CITATION: Kuiper v. Cook (Canada) Inc., 2018 ONSC 6487
COURT FILE NO.: CV-17-578210CP
DATE: 2018/10/31

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:	
Arie Kuiper, Wendy Kopeck and Garry Kopeck Plaintiffs	*Jill S. McCartney, Matthew D. Baer, Emily Assini* and *Elizabeth De Boer* for the Plaintiffs
– and –	
Cook (Canada) Inc., Cook Medical LLC, Cook Medical Incorporated A/K/A Cook Medical, Inc., Cook Incorporated, Cook Group, Inc. and William Cook Europe APS Defendants	*Paul J. Martin, Sarah Armstrong* and *Mitch Stephenson* for the Defendants
Proceeding under the *Class Proceedings Act, 1992*	**HEARD**: October 10-12, 2018

PERELL, J.

REASONS FOR DECISION

A. INTRODUCTION

[1] Pursuant to the *Class Proceedings Act, 1992,*[1] Arie Kuiper, Wendy Kopeck, and Garry Kopeck sue Cook (Canada) Inc., Cook Medical LLC, Cook Medical Incorporated, Cook Incorporated, Cook Group, Inc., and William Cook in a medical device products liability action.

[2] The Plaintiffs bring the action on behalf of the following class:

> All persons resident in Canada who have been implanted with an IVC Filter Product (namely: (1) the Cook Gunther Tulip Vena Cava Filter Set, (2) Cook Celect Vena Cava Filter Set, and (3) Cook Celect Platinum Vena Cava Filter Set) at any time on or before the date of the certification order which was manufactured, marketed, and/or sold or otherwise placed into the stream of commerce in Canada by the defendants; and
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> All persons resident in Canada who by virtue of a personal relationship to one or more of such

[1] S.O. 1992, c. 6.

persons described in (a) above, have standing in this action pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, or equivalent legislation in a respective jurisdiction, or the common law.

[3] The Plaintiffs' principal allegations in this proposed class action are two-fold: (1) Cook's retrievable IVC filters are defective in design; and, (2) Cook's warnings about complications that might arise from the use of an optionally retrievable filter, including ailments, injuries, and non-retrievability, are inadequate.

[4] The Defendants resist certification and submit that, save for the identifiable class criterion, the proposed class action does not satisfy the criteria for certification as a class action.

[5] For the reasons that follow, I dismiss the certification motion.

B. PROCEDURAL BACKGROUND

[6] The action was commenced on February 22, 2016, and the Plaintiffs delivered a Fresh as Amended Consolidated Statement of Claim on December 13, 2016.

[7] In the Statement of Claim, the Plaintiffs allege that the Defendants owed the Plaintiffs a duty of care to design and manufacture Cook IVC filters fit for their intended and/or reasonably foreseeable use, to conduct appropriate testing and monitoring to identify risks, and to adequately warn patients, physicians, and Health Canada of risks from the use of Cook IVC filters. The Plaintiffs allege that Cook was negligent and breached its duty of care and as a consequence the Class Members suffered injuries and damages.

[8] The Plaintiffs allege that the design requirements for the Cook IVC filters to be retrievable rendered them unable to withstand the normal anatomical and physical loading cycles exerted *in vivo*. The Plaintiffs allege that the design of the Cook IVC filters caused apparent device malfunctions and injuries that increase the longer the device is in place in the body.

[9] The Plaintiffs allege that Cook's Information for Use ("IFU") pamphlet did not properly caution doctors or patients that: (a) there are dangerous device malfunctions and injuries associated with their retrievable IVC filters that increase with the amount of time the filters are in place; and, (b) retrieval attempts may be unsuccessful.

[10] The Plaintiffs allege that Class Members did not know and could not have known the risks associated with the IVC filters. The Plaintiffs allege that the Class Members' injuries would not have occurred but for Cook's negligence. The Plaintiffs alleges that because of Cook's negligence, the Class Members have suffered and continue to suffer injuries. The Plaintiffs claim pecuniary and special damages of $500,000 for each person implanted with the Defendants IVC and $100,000 for each *Family Law Act*[2] or similar legislation claimant. The Plaintiffs claim punitive damages of $20 million.

[11] The Plaintiffs propose thirteen common issue questions. Four questions concern design negligence. Eight questions concern the duty to warn, and there is a punitive damages question.

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[2] R.S.O. 1990, c. F.3, s. 61.

C. THE PLAINTIFFS

Arie "Bob" Kuiper

[12] The Plaintiff, Arie Kuiper, resides in Oshawa, Ontario. In August 2015, during a hospitalization for a breathing problem, it was discovered that Mr. Kuiper had suffered a pulmonary embolism, *i.e.,* a blood clot that had reached the lungs. Unfortunately, the physicians also discovered that Mr. Kuiper had a large cancerous mass that required urgent surgery. Because of the bleeding risk posed by the surgery, anticoagulants, the normal treatment for blood clots, were not an option for preventing another embolism. Mr. Kuiper consented to the insertion of an IVC filter, a medical device designed to trap embolisms moving toward the heart and lungs. He was told that the filter would be temporary. An IVC Cook filter was placed, and the cancer surgery proceeded.

[13] In October 2015, an attempt was made to retrieve the filter, but the struts of the filter were stuck in the walls of Mr. Kuiper's vein, and it was not possible to extract the filter at that time. A second attempt at retrieval was made on January 25, 2016, but the procedure was again unsuccessful. A third unsuccessful retrieval was attempted on February 29, 2016.

[14] The IVC filter remains in his body and Mr. Kuiper is on anticoagulation therapy. His doctors believe that the filter has trapped blood clots.

[15] Mr. Kuiper deposed that had he been aware of the risks associated with a permanently implanted filter, he would not have consented to having the IVC filter implanted.

Wendy Kopeck

[16] The Plaintiff, Wendy Kopeck, resides in Red Deer, Alberta. In the summer of 2013, Mrs. Kopeck urgently required surgery to remove a tumor in her femur, but, unfortunately, it was discovered that she also had a deep vein thrombosis (a "DVT") (blood clot). Because of the bleeding risk posed by the surgery for the tumor, anticoagulants, the normal treatment for blood clots, was not an option to treat Mrs. Kopeck's DVT, and for the tumor surgery to proceed, a Cook IVC filter was implanted on August 29, 2013. Mrs. Kopeck was advised that the filter was temporary, and that it would be retrieved once the threat of a pulmonary embolism had passed. She consented to the implant. During the surgery a clot broke loose, but the embolism was captured by the filter, which saved her from a life-threatening pulmonary embolism.

[17] In the fall of 2013, the retrieval procedure - which was scheduled for October 2, 2013 - was postponed because medical imaging of Mrs. Kuiper revealed that there were blood clots in the filter. The filter was not removed and Mrs. Kuiper was also placed on anticoagulant therapy, the normal treatment for embolisms.

[18] On October 24, 2013 a PET scan revealed that the IVC filter had broken and migrated. In these circumstances, Mrs. Kopeck's doctors decided not to retrieve the filter. Mrs. Kopeck remains on anticoagulants and experiences side effects common to anticoagulants such as bleeding and bruising.

[19] Mrs. Kopeck deposed that had she been aware of the risks of having a Cook filter implanted, she would not have he would not have consented to having the IVC filter implanted.

Gary Kopeck

[20] The Plaintiff, Garry Kopeck, is the spouse of Mrs. Kopeck and advances a family law

claim for loss of care, guidance, and companionship.

D. THE DEFENDANTS

[21] The Plaintiffs sue: (1) Cook (Canada) Inc.; (2) Cook Medical LLC; (3) Cook Medical Incorporated, a/k/a Cook Medical, Inc.; (4) Cook Incorporated; (5) Cook Group, Inc.; and, (6) William Cook Europe APS. I shall refer to the Defendants collectively simply as "Cook."

[22] Cook (Canada) Inc. ("Cook Canada") is a subsidiary of Cook Medical Holdings, LLC, which, in turn is a subsidiary of Cook Group Incorporated ("CGI").

[23] Cook Canada is solely a sales and distribution entity and does not design or manufacture medical devices. Cook Incorporated and William Cook Europe APS manufacture and hold medical device licences from Health Canada in respect of the IVC filters.

[24] The Plaintiffs have advanced no evidence in support of the claims against: (1) Cook Medical LLC; (2) Cook Medical Incorporated, a/k/a Cook Medical, Inc.; or, (3) Cook Group, Inc. and, therefore, in any event, I would not certify the proposed class action as against these Defendants.[3]

E. EVIDENTIARY BACKGROUND

[25] The Plaintiffs supported their certification motion with the following evidence:

- **Mark Crowther**, M.D. swore an affidavit dated June 29, 2017. Dr. Crowther is a medical doctor with Canadian Board certification in Internal Medicine and Hematology. He is the Professor and Chair of the Department of Pathology and Molecular Medicine at McMaster University, as well as a Professor in the Departments of Medicine and Clinical Epidemiology and Biostatistics. Dr. Crowther was cross-examined.
- The Plaintiff **Wendy Kopeck** swore an affidavit dated July 10, 2017. Mrs. Kopeck was cross-examined.
- The Plaintiff **Garry Kopeck** swore an affidavit dated July 10, 2017. Mr. Kopeck was cross-examined.
- The Plaintiff **Arie Kuiper** swore an affidavit dated June 26, 2017. Mr. Kuiper was cross-examined.

[26] Cook resisted the certification motion with the following evidence:

- **Jennifer Brown,** Ph.D. swore an affidavit dated February 23, 2018. Dr. Brown is the Director for Global Regulatory Science - Vascular for Cook Medical and Director of Regulatory Affairs for Cook Research Incorporated. She authored a report that provided a summary of data about Cook IVC filters. Dr. Brown was cross-examined.
- **Peter Fryzek**, Ph.D., M.P.H. swore an affidavit dated February 26, 2018. Dr. Fryzek is an epidemiologist who has a doctoral degree in Epidemiologic Science and a Master of

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[3] See *Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681.

Public Health in Epidemiology and International Health. Dr. Fryzek did a systematic review of the scientific literature and the data regarding Cook IVC filters. Dr. Fryzek was cross-examined.

- **Gregory LeBlanc** sworn an affidavit dated February 28, 2018. Mr. Leblanc is the Director of Regulatory Affairs and Quality Systems for Cook Canada. He serves as the liaison with Health Canada on behalf of all Cook companies. He advises Cook about Health Canada's regulatory requirements, oversees filings for licencing and regulatory submissions, and serves as the point of contact for complaint reporting and general regulatory correspondence. Mr. Leblanc deposed about the licensing and marketing of Cook's IVC filters and provided after-market data. Mr. LeBlanc was cross-examined.
- **Timothy Morris**, M.D. swore an affidavit dated February 27, 2018. Dr. Morris is an academic and clinical pulmonary and critical care physician at the University of California, San Diego. Dr. Morris opined about the use and efficacy of IVC filters and reviewed the scientific literature regarding complications. Dr. Morris was cross-examined.
- **Scott W. Robertson**, Ph.D. swore an affidavit dated February 23, 2018. Dr. Robertson is a material science engineer with a doctorate in material science and engineering from the University of California, Berkley in 2006. He provided opinion expert evidence about the design of the Cook IVC filters. Dr. Robertson was cross-examined.

F. IVC ("INFERIOR VENA CAVA") FILTERS AND THE TREATMENT OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM ("PE")

[27] The pathological process of the formation of a blood clot in a vein is known as venous thromboembolism ("VTE"). Blood clots in the veins are caused by: (a) injuries; (b) stasis, *i.e.,* slow blood flow; or (c) hypercoagulability; *i.e.,* an enhanced potential of the blood to clot.

[28] Blood clots that form in large veins are known as a deep vein thrombosis ("DVT"). DVT can form for a variety of reasons, including cancer, blood abnormalities, and injuries. The most likely place that a DVT will occur is in the veins of the leg.

[29] In many cases, a DVT will break off from where it is formed in the vein and float along with the blood to the heart and lungs. The largest vein in the body is the Inferior Vena Cava ("IVC"). The IVC returns blood from the lower body to the heart.

[30] A moving clot is called an "embolism," so when the DVT floats into the pulmonary arteries, it is called a "pulmonary embolism" ("PE").

[31] A pulmonary embolism is a life-threatening condition that can cause catastrophic acute heart failure, circulatory collapse, and death.

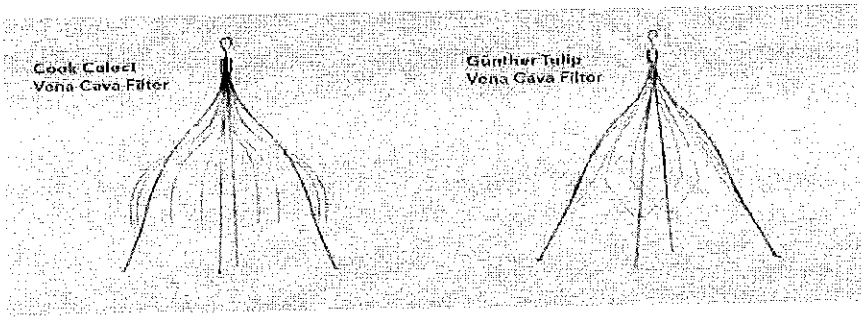
[32] The preferred and predominant treatment of VTE is anticoagulant medications (sometimes known as blood thinners), which are drugs that diminish clot formation and clot growth allowing the clot to dissolve in the body.

[33] In treating VTE, anticoagulants may pose a risk for some patients. The risk arises because clotting is necessary to arrest potentially fatal bleeding and patients at risk of bleeding have a substantially higher risk if prescribed an anticoagulant. Thus, for a small proportionate number

of VTE patients, anticoagulants are contraindicated because of the risk of uncontrolled bleeding. For these patients, the treatment for a VTE is an IVC filter; *i.e.*, a filter placed in the Inferior Vena Cava. The filter, an implanted medical device is designed to trap blood clots ("thrombi") that have formed in the patient's legs (most often due to VTE) and to thereby prevent the blood clots from reaching the heart and lungs and causing a life-threatening pulmonary embolism.

[34] IVC filters are percutaneously (*i.e.*, needle puncture through the skin) placed and retrieved through either the femoral or jugular vein.

[35] Cook's IVC filters are shaped like cones. The cone is made out of very thin metal legs that converge to a point. The legs have hooks to affix to the wall of the vein to station the filter and to stop it from moving. The IVC filters catch the clot at the centre of the cone while blood continues to flow around the edges of the filter.



[36] In the 1980s, IVC filters were introduced to health care practitioners. The filters were designed to be permanent implants. Approximately 20 years later, retrievable filters were developed. Retrievable filters are designed to be more flexible than the permanently placed devices. The components of a retrievable IVC filter must allow both deployment with anchors to the vascular wall and also recapture with anchors that can disengage from the vascular wall.

[37] As explained further below, the key performance features of IVC filters ranked in order of importance are: clot capture, migration resistance, fracture resistance, perforation resistance, tilt resistance, retrievability, and occlusion resistance (resistance to blockage of blood flow).

[38] Some of these performance features of IVC filters are complementary, whereas others are antagonist. For examples: (a) a filter designed to enhance clot capture may diminish occlusion resistance; (b) a filter designed to enhance clot capture may diminish migration resistance; *i.e.*, make the device more prone to migrate; (c) a filter designed to enhance migration resistance may diminish perforation resistance; *i.e.*, make the filter more prone to perforate the vein to which the filter is affixed; (d) a filter designed to enhance retrievability may diminish migration resistance; (e) a filter designed to enhance fracture resistance may diminish retrievability; and (f) a filter designed to enhance migration resistance may diminish retrievability.

G. COOK'S IVC FILTERS

[39] Cook manufactures four IVC filters: one is designed for permanent placement and three are designed for permanent placement and to be optionally retrievable. The retrievable IVC filters are the subject matter of this proposed class action.

[40] Cook's IVC filters are all Class IV medical devices as regulated under the *Food and Drugs Act*[4] and the *Medical Devices Regulations*[5] enacted under that Act.

[41] Cook sought regulatory approval for the retrievable filters based on the safety and efficacy profile of the Cook Bird's filter, which was a device that designed for permanent placement in the body.

[42] In 1998, the Günther Tulip Vena Cava filter was introduced in Canada. Up until January 31, 2018, 8,224 Cook Günther Tulip filters have been sold in Canada.

[43] In 2006, the Cook Celect Vena Cava filter was introduced in Canada. It was replaced in the Canadian market in 2017 with the introduction of the Cook Celect Platinum filter. Up until January 31, 2018, 10,954 Cook Celect Vena Cava filters have been sold in Canada.

[44] In 2014, the Cook Celect Platinum filter was introduced in Canada. Up until January 31, 2018, 3,616 Cook Celect Platinum filters have been sold in Canada. Thus, approximately 23,000 Cook IVC filters have been sold in Canada.

[45] There are both similarities and differences among Cook's three retrievable IVC filters. They share a common purpose of blocking embolisms. They are all made of a cobalt-chromium alloy called "Elgiloy" or "Conichrome". They are all conical or have an umbrella like shape, consisting of a central body and anchoring struts, thin metal legs, and anchors to pierce the vein wall and attach the filter. They are all designed to be implanted permanently or to be optionally retrievable. They are all collapsible to permit deployment and retrieval. For retrievability, they all employ the same anchoring mechanism that is designed to disengage from the vascular wall to permit retrieval.

[46] Cook's first generation of IVC filters were designed to be permanently affixed in the body. The Cook IVC filters that are the subject of the proposed class action are designed to be permanently affixed or optionally they are retrievable. These filters were designed with retrieval in-mind.

[47] There was no suggestion that a risk-free IVC filter could be manufactured by Cook, or anybody else for that matter, and there was no suggestion that Cook had manufactured its IVC filters with manufacturing errors or defects. The issues in the case concern whether Cook had negligent designed its properly manufactured IVC filter and whether its IFU pamphlets gave adequate warnings about the use of its filters.

[48] While the Plaintiffs' expert witness, Dr. Crowther, had something to say about the design of IVC filters (including Cook's IVC filters), the only witness qualified to give expert evidence about design was Dr. Robertson Cook's expert witness. He testified that the therapeutic purpose of IVC filters was to capture life-threatening blood clots before the clots reach the lungs. He said that filters must be designed to capture clots and to not themselves migrate in the body, since migration can also result in a life-threatening event.

[49] Dr. Robertson testified that in descending order of importance, the primary performance features of an IVC filter are: (a) clot capture; (b) migration resistance; (c) fracture resistance;

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[4] RSC 1985, c F-27.
[5] 12 SOR/98-282.

(d) perforation resistance; (e) tilt resistance; (f) optional retrievability; and, (g) occlusion resistance (not blocking blood flow). He explained that the performance features affect one another. For example, clot capture, the primary purpose of the device, can be maximized by the choice of the geometry of the struts that would reduce the size of the gaps between the struts, but this choice would increase the risk of occlusion, which, in turn, would increase the risk of device migration because of the pressure of the blocked blood flow. For another example, migration resistance can be enhanced by stiffer material in the radial struts; however, with an increase of stiffness, the filter may be more prone to perforate the vein, and with increased migration resistance, the retrievability of the filter may be diminished. Dr. Robertson said that the performance aspects formed a matrix of considerations that as a matter of appropriate filter design had to be balanced to find an optimal balance.

[50] Although in his descending ranking of important performance features, Dr. Robertson ranked optional retrievability as the next to last performance feature of an IVC filter, the evidence revealed that optional retrievability was an improvement, advance, or optimization of the therapeutic purpose of IVC filters, which purpose was to provide a stop gap measure to capture life-threatening blood clots when the preferred measure of anticoagulants was contraindicated.

[51] In other words, the purpose of IVC filters (as a secondary or last choice way of dealing with the problems of embolisms) was better achieved by designing the filters to be optionally temporary and not permanent. Retrievability enhanced patient safety because the filters were more dangerous the longer they were implanted in the body. That retrievability was a design improvement is evidenced by the recommendations of the regulators discussed in the next section of these Reasons for Decision. In a letter to physicians, Health Canada did not suggest that IVC filters should not be used; rather, Health Canada encouraged physicians to consider retrieving IVC filters as soon as the preferred means of protecting a patient from pulmonary embolisms could be employed or re-employed.

[52] For the purposes of deciding this certification motion, this last point about retrievability and several associated points should be kept in mind because, as the discussion below, will reveal the Plaintiffs' failure to identify a design defect was the Achilles heel in what the Plaintiffs depicted (as Plaintiffs typically do) to be a quintessentially certifiable products liability case.

[53] The points to keep in mind are that: (a) IVC filters are not risk-free products; (b) the risks of IVC filter malfunction and adverse consequences are reduced if the filters are retrieved; (c) IVC filters should be retrieved as soon as possible; (d) optional retrievability in an IVC filter is itself not itself a design defect; (e) achieving retrievability is an improvement on product safety - provided that other safety features are not compromised; and (f) a design choice made to achieve retrievability could be negligent design choice if safer choices were feasible.

[54] Dr. Robertson opined that Cook's Gunther Tulip and Celect IVC filter designs are not defective and their benefits far outweigh their risks. He opined that Cook's design process and testing procedures were appropriate, state of the art, and Cook provided the information needed to confirm the designs' functionality, safety, and efficacy.

[55] The Plaintiffs did not provide any expert evidence to contradict Dr. Robertson. Rather, in addition to the evidence of Dr. Crowther and the personal experiences of Mrs. Kopeck and Mr. Kuiper, the Plaintiffs relied on Dr. Robertson's evidence to submit that there was some basis

in fact for a design problem in the immediate case.

[56] Since the introduction of Cook's retrievable filters in Canada, thirty-one incidents of possible complications have been reported to Health Canada in a Mandatory Device Problem Report ("MDPR"). None of the licences for the Cook IVC filters have ever been suspended. There have been no product recalls.

H. RISKS ASSOCIATED WITH THE PERMANENT PLACEMENT AND WITH THE RETRIEVAL OF IVC FILTERS

[57] As noted above, the first generation of IVC filters were designed to be permanent implants but subsequent generations of filters, including Cook's IVC filters, were designed to permanent or optionally retrievable.

[58] As noted above, retrieving the filter is regarded as a therapeutically good idea. However, many filters are not retrieved. In some instances, the patient's physician will recommend permanent placement. In other instances, there is a failure by the patient or his or her physician to follow up and retrieve the filter after the need for it is spent. In other instances, as demonstrated by the experiences of Mrs. Kopeck and Mr. Kuiper, retrievability is not achieved. Thus, as noted by Dr. Crowther, many optionally retrievable filters are not retrieved.

[59] In 2007, the United Kingdom's Competent Authority, the Medicines & Healthcare Products Regulatory Agency ("MHRA"), released a safety alert regarding retrievable IVC filters which was updated by a second alert in May 2013, in which the MHRA encouraged physicians to be diligent about retrieving filters when the risk of PE had passed. The MHRA reminded physicians that procedures to retrieve filters are not always risk-free. The MHRA encouraged manufacturers to include in IFU pamphlets information about the duration during which a filter may be considered safe to retrieve.

[60] In August of 2010, in the United States, the Food and Drug Administration ("FDA") issued a safety communication to healthcare professionals expressing concern about the potential of retrievable IVC filters to fracture, the possibility that some of the device components may detach, and that part or all of a filter may spontaneously migrate and perforate the vena cava. This communication encouraged physicians to consider retrieving filters as soon as protection from pulmonary embolism was no longer needed.

[61] On May 14, 2014, the FDA updated its initial findings and recommended that IVC filters be retrieved between 29 and 54 days after implantation. The FDA relied in part on a 2013 study that concluded that once the risk of PE had passed the risks of complications start to outweigh the protective benefits of the filter.

[62] In July 2016, Health Canada released a Safety Alert regarding IVC filters. The Safety Alert warned of serious complications associated with IVC filters remaining in place longer than thirty days, including: caval perforation, caval thrombosis, filter fracture and fragment embolization, intracardiac migration, cardiac perforation, cardiac tamponade, and death. Health Canada advised consumers that retrievable filters are intended for temporary use only. Health Canada took the position that "retrievable IVC filters are intended for short-term placement and, when possible, should be removed when anticoagulation therapy can be started or if a patient's risk for PE subsides." Excerpts from Health Canada's Safety Alert are set out below:

Recalls and safety alerts

Inferior Vena Cava (IVC) filters - Risk of Serious Complications

Dear Healthcare Professional Letter

Audience

Physicians who request or implant Inferior Vena Cava (IVC) filters and clinicians responsible for follow-up care, radiologists, cardiologists, vascular surgeons, thrombosis specialists, internalists, emergency physicians, bariatric surgeons, orthopaedic surgeons, primary care physicians.

Please distribute to relevant Departments and appropriate personnel who use these filters.

Key Messages

- **Serious complications have been reported in patients implanted with an IVC filter, including caval perforation, caval thrombosis, filter fracture and fragment embolization, intracardiac migration, cardiac perforation, cardiac tamponade, and death. Many of these complications occurred with long-term (greater than 30 days) filter implantation.**
- **Healthcare professionals should carefully consider the indications for IVC filters. Health Canada considers the following indications appropriate given available clinical data:**
    - **Patients with acute proximal deep vein thrombosis (DVT) of the leg and a contradiction to coagulation**
    - **Patients with acute pulmonary embolism (PE) and a contraindication to anticoagulation**
- **Retrievable IVC filters are intended for short-term placement and, when possible, should be removed when anticoagulation therapy can be started or if a patient's risk of PE subsides.**
- **Health Canada encourages each hospital to identify all patients who have a retrievable IVC filter placed to develop formal strategy to assess these patients for filter removal.**

[...]

Information for healthcare professionals

Although clinical decisions must be made on a case-by-case basis, Health Canada considers that the following indications for use, which are consistent with the recommendations made by the American College of Chest Physicians guidelines (10th ed.) state on the use of IVC filters for the prevention of pulmonary embolism, are appropriate given the available clinical evidence at this time:

- Patients with acute proximal deep vein thrombosis (DVT) of the leg and a contradiction to coagulation
- Patients with acute pulmonary embolism (PE) and a contraindication to anticoagulation

Retrievable IVC filters are intended for short-term placement and should be removed when anticoagulation therapy can be started or if a patient's risk of PE subsides. Patients who receive a retrievable IVC filter should be scheduled for a retrieval assessment at the time of placement of an IVC filter. If the individual risk/benefit assessment indicates that a retrievable IVC filter should be removed, the patient should be referred for IFC filter removal when feasible.

[...]

I. COOK'S INSTRUCTIONS FOR USE

[63] Cook's retrievable filters have similar but not identical IFU pamphlets. For present purposes, the relevant provisions from the Cook Celect Platinum filter are set out below:

Cook Celect® Platinum Vena Cava filter Set for Femoral Vein Approach

Instructions for Use

[...]

DEVICE DESCRIPTION

The Cook Celect Platinum filter Set consists of a paramagnetic filter (30 mm diameter, 49 mm long) with platinum markers, preloaded on a femoral filter introducer with a flexible tip, a 7.0 Fr coaxial introducer system (compatible with a .035inch wire guide) and a hydrophilically coated 10.0 Fr pre-dilator. The introducer dilator has 8 sideports and two radiopaque markers 30 mm apart (end-to-end).

INTENDED USE

The Cook Celect Platinum filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

• Pulmonary thromboembolism when anticoagulant therapy is contraindicated;

• Failure of anticoagulant therapy in thromboembolic diseases;

• Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and

• Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Cook Celect Platinum filter implant may be retrieved. Please refer to the Instructions for Use provided with the Gunther Tulip Vena Cava Retrieval Set (not included in the filter set).

The product is intended for percutaneous placement via a femoral vein for filtration of inferior vena cava (IVC) blood to prevent PE.

CONTRAINDICATIONS

filter Placement

• Megacava (diameter of the IVC > 30 mm).

• Diameter of the IVC < 15 mm.

• Extensive thrombus in the vein chosen for approach.

• Vena Cava filters should not be implanted in patients with risk of septic embolism due to the risk of infection. The decision should be based on the patient's individual risk/benefit profile.

Optional filter Retrieval

• Retrieval of the filter with significant amounts of trapped thrombus (greater than 25% of t he volume of the cone).

• Retrieval of the filter for patients with an on-going high risk for PE.

WARNINGS

filter Placement

• Manipulation of products requires imaging control.

[...]

• Excessive force should not be exerted to place filter. If severe resistance is met when advancing the wire guide, then retract the wire guide and choose a different approach.

Optional filter Retrieval

• Excessive force should not be exerted to retrieve the filter.

• An inferior vena caval evaluation for residual captured thrombus should be performed prior to

attempted retrieval.

• Available data from retrievals in a prospective, multicenter study demonstrate that the device can be safely retrieved. Please refer to the Clinical Studies section of this booklet for clinical study references to the retrieval of this filter.

PRECAUTIONS

• Possible allergic reactions should be considered.

• The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.

• Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.

filter Placement

• For placement of the filter, the right femoral vein is usually preferred due to the route to the vena cava. The left femoral vein can be used but is more tortuous. Prior to choosing an approach, assess the patient's size, anatomy and the location of the venous thrombosis.

[...]

Optional filter Retrieval

• For filter retrieval, a right jugular vein approach is preferable. An approach via the left jugular vein is possible; however, no data are available demonstrating the safety or effectiveness of filter retrieval via the left jugular vein.

• The filter has been designed to be retrieved with the Gunther Tulip Vena Cava filter Retrieval Set, (not included in the filter set). Cook has not performed testing to evaluate the safety or effectiveness of filter retrieval using other retrieval systems.

• Never re-deploy a retrieved filter.

• The decision to remove a filter should be based on the patient's individual risk/benefit profile. Retrieve the filter when feasible and clinically indicated.

[...]

POTENTIAL ADVERSE EVENTS

• Damage to the vena cava

• Pulmonary embolism

• filter embolization

• Vena cava perforation/penetration

• Vena cava occlusion or thrombosis

• Hemorrhage

• Hematoma at vascular access site

• Infection at vascular access site

• Cardiac tamponade

• filter malpositioning

• Postphlebitic syndrome

• Death

CLINCIAL STUDIES

Previously published clinical studies for the Celect filter suggest probable clinical results from the

successful retrieval of the Celect Platinum filter.

A prospective international multicentre registry study to assess the safety, performance, and retrieval of the Cook Celect filter in patients with high risk of pulmonary thromboembolism (PE) was conducted. There were 28 female and 46 male patients enrolled. The average age of patients was 50 +/- 20 years (range: 18 to 89 years). Indications for placement were: contradiction, complication or failure of anticoagulation with PE or DVT (n=26), severe trauma without PE or DVGT (n=18), high risk patients for PE or DVT (n=17), massive PE with DVT at risk for further PE (n=10), severe cardio=pulmonary disease and DVT (n=2), free-floating iliofemoral or IVC thrombus (n=1). Leading comorbidities for patients enrolled in this study included trauma (43%), current DVT (37%), current PE (37%), and pulmonary disease (24%). The implementation procedure was uneventful, with filters successfully placed in a satisfactory location in all 74 patients. In one patient, a malfunction of the introducer resulted in a minor filter tilt of 6-10 degrees. In one patient, the filter was initially deployed in the gonadal vein. The filter was snared and repositioned to the desired location within the IVC.

In the 74-patient cohort, follow-up was conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound. No device related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture, or significant filter migration) have occurred. X-ray imaging has not detected filter migration greater than 20mm in any patient. Imaging by X-ray and duplex ultrasound has revealed no evidence of vena cava perforation. There have been 8 deaths (occurring from 1 to 295 days post-implant) that the independent Clinical Events Committee adjudicated as 6 not related to the device or the procedure; one death was attributed to pulmonary embolism adjudicated as device – or procedure – related, and one death was adjudicated as procedure-related.

Retrieval

A later analysis on a subset of patients with intent to retrieve the filter was conducted.

Forty-three patients (12 female, 31 male) had retrieval attempts, and forty-one retrievals were successful. Two filters were not retrieved (360 and 385 days following insertion) because the retrieval snare could not engage the filter hook that was embedded in tissue growth at the vena caval wall.

Time to retrieval ranged from 1-67 weeks.

[...]

A Kaplan-Meier analysis predicts an 89% probability of a successful retrieval at 52 weeks (see following graph).

No adverse events relating to the filter retrieval procedure were reported in the retrieval group demonstrating the safety of filter retrieval in patients who no longer require a vena cava filter.

[64] Retrieval is also addressed in the Patient Guide, which accompanies the Instructions for Use, which states:

> The Gunther Tulip and Celect vena cava filters can stay in place permanently or they can be removed, or "retrieved," after the risk of PE is reduced. Ask your doctor whether your filter will be permanent or temporary.
>
> [...]
>
> And sometimes, retrievable filters just can't be removed. Every patient is different. That's why you and your doctor should weigh the risks and benefits of vena cava filter placement and retrieval.

[65] As may be noted, Cook's IFU warns that IVC filters are not designed to be used as the primary treatment for DVT and PE. Cook's IFU states that the filters are indicated only where anticoagulants cannot be used or where anticoagulants have been proven to be ineffective.

[66] Cook's IFU identifies filter embolization, which would arise from filter migration, and vena cava damage, occlusion, or perforation as potential adverse events. The IFU reveals that the IVC filter might not be and was not retrievable in all cases, and that there is a risk that retrieval efforts may not succeed.

[67] Dr. Brown testified that Cook has drafted amendments to its IFU that are pending approval by Health Canada. The proposed amendments include new information about adverse events and complications and advice about precautions and the importance of timely removal of the IVC filter. The revisions to Cook's IFU indicate that the possibility of a successful retrieval of an IVC filter becomes more challenging with time because tissue growth may encapsulate the filter legs or the hook in a tilted filter.

J. DR. CROWTHER'S EVIDENCE

[68] Dr. Crowther was the only expert witness proffered by the Plaintiffs for the certification motion. In this section of my reasons, I shall make some of my findings of fact about Dr. Crowther's evidence and some of my findings about its significance to the Plaintiffs' certification motion.

[69] Cook submits that Dr. Crowther is not qualified to provide the opinion evidence that he provided to assist the court. Further, Cook submits that if qualified as an expert witness, Dr. Crowther's has been discredited by his admissions and by his testimony during cross-examination. Although Cook agrees with Dr. Crowther's evidence about hematology and about the formation of blood clots, it argues that none of Dr. Crowther's opinion evidence is admissible and, therefore, the Plaintiffs' certification motion should be dismissed because there is no basis in fact for the four certification criteria that require some evidence.

[70] I disagree with Cook's submissions. For the reasons that follow, I shall admit Dr. Crowther's evidence in the areas in which he is qualified to provide an opinion, and I shall give his evidence the weight it deserves keeping in mind that although evidence on a certification motion must meet the usual standards for admissibility, the weighing and testing of the evidence is not meant to be extensive, and if the expert evidence is admissible, the scrutiny of it is modest.[6] In a class proceeding, the close scrutiny of the evidence of experts should be reserved for the trial judge.[7]

[71] At the outset of a discussion of Dr. Crowther's evidence and its significance to the certification motion, it is necessary to put his evidence in context and even more necessary to also keep in mind that the scope of the Plaintiffs' action was substantially changed at the time of the certification motion from its ambitious scope at the time the action was commenced and Dr. Crowther was first retained.

[72] At the outset of the action, as pleaded in the Statement of Claim, the Plaintiffs advanced the widest-possible products liability claim against Cook with allegations of negligence in research, design, development, testing, licensing, manufacture, labelling, warning, marketing,

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[6] *Griffin v. Dell Canada Inc.*, [2009] O.J. No. 418 at para. 76 (S.C.J.).
[7] *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057, aff'd 2012 BCCA 260.

distribution, sale, and monitoring. The Plaintiffs also advanced misrepresentation claims. Although these extensive and wide-ranging allegations of negligence continued through the run up to the certification motion, at the certification motion, Class Counsel rested its case on design negligence and a breach of the duty to warn.

[73] Relying on the low evidentiary standard of some basis in fact, discussed below, it seems that Class Counsel concluded that certification on these two issues could be achieved just with the evidence of a single expert witness, Dr. Crowther, along with Mrs. Kopeck's and Mr. Kuiper's evidence of their own experiences with the Cook IVC filters.

[74] Still discussing the context of Dr. Crowther's expert evidence, Cook responded to it with five witness, three of them highly qualified independent experts, one of them an internal Cook expert, and one of them Cook's internal expert on regulatory compliance in Canada. Cook also responded with a knuckle-duster attack on Dr. Crowther's expertise and Mrs. Kopeck's and Mr. Kuiper's qualifications to be representative plaintiffs. I will briefly discuss the attack on Mrs. Kopeck's and Mr. Kuiper's qualifications later in these Reasons for Decision.

[75] Still discussing the context of Dr. Crowther's expert evidence, Dr. Crowther's report is dated June 29, 2017. Exactly a year later, on June 29, 2018, he was cross-examined. The certification motion was heard almost four months later on October 10-12, 2018. The first observation to make about Dr. Crowther's report and about his evidence is the overwhelming preponderance of his report does not address the two issues that ultimately were at the frontline of the battle for certification; *i.e.*, the design of the filters and the adequacy of Cook's warning.

[76] The overwhelming preponderance of Dr. Crowther's report concerns issues about which he was eminently, indeed superbly, qualified to provide an opinion and to assist the court, but at the hearing of the certification motion, the Plaintiffs advanced their case based on two issues that were peripheral to Dr. Crowther's report and peripheral to his expertise.

[77] In my opinion, Dr. Crowther was qualified as an internationally recognized expert in the field of thrombosis and hematology with extensive clinical and research experience in the diagnosis, treatment, and management of thromboembolic disease to express an opinion about the use and utility of IVC filters, but as it turned out, the certification motion focussed on the peripheral aspects of his expertise and the peripheral aspects of his expert's report.

[78] Having read his report, I would estimate that approximately eighty to ninety percent of it illuminated Dr. Crowther's opinions about the labelled and off-label uses that were being made of IVC filters by doctors treating blood clots or endeavoring to prevent blood clots, about the efficacy of IVC filters, and about the diagnostic and clinical competence of the physicians that prescribed IVC filters. He describes why and how IVC filters may be dangerous or may cause harm if they migrate, perforate the vein wall, or occlude (block) blood flow. He offers a plausible explanation as to why a filter may fracture, deteriorate, migrated, occlude blood flow, or embolize, because of an inability to withstand the mechanical strains of body tissue and blood flow.

[79] Dr. Crowther opines that Cook retrievable IVC filters are unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo,* and he states that injury occurs because of the chronic cycling of the filter as a result of natural changes in pressure in the inferior vena cava and the surrounding tissues. Dr. Crowther hypothesizes that perforation likely

occurs as a result of the failure of the vessel wall allowing that strut to impinge upon surrounding structures. Fracture likely results due to mechanical strain on the filter device.

[80] In the bulk of his report, Dr. Crowther was very sceptical that IVC filters actually arrested and captured blood clots and did any therapeutic good. He believed that temporary IVC filters actually increased the risk of pulmonary embolism in patients with acute DVT. He felt that filters should not be used in patients who can be treated with anticoagulation. His major conclusion was that "despite decades of use, there is little or no methodologically rigorous evidence to support any therapeutic effect from IVC filter insertion." He was critical of the evidence and testing done by manufacturers as to the efficacy of the devices or as to the superiority of retrievable filters as opposed to permanent ones. He was critical of the regulatory regime which he felt did not subject medical devices to the quality standards applied to pharmaceutical products. He was critical of the extent of complications arising from the use of retrievable IVC filters particularly because optionally retrievable filters are very often not retrieved.

[81] Dr. Crowther, however, conceded in cross-examination that notwithstanding what he knows about the efficacy of IVC filters and regardless of whom is the manufacturer, he prescribes and has prescribed IVC filters when anticoagulant are contraindicated and something must be done because of the risk of an embolism.

[82] In his report, Dr. Crowther criticized his fellow physicians for prescribing IVC filters as a prophylactic treatment for PE and for not following up to remove filters when they were prescribed. He said that there was sufficient financial rewards for physicians and hospitals inserting filters, which was a straightforward procedure, but the process of retrieving the filter required a follow-up system for which there was no economic incentive and so follow-up was not prioritized by hospitals. He was even more critical of physicians prescribing the use of IVC filters prophylactically to prevent pulmonary embolisms. He was adamant that anticoagulation was the preferred and predominant treatment and should not be augmented by IVC filters as a regular preventive measure.

[83] Dealing with the efficacy issues that comprised the preponderance of Dr. Crowther's report, I can say that for the purpose of the certification motion, much of Cook's criticism is now irrelevant save insofar that Dr. Crowther's evidence remained pertinent to the design and warning issues. (I will describe and discuss what little Dr. Crowther had to say about design and about warnings below.) Cook's criticism of Dr. Crowther is now largely irrelevant because the parameters of the action for which certification is being sought are much narrower than the widest-possible products liability claim that was pleaded at the time Dr. Crowther was retained.

[84] On these now irrelevant issues, I need not make and I will not make any comment about whether Dr. Crowther's evidence meets the some-basis-in-fact standard. I shall, however, explain why I am admitting Dr. Crowther's evidence and why I shall treat Cook's objections to his evidence as going to the weigh to be given his evidence about the design issue and the duty to warn issue that remain pertinent to the certification motion.

[85] In my opinion, some of Cook's criticism of Dr. Crowther was simply misdirected or unfair. As an example of what I regard as a quite unfair criticism of Dr. Crowther's expertise, he was criticized for, as he candidly admitted during his cross-examination, preparing his expert report in this action by using, with virtually no changes, an expert report that he had prepared for another proposed class action about IVC filters against Bard Canada Inc., a competitor of Cook. I

say that this criticism is unfair because Dr. Crowther was simply being consistent. He has an opinion about filters generally and it is understandable and to be expected that he would not retailor his expert report when there was no reason to do so.

[86] As another example of what I regard as a quite unfair criticism of his expertise, Dr. Crowther was criticized for not reviewing the medical records of Mrs. Kopek and Mr. Kuiper and for not speaking to their physicians. Dr. Crowther was not retained to provide evidence about individual cases; he was retained to provide an opinion about whether there were common issues applicable commonly to all Class Members, and he provided an opinion that in its essence was directed at the inefficacy of IVC filters for their intended purpose.

[87] For present purposes no more need to be said about Dr. Crowther's evidence about the efficacy of IVC filters because the Plaintiffs no longer seek certification based on the want of utility of the devices. I turn now to Dr. Crowther's evidence about design and about warnings. While I shall give very little weight to his evidence about these matters, in my opinion, the evidence was admissible. Notwithstanding the objections of Cook, Dr. Crowther did not go beyond his area of expertise and his opinion evidence was admissible.

[88] As already noted above, while Dr. Crowther describes the design components of IVC filters, he actually says very little about design flaws generally and nothing in particular about design flaws in Cook's IVC filters. His evidence about the design problematic of a retrievable filter being sufficiently flexible to be retrievable without being too weak to withstand the dynamic forces within the body is consistent with Dr. Robertson's explanation.

[89] Dr. Crowther was candid and forthcoming to admit that he has no expertise in the design of medical devices, and he did not offer any opinion on matters of filter design or engineering. He did not suggest that the devices of Cook's competitors were safer or better designed. His criticisms of filters, which focussed on efficacy, were general criticisms about IVC filters regardless of who was the manufacturer or designer, or in Dr. Crowther's words, "for me, a filter is a filter", "filters are generic."

[90] I did not find in Dr. Crowther's report the identification of a mistaken design choice. The most that can be said is that he speculated that a safer retrievable filter could be designed. He did not speculate in saying that a retrievable filter should be retrieved sooner than later, a point upon which everybody seems to agree.

[91] In his report, Dr. Crowther had more to say about warnings that he did about design, although to be fair to him, I repeat that his views about design and about warnings had only a peripheral role to play because his predominant focus was on the utility, if any, of IVC filters. On the issue of warnings, I extract the following passages from Dr. Crowther's report:

> In more than 20 years as a thromboembolism specialist I do not recall ever receiving any specific instructions or education on the use of IVC filters from the manufacturers. I have always found this unusual because as a "thrombosis expert" it is I, not radiologists or vascular surgeons (who presumably were the "target" of educational efforts by the manufacturers), who make the initial decision to consider the insertion of filters. Similarly, others making these decisions would include trauma and bariatric surgeons, respirologists and general internists. Radiologists and vascular surgeons, who insert the filters, are rarely in a position where they can consider whether a filter should be inserted; rather, they are "asked" to provide a service which they logically then provide. This contrasts remarkably with my experience with pharmaceutical companies where there is a great deal of education of the clinicians directly providing care to patients, helping them to understand the various choices they can make. Further, even if training had been available, the

> abject lack of clinical data on relative safety and efficacy would have made it impossible for clinicians to make an informed decision about the use of filters (as described later in this report). .... (pp. 5-6)
>
> [...]
>
> .... To my reading, after review of the IFU, nowhere is the need for retrieval explicitly spelled out, nor are user warned that filter complications will continue if the filter is left *in situ.* .... (p. 6)
>
> [...]
>
> ..., Health Canada issued a "recall and safety alert" dated July 25, 2016 outlining a series of key messages for clinicians. These include noting the complications delineated above, recommending careful consideration of indications for use limited exclusively to patients with deep vein thrombosis who cannot be anticoagulated or patients with primary embolism who cannot be anticoagulated, recommending removal as soon as possible, and encouraging health care facilities to identify all patients who have had filters placed and to develop a formal strategy for filter removal. A careful review of both IFUs as well as patient information on Cook filters performed using google searches as well as the Cook Medical website on June 14th, 2017 failed to identify any notification to consumers or medical professionals about the Health Canada warning identified above. (p. 13)

[92] On the matter of warnings, much if not all of Cook's criticism of Dr. Crowther and his report was fair and proper, but these criticisms go to the weight to be given Dr. Crowther's opinions. In this regard, there were many weaknesses in Dr. Crowther's evidence about whether or not there was some basis in fact for a common issue about the adequacy of the warnings in Cook's IFUs.

[93] Dr. Crowther's evidence on warnings was weak because: (a) he was not aware of the history of the development of Cook's IFUs; (b) he did not review the IFUs approved by Health Canada and distributed with the Cook IVC filters; (c) he admitted that he personally does not make much use of IFUs, unless writing a report or article; (d) he has never reviewed an IFU with a patient when he has recommended or prescribed an IVC filter; (e) he mistakenly criticized the device manufacturers for not providing education and training when training and educational materials were actually being provided; (f) he was not familiar with the informed consent practices of the interventional radiologists who are the specialist physicians who place or retrieve filters and who typically obtain the informed consent for the procedures; (h) notwithstanding his views about their efficacy, he prescribed IVC filters for their prescribed use; and (i) he believed that he had adequately informed his own patients of the risks associated with IVC filters.

[94] I will return to the matter of Dr. Crowther's (and other's) evidence about design and warnings below, but I conclude this review of Dr. Crowther's evidence by concluding that in my opinion, Dr. Crowther's evidence should not be struck and rather it should be admitted and given the weigh it deserves.

[95] The weight to be given to Dr. Crowther's evidence and whether the Plaintiffs have satisfied the low evidentiary burden placed on them by a certification motion will also be considered below. I foreshadow to say that Dr. Crowther's evidence does not provide some basis in fact for the existence of a common issued about design negligence or about a duty to warn.

K. CERTIFICATION: GENERAL PRINCIPLES

[96] The court has no discretion and is required to certify an action as a class proceeding when the following five-part test in s. 5 of the *Class Proceedings Act, 1992* is met: (1) the pleadings

disclose a cause of action; (2) there is an identifiable class of two or more persons that would be represented by the representative plaintiff; (3) the claims of the class members raise common issues; (4) a class proceeding would be the preferable procedure for the resolution of the common issues; and (5) there is a representative plaintiff who: (a) would fairly and adequately represent the interests of the class; (b) 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 (c) does not have, on the common issues for the class, an interest in conflict with the interests of other class members.

[97] For an action to be certified as a class proceeding, there must be a cause of action shared by an identifiable class from which common issues arise that can be resolved in a fair, efficient, and manageable way that will advance the proceeding and achieve access to justice, judicial economy, and the modification of behaviour of wrongdoers.[8] On a certification motion, the question is not whether the plaintiff's claims are likely to succeed on the merits, but whether the claims can appropriately be prosecuted as a class proceeding.[9] The test for certification is to be applied in a purposive and generous manner, to give effect to the goals of class actions; namely: (1) providing access to justice for litigants; (2) encouraging behaviour modification; and (3) promoting the efficient use of judicial resources.[10]

[98] The purpose of a certification motion is to determine how the litigation is to proceed and not to address the merits of the plaintiff's claim; there is to be no preliminary review of the merits of the claim.[11] However, the plaintiff must show "some basis in fact" for each of the certification criteria other than the requirement that the pleadings disclose a cause of action.[12] In the context of the common issues criterion, the some-basis-in-fact standard involves a two-step requirement that: (1) the proposed common issue actually exists; and (2) the proposed issue can be answered in common across the entire class.[13]

[99] The some-basis-in-fact standard sets a low evidentiary standard for plaintiffs, and a court should not resolve conflicting facts and evidence at the certification stage or opine on the strengths of the plaintiff's case.[14] In particular, there must be a basis in the evidence to establish the existence of common issues.[15] To establish commonality, evidence that the alleged

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[8] *Sauer v. Canada (Attorney General)*, [2008] O.J. No. 3419 at para. 14 (S.C.J.), leave to appeal to Div. Ct. refused, [2009] O.J. No. 402 (Div. Ct.).
[9] *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 16.
[10] *Hollick v. Toronto (City)*, 2001 SCC 68 at paras. 15 and 16; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at paras. 26 to 29.
[11] *Hollick v. Toronto (City)*, 2001 SCC 68 at paras. 28 and 29.
[12] *Hollick v. Toronto (City)*, 2001 SCC 68 at paras. 16-26.
[13] *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 53, aff'd, 2017 ONSC 6098 (Div. Ct.), leave to appeal refused (28 February 2018) (C.A.); *Dine v. Biomet*, 2015 ONSC 7050, aff'd 2016 ONSC 4039 (Div. Ct.); *Good v. Toronto Police Services Board*, 2014 ONSC 4583 (Div. Ct.); *McCracken v. Canadian National Railway Company*, 2012 ONCA 445; *Fulawka v. Bank of Nova Scotia*, 2012 ONCA 443; *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744; *Williams v. Canon Canada Inc.*, 2011 ONSC 6571, aff'd 2012 ONSC 3992 (Div. Ct.).
[14] *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57; *McCracken v. CNR Co.*, 2012 ONCA 445.
[15] *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42 at para. 140; *Fresco v. Canadian Imperial Bank of Commerce*, [2009] O.J. No. 2531 at para. 21 (S.C.J.); *Dumoulin v. Ontario*, [2005] O.J. No. 3961 at para. 25 (S.C.J.).

misconduct actually occurred is not required; rather, the necessary evidence goes only to establishing whether the questions are common to all the class members.[16]

[100] On a certification motion, evidence directed at the merits may be admissible if it also bears on the requirements for certification but, in such cases, the issues are not decided on the basis of a balance of probabilities, but rather on the much less stringent test of some basis in fact.[17] The evidence on a motion for certification must meet the usual standards for admissibility.[18] While evidence on a certification motion must meet the usual standards for admissibility, the weighing and testing of the evidence is not meant to be extensive, and if the expert evidence is admissible, the scrutiny of it is modest.[19] In a class proceeding, the close scrutiny of the evidence of experts should be reserved for the trial judge.[20]

[101] The representative plaintiff must come forward with sufficient evidence to support certification, and the opposing party may respond with evidence of its own to challenge certification.[21] Certification will be denied if there is an insufficient evidentiary basis for the facts on which the claims of the class members depend.[22] The certification motion is not a merits-based screening of the action but it is a meaningful screening device. In *Pro-Sys Consultants Ltd. v. Microsoft Corporation*,[23] the Supreme Court of Canada stated:

> 103. [I]t is worth reaffirming the importance of certification as a meaningful screening device. The standard for assessing evidence at certification does not give rise to "a determination of the merits of the proceeding" (CPA, s. 5(7)); nor does it involve such a superficial level of analysis into the sufficiency of the evidence that it would amount to nothing more than symbolic scrutiny.

L. CAUSE OF ACTION CRITERION

1. Introduction

[102] Cook submits that the Plaintiffs do not satisfy the cause of action criterion for either a design defect negligence claim or for a failure to warn cause of action. For either cause of action,

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[16] *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 110.
[17] *Cloud v. Canada* (2004), 73 O.R. (3d) 401 at para. 50 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.); *Hollick v. Toronto (City)*, 2001 SCC 68 at paras. 16-26.
[18] *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744; *Williams v. Canon Canada Inc.*, 2011 ONSC 6571, aff'd 2012 ONSC 3992 (Div. Ct.); *Schick v. Boehringer Ingelheim (Canada) Ltd.*, 2011 ONSC 63 at para.13; *Ernewein v. General Motors of Canada Ltd.* 2005 BCCA 540 (C.A.), leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 545.
[19] *Griffin v. Dell Canada Inc.*, [2009] O.J. No. 418 at para. 76 (S.C.J.).
[20] *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057, aff'd 2012 BCCA 260.
[21] *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 22.
[22] *Williams v. Canon Canada Inc.*, 2011 ONSC 6571, aff'd 2012 ONSC 3992 (Div. Ct.); *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540 (C.A.), leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 545; *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd [2003] S.C.C.A. No. 106; *Taub v. Manufacturers Life Insurance Co.*, 40 O.R. (3d) 379 (Gen. Div.), aff'd (1999), 42 O.R. (3d) 576 (Div. Ct.).
[23] 2013 SCC 57 at para. 103. See also *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 6098 at para. 19 (Div. Ct.).

Cook focuses on deficiencies in how the Plaintiffs have pleaded, and Cook submits that the pleadings do not disclose a reasonable cause of action.

[103] With respect to the design negligence claim, Cook's basic argument is that the Plaintiffs' Statement of Claim never identifies a design defect. Cook submits that the Plaintiffs just conclusively assert without material facts that the Cook IVC filters are defectively designed. Cook submits that the Plaintiffs never identify what is the design defect nor explain why Cook made a negligent choice given the design choices available to it.

[104] With respect to the duty to warn claim, Cook's basic argument is similar. Cook submits that it is at a loss to know what the Plaintiffs' complaint is really about. Cook submits that it is indisputable that Cook did warn about the risks associated with permanently placed or retrievable IVC filters, and Cook submits that the Plaintiffs never identify what is inadequate about these warnings.

[105] Cook submits that the deficiencies are such that I should not grant leave to amend and that I should just rather rule that the cause of action criterion has not been satisfied.

[106] I agree with Cook's argument with respect to the design negligence claim but not with respect to the duty to warn cause of action. For the reasons that follow, I conclude that for the latter but not the former cause of action, the Plaintiffs satisfy the cause of action criterion.

2. General Principles: Cause of Action Criterion

[107] The first criterion for certification is that the plaintiff's pleading discloses a cause of action. The "plain and obvious" test for disclosing a cause of action from *Hunt v. Carey Canada,*[24] is used to determine whether a proposed class proceeding discloses a cause of action for the purposes of s. 5(1)(a) of the *Class Proceedings Act, 1992*. To satisfy the first criterion for certification, a claim will be satisfactory, unless it has a radical defect, or it is plain and obvious that it could not succeed.[25]

[108] In a proposed class proceeding, in determining whether the pleading discloses a cause of action, no evidence is admissible, and the material facts pleaded are accepted as true, unless patently ridiculous or incapable of proof. The pleading is read generously, and it will be unsatisfactory only if it is plain, obvious, and beyond a reasonable doubt that the plaintiff cannot succeed.[26]

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[24] [1990] 2 S.C.R. 959.
[25] *176560 Ontario Ltd. v. Great Atlantic & Pacific Co. of Canada Ltd.* (2002), 62 O.R. (3d) 535 at para. 19 (S.C.J.), leave to appeal granted, 64 O.R. (3d) 42 (S.C.J.), aff'd (2004), 70 O.R. (3d) 182 (Div. Ct.); *Anderson v. Wilson* (1999), 44 O.R. (3d) 673 at p. 679 (C.A.), leave to appeal to S.C.C. ref'd, [1999] S.C.C.A. No. 476.
[26] *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 41 (C.A.), leave to appeal to the S.C.C. refused, [2005] S.C.C.A. No. 50, rev'g, (2003), 65 O.R. (3d) 492 (Div. Ct.); *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 25; *Abdool v. Anaheim Management Ltd.* (1995), 21 O.R. (3d) 453 at p. 469 (Div. Ct.).

3. Legal Background: Products Liability Claims for Design Defects and for Breach of the Duty to Warn

[109] The elements of a claim in negligence are: (1) the defendant owes the plaintiff a duty of care; (2) the defendant's behaviour breached the standard of care; (3) the plaintiff suffered compensable damages; (4) the damages were caused in fact by the defendant's breach; and, (5) the damages are not too remote in law.[27]

[110] For products liability claims, there are four established categories. First, manufacturers have a duty of care to consumers to see that there are no defects in manufacture that are likely to give rise to injury in the ordinary course of use.[28] Second, manufacturers have a duty of care to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge.[29] Third, manufacturers have a duty of care in designing the product to avoid safety risks and to make the product reasonably safe for its intended purposes.[30] Fourth, there is a pure economic loss claim in negligence because manufacturers have a duty of care to compensate consumers for the cost of repairing a dangerous product that presents a real and substantial danger to the public.[31]

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

[112] The underlying argument in a design negligence action is that a manufacturer has a duty of care not to design a product negligently because the manufacturer should and can fairly be held responsible for the choices it makes that affect the safety of the product. The manufacturer has a duty to make reasonable efforts to reduce any risk to life and limb that may be inherent in its design.[32] In *Rowe (Guardian ad litem of) v. Sears Canada*[33], Justice Cameron of the Newfoundland and Labrador Court of Appeal describes the nature of a design negligence cause of action as follows:

> 20. Design defect is not the result of something having gone wrong in the production of the product but an error in the design of the product. The central question is whether a different design ought to have been used by the manufacturer. In cases of design defect, it is the design specifications themselves which create the risk to the consumer. ... a finding that there had been a design defect results in a whole line of products being defective.

[113] In the case of negligence in designing a product, the defendant is blameworthy for not designing its product in a safer manner. Negligence in design involves the innovator making

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[27] *Mustapha v. Culligan of Canada Ltd.*, 2008 SCC 27 at para. 3.
[28] *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.).
[29] *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 20; *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569 at p. 574; *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1997] 3 S.C.R. 1210.
[30] *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (S.C.J.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.).
[31] *Winnipeg Condominium Corporation No. 36 v. Bird Construction Co. Ltd.*, [1995] 1 S.C.R. 85.
[32] *Gallant v. Beitz* (1983), 42 O.R. (2d) 86 at p. 90 (H.C.J.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.).
[33] 2005 NLCA 65.

poor choices and managing risk poorly when deciding how a product should be planned or put together.[34]

[114] In *Nicholson v. John Deere Ltd.*,[35] Justice Smith noted that a manufacturer does not have the right to manufacture an inherently dangerous article when a method exists of manufacturing the same article without risk of harm. In this category of duty of care, whether a manufacturer breaches its duty is determined by a risk-utility analysis that measures whether the utility of the chosen design outweighs the foreseeable risks associated with the chosen design.[36] Liability for a blameworthy design has greater scope than the liability for a defective product because a defective product may be a single aberration, but a design defect extends to all of the products manufactured with that chosen design.[37]

[115] In negligent design cases, the determination of whether a manufacturer breaches its duty of care in designing a product depends upon a risk-utility analysis that measures whether the utility of the chosen design outweighs the foreseeable risks associated with the chosen design.[38] This risk-utility analysis requires weighing any foreseeable risk against the foreseeable utility of the product based on the information available to the manufacturer at the time of distribution or implantation and without the benefit of hindsight.[39] Manufacturers are required to weigh the likelihood of both the benefit and the risk offered by a product as well as the value of the potential benefit and the seriousness of the potential risks.[40]

[116] To succeed in a cause of action for negligent design of a product, the plaintiff must identify the design defect in the product and establish that the defect created a substantial likelihood of harm and that there is safer and more economically feasible ways to manufacture the product.[41]

[117] In *Rentway v. Laidlaw*,[42] Justice Granger compiled a list of factors to consider when balancing the risks inherent in the product, as designed, against its utility and cost, namely: (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product - that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread around any costs related to improving the safety of the design.

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[34] *Goodridge v. Pfizer Canada Inc.*, 2010 ONSC 1095.
[35] (1986), 58 O.R. (2d) 53 (H.C.J.), varied on other grounds (1989), 68 O.R. (2d) 191 at p. 60 (C.A.).
[36] *Ragoonanan v. Imperial Tobacco Canada Ltd.*, (2000), 51 O.R. (3d) 603 (S.C.J.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.).
[37] *Rowe (Guardian ad litem of) v. Sears Canada,* 2005 NLCA 65 at paras. 19-21.
[38] *Goodridge v. Pfizer Canada Inc.*, 2010 ONSC 1095.
[39] *Andersen v. St. Jude Medical Inc.*, 2012 ONSC 3660 at para. 61.
[40] *Andersen v. St. Jude Medical Inc.*, 2012 ONSC 3660 at para. 62.
[41] *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 at paras. 135-137, aff'd 2013 ONSC 1169 (Div. Ct.); *Kreutner v. Waterloo Oxford Co-operative Inc.* (2000), 50 O.R. (3d) 140 at para. 8 (C.A.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.); *Cantlie v. Canadian Heating Products Inc.*, 2017 BCSC 286 at para. 197.
[42] *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.).

[118] Turning to the duty to warn, manufacturers have a duty of care to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge.[43] The warnings must be reasonably communicated and detailed to give the consumer a full indication of each of the specific dangers that arise from the ordinary use of the product.[44] If a product, although suitable for the purpose for which it is manufactured, is at the same time dangerous to use, the manufacturer of the product has a duty to warn of the attendant dangers in using the product.[45]

[119] In *Hollis v. Dow Corning Corp.*[46] at para. 21, Justice La Forest explained the rationale for a manufacturer's duty of care to warn. He stated:

> 21. .... When manufacturers place products into the flow of commerce, they create a relationship of reliance with consumers, who have far less knowledge than the manufacturers concerning the dangers inherent in the use of the products, and are therefore put at risk if the product is not safe. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.

[120] In the case of medical products, given their substantial risk of harm from improper use, the standard of care is correspondingly high and there will almost always be a heavy onus on the manufacturer to provide clear, complete and current information concerning the dangers inherent in the ordinary use of its product.[47] There is a high standard of care. In *Buchan v. Ortho Pharmaceutical (Can.) Ltd.*,[48] Justice Robins stated at para. 18:

> 18. Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard; and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. The nature and extent of any given warning will depend on what is reasonable having regard to all the facts and the circumstances relevant to the product in question.

[121] As noted by Justice Robins, the nature and extent of any given warning will depend on what is reasonable having regard to all the facts and circumstances relevant to the product in question. In *Lambert v. Lastoplex Chemicals Co.*,[49] Justice Bora Laskin, as he then was, stated that the required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product. In *Hollis v. Dow Corning Corp.*,[50] Justice La Forest stated:

> 22. The nature and scope of the manufacturer's duty to warn varies with the level of danger entailed by the ordinary use of the product. Where significant dangers are entailed by the ordinary

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[43] *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1997] 3 S.C.R. 1210; *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 20; *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569 at p. 574.
[44] *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at paras. 20-21; *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569 at pp. 574-75.
[45] *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569.
[46] [1995] 4 S.C.R. 634.
[47] *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 23.
[48] (1986), 54 O.R. (2d) 92 (C.A.).
[49] [1972] S.C.R. 569 at p. 574.
[50] [1995] 4 S.C.R. 634 at para.

> use of the product, it will rarely be sufficient for manufacturers to give general warnings concerning those dangers; the warnings must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from the use of the product.

[122] In cases involving highly technical products intended to be used under the supervision of experts or where the nature of the product is such that the consumer will not realistically receive information directly from the manufacturer without the intervention of a learned intermediary, the duty of the manufacturer is discharged if the manufacturer provides the learned intermediary (for example, physicians or surgeons), rather than the consumers, with an adequate warning of the potential dangers associated with the use of its product.[51]

[123] The legal theory here is that where a consumer places primary reliance on the judgment of a learned intermediary, then the manufacturer will satisfy its duty to warn the consumer by adequately warning the learned intermediary of the risks inherent in the use of the product.[52] Under the learned intermediary rule, the manufacturer is entitled to warn the physician of the risks associated with the pharmaceutical or medical device without warning the patient directly. In the context of manufacturers of pharmaceuticals and medical devices, the learned intermediary is the physician that prescribes the drug or medical device.

4. Discussion and Analysis – Negligence in Design

[124] As the above outline of the law reveals, to plead a reasonable cause of action for design defect, a plaintiff must identify the design defect that made the product dangerous to use or that made the product more dangerous to use that it would have been had other and safer design choices been made.[53] Medical devices that are implanted in a human body, like Cook's IVC filter, are inherently dangerous and the manufacturer is not liable for design negligence simply because the dangers materialize; rather, liability depends upon the manufacturer carelessly making a particular design choice when safer choices could have been made.

[125] In the immediate case, the closest that the Plaintiffs come to identifying a design defect is the allegation in the Statement of Claim that the design requirements for the Cook IVC filters to be retrievable rendered them unable to withstand the normal anatomical and physical loading cycles exerted in vivo causing them to be prone to malfunctions and injuries that increase as the amount of time the device is in place increases.

[126] However, in the immediate case, given that retrievability is generally regarded by the medical community as a desirable feature for a medical device meant to be a last choice and temporary measure and given that achieving the option of retrievability was the purpose of the design of Cook's (and its competitors) IVC filters, retrievability as such is not a design defect. In

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[51] *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at paras. 28-29; *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, (1986), 54 O.R. (2d) 92 at paras. 23, 59 (C.A.).

[52] *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at para. 27.

[53] There have design negligence cases about IVC filters in the United States and several of these cases have been dismissed because the plaintiffs have been unable to identify what was the design defect or have been unable to suggest what the defendant manufacturer might have done to make the device safer. See: *Oden v. Boston Scientific Corp.*, 2018 U.S. Dist. LEXIS 102639 (E.D. N.Y.); *Quintana v. B. Braun Medical Inc.* 2018 U.S. Dist. LEXIS 123718 (E.D. N.Y.); *Reed v. Pfizer*, Inc., 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012).

the immediate case, the Plaintiffs' allegation that the requirement of retrievability made the filters prone to malfunction over time does not identify the design defect in achieving retrievability; the Plaintiffs' allegation rather assumes in some sort of *res ipsa loquitor* inference that there is a defect associated with retrievability that causes the filter to malfunction causing harm without explaining what the defect is and without identifying what choice would have been better and would have reduced the risk to safety while achieving retrievability.

[127] In attempting to clarify what was the defect in the design of the IVC filters, during the oral argument, the Plaintiffs' withdrew their allegation that Cooks' IVC filters were not effective for their intended purpose of catching blood clots, and revised their design negligence common issue. Plaintiffs' counsel submitted that it was a matrix of factors associated with the conical shape, the choice of a cobalt-chromium alloy, and the anchoring mechanism that constituted the design defect in the filters that made the Cook IVC filters malfunction.

[128] I shall assume that this allegation of a matrix design defect is a part of the Plaintiffs' pleading, but this additional information does not assist the Plaintiffs, because all filters have a shape, materials, and anchors and what was wrong with the choice of shape, materials, and anchors taken as a matrix or as discrete design choices still is not identified.

[129] The case at bar is like *O'Brien v. Bard*,[54] where the action was not certified because the Plaintiffs could not identify a common design defect for 18 different transvaginal mesh medical devices.

[130] The case at bar is like *Vester v. Boston Scientific Ltd.* [No. 1][55] without the happy ending of *Vester v. Boston Scientific Ltd.* [No. 2][56] In *Vester* [No. 1], another transvaginal mesh case, the action was not certified because the plaintiffs failed to identify a design defect, but the plaintiffs returned in *Vester* [No. 2] to identify the type of polypropylene as the common design defect.

[131] The case at bar is like, *Martin v. Astrazeneca Pharmaceuticals PLC*,[57] a pharmaceutical design negligence case, where Justice Horkins found that the plaintiff's pleading did not satisfy the cause of action criterion because the plaintiff did not identify the design defect.

[132] Thus, as matter of pleading, the Plaintiffs do not plead the material facts necessary to constitute a reasonable cause of action for design negligence. This is both procedurally and substantively unfair because defendants are entitled to know the case they must meet.[58] In my opinion, the defect in the pleading is plain and obvious and, therefore, the Plaintiffs do not satisfy the cause of action criterion for certification for the design negligence claim.

[133] But there is more; moving from assumed facts to the evidence proffered for this certification motion, the Plaintiffs do not satisfy the common issues criteria because on a some-basis-in-fact standard of proof, they fail to show that the proposed common issues about design negligence actually exist. This is significant, because it entails that no purpose would be served by granting the Plaintiffs leave to amend their pleadings to reapply for certification.

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[54] 2015 ONSC 2470.
[55] 2015 ONSC 7950.
[56] 2017 ONSC 1095.
[57] 2012 ONSC 2744.
[58] *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 2744 at para. 132; *Cerqueria v. Ontario*, 2010 ONSC 3954 at para. 12.

[134] The some-basis-in-fact standard is low, but it is not subterranean. Although Dr. Crowther was qualified to provide evidence that was relevant to the design problematic of IVC filters, the focus of Dr. Crowther's opinion was not about design defects. He was candid to say that he had no design expertise whatsoever. He did not identify a design defect. Without directing his attention at Cook's filters in particular, Dr. Crowther speculated that there must be a design defect because his research about the efficacy of filters – not the design of them - led him to conclude that all IVC filters – regardless of who was the manufacturer - had intolerably high adverse events. But that speculation is not some basis in fact for the existence of a common issue about a design defect. This is not to discredit Dr. Crowther generally. The main thrust of his evidence was about efficacy of filters, and, as noted already, he actually provided very little, if any, evidence about design as such.

[135] Thus, the Plaintiffs did not satisfy the some-basis-in-fact standard from Dr. Crowther's evidence. Moreover, assumed to be true allegations in a statement of claim and the experiential evidence of Mrs. Kopeck and Mr. Kuiper do not provide some basis in fact for a design defect in the immediate case.

[136] Dr. Robertson's evidence, which the Plaintiffs attempted to rely on as some basis in fact for a design defect was that there was no apparent design defect in Cook's IVC filters and no defect in Cook's approach to designing an IVC filter. Dr. Robertson's evidence does not provide some basis in fact for a cause of action or common issues about design negligence.

[137] I conclude that the Plaintiffs do not satisfy the cause of action criterion and the common issues criterion for a design negligence case.

5. Discussion and Analysis – Duty to Warn Cause of Action

[138] I turn now to the matter of whether the Plaintiffs satisfy the cause of action criterion for a duty to warn cause of action. Cook's argument is similar to the argument it made about the Plaintiffs' design negligence pleading, *i.e.*, Cook submits that it is plain and obvious that the Plaintiffs have not pleaded the material facts necessary to constitute a legally viable claim for a duty to warn cause of action.

[139] I disagree. In my opinion, the Plaintiffs' Statement of Claim does set out a reasonable cause of action of a failure to warn. The following paragraphs of the pleading address the duty to warn cause of action.

> 38. The Injuries, Conditions, and Complications suffered due to the Defendants' IVC filters include but are not limited to:
>
> (a) device migration, where the IVC filter migrates from the deployed position to another part of the IVC, to the heart, or to the pulmonary arterial tree;
>
> (b) device perforation, where one or more of the Conichrome struts punctures the wall of the IVC;
>
> (c) device fracture, where one of more of the Conichrome struts breaks loose. The strut may travel in the bloodstream and become lodged in an organ;
>
> (d) device embolization, where the entire device or fragments of the device enters the heart or lungs;
>
> (e) the inability to retrieve the device. After implantation, the body forms a coating around the device called endothelialisation making percutaneous removal of the device

difficult or impossible. Tilting of the filter or device perforation can also complicate the retrieval of the device. In such cases, advanced retrieval procedures are required in highly advanced centres;

(f) hemorrhage;

(g) severe and persistent pain;

(h) cardiac arrhythmia;

(i) the continued risk of additional medical and surgical procedures;

(j) long-term anticoagulation therapy and its associated risks and complications; and

(k) death.

[...]

48. While not inclusive of all medical studies published during the relevant time period, the above references demonstrate that the Defendants failed to disclose to physicians, patients and/or Plaintiffs that its IVC Filers were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true.

[...]

53. At all material times, the Defendants knew or should have known that the risks of using their IVC filters included severe Injuries, Conditions, and Complications.

[...]

55. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiffs and putative class members, of the risk of Injuries, Conditions and Complications caused by their IVC filters.

[...]

57. At all material times, the Defendants, through its servants and agents, negligently, recklessly and or carelessly marketed, distributed and/or sold their IVC filters without adequate warnings of the products' serious side effects and unreasonably dangerous risks.

[...]

74. Had Mr. Kuiper and Ms. Kopek been aware of the magnitude of risks of developing Injuries, Conditions, and Complications, they would never have agreed to being implanted with the Defendants IVC filter. But for the Defendants' wrongful conduct, the Plaintiffs would not have incurred damages.

[...]

CAUSES OF ACTION

76. The Defendants at all material times owned a duty of care to the Plaintiffs to: ....

(c) properly, adequately, and fairly warn the Plaintiffs and physicians of the magnitude or risk of developing Injuries, Conditions and Complications with use of the IVC filters compared to alternative treatments;

(d) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with IVC filters;

[...]

77. The Defendants negligently breached their duty of care.

78. The Plaintiffs state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following: ....

(i) the Defendants failed to warn or adequately warn the Plaintiffs or the physicians that

> in the event of failure injury or complications, it may be impossible to easily and safety removed the Defendants' IVC filters, or to remove them at all;
>
> [...]
>
> (l) the Defendants failed to provide any or adequate updated and/or current information to the Plaintiffs, physicians, and/or Health Canada respecting the risks of their IVC filters as such information became available from time to time;
>
> [...]
>
> (n) the Defendants failed to provide adequate warnings of the risks associated with their IVC filters, including the risk of Injuries, Conditions, and Complications in all persons receiving their IVC filters on the patient information pamphlets in Canada;
>
> (o) the Defendants, after noticing problems with their IVC filters, failed to issue adequate warnings, timely recall their IVC filters, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiffs and their physicians of their IVC filters inherent dangers, including but not limited to the danger of Injuries, Conditions, and Complications;

[140] It is not plain and obvious from the above pleadings that the Plaintiffs' claim for breach of a duty to warn is meritless and doomed to fail. I conclude that the Plaintiffs satisfy the cause of action criterion for the duty of warn claim.

[141] However, by way of foreshadowing of the discussion below, I later conclude that the Plaintiffs have not shown some basis in fact for a duty to warn cause of action.

M. IDENTIFIABLE CLASS CRITERION

1. Introduction

[142] In its factum, Cook conceded that the Plaintiffs satisfied the identifiable class criterion, but in a lengthy footnote, Cook argued that the class definition was overbroad, because the definition included persons who would be outside the pleaded causes of action.

[143] I disagree. In my opinion, as I shall explain below, because of the Plaintiffs' duty to warn claim, the class definition is not overbroad.

2. General Principles: Identifiable Class Criterion

[144] The second certification criterion is the identifiable class criterion. 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.[59]

[145] In *Western Canadian Shopping Centres v. Dutton*,[60] the Supreme Court of Canada explained the importance of and rationale for the requirement that there be an identifiable class:

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[59] *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 (Gen. Div.).
[60] 2001 SCC 46 at para. 38.

> 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.

[146] In identifying the persons who have a potential claim against the defendant, the definition cannot be merits-based.[61] In *Frohlinger v. Nortel Networks Corporation*[62] at para. 21, Justice Winkler, as he then was, explained why merits-based definitions are prohibited; he stated:

> 21. The underlying reason for each of these prohibitions is readily apparent. Merits-based class definitions require a determination of each class member's claim as a pre-condition of ascertaining class membership. Carrying that concept to its logical conclusion, it would mean that at the conclusion of a class proceeding only those individuals who were successful in their claims would be members of the class and, therefore, bound by the result. Theoretically, unsuccessful claimants would not be "class members" and would be free to commence further litigation because s. 27(3) of the CPA, which states in part:
>
> > A judgment on common issues of a class or subclass binds every class member who has not opted out of the class proceeding [....]
>
> would not bind them or bar them from commencing further actions.

[147] In defining the persons who have a potential claim against the defendant, there must be a rational relationship between the class, the cause of action, and the common issues, and the class must not be unnecessarily broad or over-inclusive.[63] An over-inclusive class definition binds persons who ought not to be bound by judgment or by settlement, be that judgment or settlement favourable or unfavourable.[64] The rationale for avoiding over-inclusiveness is to ensure that litigation is confined to the parties joined by the claims and the common issues that arise.[65] The class should not be defined wider than necessary, and where the class could be defined more narrowly, the court should either disallow certification or allow certification on condition that the definition of the class be amended.[66]

[148] A proposed class definition, however, is not overbroad because it may include persons who ultimately will not have a successful claim against the defendants.[67]

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[61] *Keatley Surveying Ltd. v. Teranet Inc.*, 2012 ONSC 7120 at paras. 159-167; *Frohlinger v. Nortel Networks Corporation,* [2007] O.J. No. 148 at para. 21 (S.C.J.); *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd [2003] S.C.C.A. No. 106; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 38.

[62] [2007] O.J. No. 148 (S.C.J.).

[63] *Pearson v. Inco Ltd.* (2006), 78 O.R. (3d) 641 at para. 57 (C.A.), rev'g [2004] O.J. No. 317 (Div. Ct.), which had aff'd [2002] O.J. No. 2764 (S.C.J.).

[64] *Robinson v. Medtronic Inc.*, [2009] O.J. No. 4366 at paras. 121-146 (S.C.J.).

[65] *Frohlinger v. Nortel Networks Corporation,* [2007] O.J. No. 148 at para. 22 (S.C.J.).

[66] *Fehringer v. Sun Media Corp.*, [2002] O.J. No. 4110 at paras. 12-13 (S.C.J.), aff'd [2003] O.J. No. 3918 (Div. Ct.); *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 21.

[67] *Silver v. Imax Corp.*, [2009] O.J. No. 5585 at para. 103-107 (S.C.J.) at para. 103-107, leave to appeal to Div. Ct. refused 2011 ONSC 1035 (Div. Ct.); *Boulanger v. Johnson & Johnson Corp.*, [2007] O.J. No. 179 at para. 22 (S.C.J.), leave to appeal ref'd [2007] O.J. No. 1991 (Div. Ct.); *Ragoonanan v. Imperial Tobacco Inc.* (2005), 78

3. Analysis: Identifiable Class Criterion

[149] In its factum, Cook conceded that there was an identifiable class, but in a lengthy footnote, without challenging that the identifiable class criterion was satisfied, Cook argued that the class definition was overbroad because it included persons who were outside the pleaded causes of action.

[150] To show that the class definition was overbroad, Cook gave the example of patients who would have no cause of complaint because the Cook IVC filter apparently functioned or caused no harm while it was implanted and was the filter was successfully retrieved without incident. As another example, Cook pointed to patients who would have no cause for complaint because the Cook IVC filter actually worked to stop blood clots and could have been successfully retrieved had the patient or his or her physician properly followed up to retrieve the filter. As yet another example, Cook pointed to patients who consented to a permanent placement of the filter and who would have no cause for complaint because the Cook IVC filter functioned or caused no harm and so the patient would have no cause for complaint about retrieving the filter.

[151] In my opinion, if the Plaintiffs' case was confined to the design negligence case, then there would be traction to Cook's argument that the class definition is overbroad.

[152] In other words, if the case just concerned design defects, then the proposed definition is arguable overbroad. The overbreadth, however, would not be fatal to certification. I am confident that with some qualifiers added to the definition (provided that the qualifiers were not merits-based), then the arguable overbreadth of the current definition could be ameliorated.

[153] However, the Plaintiffs advance more than a design negligence cause of action. They advance a duty to warn cause of action, and as currently defined all putative Class Members have a rational relationship to that cause of action and to associated duty to warn common issues. In other words, for a duty to warn cause of action, the current class definition is not overbroad.

[154] I, therefore, conclude that the Plaintiffs satisfy the identifiable class criterion for certification.

N. COMMON ISSUES CRITERION

1. Introduction

[155] The Plaintiffs propose thirteen common issue questions. Four questions concern design negligence. Eight questions concern the duty to warn, and there is a punitive damages question.

[156] I have already concluded above that the design negligence questions do not satisfy the common issues criterion because on a some-basis-in-fact standard of proof, the Plaintiffs fail to show that the proposed common issues about design negligence actually exist. In the discussion below, I come to the same conclusion about the duty to warn cause of action.

O.R. (3d) 98 (S.C.J.), leave to appeal ref'd [2008] O.J. No. 1644 (Div. Ct.); *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 at para. 10 (Gen. Div.)

[157] Thus, apart for the question about punitive damages, there are no certifiable common issues. Standing alone, a punitive damages question does not provide a basis for a class action. A common issue questions about punitive damages is not certifiable in the absence of other certifiable common issues.[68]

[158] I, therefore, for the reasons set out below, I conclude that the Plaintiffs do not satisfy the common issues criterion, which is the most important criterion for certification.

2. General Principles: Common Issues

[159] The third criterion for certification is the common issues criterion. For an issue to be a common issue, it must be a substantial ingredient of each class member's claim and its resolution must be necessary to the resolution of each class member's claim.[69] The underlying foundation of a common issue is whether its resolution will avoid duplication of fact-finding or legal analysis of an issue that is a substantial ingredient of each class member's claim and thereby facilitate judicial economy and access to justice.[70] In *Pro-Sys Consultants Ltd. v. Microsoft Corporation*,[71] the Supreme Court of Canada describes the commonality requirement as the central notion of a class proceeding which is that individuals who have litigation concerns in common ought to be able to resolve those common concerns in one central proceeding rather than through an inefficient multitude of repetitive proceedings.

[160] All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent. The answer to a question raised by a common issue for the plaintiff must be capable of extrapolation, in the same manner, to each member of the class.[72]

[161] An issue is not a common issue if its resolution is dependent upon individual findings of fact that would have to be made for each class member.[73] Common issues cannot be dependent upon findings which will have to be made at individual trials, nor can they be based on assumptions that circumvent the necessity for individual inquiries.[74]

[162] Commonality is a substantive fact that exists on the evidentiary record or it does not, and commonality is not to be semantically manufactured by overgeneralizing; *i.e.*, by framing the

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[68] *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 53, aff'd 2017 ONSC 6098 (Div. Ct.).
[69] *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 18.
[70] *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at paras. 39 and 40.
[71] 2013 SCC 57 at para. 106.
[72] *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 53, aff'd, 2017 ONSC 6098 (Div. Ct.), leave to appeal refused (28 February 2018) (C.A.); *Amyotrophic Lateral Sclerosis Society of Essex County v. Windsor (City)*, 2015 ONCA 572 at para. 48; *McCracken v. CNR*, 2012 ONCA 445 at para. 183; *Merck Frosst Canada Ltd. v. Wuttunee*, 2009 SKCA 43 at paras. 145-46 and 160, leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 512; *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540 (C.A.), leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 545; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 40.
[73] *Fehringer v. Sun Media Corp.*, [2003] O.J. No. 3918 at paras. 3, 6 (Div. Ct.).
[74] *McKenna v. Gammon Gold Inc.*, [2010] O.J. No. 1057 at para. 126 (S.C.J.), leave to appeal granted [2010] O.J. No. 3183 (Div. Ct.), var'd 2011 ONSC 3882 (Div. Ct.); *Nadolny v. Peel (Region)*, [2009] O.J. No. 4006 at paras. 50-52 (S.C.J.); *Collette v. Great Pacific Management Co.*, [2003] B.C.J. No. 529 at para. 51 (B.C.S.C.), var'd on other grounds (2004) 42 B.L.R. (3d) 161 (B.C.C.A.).

issue in general terms that will ultimately break down into issues to be resolved by individual inquiries for each class member.[75] In *Rumley v. British Columbia*,[76] Chief Justice McLachlin stated that an issue would not satisfy the common issues test if it was framed in overly broad terms; she stated:

> [....] It would not serve the ends of either fairness or efficiency to certify an action on the basis of issues that are common only when stated in the most general terms. Inevitably such an action would ultimately break down into individual proceedings. That the suit had initially been certified as a class action could only make the proceeding less fair and less efficient.

[163] However, the commonality requirement does not mean that an identical answer is necessary for all the members of the class, or even that the answer must benefit each of them to the same extent; it is enough that the answer to the question does not give rise to conflicting interests among the members; success for one member must not result in failure for another.[77]

[164] The common issue criterion presents a low bar.[78] An issue can be a common issue even if it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution.[79] Even a significant level of individuality does not preclude a finding of commonality.[80]A common issue need not dispose of the litigation; it is sufficient if it is an issue of fact or law common to all claims and its resolution will advance the litigation.[81]

[165] As already noted above, in the context of the common issue criterion, the some-basis-in-fact standard involves a two-step requirement that: (1) the proposed common issue actually exists; and (2) the proposed issue can be answered in common across the entire class.

[166] Where questions relating to causation or damages are proposed as common issues, the plaintiff must demonstrate with supporting evidence that there is a workable methodology for determining such issues on a class-wide basis.[82]

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[75] *McCracken v. Canadian National Railway Company*, 2012 ONCA 445 at para. 132; *Microcell Communications Inc. v. Frey*, 2011 SKCA 136 at para. 48-50, leave to appeal refused, [2012] S.C.C.A. No. 42; 197; *Merck Frosst Canada Ltd. v. Wuttunee*, 2009 SKCA 43, leave to appeal refused, [2008] S.C.C.A. No. 512; *Rumley v. British Columbia*, [2001] 3 S.C.R. 184 at para. 29.

[76] [2001] 3 S.C.R. 184 at para. 29.

[77] *Vivendi Canada Inc. v. Dell'Aniello*, 2014 SCC 1 at paras. 44–46.

[78] *203874 Ontario Ltd. v. Quiznos Canada Restaurant Corp.*, [2009] O.J. No. 1874 (Div. Ct.), aff'd [2010] O.J. No. 2683 (C.A.), leave to appeal to S.C.C. refused [2010] S.C.C.A. No. 348; *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 52 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.); *Carom v. Bre-X Minerals Ltd.* (2000), 51 O.R. (3d) 236 at para. 42 (C.A.).

[79] *Cloud v. Canada (Attorney General)*, (2004), 73 O.R. (3d) 401 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.).

[80] *Hodge v. Neinstein*, 2017 ONCA 494 at para. 114; *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 112; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 54.

[81] *Harrington v. Dow Corning Corp.*, 2000 BCCA 605, leave to appeal to S.C.C. ref'd [2001] S.C.C.A. No. 21.

[82] *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at paras. 114-119; *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd [2003] S.C.C.A. No. 106.

3. The Proposed Common Issues

[167] The Plaintiffs propose the following common issues:

Design Negligence

1. Is there insufficient evidence that Cook IVC Filter Products are effective in treating venous thromboembolism, such as to render them defective in design and/or unfit for their intended use?

2. Does the structural design of Cook IVC Filter Products, including the conical shape, Conichrome material, and four primary strut anchoring mechanism, constitute a design defect or render it unfit for its intended use?

3. If the answer to (1) and/or (2) is "yes", did the Defendants breach the standard of care with respect to the design, development, and/or testing of their IVC Filter Products?

4. Do IVC Filter Products cause, or where removal is not timely cause an increased risk of, complications including migration, perforation, fracture, and embolization?

Duty to Warn

5. Did the Defendants' failure to disclose, or failure to sufficiently disclose, in their IFUs that IVC Filter Products may cause injuries and complications, including device migration, perforation, fracture, and embolization constitute a breach of their duty to warn?

6. If the answer to (5) is "yes", when did the breach of duty occur?

7. Did the Defendants' failure to disclose, or failure to sufficiently disclose, in their IFUs that thee may be no clinical benefit to implantation with an IVC Filter Product constitute a breach of their duty to warn?

8. If the answer to (7) is "yes", when did the breach of duty occur?

9. Did the Defendants' failure to disclose, or failure to sufficiently disclose, in their IFUs the importance of timely removal of IVC Filter Products to avoid, reduce, or remediate complications constitute a breach of the duty to warn?

10. If the answer to (9) is "yes", when did the breach of duty occur?

11. Did the Defendants' failure to disclose, or failure to sufficiently disclose, in their IFUs that the removal of their IVC Filter Products to avoid, reduce, or remediate complications may not be possible, and if possible, could require multiple surgeries, constitute a breach of the duty to warn?

12. If the answer to (11) is "yes", when did the breach of duty occur?

Punitive Damages

13. If the answer(s) to any of questions (3), (5), (7), (9), or (11) is "yes", would the Defendants' breach of duty justify an award of exemplary or punitive damages?

4. Discussion and Analysis

[168] For the purposes of the certification motion, during the oral argument, the Plaintiffs withdrew the allegations that the Cook IVC filters were ineffective or not sufficiently effective in catching embolisms or in treating PE. One consequence of this withdraw of allegations is that Questions 1, 7, and 8 are no longer proposed common issues. I shall nevertheless consider all of the proposed common issues.

[169] The analysis may begin with Cook's argument. Assuming without agreeing that the Plaintiffs have pleaded a reasonable cause of action for design negligence or for a failure to

warn, Cook submits that the Plaintiffs have not met the onus of showing some basis in fact that the common issues actually exist.

[170] Cook also makes the conventional argument that the common issues want for commonality and fail the preferable procedure criterion, but Cook's main argument is that there is no evidentiary basis, no some basis in fact, for a design defect or for a duty to warn products liability class action.

[171] I have already addressed the matter of whether there are common issues about a design negligence cause of action and have concluded that there are none. I, therefore, conclude that Questions 1 to 4 are not certifiable.

[172] With respect to the duty to warn claim, Cook submits that the Plaintiffs have failed to demonstrate how the warnings that were provided were inadequate by commission or by omission of information. Cook submits that the Plaintiffs have failed to show that the proposed duty to warn common issues actually exist.

[173] I agree with Cook's argument. While well-qualified to provide some expert opinion evidence that would be relevant to whether or not there a common duty to warn issue, I give no weight to Dr. Crowther's opinion, such as it was, that Cook's IFU did not provide an adequate warning. Dr. Crowther's opinion, such as it was, rather suggests that Cook and other IVC filter manufacturers did provide an adequate warning for the indicated uses of their IVC filters.

[174] During his cross-examination, Dr. Crowther admitted that the interventional radiologists that he works with would have an intimate understanding of the risks of IVC Filter placement in line with the appropriate medical standard. Further, during his cross-examination, Dr. Crowther, who, it needs to be kept in mind, does prescribe IVC filters for his patients notwithstanding his considerable research and scepticism about their efficacy, admitted that he had no difficultly knowing what to advise his patients; visualize:

> Q.664 But in respect of that hypothetical patient, let's call them "the Dr. Crowther Cook patient", certainly not your view that they were in any way ill-informed of the risks and benefits of filter placement?
>
> A. Not if I was responsible for it or if it was done under my watch, no.

[175] In prescribing IVC filters in appropriate cases, Dr. Crowther did not concern himself with whom was the particular manufacturer of the device. He also did not concern himself with the IFUs of the manufacturers. That he was not concerned about who manufactured the device and not concerned about the IFUs suggests that the warnings of the manufacturer about the consequences of implanting any medical device and of implanting an IVC filter would already be known to the radiologists, cardiologists, vascular surgeons, hematologists, thrombosis specialists, internalists, emergency physicians, bariatric surgeons, orthopaedic surgeons, and primary care physicians that prescribed IVC filters.

[176] Dr. Crowther did not read the IFUs warnings, save for research and for expert reports because he did not need to be warned that medical devices implanted in the body are dangerous, have complications, and may be difficult to retrieve. To satisfy its duty to warn, the manufacturer of a medical device should provide information that learned intermediary physician needs to know and does not already know. Physicians and surgeons already know about the general risks associated with implanting medical devices in the body and they already know about the general risks associated with retrieving an implanted device. It would appear from Dr. Crowther's

evidence that he and his associates already knew about the particular risks and benefits of IVC filters for the indicated uses.

[177] Since he did not even analyze the IFUs and knew nothing about the IFUs drafting, editing, and regulatory history, including the reviews by Health Canada, Dr. Crowther did not identify what precisely was inadequate about Cook's IFUs. Dr. Crowther did not do the analysis necessary to opine meaningfully about the inadequacies of the warning provided by Cook's IFU because, as noted earlier, it seems that that was not the focus of his report and his opinion. In addition to the weaknesses noted earlier, Dr. Crowther did not know anything about the history of Cook's IFUs and given his lack of familiarity with them, he was unable to have a meaningful discussion about the IFUs during his cross-examination. He did not undertake a comprehensive or detailed opinion on the adequacy of Cook's IFUs, which pamphlets do outline the risks associated with the Cook IVC Filters. He never personally reviewed an IFU with any of his patients leaving this task to the radiologists who performed the implant procedure. Although he concluded that Cook's IFUs provided inadequate warnings, much like his design negligence evidence, Dr. Crowther does not identify what was the inadequacy in the information provided by Cook and since Cook did provide warnings, one is left to ponder what it is about these warnings that was inadequate.

[178] Dr. Crowther's evidence does not show some basis in fact for a common issue that Cook did not provide an adequate warning about the complications that might arise from the use of an optionally retrievable filter. In other words, while the Plaintiffs pleaded that Cook's IFUs omitted to provide warnings about the complications that might arise from the use of an optionally retrievable IVC filter, including ailments and injuries, an actually examination of Cook's IFU reveals that Cook did warn about the risks of adverse events, including death, and it did warn about the filters damaging the vena cava and about filter embolization.

[179] In *Martin v. Astrazeneca Pharmaceuticals PLC*, *supra*, Justice Horkins, amongst other reasons, did not certify the duty to warn cause of action because the evidence showed that the warnings were in fact given or did not need to be given. Much the same thing can be said about the case at bar.

[180] While I did not rule Dr. Crowther's evidence about the duty to warn cause of action inadmissible, his evidence does not provide some basis in fact for any duty to warn common issues. I borrow what Justice Horkins had to say in *Martin v. Astrazeneca Pharmaceuticals PLC*,[83] at para. 321:

> 321. It is worth noting that it is a struggle to understand what the plaintiffs' experts have to say about the failure to warn issue. On such a key issue in this case, the plaintiffs argue that there is some evidence to support the failure to warn common issue. However, when the reader puts the pieces of this evidence together (without embarking on any weighing of the evidence) it becomes apparent that there is no evidence to support this core issue.

[181] I, therefore, conclude that the common issues criterion is not satisfied in the immediate case.

[182] Before leaving this criterion to discuss the preferable procedure criterion, I need to point out that in reaching my decision that the common issues criterion is not satisfied, I did not rely

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[83] 2012 ONSC 2744.

on Cook's argument that built on the premise that the adequacy of its IFU was made manifest because the IFU warned of the possible risk of death. The argument was made at paragraph 126 of Cook's factum as follows:

> 126. Lastly, this proposed common issue is not one that "actually exists" because the evidence does not support the allegation that any failure to warn caused any injury to the class members. Significantly the IFUs for the IVC Filters expressly warn that the placement of a filter could result in a number of different potential complications, including the patient's death. Despite being warned of this risk, each class member consented to have a filter placed. It may be inferred that each class member was of the view that, despite the risk of death from the filter, the risk of death from PE in the absence of an IVC Filter was even greater. In light of this fact, further warnings about potential non-fatal complications could not possibly have caused a reasonable class member to withhold consent.

[183] I did not rely on this argument in reaching my own conclusion for three reasons.

[184] First, the argument conflates individual or specific causation, which never is a common issue, with the common issues about the adequacy of the warning to the learned intermediary. That a Class Member may not be able to prove that the breach of the duty to warn caused him or her damage is not a reason for rejecting a common issue about whether there was a breach of the duty to warn.

[185] Second, in conflating breach and causation, Cook's argument conflates the duty to warn - when there is a learned intermediary, which is the situation of the immediate case, with the duty to warn - when there is a necessarily direct line of communication between the consumer and the pharmaceutical or medical device manufacturer, which is not the situation of the immediate case. The immediate case is about whether Cook provided adequate information to the physicians who prescribed the IVC filters. The issues in the immediate case for a common issues trial are not about how individual Class Members might react to the IFU and its warning about death. Cook's argument about the adequacy of the IFU to warn patients directly misses the target of the common issues trial.

[186] Third, the argument about the adequacy of the IFU based on the warning of death misses the target even if the case at bar did not involve a learned intermediary. In such a case, the patient or consumer of the medical product or device is entitled to make up his or her own mind about the imminence of death or any other adverse event complication, and when quality of life is put into the decision problematic, death may not be the worst risk. The Plaintiffs make this point in paragraph 13 of their Reply Factum as follows:

> It is fanciful, and inconsistent with existing jurisprudence, for Cook to assert that because one accepts death as a possible consequence of IVC Filter implantation, one would necessarily accept all other risks – regardless of the relative rate of such risk occurring – including risks that could significantly impair his or her quality of life. This argument is wholly inconsistent with the nature and scope of the manufacturer's duty to warn, which requires the warning to be sufficiently detailed to give the consumer *a full indication of each of* the specific dangers arising from the use of the product.

[187] In the immediate case, whether individual Class Members were adequately or inadequately informed by their own physicians is an issue for the individual issues trials, if the action got that far. Informed consent is not a class-wide common issue. The common issue about a duty to warn is whether the information provided by Cook's IFUs to the physicians who prescribed IVC filters was adequate. However, there is no basis in fact that this common issue actually exists.

[188] I, therefore, conclude that there are no certifiable common issues in the case at bar.

O. PREFERABLE PROCEDURE CRITERION

1. Introduction

[189] It is axiomatic that if the common issues criterion is not satisfied, then the preferable procedure criterion is not satisfied.[84] Therefore, in the immediate case, I can quickly conclude that the preferable procedure criterion is not satisfied.

[190] However, since the Plaintiffs may appeal, I shall address Cook's arguments that if there are certifiable common issues about either or both of the design negligence cause of action or the duty to warn cause of action, a class action is not the preferable procedure.

[191] As the discussion below will reveal, I disagree with Cook's arguments. Assuming that the other certification are satisfied, in my opinion, the Plaintiffs would have satisfied the preferable procedure criterion.

2. General Principles: Preferable Procedure

[192] Under the *Class Proceedings Act, 1992*, the fourth criterion for certification is the preferable procedure criterion. Preferability captures the ideas of: (a) whether a class proceeding would be an appropriate method of advancing the claims of the class members; and (b) whether a class proceeding would be better than other methods such as joinder, test cases, consolidation, and any other means of resolving the dispute.[85]

[193] In *AIC Limited v. Fischer*,[86] the Supreme Court of Canada emphasized that the preferability analysis must be conducted through the lens of judicial economy, behaviour modification, and access to justice. Justice Cromwell for the Court stated that access to justice has both a procedural and substantive dimension. The procedural aspect focuses on whether the claimants have a fair process to resolve their claims. The substantive aspect focuses on the results to be obtained and is concerned with whether the claimants will receive a just and effective remedy for their claims if established. Thus, for a class proceeding to be the preferable procedure for the resolution of the claims of a given class, it must represent a fair, efficient, and manageable procedure that is preferable to any alternative method of resolving the claims.[87] Arguments that no litigation is preferable to a class proceeding cannot be given effect.[88] Whether a class proceeding is the preferable procedure is judged by reference to the purposes of access to

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[84] *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 53 at para. 209, aff'd, 2017 ONSC 6098 (Div. Ct.), leave to appeal to C.A. refused (February 28, 2018); *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7950 at para. 140, additional reasons, 2017 ONSC 1095; *O'Brien v. Bard Canada Inc.*, 2015 ONSC 2470 at para. 221.

[85] *Markson v. MBNA Canada Bank*, 2007 ONCA 334 at para. 69, leave to appeal to SCC ref'd [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, 2001 SCC 68.

[86] 2013 SCC 69 at paras. 24-38.

[87] *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 52 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.).

[88] *1176560 Ontario Ltd. v. The Great Atlantic and Pacific Company of Canada Ltd.* (2002), 62 O.R. (3d) 535 at para. 45 (S.C.J.), aff'd (2004), 70 O.R. (3d) 182 (Div. Ct.).

justice, behaviour modification, and judicial economy and by taking into account the importance of the common issues to the claims as a whole, including the individual issues.[89]

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

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

[195] To satisfy the preferable procedure criterion, the proposed representative plaintiff must show some basis in fact that the proposed class action would: (a) be a fair, efficient and manageable method of advancing the claim; (b) be preferable to any other reasonably available means of resolving the class members' claims; and (c) facilitate the three principal goals of class proceedings; namely: judicial economy, behaviour modification, and access to justice.[90]

[196] In considering the preferable procedure criterion, the court should consider: (a) the nature of the proposed common issue(s) and their importance in relation to the claim as a whole; (b) the individual issues which would remain after determination of the common issue(s); (c) the factors listed in the *Act*; (d) the complexity and manageability of the proposed action as a whole; (e) alternative procedures for dealing with the claims asserted; (f) the extent to which certification furthers the objectives underlying the *Act*; and (g) the rights of the plaintiff(s) and defendant(s).[91]

[197] The court must identify alternatives to the proposed class proceeding.[92] The proposed representative plaintiff bears the onus of showing that there is some basis in fact that a class proceeding would be preferable to any other reasonably available means of resolving the class members' claims, but if the defendant relies on a specific non-litigation alternative, the defendant has the evidentiary burden of raising the non-litigation alternative.[93] It is not enough for the plaintiff to establish that there is no other procedure which is preferable to a class proceeding; he or she must also satisfy the court that a class proceeding would be fair, efficient and manageable.[94]

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[89] *Markson v. MBNA Canada Bank*, 2007 ONCA 334; *Hollick v. Toronto (City)*, 2001 SCC 68.
[90] *Musicians' Pension Fund of Canada (Trustee of) v. Kinross Gold Corp.*, 2014 ONCA 901; *AIC Limited v. Fischer*, 2013 SCC 69; *Hollick v. Toronto (City)*, 2001 SCC 68.
[91] *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 52 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.); *Chadha v. Bayer Inc.* (2003), 63 O.R. (3d) 22 (C.A.), leave to appeal to S.C.C. ref'd [2003] S.C.C.A. No. 106.
[92] *AIC Limited v. Fischer*, 2013 SCC 69 at para. 35; *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 28.
[93] *AIC Limited v. Fischer*, 2013 SCC 69 at paras. 48-49.
[94] *Amyotrophic Lateral Sclerosis Society of Essex County v. Windsor (City)*, 2015 ONCA 572 at para. 62; *Caputo v. Imperial Tobacco Ltd.*, [2004] O.J. No. 299 at para. 62-67 (S.C.J.).

[198] In *AIC Limited v. Fischer,* Justice Cromwell pointed out that when the court is considering alternatives to a class action, the question is whether the alternative has potential to provide effective redress for the substance of the plaintiff's claims and to do so in a manner that accords suitable procedural rights. He said that there are five questions to be answered when considering whether alternatives to a class action will achieve access to justice: (1) Are there economic, psychological, social, or procedural barriers to access to justice in the case? (2) What is the potential of the class proceeding to address those barriers? (3) What are the alternatives to class proceedings? (4) To what extent do the alternatives address the relevant barriers? and (5) How do the two proceedings compare?[95]

[199] And in light of the Supreme Court of Canada's directives in *Hryniak v. Mauldin*[96] and *Bruno Appliance and Furniture, Inc. v. Hryniak,*[97] one should now add to the preferable procedure factors the factor of the relationship between access to justice, which is the preeminent concern of class proceedings, and proportionality in civil procedures. The proportionality analysis, which addresses how much procedure a litigant actually needs to obtain access to justice, fits nicely with the focus on judicial economy and with the part of the preferable procedure analysis that considers manageability and whether the claimants will receive a just and effective remedy for their claims.

[200] In cases, particularly cases where the individual class members' respective harm is nominal, or cases where an aggregate assessment of damages in whole or in part is possible, a class action may more readily satisfy the preferable procedure criterion because the common issues trial may be the only viable means for remedying the wrong and for calling the wrongdoer to account because individual litigation may be prohibitively expensive.[98]

[201] In undertaking a preferable procedure analysis in a case in which individual issue trials are inevitable, it should be appreciated that the *Class Proceedings Act, 1992* envisions the prospect of individual claims being litigated and it should be noted that sections 12 and 25 of the *Act* empower the court with tools to manage and achieve access to justice and judicial economy; thus the inevitability of individual issues trials is not an obstacle to certification. In the context of misrepresentation claims, numerous actions have been certified notwithstanding individual issues of reliance and damages.[99]

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[95] *Musicians' Pension Fund of Canada (Trustee of) v. Kinross Gold Corp.*, 2014 ONCA 901 at para. 125; *AIC Limited v. Fischer*, 2013 SCC 69 at paras. 27-38.

[96] 2014 SCC 7.

[97] 2014 SCC 8.

[98] *Marcantonio v. TVI Pacific Inc.*, [2009] O.J. No. 3409 (S.C.J.) at para. 9; *Silver v. IMAX Corp.*, [2009] O.J. No. 5585 at paras. 215-216 (S.C.J.), leave to appeal to Div. Ct. refused, 2011 ONSC 1035 (Div. Ct.); *Markson v. MBNA Canada Bank*, 2007 ONCA 334.

[99] *Fantl v. Transamerica Life Canada*, 2016 ONCA 633; *OPA v. Ottawa Police Services Board*, 2014 ONSC 1584 at para. 59 (Div. Ct.); *Cannon v. Funds for Canada Foundation*, 2012 ONSC 399 at paras. 340, 350-351, leave to appeal to Div. Ct. refused, 2012 ONSC 6101 (Div. Ct.); *Ramdath v. George Brown College of Applied Arts & Technology*, 2010 ONSC 2019 at para. 103; *Silver v. Imax Corp.*, [2009] O.J. No. 5585 (S.C.J.), leave to appeal to Div. Ct. refused, 2011 ONSC 1035 (Div. Ct.); *Hickey-Button v. Loyalist College of Applied Arts & Technology* (2006), 267 D.L.R. (4th) 601 (Ont. C.A.); *Murphy v. BDO Dunwoody LLP*, [2006] O.J. No. 2729 (S.C.J.); *Lewis v. Cantertrot Investments Ltd.*, [2005] O.J. No. 3535 at para. 20 (S.C.J.); *Canadian Imperial Bank of Commerce v. Deloitte & Touche*, [2003] O.J. No. 2069 at para. 35 (Div. Ct.); *Carom v. Bre-X Minerals Ltd.* (2000), 51 O.R. (3d)

[202] That said, in a given particular case, the inevitability of individual issues trials may obviate any advantages from the common issues trial and make the case unmanageable and thus the particular case will fail the preferable procedure criterion.[100] Or, in a given case, the inevitability of individual issues may mean that while the action may be manageable, those individual issue trials are the preferable procedure and a class action is not the preferable procedure to achieve access to justice, behaviour modification, and judicial economy. A class action may not be fair, efficient and manageable having regard to the common issues in the context of the action as a whole and the individual issues that would remain after the common issues are resolved.[101] A class action will not be preferable if, at the end of the day, claimants remain faced with the same economic and practical hurdles that they faced at the outset of the proposed class action.[102]

3. Analysis: Preferable Procedure

[203] Cook submits that the Plaintiffs' action does not satisfy the preferable procedure criterion because it will require individual personal injury trials during which the court would have to explore a myriad of patient-specific individual issues that would dwarf any progress made at the common issues trial.

[204] There are cases where Cook's atomization argument works. The case at bar is not one such case. Products liability cases involving any combination of the four main genres of products liability can satisfy the preferable procedure criterion notwithstanding that there is plethora of individual issues that still need to be decided. Assuming that the common issues criterion had been satisfied, the case at bar is not one where the myriad of patient-specific individual issues would dwarf any progress made at the common issues trial.

[205] Had the Plaintiffs in the immediate case identified a design defect or a common issue about a duty to warn, then there would have been a very worthwhile common issues trial. If the Representative Plaintiffs were successful at the common issues trial, then there would have been worthwhile individual issues trials for those individual Class Members wishing to soldier on to an individual issues trial. And, if there was no design defect proven, a class action would be a worthwhile endeavor for Cook, because Cook would discharge itself from a liability reckoned to be in the range of $11.5 billion and there would be no individual issues trials at all to worry about.

[206] In my opinion, but for the absence of common issues, the case at bar would be the preferable procedure for the approximately 23,000 Class Members, who otherwise would not have access to justice.

[207] However, although I disagree with Cook's preferable procedure arguments, there are no common issues, and it follows that the Plaintiffs do not satisfy the preferable procedure criterion.

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236 at paras. 48-49 (C.A.), rev'g (1999), 44 O.R. (3d) 173 (S.C.J.), leave to appeal to S.C.C. refused, [2000] S.C.C.A. No. 660.

[100] *Arabi v. Toronto-Dominion Bank,* [2006] O.J. No. 2072 (S.C.J.), aff'd [2007] O.J. No. 5035 (Div. Ct.); *Mouhteros v. DeVry Canada Inc.* (1998), 41 O.R. (3d) 63 (Gen. Div.).

[101] *Musicians' Pension Fund of Canada (Trustee of) v. Kinross Gold Corp.*, 2014 ONCA 901.

[102] *Fantl v. Transamerica Life Canada*, 2016 ONCA 633 at para. 26.

P. REPRESENTATIVE PLAINTIFF CRITERION

1. General Principles: Representative Plaintiff Criterion

[208] The fifth and final criterion for certification as a class action is that there is a representative plaintiff who would adequately represent the interests of the class without conflict of interest and who has produced a workable litigation plan. The representative plaintiff must be a member of the class asserting claims against the defendant, which is to say that the representative plaintiff must have a claim that is a genuine representation of the claims of the members of the class to be represented or that the representative plaintiff must be capable of asserting a claim on behalf of all of the class members as against the defendant.[103]

[209] Provided that the representative plaintiff has his or her own cause of action, the representative plaintiff can assert a cause of action against a defendant on behalf of other class members that he or she does not assert personally, provided that the causes of action all share a common issue of law or of fact.[104]

[210] Whether the representative plaintiff can provide adequate representation depends on such factors as: his or her motivation to prosecute the claim; his or her ability to bear the costs of the litigation; and the competence of his or her counsel to prosecute the claim.[105]

[211] While a litigation plan is a work in progress, it must correspond to the complexity of the particular case and provide enough detail to allow the court to assess whether a class action is: (a) the preferable procedure; and (b) manageable including the resolution of the common issues and any individual issues that remain after the common issues trial.[106] The litigation plan will not be workable if it fails to address how the individual issues that remain after the determination of the common issues are to be addressed.[107]

2. Analysis: Representative Plaintiff

[212] Given the findings above with respect to the cause of action, common issues, and preferable procedure criterion, it is not necessary to do a deep analytical dive into the representative plaintiff criterion. In particular, it is otiose to address Cook's arguments about the

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[103] *Drady v. Canada (Minister of Health)*, [2007] O.J. No. 2812 at paras. 36-45 (S.C.J.); *Attis v. Canada (Minister of Health)*, [2003] O.J. No. 344 at para. 40 (S.C.J.), aff'd [2003] O.J. No. 4708 (C.A.).
[104] *Voutour v. Pfizer Canada Inc.*, [2008] O.J. No. 3070 (S.C.J.); *LeFrancois v. Guidant Corp.*, [2008] O.J. No. 1397 at para. 55 (S.C.J.); *Matoni v. C.B.S. Interactive Multimedia Inc.*, [2008] O.J. No. 197 at paras. 71-77(S.C.J.); *Boulanger v. Johnson & Johnson Corp.*, [2002] O.J. No. 1075 at para. 2 (S.C.J.), leave to appeal granted, [2002] O.J. No. 2135 (S.C.J.), varied (2003), 64 O.R. (3d) 208 (Div. Ct.), varied [2003] O.J. No. 2218 (C.A.).
[105] *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 41.
[106] *Carom v. Bre-X Minerals Ltd.* (1999), 44 O.R. (3d) 173 (Div. Ct.), rev'd on other grounds (2000), 51 O.R. (3d) 236 (C.A.); *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 95 (C.A.); *Caputo v. Imperial Tobacco Ltd.*, [2004] O.J. No. 299 at para. 76 (S.C.J.); *Griffin v. Dell Canada Inc.*, [2009] O.J. No. 418 at para. 100 (S.C.J.).
[107] *Caputo v. Imperial Tobacco Ltd.*, [2004] O.J. No. 299 at paras. 62-67 (S.C.J.); *Griffin v. Dell Canada Inc.*, [2009] O.J. No. 418 (S.C.J.).

deficiencies of the Plaintiffs' litigation plan, which typically, standing alone, is not a reason to reject an otherwise satisfactory class proceeding. Deficient litigation plans can be fixed; however, a class action that does not satisfy the other certification criterion cannot have a fixable litigation plan.

[213] Because of the possibility of an appeal of my decision, I, however, shall for the record, very briefly address, Cook's arguments about whether the proposed Representative Plaintiffs are qualified to be representative plaintiffs.

[214] I disagree with Cook's arguments about the qualifications of Ms. Kopeck, Mr. Kopeck, and Mr. Kuiper to be representative plaintiffs. In my opinion, the proposed Representative Plaintiffs are all qualified to be representative plaintiffs. Thus, for the record, but for their failure to satisfy other certification criteria, the Plaintiffs would have satisfied the Representative Plaintiff criterion.

Q. CONCLUSION

[215] For the above reasons, I dismiss the certification motion. If the parties cannot agree about the matter of costs, they may make submissions in writing beginning with Cook's submissions within twenty days of the release of these Reasons for Decision followed by the Plaintiffs' submissions within a further twenty days.

Perell, J.

Released: October 31, 2018

CITATION: Kuiper v. Cook (Canada) Inc., 2018 ONSC 6487
COURT FILE NO.: CV-17-578210CP
DATE: 2018/10/31

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

Arie Kuiper, Wendy Kopeck and Garry Kopeck

Plaintiff

– and –

Cook (Canada) Inc., Cook Medical LLC, Cook Medical Incorporated A/K/A Cook Medical, Inc., Cook Incorporated, Cook Group, Inc. and William Cook Europe APS

Defendants

REASONS FOR DECISION

PERELL J.

Released: October 31, 2018