Court File No. CV-17-00579153-OOCP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

BRUNO NARDI

Plaintiff

- and -

SORIN GROUP DEUTSCHLAND GMBH
and LIVANOVA CANADA CORP.

Defendants

Proceeding under the *Class Proceedings Act*, 1992

STATEMENT OF DEFENCE

1. The defendants, Sorin Group Deutschland GMBH and LivaNova Canada Corp., admit the allegations contained in paragraph 12 of the plaintiff's Amended Amended Statement of Claim (the "Claim").

2. The defendants deny the allegations contained in paragraphs 5-6, 9-11, and 13-83 of the Claim except as hereinafter otherwise stated, deny that the claims of breach of statutory duty in paragraphs 53-57 and allegations related to the FDA or other foreign regulators in paragraphs 15, 22, 30, 31, 32, and 34-36 are sustainable, relevant or admissible and plead that such paragraphs ought to be struck, and further deny that the plaintiff is entitled to the relief claimed in paragraph 1 of the Claim.

3. With respect to paragraphs 19, 21, 27-28, 31, 33, and 37-38 of the Claim, without admitting the admissibility or relevance of the communications and publications, the defendants admit that communications and publications referenced in these paragraphs

were disseminated or published, as applicable, on or about the dates referenced in those paragraphs. The referenced communications and publications speak for themselves and should be read as a whole. The defendants deny the plaintiff's characterization of these communications and publications and deny any other allegations contained in these paragraphs.

4. With respect to paragraph 20 of the Claim, the defendants admit that non-tuberculous mycobacteria ("NTM"), including *M. Chimaera* and *M. Abscessus*, are commonly found in the environment, including soil, water and surfaces, and rarely cause illness. The defendants deny the balance of the allegations contained in paragraph 20 unless hereinafter specifically admitted. NTM are not typically harmful, but in certain individual circumstances can cause infections that may in some instances become severe.

5. With respect to paragraph 25 of the Claim, the defendants admit that on or about July 2014, LivaNova sent an "Important Information Letter" to customers. This letter speaks for itself and should be read as a whole. The defendants deny the plaintiff's characterization of the letter and deny the balance of the allegations contained in paragraph 25.

6. With respect to paragraphs 23 and 26 of the Claim, the defendants admit that in January 2014, Sorin Group Deutschland GMBH ("Sorin") became aware of cases of NTM infections following open heart surgery during which the Stockert Heater Cooler System 3T (the "3T Device") was used, and that LivaNova offered a deep disinfection service for 3T Devices performed at Sorin's Munich facilities beginning in May 2015.

7. With respect to paragraph 46 of the Claim, the defendants admit that they owed a duty to take reasonable care in the design and manufacture of each of the 3T Devices. The defendants deny that they breached any such duty in respect of any 3T Device used in any patient's surgery.

8. The defendants have no knowledge or insufficient knowledge to plead in respect of the allegations contained in paragraphs 2-4 of the Claim.

The Defendants

9. As to paragraphs 9 and 14 of the Claim, Sorin, which is now called LivaNova Deutschland GmbH, has its principal place of business in Munich, Germany. Sorin is identified as the manufacturer of the 3T Device on the Health Canada medical device licence for regulatory purposes. To the knowledge of Health Canada, the 3T Devices were manufactured by a third-party manufacturer. Sorin also participated in the research, development, and premarket testing, and prepared the Instructions for Use for the 3T Device as amended and reviewed by Health Canada from time to time.

10. As to paragraph 9a of the Claim, LivaNova Canada Corp. is a Nova Scotia corporation with its principal place of business in Markham, Ontario ("LivaNova" or the "Company"). Persons in the employ of LivaNova market and sell 3T Devices to Canadian hospitals, and provide regulatory submissions and reporting to Health Canada in respect of same.

11. At all material times, LivaNova sold and distributed the 3T Devices directly to Canadian hospitals, clinical research centres, or hospital buying groups; at no time has

the Company sold 3T Devices directly to Canadian patients or to healthcare professionals.

The 3T Device

12. The 3T Device is a non-sterile electromechanical device utilized in the operating room in conjunction with the heart lung machine, both of which are intended to be placed outside the "sterile field." The "sterile field" describes the area around the patient in an operating room that is intended to be kept sterile, including the wound site. Heater-cooler devices like the 3T Devices are not intended to come into contact with patients.

13. The 3T Device is intended to provide temperature-controlled water to heat exchanger devices to warm or cool a patient during cardiopulmonary bypass procedures lasting six hours or less. It serves a critical role in life-supporting/life-sustaining cardiothoracic procedures.

14. Every 3T Device is distributed with written Operating Instructions as they exist at the time of the sale of each device, also referred to as written Instructions for Use ("IFU" or the "Operating Instructions"), which describe, among other things: the components included in the 3T Device, the procedures then considered appropriate for use, the purpose of the 3T Device and the conditions for which it is intended to be used ("indications"), a description of the circumstances in which the product should not be used ("contraindications"), warnings and precautions, and detailed cleaning, disinfection and maintenance instructions for the 3T Device. The 3T Device has never been and is not considered a sterile product, either at the time of sale or within the operating room itself.

15. While the Operating Instructions applicable to each 3T Device set out detailed cleaning, disinfection and maintenance instructions, additional communications have occurred between the Company and individual hospitals and their staff in that regard. Each hospital has its own practices with respect to cleaning, disinfection, and maintenance, and they vary from institution to institution. A hospital's adherence to the cleaning, disinfection and maintenance instructions in the Operating Instructions as they exist at each relevant time, and to any other communications from the Company, as well as its level of adherence, vary from institution to institution and often also vary over time.

Authorization for Sale by Health Canada

16. Prior to the 3T Device's alleged use in the surgery of the representative plaintiff, Bruno Nardi ("Mr. Nardi"), and any other patient, the applicable IFU for the relevant 3T Device was reviewed by Health Canada in conjunction with its authorization for sale of that 3T Device.

17. The 3T Device was first authorized for sale by Health Canada on April 27, 2006. It was and is still authorized to be used "during extracorporeal perfusion with ... any heart-lung machine permitting separate temperature control" and to "cool or heat blood (in a cardiopulmonary bypass oxygenator), hypothermia/hyperthermia blankets, or cardioplegic solutions."

18. The 3T Device was authorized for sale by Health Canada as a non-sterile medical device. Health Canada requires sterile devices to be labeled, designated, reviewed, and authorized by Health Canada as a sterile device, and requires that a description of the sterilization method be included in the medical device application.

19. The 3T Device remains on the market today and continues to be used in operating rooms in Canadian hospitals. LivaNova developed a vacuum canister and internal sealing change to the 3T Device, which was authorized for sale by Health Canada on or around April 21, 2017.

20. The warnings and instructions provided by the defendants in each of the IFUs were reasonable at the time each 3T Device was used in Mr. Nardi's and any other patient's surgery, having regard to the state of the art and scientific knowledge at the specific time each device was used in each patient's surgery.

Cardiac Surgery and Patient Factors Affecting Risk for Surgery

21. Cardiac surgery, supported by cardiopulmonary bypass and hypothermia, is used to treat a wide range of cardiac diseases. The most common cardiac surgical procedure is coronary artery bypass grafting, used to treat obstructed or blocked arteries supplying blood to the heart. Infection is a known risk of all cardiac surgery.

22. There are many factors that affect the outcome of cardiac surgery in an individual patient. Many patients undergoing cardiac surgery have had heart disease for months to years. They may have undergone one or several coronary artery stenting procedures. Patients may also have a wide range of other related and non-related medical conditions including, among other things, hypertension, diabetes mellitus, renal failure, morbid obesity, advanced age, atrial fibrillation, depression, and the need for medications that increase the risk of bleeding. Each of these raise the risk of complications and death with cardiac surgery, and also raise the risk of infection that accompanies surgery.

Nontuberculous Mycobacterium, *Mycobacterium Chimaera*, and *Mycobacterium Abscessus*

23. NTM are naturally-occurring organisms found in soil and water. NTM is ubiquitous. It is widely distributed in the environment, and can come from a variety of sources inside or outside an operating room including from tap water, from dust, and from a variety of surfaces. There are more than 150 species of NTM, including Mycobacterium chimaera *(M. Chimaera)* and Mycobacterium abscessus *(M. Abscessus)*.

24. Prior to 2014, there were no reports to the defendants or in the published literature of patient infection in association with the use of a 3T Device. In 2014, Sorin became aware through case reports of a newly identified risk for cardiac surgery patients who underwent surgery with a heater-cooler device with regards to a slow growing *M. Chimaera*, a species of NTM.

25. There are different types of NTM, including *M. Chimaera* and *M. Abscessus*, and different sources of NTM that may cause a cardiac surgery patient's infection, if any, including the ones noted above. There are also different general and individual presentations of infection, with differing prognoses, which may vary in part based on the particular medical and health condition of an individual person.

26. The defendants deny that any and each 3T Device used in a patient's surgery was "infected" with NTM, including *M. Chimaera* or *M. Abscessus*, during the manufacture of each device, as alleged in paragraph 17a of the Claim. Any bacteria present in a 3T Device at the time of a patient's surgery appeared in that device after the device had been

cleaned and disinfected by the hospital one or more times, and not as a result of any alleged conduct by the defendants' during manufacture of that device.

27. Even if NTM, including *M. Chimaera* or *M Abscessus,* was present in the device used in a patient's surgery at the time of the surgery, there are several factors that influence the propensity for an individual patient to be exposed to such bacteria if it is present in a 3T Device at the time that device is used during a specific surgical procedure. These factors include, but are not limited to: the size and shape of each operating room; the HVAC system used in each operating room; the location and orientation of the 3T Device within each operating room for each surgery; the level of bacteria in the water of the specific 3T Device at the time of each surgery, which in turn can depend on a number of factors including the water source for the hospital, the treatment of the water once in the machine, the age of the 3T Device, frequency of use, time since the last disinfecting cycle was performed, and frequency of draining/water in the 3T Device; and additional device-specific issues.

28. According to scientific literature, the risk of *M. Chimaera* infection from a heater-cooler unit during surgery is extremely low – less than 1%. To date, there have been very few patient infections reported to Health Canada in association with the use of a heater-cooler unit.

Communications regarding the Cleaning and Disinfection of Heater-Cooler Units

29. At the time that each patient's surgery was performed, the defendants took reasonable measures to address any known clinically relevant risk of infection in light of the then state of scientific knowledge and state of the art.

30. The Company sent a number of communications regarding the importance of strict adherence to the cleaning, disinfection and maintenance instructions for the 3T Device. Other manufacturers of heater-cooler devices used in Canada including Maquet, Terumo, and Hemotherm, issued similar communications.

31. In July 2014, the Company sent a communication to all customers drawing their "attention to the Heater Cooler Operating Instructions and need for strict adherence to the cleaning, disinfection and maintenance" of the 3T Device. It reminded customers that water in the 3T Device is not intended to have direct contact with the patient, and emphasized "the importance of adhering to the correct maintenance of the device at all times and in particular to assure that the cleanliness of the water in the device is maintained." The communication also enclosed the Company's latest version of the Operating Instructions for the 3T Device.

32. On June 15, 2015, the Company sent a Field Safety Notice to all customers, advising that the Company "has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use". The Company provided notification to: "(1) remind you of the importance of following the company's disinfection and maintenance procedures; (2) inform you that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and (3) provide you with updated Instructions for Use regarding disinfection and maintenance procedures".

33. In October 2016, the Company issued a Field Safety Notice, recommending removal of 3T Devices suspected to be contaminated from the operating room, or if feasible, from service as soon as practicable. The Company also advised customers to contact LivaNova/Sorin to have deep disinfection services performed on suspected 3T Devices prior to further use.

34. In addition to the Company's various Field Safety Notices, persons in the employ of the Company had individual discussions with hospitals regarding the various updated IFUs and the information contained therein. These individual discussions varied from institution to institution and varied over time.

No Negligence

35. The defendants deny that there was any negligence, breach of duty or want of care on any of their parts which caused or contributed to Mr. Nardi's and any other patient's injuries, loss or damage, if any, and specifically deny the allegations of negligence in paragraphs 39-60 of the Claim.

36. Any complication experienced by any individual patient with a 3T Device was caused by persons or circumstances beyond the control of the defendants, not by any alleged fault on the part of the defendants.

No Negligent Design and No Negligent Manufacture

37. With respect to paragraphs 39(a), 40, 41, and 45-48 of the Claim, each 3T Device used in each patient's surgery was, in all relevant respects, designed, researched, developed, tested, manufactured, inspected, packaged, labelled, marketed and sold in

accordance with industry standards applicable at the relevant time, and in accordance with the reasonable standard of care applicable at that time. Each 3T Device used in each patient's surgery was neither defective nor unreasonably dangerous as alleged, at the time of such surgery or any other relevant time, to the extent such allegations are material to a cause of action pleaded in negligence, which is not admitted but expressly denied.

38. Further, the defendants deny that any alleged defect in any 3T Device caused or materially contributed to any alleged injury or harm alleged to have been suffered by Mr. Nardi or any other patient. Each 3T Device used in each patient's surgery conformed to state-of-the-art specifications and state of scientific knowledge for such devices at the time each 3T Device was distributed to a hospital.

No Failure to Warn and No "Duty to Withdraw"

39. With respect to paragraphs 39(b) and (c), 41, 43, 45, 46, and 49 of the Claim, the defendants deny that they were under any duty to "withdraw the HCU from use in Canada" and plead that a "duty to recall" is not tenable in fact or in law. Furthermore, the defendants deny that they owed any alleged duty to warn Mr. Nardi and other patients in the circumstances of this device, which was neither implanted in a patient nor used by the patient.

40. At each and all material times, the IFU for each 3T Device, as reviewed by Health Canada, contained appropriate, adequate and timely warnings regarding the risks inherent in the use of each 3T Device.

41. As the defendants learned of or received new information about the 3T Device, the defendants, where appropriate, prepared communications and Field Safety Notices to Canadian hospitals and healthcare professionals advising them of this new information, if any, including new information regarding known risks and warnings, as well as new information regarding the maintenance, cleaning, and disinfection of the device, based on the evolving state of medical and scientific knowledge over time.

42. At the time of each patient's surgery, the defendants provided appropriate and adequate disclosure of risks associated with the use of the 3T Device to Health Canada, hospitals and relevant health care professionals. Further, or in the alternative, the risks of infection in cardiac surgery, as well as the potential for the presence of bacteria in any water source or other surface in an operating room was well known to each patient's health care professional at the time of each surgery regardless of any communication from the defendants.

43. Further, each 3T Device is highly technical in nature and could only be used by each of Mr. Nardi's and other patients' physicians, perfusionists, biotechnicians, and/or hospitals. In the event that there was any duty to warn any patient, which is denied, the learned intermediary exception to the duty to warn applies in these circumstances. The defendants met any duty to warn Mr. Nardi and each other individual patient of the risks inherent in the use of the 3T Device by warning these learned intermediaries of such risks.

44. The defendants took all reasonable steps to inform healthcare providers of Mr. Nardi and each other patient regarding proper use, cleaning, disinfection, and maintenance of the 3T Device and, to the extent required, to provide appropriate and

adequate instructions and warnings regarding each 3T Device. At all material times, each 3T Device was distributed in Canada with proper warnings, information, cautions, and instructions in accordance with the generally recognized and prevailing standards in existence at the time and in accordance with a reasonable standard of care.

45. The defendants do not have full information regarding Mr. Nardi's and each patient's medical conditions and communications with their physicians regarding the use of the 3T Device in their surgeries, and accordingly plead at this time that:

(a) Mr. Nardi and other patients were aware at all material times of the alleged risks associated with use of the 3T Device, from their physicians and other sources that they consulted prior to the 3T Device being used in their surgeries. They were each advised of the risk of infection from surgery, and their health care providers were aware of same. They voluntarily assumed the alleged risks associated with the use of the 3T Device; and

(b) Mr. Nardi and other patients would have elected to have the 3T Device used in their surgery had they been provided with any additional or different warning that the plaintiff alleges should have been provided regarding the 3T Device, if any, which is denied.

No Breach of Regulatory Duties

46. With respect to paragraphs 39(d), and 51-57 of the Claim, the defendants plead that they complied with all relevant provisions of the *Food and Drugs Act* and the *Medical Device Regulations*, (collectively, the "Regulations") and Health Canada's requirements

with respect to the IFU of the 3T Device, in all relevant respects at the time each patient had a 3T Device used in their surgery.

47. At the time of each patient's surgery, the defendants exercised reasonable care in the monitoring and reporting to Health Canada of the performance of the 3T Device.

48. After the 3T Device was introduced into the Canadian market, as part of its post-market surveillance of the 3T Device, the defendants monitored reports and studies of patient experience with the 3T Device. As the defendants received new information about the 3T Device through post-market surveillance, the defendants, where appropriate, advised Health Canada of the new information and recommended changes to the IFU for Health Canada's consideration. The defendants also worked with Health Canada, as appropriate, to prepare letters to Canadian hospitals and healthcare professionals advising them of new information in relation to the 3T Device, if any, including new information regarding the maintenance, cleaning, and disinfection of the device, based on the evolving state of medical and scientific knowledge over time.

49. In the alternative, to the extent that any of the defendants failed to comply with the Regulations at the time the 3T Device was used in the surgery of any patient, which is denied, such non-compliance does not give rise to any liability at law, is too remote, and did not foreseeably or proximately cause loss to Mr. Nardi or any patient.

No Waiver of Tort

50. With respect to paragraphs 39(e), and 58-60 of the Claim, the defendants deny that any patient is entitled to "waive the tort" and "require the defendants to account for

all the revenue they received from the sale of" the 3T Device in Canada during the class period. The defendants deny that Mr. Nardi is entitled to elect an accounting or other restitutionary remedy on his own behalf, or on behalf of other patients, and deny that any individual patient is entitled to elect such a remedy as a matter of law, equity or fact. Further, or in the alternative, no such right or remedy should be recognized or granted for the following reasons, among others pled by the defendants elsewhere in the statement of defence:

(a) Each patient, including Mr. Nardi, received benefit from the use of the 3T Device;

(b) There was no "wrongful conduct" on the part of the defendants in relation to any and each patient, and in fact, the defendants acted appropriately and met or exceeded the applicable standard of care at all material times, and in that regard;

(c) There is no connection between any individual patient and the defendants' revenues from the sale of any of the 3T Devices;

(d) Individual patients, including Mr. Nardi, did not provide any direct benefit to the defendants, and provincial health insurers are not entitled at law to recover revenues or profits from the defendants;

(e) To the extent any of the defendants were enriched, if at all, by way of the sale of any of the 3T Devices, individual patients, including Mr. Nardi, did

not have any corresponding deprivation that would warrant the recovery claimed.

Alleged Damages

51. The defendants deny that any 3T Device and/or their alleged conduct caused or materially contributed to any injury or loss that Mr. Nardi or any patient may have experienced while having the 3T Device used in their surgery. Any harm, injury, or loss that they may have experienced was caused by pre-existing medical conditions, risks inherent to those medical conditions, the procedures used to treat those conditions, or by the conduct of others and/or circumstances beyond the knowledge and control of the defendants.

52. With respect to the FLA Class Members (as described in this action) and paragraph 72 of the Claim, the defendants deny that they have sustained or will sustain any damages, or are entitled to recover any damages, as a matter of law. The defendants plead and rely on the laws of the province applicable to the claims of each family class member. In the alternative, the defendants plead that if the family class members did sustain any such damages, which is denied, those damages did not result from and were not caused by the defendants' alleged conduct.

53. With respect to claims for past and future medical expenses, the defendants deny that any individual patient has incurred or will incur medical expenses, including future care and services as a result of undergoing surgery with a 3T Device or any alleged conduct by the defendants.

54. With respect to the cost of past and future insured health services provided by the Ontario Health Insurance Plan ("OHIP") and other provincial insurers to each individual patient, the defendants deny that any alleged conduct on their part caused or contributed to the need for any of these alleged services in any of these individual cases and puts the representative plaintiff and each patient to strict proof with respect to these allegations and each and every insured service that is being claimed in each individual's own unique set of circumstances. The defendants specifically deny that any patient, OHIP or any other health insurer is entitled to recover any alleged medical costs incurred in the screening, diagnosis and treatment of medical conditions allegedly caused by the use of a 3T Device in any patient's surgery.

55. With respect to the claim for punitive, aggravated and exemplary damages as alleged in paragraph 73 of the Claim, the defendants deny that there is any factual or legal basis for such an award.

56. The defendants ask that this action be dismissed with costs, against Mr. Nardi and against each and every provincial health insurer pursuing a subrogated claim for health care expenses in or through this proceeding.

April 25, 2019

BLAKE, CASSELS & GRAYDON LLP
Barristers & Solicitors
199 Bay Street
Suite 4000, Commerce Court West
Toronto ON M5L 1A9

S. Gordon McKee LSO #28557R
Tel: 416-863-3884
Fax: 416-863-2653
gordon.mckee@blakes.com

Jill Lawrie LSO#34343W
Tel: 416-863-3082
jill.lawrie@blakes.com

Lawyers for the defendants

TO:

FLAHERTY McCARTHY LLP
95 Wellington Street West
10th Floor Suite 1000
Toronto, ON M5J 2N7

Sean A. Brown LSO#42202W
sbrown@fmlaw.ca

Candace Mak LSO# 60199L
cmak@fmlaw.ca

Tel: 416-368-0231
Fax: 416-368-9229

WADDELL PHILLIPS PROFESIONAL CORPORATION
36 Toronto Street, Suite 1120
Toronto, ON M5C 2C5

Margaret L. Waddell LSO# 29860U
marg@waddellphillips.ca

Patti Shedden LSO#46210W
patti@waddellphillips.ca

John-Otto Phillips LSO# 70097N
otto@waddellphillips.ca

Tel: 647-261-4486
Fax: 416-477-1657

Solicitors for the Plaintiff

NARDI	-and-	LIVANOVA CANADA CORP et al	Court File No. CV-17-00579153-OOCP
Plaintiff		Defendants	

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding commenced at Toronto

STATEMENT OF DEFENCE

BLAKE, CASSELS & GRAYDON LLP
Barristers & Solicitors
199 Bay Street
Suite 4000, Commerce Court West
Toronto ON M5L 1A9

S. Gordon McKee LSO #28557R
Tel: 416-863-3884
gordon.mckee@blakes.com

Jill Lawrie LSO # 34343W
Tel: 416-863-3082
jill.lawrie@blakes.com

Lawyers for the Defendants