CITATION: Harper v. American Medical Systems Canada Inc., 2015 ONSC 3434
COURT FILE NO.: CV-15-527760-00CP
COURT FILE NO.: CV-15-529000-00CP
DATE: 20150528

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:	
SHARON HARPER and GERALD HARPER Plaintiffs	*Daniel E.H. Bach* and *Ronald Podolny* for the Plaintiffs
– and –	
AMERICAN MEDICAL SYSTEMS CANADA INC., AMERICAN MEDICAL SYSTEMS INC., and ENDO PHARMACEUTICALS Defendants	*Jill Lawrie* and *Sarah Emery* for the Defendants
Proceeding under the *Class Proceedings Act, 1992*	
AND BETWEEN:	
LINDA-SUE MIDDLETON and HOWARD BOSSCHER Plaintiffs	*Daniel E.H. Bach* and *Ronald Podolny* for the Plaintiffs
- and –	
AMERICAN MEDICAL SYSTEMS CANADA INC., AMERICAN MEDICAL SYSTEMS INC., and ENDO PHARMACEUTICALS Defendants	*Jill Lawrie* and *Sarah Emery* for the Defendants
Proceeding under the *Class Proceedings Act, 1992*	**HEARD**: May 28, 2015

PERELL, J.

REASONS FOR DECISION

[1] Pursuant to the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, the Plaintiffs Sharon Harper and Gerald Harper commenced a products liability negligence class action against the Defendants American Medical Systems Canada Inc., American Medical Systems Inc. and Endo Pharmaceuticals.

[2] Mrs. Harper's proposed class action was originally about two types of transvaginal mesh medical devices. On consent, the parties move for the certification of Mrs. Harper's proposed class action which has been amended to be about just one of the medical devices.

[3] The other medical device is now the subject of a second proposed class action brought by the Plaintiffs Linda-Sue Middleton and Howard Bosscher. The Plaintiffs to this proposed class action move for certification, also on consent.

[4] The Plaintiffs in the *Harper* action and the Plaintiffs in the *Middleton* action also seek approval of the certification notices and notice programs for their respective actions.

[5] For the reasons that follow, the Plaintiffs' motions are granted.

[6] The Defendants designed, marketed and sold medical devices that incorporate transvaginal mesh for the treatment of: (1) stress urinary incontinence ("SUI"); and (2) pelvic organ prolapse ("POP"), which are different conditions and different treatments.

[7] The medical devices contain synthetic, polypropylene mesh that is surgically inserted for the purpose of providing support for pelvic floor muscles.

[8] The Plaintiffs allege that the Defendants' transvaginal mesh devices are unsafe. The Defendants deny all of the Plaintiffs' allegations.

[9] The principal Plaintiffs in the two class actions are women who were implanted with devices designed to treat SUI and POP, respectively.

[10] The Plaintiffs and the Defendants have agreed on the form and content of a short-form and a long-form Notice of Certification ("Notice Plan") in both actions.

[11] The Plaintiffs and the Defendants have also agreed on a plan for disseminating the Notice Plan in both actions. It is proposed that the short-form Notice Plan be disseminated as follows: (a) sent by email or direct mail by Siskinds LLP and Rochon Genova LLP ("Class Counsel") to any person who has inquired about the class action or who has registered to receive updates on Class Counsel's respective websites, or any law firm with transvaginal mesh clients known to Class Counsel; (b) posted by Class Counsel, in English and in French, on their respective websites; (c) disseminated to all hospitals in Canada together with a request that it be forwarded to all hospital personnel who may treat patients who have received an American Medical Systems ("AMS") transvaginal mesh device; (d) posted by the Defendants, in English and the French, on www.americanmedicalsystems.com; (e) issued in English and French through Canada Newswire; and (g) sent by Class Counsel to any person who requests it.

[12] The short-form Notice Plan will also be published once in the following newspapers, in English or French, as appropriate for each newspaper: *The Globe and Mail*, national edition; *National Post*, national edition; *The Calgary Sun*; *The Chronicle-Herald* (Halifax, NS); *Courier*

(Kelowna, BC); *L'écho de Shawinigan* (Shawinigan, QC); *L'écho de Trois-Rivières* (*Trois-Rivières*, QC); *The Edmonton Journal*; *The Gazette* (Montréal, QC); *The Guardian* (Charlottetown, PEI); *Le Journal de Québec* (Québec City, QB); *The Leader-Post* (Regina, SK); *Lethbridge Herald*; *The London Free Press*; *New Brunswick Telegraph Journal* (Saint John, NB); *Le nouvelliste* (Trois-Rivières, QC); *Ottawa Citizen*; *Le point du Lac St-Jean*; *La Presse* (Montréal, QC); *The Province* (Vancouver, BC); *Red Deer Advocate*; *Le réveil* (Saguenay, QC); *The Sault Star; The Spectator* (Hamilton, ON); *The StarPhoenix* (Saskatoon, SK); *The Telegram* (St. John's, NL); *Times Colonist* (Victoria, BC); *Times-Transcript* (Moncton, NB); *Toronto Star*; *Waterloo Region Record*; *The Windsor Star*; *Winnipeg Free Press*; and *Le quotidien* (Chicoutimi, QC).

[13] The parties have also agreed on the form and content of an opt-out form.

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

[15] In the present case, the pleadings in both actions disclose a cause of action in negligence.

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

[17] In the *Harper* action, the parties have agreed to the following definitions for the class:

> (a) All persons resident in Canada who were or are implanted with an AMS SUI Transvaginal Mesh Device at any time on or before [the date of the certification order] (the "Patients' Class"); and
>
> (b) All persons resident in Canada who by virtue of a personal relationship to one or more such persons described in (a) above, have standing in this action pursuant to section 6(1) of the Family Law Act, RSO 1990, c. F. 3 or analogous provincial legislation or at common law (the "Family Class").
>
> Where "AMS SUI Transvaginal Mesh Device" means each of SPARC® (including, but not limited to, SPARC® Sling System), BioArc® (including, but not limited to, BioArc® TO Sling Kit, BioArc® TO System with InteXen® LP, BioArc® SP Sling Kit and BioArc® SP System with InteXen® LP), Monarc® (including, but not limited to, Monarc® Subfascial Hammock, Monarc® C Subfascial Hammock and Monarc® + Subfascial Hammock), MiniArc® (including, but not limited to, MiniArc® Single-Incision Sling System, MiniArc® Precise™ Single-Incision Sling System, and MiniArc® Pro™ Single-Incision Sling System), In-Fast® (including, but not limited to, In-Fast® Bone Screw System, In-Fast Ultra® Bone Screw System, In-Fast® Sling System, In-Fast Ultra® Sling System and In-Fast® with Influence-TRG Gelseal) and RetroArc™ (including, but not limited to, RetroArc™ Retropubic Sling System).

[18] In the *Middleton* action, the parties have agreed on the following definitions for the class:

> (a) All persons resident in Canada who were or are implanted with an AMS POP Transvaginal Mesh Device at any time on or before [the date of the certification order] (the "Patients' Class"); and

(b) All persons resident in Canada who by virtue of a personal relationship to one or more such persons described in (a) above, have standing in this action pursuant to section 6(1) of the Family Law Act, RSO 1990, c. F. 3 or analogous provincial legislation or at common law (the "Family Class").

Where "AMS POP Transvaginal Mesh Device" means each of Apogee® (including, but not limited to, Apogee® Vault Suspension System, Apogee® System with Cape, Apogee® System with Bio-Cape, Apogee® Enhanced, Apogee® System with IntePro®, Apogee® System with IntePro® Lite, and Apogee® System with InteXen® LP), Elevate® (including, but not limited to, Elevate® Apical and Posterior Prolapse Repair System with IntePro® Lite, Elevate® Apical and Posterior Prolapse Repair System with InteXen® LP, Elevate® Anterior & Apical Prolapse Repair System with IntePro® Lite, Elevate® Anterior & Apical Prolapse Repair System with InteXen® LP, Elevate® PC Apical & Posterior Prolapse Repair System, and Elevate® PC Anterior & Apical Prolapse Repair System), and Perigee® (including, but not limited to, Perigee® System, Perigee® System with IntePro®, Perigee® System with Biologic InteGraft, Perigee® Enhanced, Perigee® System with IntePro® Lite, Perigee® Plus, Perigee® Plus with IntePro® Lite and Perigee® System with InteXen® LP).

[19] I am satisfied that the Plaintiffs, respectively, have satisfied the second criterion for certification.

[20] The third criterion for certification is the common issues criterion. The parties have agreed on the following common issues for the *Harper* action:

(a) Did the defendants or any of them breach the standard of care with respect to the design, development, testing, licensing, labelling, marketing, instructions for use, distribution and/or sale of their AMS SUI Transvaginal Mesh Devices? If so, when and how?

(b) Is AMS SUI Transvaginal Mesh associated with a materially increased risk of complications as compared to traditional and/or other medical management and/or surgical management options? If so, what are those complications?

(c) Is AMS SUI Transvaginal Mesh defective or unfit for the purpose for which it was intended as designed, developed, tested, licensed, labelled, marketed, instructed for use, distributed, sold and/or otherwise placed into the stream of commerce in Canada by the defendants or any of them?

(d) If one or more of common issues (a)-(c) are answered affirmatively, did the defendants, or any of them, breach a duty to warn?

[21] The parties have agreed on the following common issues for the *Middleton* action:

(a) Did the defendants or any of them breach the standard of care with respect to the design, development, testing, licensing, labelling, marketing, instructions for use, distribution and/or sale of their AMS POP Transvaginal Mesh Devices? If so, when and how?

(b) Is AMS POP Transvaginal Mesh associated with a materially increased risk of complications as compared to traditional and/or other medical management and/or surgical management options? If so, what are those complications?

(c) Is AMS POP Transvaginal Mesh defective or unfit for the purpose for which it was intended as designed, developed, tested, licensed, labelled, marketed, instructed for use, distributed, sold and/or otherwise placed into the stream of commerce in Canada by the defendants or any of them?

(d) If one or more of common issues (a)-(c) are answered affirmatively, did the defendants, or any of them, breach a duty to warn?

[22] Notably, common issues (b) and (c) for each class action focus on the "transvaginal mesh" used to treat just one same medical problem, rather than including in one class action all the devices produced by the Defendants for more than one medical problem.

[23] In contrast to *O'Brien v. Bard Canada Inc.,* 2015 ONSC 2470, a proposed transvaginal mesh class action that I declined to certify for want of a common issue, the common issues trials in the cases at bar will focus on the alleged common design defects of devices using the same type of mesh to treat the same type of condition. There is evidence that these issues can be addressed in common.

[24] In contrast to *O'Brien v. Bard Canada Inc.,* in the cases at bar, there is evidence to establish some basis in fact to support the allegation that the mesh constitutes a common design defect for each action dealt with discretely. By focusing on the type of medical condition treated by the devices and on the common design feature (Type I polypropylene mesh) shared by the devices, these two class actions avoid the problems I identified in the *O'Brien* case.

[25] In all the circumstances, I am satisfied that the preferable procedure criterion and the representative plaintiff criterion are satisfied in each action.

[26] I am also satisfied that the notices and notice plans for the respective actions should be approved.

[27] Accordingly, I grant the Plaintiffs' motions in both actions.

Perell, J.

Released: May 28, 2015

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SHARON HARPER AND GERALD HARPER

Plaintiffs

– and –

AMERICAN MEDICAL SYSTEMS CANADA INC., AMERICAN MEDICAL SYSTEMS INC., and ENDO PHARMACEUTICALS

Defendants

AND BETWEEN:

LINDA-SUE MIDDLETON and HOWARD BOSSCHER

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AMERICAN MEDICAL SYSTEMS CANADA INC., AMERICAN MEDICAL SYSTEMS INC., and ENDO PHARMACEUTICALS

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REASONS FOR DECISION

PERELL J.

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