As I have said, however, the resolution of the common issues of whether the Durom Cup was defective and the duty of the defendants to inform surgeons as to the technique required to implant this device and to warn that there are some dangers associated with the implantation will advance the litigation. If those issues are decided in favour of the plaintiffs, while

some individual causes may have to be considered, they will be significantly subordinated to the common ones. On the other hand, if the common issues are resolved in favour of the defendants, that could well bring the class proceedings to an end.

[89] The defendants say that there is only a small number of claims relating to revisions of the Durom Cup and there is no evidence that a class proceeding will enhance judicial economy. In my view, if there are 33 potential claims, judicial economy will be enhanced by a class proceeding, when compared to 33 separate proceedings to determine what I have found to be common issues.

[90] The defendants argue that there is no evidence that the individual plaintiffs cannot afford to litigate their claims. While I do not accept that affordability of the litigation is something that the plaintiffs have to address, it seems to me that individual plaintiffs could probably proceed with their separate claims on a contingency basis but that would not serve to enhance judicial economy. Rather, it would potentially increase the number of proceedings, increase the costs and add to the backlog in the courts.

[91] In my view, a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues. In reaching that conclusion I have considered the factors enumerated in s. 4(2) of the *Act* and the other matters referred to by counsel.

[92] With reference to s. 4(2)(c), the plaintiffs inform the Court that when this proceeding was commenced it was the only proposed class action against the defendants with respect to the Durom Cup in Canada. Two class actions were subsequently filed in Ontario; one by the plaintiffs' solicitors on August 10, 2010, and one by another law firm on October 27, 2010. The plaintiffs submit that in the interests of judicial economy, this action should be certified on a national basis.

Is there an Appropriate Representative Plaintiff?

[93] It is also necessary to determine that there is a representative plaintiff who would fairly and adequately represent the interests of the class; has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding; and does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[94] The defendants do not question that there is a representative plaintiff who would fairly and adequately represent the interests of the class.

[95] The defendants say, however, that there is no workable plan for this proceeding. They say that the plaintiffs' proposed plan is no more than a boilerplate plan that offers no substance and fails to acknowledge or tackle the complexities of this case.

[96] Subject to my comments regarding the costs of notice, in my view the plaintiffs have proposed a reasonable litigation plan. As the plaintiffs say, it need not be perfect, and it is invariably a work in progress which changes as the litigation proceeds. Importantly, the litigation plan proposed by the plaintiffs is based on litigation plans that have been approved by this court in other certified class actions: *Fakhri v. Alfalfa's Canada Inc.*, 2003 BCSC 1717; *Ruddell v. B.C. Rail Ltd.*, 2005 BCSC 1504; *Lieberman and Morris v. Business Development Bank of Canada*, 2006 BCSC 242; *Chalmers v. AMO Canada Company*; and *MacKinnon v. National Money Mart Company*, 2007 BCSC 348.

Conclusion

[97] For the reasons given, this action is certified as a class proceeding.

[98] The class members shall be all persons who were implanted with the Durom acetabular hip implant in Canada.

[99] The common issues proposed by the plaintiffs are suitable for certification under the *Act* for residents of British Columbia. The common issues, other than the issue under the *BPCPA*, are also certified for non-residents of British Columbia.

[100] While either plaintiff is suitable, the representative plaintiff shall be Susan Wilkinson.

[101] The parties shall speak to the issue of costs of the plan for notice and to that end may arrange with trial scheduling to attend before me for one hour.

"Bowden J."