CITATION: Dine v. Biomet, 2015 ONSC 7050
COURT FILE NO.: CV-13-490112-CP
DATE: 20151218

SUPERIOR COURT OF JUSTICE - ONTARIO

RE: Steven Dalton Dine, Plaintiff / Moving Party

AND:

Biomet Inc., Biomet Orthopedics LLC, Biomet Manufacturing Corp., Biomet U.S. Reconstruction LLC and Biomet Canada Inc., Defendants / Responding Parties

BEFORE: Justice Edward P. Belobaba

COUNSEL: *Jonathan Ptak, Doug Lennox and Garth Myers* for the Plaintiff

Kent Thomson, Derek Ricci, Kristin Jeffery and Michael Finley for the Defendants

HEARD: September 29 and 30 and October 2, 2015

Proceedings under the *Class Proceedings Act, 1992*

CERTIFICATION DECISION

[1] The most contentious issue in the certification of class actions, and especially product liability class actions, is commonality. That is, whether the plaintiff can provide some evidence that the proposed common issue exists in fact and can be answered in common across the entire class. Class counsel generally understands that only a minimal amount of evidence is needed to satisfy the commonality requirement. Defence counsel generally does not and presents far too much merit-based evidence that has no place at certification and is better left for trial.

[2] That's what happened here. Much of the defendants' written and oral submissions were mired in the minutiae of evidentiary analysis. This level of detail is neither required nor appropriate on a certification motion. The defendants may well prevail at trial or on a summary judgment motion when the merits of this action will be fully adjudicated but at this point the plaintiff has satisfied the modest requirements for certification.

[3] For the reasons set out below, the motion for certification is granted.

Background

[4] The plaintiff alleges that the large-head metal-on-metal ("MoM") hip implants designed, manufactured and distributed by the Biomet defendants are defective and dangerous and cause serious injury. Three hip implant systems are at issue - the Biomet M2a Magnum, the Biomet M2a 38 and the Biomet Recap Resurfacing system. The M2a Magnum and the M2a 38 implants are total hip replacement systems and the Recap Resurfacing system, as the name suggests, is a more limited resurfacing technology. But all three can be described as large-head MoM hip implants.

[5] Large-head MoM hip implants have long been the subject of negative medical commentary and product recalls,[1] and more recently, class actions.[2] The primary complaint is that large-head MoM hip implants are inherently unsafe because they result in higher than acceptable levels of revision surgeries and release metal ions that harm adjacent hip tissue. Few if any such systems remain on the market. As the defendants' expert, Mr. Lavigne explained, "I think all surgeons view the whole class [of large-head MoM hip implants] as a problem."

[6] Just over 9200 of the Biomet hip systems were sold and implanted in Canada from the middle of 2003 to the end of 2014. The M2a Magnum accounted for about 80 per cent of these sales. Biomet stopped selling the three systems in Canada in 2014 and recently stopped selling them worldwide.

The parties

[7] The proposed representative plaintiff, Steven Dine, is 59 years old and lives in Kingston. Over the course of seven years, Mr. Dine has had three hip implant surgeries. In 2006, he was implanted with the Biomet ReCap Resurfacing system in his left hip but continued to suffer from intense and increasing pain, could no longer work, and was forced to go on long-term disability from his job with the federal government.

[8] In 2008, Mr. Dine had revision surgery to replace the ReCap Resurfacing system with the M2a Magnum hip implant. The problems continued. In 2013, Mr. Dine

---

[1] The history of the MoM hip implant is not in dispute. The first generation of MoM implants used in the 1970s and 1980s was abandoned because of high revision rates, concerns over metal sensitivity and cobalt toxicity, and increased torque as compared to the main alternative, metal-on-polyethylene. In the 1990s, another generation of MoM implants was developed using larger femoral head sizes, that is, head sizes larger than 32 mm. The M2a Magnum, the M2a 38, and the ReCap Resurfacing system are all second generation large-head metal-on-metal implants.

[2] See, for example, *Jones v Zimmer GMBH*, [2011] B.C.J. No. 1680 (B.C.S.C.); *Crisante v. DePuy Orthopaedics*, 2013 ONSC 5186; and *Warner v. Smith & Nephew Inc.*, [2015] A.J. No. 246 (A.B.Q.B.).

underwent a second revision surgery that replaced the M2a Magnum implant with a non-MoM hip implant. Mr. Dine says that defects in the Recap and M2a Magnum implants caused significant and long-lasting injury to himself and other class members. He has also filed affidavits from Messrs. Hall and McLean, who were implanted with the M2a Magnum and were also required to undergo painful revision surgeries. Messrs. Hall and McLean would be willing if necessary to act as representative plaintiffs.

[9] Biomet Inc. is a multinational medical device company, headquartered in Warsaw, Indiana, that together with the four subsidiaries also named as defendants, designs, manufactures and distributes a wide range of orthopaedic reconstructive implants, including hip implants.

[10] The plaintiff alleges that the five Biomet defendants functioned as a joint enterprise in the research, design, manufacture, regulatory licensing, marketing and post-market monitoring of the Biomet implants, and that each defendant is responsible for the acts and omissions of the other defendants.

The only issue is commonality

[11] The defendants contest only two of the five requirements set out in s. 5(1)(a) to (e) of the *Class Proceedings Act*, ("CPA")[3] – commonality under s. 5(1)(c) and preferability under s. 5(1)(d). The other three requirements, cause of action, identifiable class, and suitable plaintiff are readily satisfied. The claim in negligence (which includes negligent design and failure to warn) is properly pleaded and discloses a cause of action. There is an identifiable class of two or more persons[4] and there is no suggestion that Mr. Dine is not a suitable plaintiff under s. 5(1)(e) or that the proposed litigation plan is unworkable.

[12] I have set out the proposed common issues in the Appendix. It is important to note that the plaintiff has taken care to limit the proposed common issues to questions such as duty of care, medical monitoring and punitive damages, all of which can arguably be answered across the class on a common basis. More individualized issues such as causation and damages are not proposed as common issues and will be determined at the individual assessment phase after the common issues trial has been completed.

[13] In my view, the adjudication of the proposed common issues will meaningfully advance this litigation whatever its outcome. If the defendants are found to have met the

---

[3] *Class Proceedings Act*, *1992*, S.O. 1992, c. 6.

[4] The class is defined as all persons who were implanted in Canada with any of the three Biomet implants and all other persons who by reason of a personal relationship to an implant patient have standing pursuant to section 61(1) of the *Family Law Act* or equivalent legislation in other provinces and territories.

standard of care, then that finding will be dispositive of the entire litigation as in *Andersen* v. *St. Jude.*[5] And if the defendants breached the standard of care, then a class action with the trial judge utilizing the wide-ranging judicial powers provided under s. 25 of the CPA is the preferred procedural vehicle to manage and determine any subsequent individualized damage assessments. I note that, in principle, the common issues that are proposed herein are not materially different from other medical products class actions that have been certified.[6]

[14] Therefore, assuming that the proposed common issues are certified there is at least some evidence of preferability and frankly, little chance that any procedure other than a class action could be shown to be more preferable.[7] Thus, as I have already noted, the only real issue on this motion for certification is commonality under s. 5(1)(c).

The "some basis in fact" test

[15] In order to satisfy the commonality requirement under s. 5(1)(c), the plaintiff only needs to adduce some basis in fact, i.e. some evidence of the existence of the common issue.[8] This has been generally interpreted in the case law to date as a two-step requirement - some evidence that the proposed common issue actually exists *and* some evidence that the proposed issue can be answered in common across the entire class (that is, some evidence of class-wide commonality).[9]

---

[5] *Andersen v. St. Jude Medical Inc*., [2012] O.J. No. 2921 (S.C.J.), leave to appeal ref'd [2005] O.J. No. 269 (Div. Ct.).

[6] See, for example, *Zimmer, Crisante* and *Warner, supra,* note 2.

[7] Defence counsel focuses attention on the highly individualized nature of the (specific) causation and damages inquiries that will be needed to finalize both liability and compensation issues and argues that individual issues will overwhelm the common issues. I do not agree. Here, a common issues trial to determine duty of care and breach of the duty of care will substantially advance the litigation in the interests of the entire class. The remaining and admittedly important individual issues such as specific causation and damages can be organized and addressed under the wide-ranging powers provided to the court in s. 25(1) of the CPA.

[8] *Fulawka v. Bank of Nova Scotia,* 2012 ONCA 443, at para. 79 ("…some evidentiary basis indicating that a common issue *exists* beyond a bare assertion in the pleadings.") [Emphasis added.] The evolution of the "some basis in fact" requirement is critically analyzed in Brandon Kain, "Developments in Class Actions Law: The 2013-14 Term – The Supreme Court of Canada and the Still-Curious Requirement of 'Some Basis in Fact'", (2015) 68 S.C.L.R. (2d) 77. This is a must-read article for lawyers and judges involved in class action litigation.

[9] I pause to note that the plaintiff tried to argue that because of what was said by the Supreme Court in *ProSys Consultants Ltd. v. Microsoft Corp.,* 2013 SCC 57 at para. 110 ("In order to establish commonality, evidence that the acts alleged actually occurred is not required") there is no longer any need for the "first step" of the commonality analysis (some evidence that the proposed common issue actually exists) and all you need is the second step (evidence of class-wide commonality). Indeed the plaintiff suggested, tracking a provocative comment made in the Kain article, *supra,* note 7 at 107, that *ProSys* now means that "the plaintiff is under no evidentiary obligation to

[16] In product liability cases, the proposed common issues revolve around negligence and focus primarily on standard-of-care issues. The affidavit of the representative plaintiff certainly provides context and background, but the commonality requirement is typically satisfied by expert evidence. It is the plaintiff's expert who sets out some evidence of product defect (i.e. some evidence of a breach of a standard of care) and, if there are multiple products, some evidence of class-wide commonality.

[17] The case law generally falls into three categories: cases where there is evidence that the proposed common issue exists but no evidence of class-wide commonality;[10] cases where there is evidence of commonality but no evidence that the proposed issue actually exists;[11] and, of course, cases where there is some evidence of both.[12] This last category includes cases such as the collapse of a shopping mall or other mass tort events, where both the existence of the proposed common issue and its class-wide commonality is often self-evident and requires nothing more than a common sense analysis.[13]

[18] The s. 5(1)(c) commonality analysis herein requires the two-step approach because the defendants say they is no evidence of either product defect or class-wide

---

establish that the alleged grounds of liability are in fact anchored in reality." I could not disagree more. In my view, this proposition runs counter to the two-step approach taken by the Supreme Court in *Hollick v. Toronto (City)*, 2001 SCC 68, by the Court of Appeal in *Fulawka v. Bank of Nova Scotia*, 2012 ONCA 443 and *McCracken v. Canadian National Railway Company*, 2012 ONCA 445, and by countless judges, myself included, in countless certifications. See, for example, *Martin v. Astrozeneca Pharmaceuticals PLC*, 2012 ONSC 2744, at para. 277: "Even if there was some evidence of this common issue, there is no evidence that it is capable of being assessed in common" and *Good v. Toronto Police Services Board*, 2014 ONSC 4583 (Div. Ct.) at para. 67: "There is some evidence that would support this proposed common issue." Historically, the two-part test is rooted in *Hollick* where the Supreme Court needed to be satisfied (at para. 19) that "*each* of the putative class members *does indeed* have a claim, or at least what might be termed a "colourable claim" against the respondent." [Emphasis added.] The Court of Appeal's language in *Fulawka* (at para. 79) about the need for "some evidentiary basis indicating that a common issue *exists* beyond a bare assertion in the [the plaintiff's] pleadings" and to similar effect in *McCracken* at para. 125, confirms the continuing importance of the first step. If all that is needed is some evidence of class-wide commonality and no evidence that the proposed common has even a minimal basis in fact, then almost any proposed class action would have to be certified and the certification motion's role as "a meaningful screening device" would be eviscerated. I do not read *ProSys Consultants* as reversing *Hollick* and almost 15 years of subsequent case law. However, I do not have to decide this issue here because, as it turns out, and subject to some qualifications expressed below, the plaintiff has satisfied both steps of the commonality analysis.

[10] *Taub v. Manufacturers Life Insurance Co.* (1998), 40 O.R. (3d) 379 (Gen. Div.), aff'd (1999), 42 O.R. (3d) 576 (Div. Ct.) – some evidence of mould in the plaintiff's apartment but no evidence of mould in any other apartments.

[11] *Williams v. Canon Canada Inc.*, [2011] O.J. No. 5049 (S.C.J.), aff'd 2012 ONSC 3992 (Div. Ct.) – evidence of class-wide commonality (a common product) but no evidence of a product defect (the "E18 Error message" was a built-in safety feature in each of the cameras and not a design defect.)

[12] *Crisante, supra*, note 2.

[13] *Quinte v. Eastwood Mall,* 2014 ONSC 249 (S.C.J.).

commonality. The defendants intend to bring a motion for summary judgment in the very near future. As I have already noted, the defendants may well prevail when the merits are fully adjudicated, but at this stage of the proceeding merits are not being adjudicated.

[19] In my view, the plaintiff has provided some evidence of both defect and commonality that is sufficient to support the certification of all but one of the proposed common issues (as set out in the Appendix.) I will consider each of them in turn.

Analysis

(1) Common issues 1, 2 and 3

[20] Proposed common issues 1, 2 and 3 ask about a duty of care, the applicable standard of care, and whether that standard of care was breached by the defendants. Note again that neither causation nor damages are being proposed as common issues.

[21] The question for me is first, whether there is some evidence that the three impugned Biomet implants (the Recap Resurfacing, the M2a Magnum and the M2a 38) are unsafe (and thus whether there is some evidence that the defendants breached their duty of care), and secondly, whether there is some evidence that the impugned implants are sufficiently similar that the three proposed duty of care questions can be answered in common across the entire class.

Step-one: Some evidence of safety concerns/breach of a duty of care

[22] The plaintiff relies on the following to provide some basis in fact for proposed common issues 1, 2 and 3: expert evidence, peer-reviewed literature, internationally accepted revision rate guidelines, correspondence between Health Canada and Biomet and the February 10, 2015 "hazard alert." Any one of these categories or items of evidence would itself provide some evidence in fact and in combination there is sufficient basis in fact to support common issues 1, 2 and 3. I will discuss each of these categories of evidence in turn.

[23] The plaintiff's expert, Dr. Graves, is an Australian orthopaedic surgeon who has established a world-wide reputation as an expert on joint replacement surgery and the performance of arthroplasty prostheses. Dr. Graves is also the director of the Australian Orthopaedic Association National Joint Replacement Registry.

[24] The Australian Registry, which operates under the auspices of the Australian Orthopaedic Association and the federal government of Australia, has achieved an international reputation because of the high quality of its data and serves as a major

resource for regulatory agencies and medical device manufacturers throughout the world. One of the defendants' experts, Dr. Lavigne, agreed that the Australian Registry is "probably the most effective in the world."[14] There is also no dispute about the proposition that the Australian Registry data is generalizable to the Canadian population or that Health Canada itself places considerable reliance on the Australian Registry data.

[25] The gist of Dr. Graves evidence, which is based on his years of experience as an orthopaedic surgeon, his review of the relevant literature and the Australian Registry data, can be summarized as follows:

> (i) The use of large-heard metal-on-metal hip implants is one of the "most catastrophic failures of medical device development ever seen globally" and "a major safety concern." The nature of the safety concern relates to the high and ever increasing rate of revision and its attendant risks, ongoing pain and disability, secondary to extensive local soft tissue damage and the risk of illness as a result of high ion levels.
>
> (ii) These safety concerns extend to Biomet's ReCap Resurfacing system and the M2a Magnum and M2a 38 implant systems - all of which have unacceptably high rates of revision that are significantly higher (from one and half to two times higher) than other prostheses that use alternate bearing articulations.
>
> (iii) The reasons for these higher revision rates can be attributed to the design of the prosthesis rather than patient or surgeon-related factors.
>
> (iv) The Biomet implants were clinically unproven when they were introduced to the market. Biomet should have carefully assessed the clinical outcome of the Biomet implants prior to wider release. This did not happen and the consequence is that many patients will require premature revision surgeries that have the potential for long-term disability or worse. This could have been avoided had Biomet introduced this technology in a more responsible manner.

---

[14] By contrast, the stature and overall value of the Canadian implant registry is much more modest. Participation by Canadian doctors is "quite low" and the Canadian Registry is unable to identify whether or not a particular hip implant is defective. Hence, Dr. Graves – who is based in Sydney, Australia – is regularly retained by class counsel as an expert witness in Canadian hip implant actions. Health Canada specifically asked the Defendants for data from the Australian Registry when evaluating the Defendants' product. The Defendants provided that Australian Registry data in their response to Health Canada. The Defendants referred to Australian Registry data in their letters to Canadian surgeons. In short, participants in the orthopedics industry, including manufacturers, regulators, and doctors, treat Australian Registry data as reliable, and have acted upon such data.

[26] The plaintiff also relies upon peer-reviewed medical studies that document the propensity of the Biomet Implants to cause metal related pathology. He notes that one of the defendants' experts, Dr. Lavigne who argues that metal-on-plastic devices can also cause metal related pathology, concedes that the latter is more likely to occur with metal-on-metal products. The plaintiff also points to a recent paper by Dr. Cuckler, one of the original designers of the three impugned Biomet systems. Formerly a vocal proponent, Dr. Cuckler has now concluded based on the adverse outcomes with metal-on-metal implants, the increasing evidence of problems with metal-on-metal bearings and the documented intermediate failure rates of resurfacing, that the alternative bearing surface of metal-on-polyethelyene is the more successful option.

[27] In its information request letters to Biomet, Health Canada has noted that "Large femoral heads have been shown through various sources to have a poorer performance than smaller heads for stemmed MoM implants."

[28] According to the performance guideline published by the National Institute for Health and Care Excellence, a reasonably well-performing hip implant should have a revision rate after 10 years of 5 per cent or less. Each of the three impugned implant systems herein exceeds this guideline.

[29] The plaintiff also refers to the "hazard alert" that was issued on February 10, 2015 by Biomet "in consultation with" the Australian Department of Health Therapeutic Goods Administration. The hazard alert advised consumers and health professionals that the Bioment M2a Magnum and M2a 38 hip implants "have higher than expected revision rates" and further that Biomet has stopped supplying these implants and "is cancelling them" from the Australian Registry.

[30] In sum, as already noted, any one of the above-noted categories or items of evidence could by itself provide some evidence supporting the proposed "duty of care" issues. When taken together, there is obviously more than sufficient evidence for the existence of proposed common issues 1, 2 and 3.

[31] Nonetheless, the defendants take issue with almost every point made by the plaintiff and present extensive counter-evidence, including detailed counter-opinions from their own experts about, amongst other things, the validity of Dr. Graves' opinion about "safety concerns" and "unacceptably high revision rates" (and the defendants' inability to access the underlying raw data), the role and importance of patient and surgeon-related factors, and the conclusions drawn from the world-wide literature and international clinical studies about the safety of Biomet implant systems. This counter-

evidence is, to be sure, compelling but it is irrelevant at the certification stage of the proceeding.

[32] As the Supreme Court noted in *Fischer,*[15] "[t]he court cannot engage in any detailed weighing of the evidence but should confine itself to whether there is some basis in the evidence to support the certification requirements."[16] The defendants may well dispute the plaintiff's evidence, but "the certification motion is not the place for resolving the controversy."[17] The case law has long made clear that the certification motion is not the place for an adjudication of the merits.[18]

[33] Nor is it the place to resolve the conflicting expert opinions. In *Quizno's Canada*,[19] the Divisional Court was faced with conflicting expert evidence about the validity of a methodology for assessing losses amongst the franchisees. In applying the "some basis in fact" standard, the Court properly refused to engage in a weighing of the conflicting evidence at the certification stage:

> It is neither necessary nor desirable to engage in a weighing of this conflicting evidence on a certification motion … A motions judge is entitled to review the evidentiary foundation to determine whether there is some basis in fact to find that proof of aggregate damages on a class wide basis is a common issue. While that might require some review of the evidence, the assessment should not relate to the merits of the claim or the resolution of conflicting expert reports.[20]

[34] The detailed counter-arguments advanced by the defendants will be fully considered at the upcoming summary judgment motion. It is sufficient for my purposes as the judge hearing the certification motion to conclude that the plaintiff has provided some evidence of the existence of proposed common issues 1, 2 and 3 – that is, the plaintiff has

---

[15] *AIC Limited v. Fischer*, 2013 SCC 69.

[16] *Ibid.*, at para. 43.

[17] *Pearson v. Inco Ltd*. (2006), 78 O.R. (3d) 641 (C.A.) at para. 76, cited with approval in *Fischer, supra,* note 14, at para. 42.

[18] *Hollick*, *supra*, note 8, at para. 16: "The certification stage is decidedly not meant to be a test of the merits of the action" and "an inquiry into the merits of the action will not be relevant on a motion for certification." Also see s. 5(5) of the CPA: "An order certifying a class proceeding is not a determination of the merits of the proceeding."

[19] *2038724 Ontario Ltd. v. Quizno's Canada Restaurant Corp.*, [2009] O.J. No. 1874 (Div. Ct.), aff'd [2010] O.J. No. 2683 (C.A.).

[20] *Ibid.,* at para. 102.

satisfied the first step of the two-step commonality requirement and has established some basis in fact for the proposition that the defendants have breached their duty of care by manufacturing and distributing an arguably unsafe large-heard MoM hip implant product with an unacceptably high rate of revision.

Step-two: Some evidence of class-wide commonality

[35] The second step – some evidence that the "duty of care" questions can be answered in common across the entire class – arises in this case because of the defendants' submission that the three impugned implant systems have little in common and actually consist of some 150 components that can be mixed and matched - thus no product commonality. The defendants submit that this is a case like *Bard*[21] where the court was confronted with 19 medical devices with no common defective design feature and refused certification.[22]

[36] In my view, this is not *Bard.* There are not 19 products in this case. There are three product systems, one of which comprises 80% of the class. Here, unlike in *Bard,* there is sufficient evidence of product commonality – that is, some evidence that the standard-of-care questions as set out in common issues 1, 2 and 3 can be answered in common on a class-wide basis for all three of the impugned implant systems as a group.

[37] First, in regulatory submissions in the U.S., Biomet itself noted that the M2a Magnum implant is "substantially equivalent" to the M2a 38 implant. There is also evidence that the ReCap Resurfacing system uses the same bearings as the two M2a implants. Next, there is evidence that Biomet itself referred to and discussed the three impugned implants on an implant by implant or "device by device" basis and often as a group – and never as 150 component parts.

[38] The experts on both sides treated the three implant systems as a single undifferentiated product group. They did not draw distinctions between the three devices to support their opinions and counter-opinions. Recall as well Dr. Lavigne's point that "... surgeons view the whole class of [large head MoM hip implants] as a problem."

[39] There is also evidence of product commonality in the labelling and "instructions for use" information, in Biomet's licensing interactions with Health Canada and in Biomet's "Dear Surgeon" advisory letters – all of which suggest that the defendants treated their large-head MoM implants as a group. Health Canada did likewise, in both

---

[21] *O'Brien v. Bard Canada Inc.*, 2015 ONSC 2470.

[22] *Ibid.*, at paras. 123-28, 135, 141 and 190.

their licensing-information letters to Biomet (referring to "current clinical experience that has been observed with metal-on-metal hip implants") and in their information requests ("to address the safety issues with metal-on-metal hip implants"). As did the peer-reviewed medical literature.

[40] In short, the plaintiff has provided some evidence of product commonality and thus some evidence that the proposed "duty of care" issues – proposed common issues 1, 2 and 3 - can be determined in common for the three Biomet implant systems.[23] The two-part commonality requirement has been satisfied.

Changing standard of care and regulatory compliance

[41] The defendants make two further submissions that require a brief response. First, that the applicable standard of care in proposed common issues 2 and 3 would be changing and evolving over the ten-year class period defeating the commonality requirement (and the motion for certification), and secondly, that the defendants fully complied with all Health Canada regulatory requirements. In my view, neither of these submissions preclude certification of proposed common issues 1, 2 and 3.

[42] The fact that the common issues trial judge may have to identify and apply what could be a changing and evolving standard of care in the design of the impugned hip implants is not a road-block. Courts regularly certify claims for negligence where the standard of care has changed over the course of a multi-year class period.[24] It is also important to note that common issues asking if the defendants breached the standard of care, and if so, when, have been certified in other class actions alleging defective hip implants.[25]

---

[23] The plaintiff also points to the defendants' notice of motion for summary judgment which suggests that the proposed issues can be decided in common and asks that the court draw adverse inferences (favouring product commonality) from the fact that Biomet refused to produce copies of the licensing applications that relate to the three impugned implant systems. Both of these points are compelling but neither is needed given the analysis herein.

[24] For example, in *Dolmage v. Ontario*, 2010 ONSC 1726 (S.C.J.) this court certified a class action on behalf of residents of a facility for people with disabilities from 1945 to 2009. Over the course of the 64-year class period, the standard of care changed dramatically. But this did not preclude certification. Also see *Rumley v. British Columbia,* 2001 SCC 69 (42 years) and *Cloud v. Canada (Attorney General),* [2004] O.J. No. 4924 (C.A.) (16 years). The case law confirms that the class action proceeding is sufficiently flexible to deal with variations in the applicable standard of care that may arise in this case, which involves a relatively more manageable 10-year class period.

[25] *Crisante, supra,* note 2; *Zimmer, supra,* note 2; and *Taylor v. Wright Medical Technology Canada Ltd*., [2015] N.S.J. No. 285 (C.A.).

[43] Secondly, regulatory compliance is not dispositive of common law duties. Health Canada is an imperfect regulator[26] and Canadian courts have repeatedly certified class actions involving medical products that were not recalled and were still on the market.[27]

[44] In sum, there is some evidence that proposed common issues 1, 2 and 3 exist and can be answered on a class-wide basis. Their resolution will advance the litigation and help determine whether the defendants breached a duty and standard of care.

(2) Common issues 4 and 5

[45] Proposed common issue 4 ask whether class members with valid claims are entitled to special damages for medical costs incurred in the monitoring, screening, diagnosis, and treatment of illnesses or infections related to the impugned hip implants.

[46] The first-step of the commonality analysis – some evidence that monitoring concerns exist in fact – is easily satisfied. Health authorities in the U.S., the U.K. and Canada have regularly issued recommended protocols for the follow-up and monitoring of large-head MoM hip implant patients. Biomet itself in "Dear Surgeon" letters has referred to these follow-up protocols, adding that "Biomet encourages careful follow-up for all MoM patients, including close monitoring for women."

[47] The second-step of the commonality analysis is also satisfied. As I noted in *Crisante*,[28] whether "special damages" are recoverable, i.e. reasonably foreseeable, is a question that will focus on what the defendants should have known or foreseen, does not depend on individual assessments and can be answered in common. I questioned the utility of certifying a question whose answer was self-evident (these damages were obviously foreseeable to the defendants, so the answer is "yes" they are recoverable). But, as I also noted in *Crisante,*[29] "special damages for medical monitoring" questions

---

[26] Health Canada is not a testing agency. Nor is it an investigative or policing authority. And, prior to November 6, 2014, Health Canada lacked the legislative authority to recall medical products: see *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law*), S.C. 2014, c. 24, s. 21.3(1). Class counsel is probably right to describe Health Canada's role over the class period as basically a filing agency.

[27] *Heward v. Eli Lilly & Co*., [2007] O.J. No. 404 (S.C.J.); *Tiboni v. Merck Frost Canada Ltd*., [2008] O.J. No. 2996 (S.C.J.), *Parker v. Pfizer Canada Inc*., 2012 ONSC 3681 and *Stanway v. Wyeth Canada Inc*., 2011 BCSC 1057, aff'd 2012 BCCA 260.

[28] *Crisante, supra,* note 2, at para. 47.

[29] *Ibid.*

have been certified by this court in other cases[30] and I agreed to do so in that case. And I do here as well.

[48] Proposed common issue 5, which is more problematic, asks the following:

> If one or more of the common issues (1) through (3) are answered affirmatively, should the defendants be required to pay damages in respect of a medical monitoring regime, and if so, what should that regime comprise and how should it be established, and can the damages attributable thereto be assessed on an aggregate basis, and if so in what amount?

[49] The questions posed seem muddled and incoherent. The first question - should the defendants be required to pay damages in respect of a medical monitoring regime – duplicates the "special damages" question already asked in proposed common issue 4 and should be deleted. As best as I can figure, this leaves, in essence, two remaining questions:

1. What should the monitoring regime comprise and how should it be established? [I assume that it is the defendants who will be obliged to establish this monitoring system], and

2. Can the damages attributable thereto be assessed on an aggregate basis, and if so in what amount?

[50] The only evidence in the record about monitoring is the evidence (as already noted) that both regulatory authorities and Biomet recommended follow-up monitoring by doctors of their large-head MoM implant patients. Hence, there is common issue 4 about whether the "special damages" or the costs of such monitoring should be paid by the defendants – either directly to the patients to pay their doctors, or more likely in Canada, to the account of the provincial health insurers.

[51] But there is no evidence – no basis in fact – to support the suggestion that the defendants themselves as product manufacturers are obliged not only to reimburse foreseeable health costs but to actually establish and operate the suggested monitoring system. I also question, as I did in *Crisante*,[31] whether any such order (that is, a mandatory order requiring the defendant manufacturer to establish a medical monitoring system) can be made in the context of a tort claim for damages. I recognize that this

---

[30] See, for example, *Andersen, supra,* note 5, and *Heward, supra*, note 27.

[31] *Crisante, supra,* note 2 at para. 48.

particular common issue has been certified in *Andersen*[32] and in *Heward* [33] but I note that neither of the points that concern me here – about no evidence that the issue even exists in fact and the unavailability of a mandatory order in the context of a tort claim for damages – was mentioned or discussed either by the motion judge certifying this issue or by the Divisional Court. I therefore conclude, as I did in *Crisante,* that the "establishing a monitoring system" issue cannot be certified.

[52] This leaves the last question: can the damages attributable thereto [i.e. to the establishment of a monitoring system] be assessed on an aggregate basis, and if so in what amount? I don't understand this question. If the defendants are obliged to establish and operate (and thus fund) a monitoring system, then no damages would be incurred by the class members, whether individually or in the aggregate. I would delete this last question.

[53] Proposed common issue 4 is certified. Proposed common issue 5 is not.

(3) Common issue 6

[54] Proposed common issue 6 asks whether the defendants should pay punitive or exemplary damages and if so, in what amount?

[55] There is some basis in fact for the question about punitive damages. More specifically, there is some evidence in the material before me of a failure on the part of the defendants to undertake pre-market clinical trials. There is evidence that the defendants' annual disclosure to Health Canada was arguably less than complete because they failed to disclose that the Recap Resurfacing system was found to be an "outlier" by the Australian Registry. There is evidence that the defendants generally failed to update their product labelling in a timely manner as required by law.

[56] There is also evidence that the punitive damages question can be answered across the board on a class-wide basis, at least in terms of *prima facie* entitlement. Punitive damages focus on the blameworthiness of the defendant's conduct. The defendants conduct herein – the design and distribution of allegedly defective large-head MoM hip implants and the related failure to provide required information – was systemic conduct that affected the entire class. Therefore, as in *Rumley,*[34] the determination of whether punitive damages should be awarded can be made on a class-wide basis.

---

[32] *Andersen, supra,* note 5, at para. 63.

[33] *Heward, supra,* note 27, at para. 93, aff'd [2008] O.J. No, 2610 (Div. Ct.).

[34] See *Rumley v. British Columbia*, [2001] 3 S.C.R. 184 (S.C.C.), at para. 34.

[57] The plaintiff acknowledges the Supreme Court's decision in *Whiten*[35] and the Court's admonition that punitive damages are only awarded if compensatory damages are insufficient to punish the defendant.[36] The plaintiff also concedes that the amount of the punitive damages award, if such an award is made, cannot be quantified until the completion of the individual proceedings.

[58] Nonetheless, says the plaintiff, the proposed common issue about punitive damages can still be certified, on the understanding that *prima facie* entitlement may be determined at the common issues trial but quantum only after the individual assessments are concluded. The court's obligation under s. 5(1) of the CPA, says the plaintiff, is to certify a common issue. There is nothing in the CPA that precludes the common issues judge from hearing evidence on the entitlement question at the initial common issues trial and then returning to deal with quantum after he or she has decided the individual claims and determined overall compensation.[37] In other words, the trial judge could hear the entitlement evidence at the common issues trial and decide at that point there is no basis for punitive damages or that there may be a basis (for at least a nominal award) but defer deciding the actual quantum until the compensatory amount has been determined.

[59] I know that the case law is divided on whether punitive damages can be certified as a common issue where the compensatory amount (requiring findings of causation) can only be determined after the individual assessment phase.[38] I also know that much will depend on the facts of each case. In this case, and on balance, I am satisfied that the punitive damages question should be certified because of the systemic conduct at issue as already noted, and because *prima facie* entitlement and actual quantum can be bifurcated as suggested by the plaintiff. And, to the extent that this bifurcated approach runs afoul of s. 11(1)(a) of the CPA which provides that "common issues for a class shall be determined together," I note the opening words of this provision ("subject to section 12") and employ the power provided in s. 12 to allow the bifurcation of the punitive damages issue in order to ensure the fair and expeditious determination of the overall class proceeding.

---

[35] *Whiten v. Pilot Insurance Co.,* 2002 SCC 18.

[36] *Ibid*., at para. 94.

[37] As Lax J. noted in *Andersen, supra*, note 5, at para. 37-38, the *prima facie* entitlement issue can be litigated at the common issues trial and the actual amount of the punitive damages award, if any, can be determined after the conclusion of all proceedings by individual class members and the quantification of compensatory damages. But both aspects, entitlement and amount, can be certified.

[38] See the discussion in *Robinson v. Medtronic*, [2009] O.J. No. 4366 (S.C.J.) at paras. 164-91. Also see *Trillium Motor World v. General Motors of Canada,* 2014 ONSC 4336, at paras. 6-12.

[60] However, the proposed punitive damages issue needs to be amended to better explain both the intended bifurcation and the fact that the common issues trial judge will retain the discretion to determine both entitlement to punitive damages and quantum *after* the individualized damage assessments are conducted. I would suggest that the plaintiff amend his proposed common issue 6 as follows:

> 6. Should the defendants pay punitive or exemplary damages (which *may* be decided at the common issues trial) and if so, in what amount (which *must* be decided after the individual proceedings)?

[61] If the plaintiff accepts this suggested amendment, I would be pleased to certify the punitive damages issue.

(4) Defendants' motion to exclude Dr. Graves' evidence

[62] The defendants moved to exclude key portions of the evidence of Dr. Graves, the Australian Registry expert, on various grounds. As already noted, the plaintiff does not need Dr. Graves' evidence to succeed on this motion for certification. Even if this evidence were excluded, there would still be some basis in fact supporting the commonality of each of the proposed common issues.[39] The defendants' motion need not be decided.

[63] For the sake of completeness, however, I note the following. First, dealing with the defendants' complaint that they were not provided with the "raw data" underlying the Australian Registry's studies or analyses relied on by Dr. Graves, the plaintiff correctly points out that Dr. Graves did not rely on any "raw data." In giving his opinion Dr. Graves relied on published medical literature, his years of experience as a distinguished orthopaedic surgeon, and the published annual reports and unpublished data of the Australian Registry. The Registry's unpublished data, which should not be confused with raw data, was fully disclosed to the defendants. In short, everything that Dr. Graves quite properly reviewed and relied on was disclosed to the defendants.

[64] The defendants' other objections to Dr. Graves' evidence are equally untenable. There was nothing wrong in Dr. Graves receiving assistance from Registry staff in completing his expert report. Nor is there any basis for the defendants' allegations of bias, strong language or conflict of interest.

Disposition

[65] The motion for certification is granted.

---

[39] As noted above at paras. 22 and 30.

[66] Proposed common issues 1, 2, 3, and 4 as set out in the Appendix are certified. Proposed common issue 5 is not. Proposed common issue 6 will be certified if the suggested amendments are accepted by the plaintiff.

[67] Counsel shall prepare a draft Order in the form contemplated by s. 8 of the CPA.

[68] If the parties are unable to agree on the costs, I would be pleased to receive brief written submissions from the plaintiffs within 14 days and from the defendants within 14 days thereafter. Counsel should know that I am inclined to find that the plaintiff has succeeded on 95 per cent of the certification motion.

[69] My thanks to counsel for their co-operation and for their additional written submissions.

Belobaba J.

Date: December 18, 2015

Appendix: Proposed Common Issues

1. Do the Defendants owe a duty of care to the class?

2. If so, what is the standard of care applicable to the Defendants?

3. Did the Defendants breach that standard of care? If so, when and how?

4. If one or more of the common issues (1) through (3) are answered affirmatively, are class members who are subsequently able to establish valid claims entitled to special damages for medical costs incurred in the monitoring, screening, diagnosis, and treatment of illnesses or infection related to Biomet Implants?

5. If one or more of the common issues (1) through (3) are answered affirmatively, should the defendants be required to pay damages in

respect of a medical monitoring regime, and if so, what should that regime comprise and how should it be established, and can the damages attributable thereto be assessed on an aggregate basis, and if so in what amount?

6. Should the defendants pay punitive or exemplary damages and if so, in what amount?

***