SCHEDULE "A"

Court File No.: CV-17-00579153-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

BRUNO NARDI

Plaintiff

- and -

~~LIVANOVA PLC,~~ SORIN GROUP DEUTSCHLAND GMBH
and ~~SORIN GROUP USA, INC.~~ LIVANOVA CANADA CORP.

Defendants

Proceeding under the *Class Proceedings Act*, 1992

~~AMENDED~~ AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it, with proof of service in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

IF YOU PAY THE PLAINTIFF'S CLAIM, and $10,000.00 for costs, within the time for serving and filing your statement of defence you may move to have this proceeding dismissed by the court. If you believe the amount claimed for costs is excessive, you may pay the plaintiff's claim and $5,000.00 for costs and have the costs assessed by the court.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date ..... Issued by.....
Local Registrar

10th Floor, 393 University Avenue
Toronto, Ontario
M5G 1E6

~~TO: LIVANOVA PLC~~
~~20 Eastbourne Terrace~~
~~London, W2 6LG~~
~~United Kingdom~~

AND TO: SORIN GROUP DEUTSCHLAND GMBH
Lindberghstrasse 25
D-80939 München
Germany

~~AND TO: SORIN GROUP USA, INC~~
~~14401 West 65th Way~~
~~Arvada, Colorado~~
~~80004~~

AND TO: LIVANOVA CANADA CORP.
280 Hillmount Road
Suite #8
Markham, ON
L6C 3A1

CLAIM

1. The plaintiff claims on behalf of himself and the putative Class Members for the following relief:

(a) An Order pursuant to the *Class Proceedings Act*, *1992*, SO 1992 c 6, ~~amended.~~ certifying this action as a Class Proceeding;

(b) An Order defining the Class as:

(I) All persons in Ontario and elsewhere in Canada, ~~except Quebec~~, who underwent surgery during which the Sorin 3T Heater-Cooler System (the "Sorin 3T System") was used, excluding all persons who were subject to open heart cardiac surgery at the Institut de cardiologie de Montreal after January 1, 2012. (the "Patient Class") ~~and who were exposed to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium ("NTM")~~ during the period between January 1, 2010 and the date of certification of this action as a class proceeding (the "Class Period"); and

(ii) all dependents of Members of the Patient Class as defined by Section 61 of the *Family Law Act* R.S.O. 1990 s.F.3 s.61 and similar legislation in other provinces (the *FLA* Class) as set out in paragraph 71;

(c) An Order appointing Bruno Nardi as the Representative Plaintiff on behalf of the proposed Class;

(d) A Declaration that the Defendants owed a duty of care to the Plaintiff~~s~~ and the Class Members with respect to their research, development, pre-market testing, manufacturing, distribution and sale of the Sorin 3T

System and representations to Health Canada and medical practitioners regarding the use of the Sorin 3T System (also referred to herein as an "HCU");

(e) A Declaration that the Defendants owed a duty of care to the Plaintiffs and the Class Members with respect to the post-market monitoring and surveillance of the functionality of the HCU;

(f) A Declaration that the Defendants breached their duty of care to the Plaintiffs and the Class Members with respect to their research, development, pre-market testing, manufacturing and representations to regulators and medical practitioners regarding the HCU because the use of the HCU during surgery exposed the Patient Class to NTM;

(g) A Declaration that the Defendants breached their duty of care to the Plaintiffs and the Class Members with respect to the post-market monitoring and surveillance of the functionality of the HCU, because the defendants knew or ought to have known that the use of the HCU during surgery exposed the Patient Class to NTM;

(h) A Declaration that the Defendants owed a duty to warn the Plaintiffs, the Class, Health Canada and medical practitioners of any known dangers associated with the ordinary use of the HCU, and of any identified change in the functionality of the HCU or risks in using the HCU;

(I) A Declaration that the Defendants breached their duty to warm the Plaintiffs, the Class, Health Canada and medical practitioners by failing to warn that the use of the HCU during surgery exposed the Patient Class to NTM;

(j) A Declaration that the Defendants breached their duty to warn the Plaintiffs, the Class, Health Canada and medical practitioners by failing to

issue a further warning when they knew or ought to have known that the use of the HCU during surgery exposed the Patient Class to NTM;

(k) A Declaration that the Defendants breached their duty of care to the Plaintiffs and Class Members by failing to promptly recall the HCUs after the Defendants discovered that the use of the HCU during surgery exposed the Patient Class to NTM;

(l) An Order that the Defendants pay the cost of all Ontario Health Insurance Plan (OHIP) subrogated claims and all other provincial health care subrogated claims related to the testing for and treatment of NTM and all resulting medical treatments or testing of the Plaintiff and the Patient Class;

(m) The costs of providing Notice of Certification of this action as a Class Proceeding to the Class, and the costs of distributing the proceeds of any Judgment to all Class Members;

(n) Pre-judgment interest in accordance with the provisions of Section 128 of the *Courts of Justice Act,* R.S.O. 1990, s. C.43, as amended;

(o) Post-Judgment interest in accordance with the provisions of Section 129 of the *Courts of Justice Act,* R.S.O. 1990, s. C.43, as amended;

(p) Costs of this action on a substantial indemnity basis with applicable HST;

(q) Such further and other relief as this Honourable Court deems just and proper.

On behalf of Bruno Nardi and the Patient Class:

(r) Non-pecuniary damages in the amount of $250,000,000.00 to be assessed either in the aggregate or individually for each Patient Class Member;

(s) Special damages in the amount of $250,000,000.00, including out-of-pocket expenses, lost income, and impairment of future earning capacity in an amount to be assessed either in the aggregate or individually for each Patient Class Member;

(t) Special damages for the cost of past and future health services, including such insured health services as are provided by the Ontario Health Insurance Plan and all other provincial health care subrogated claims related to the testing for and treatment of NTM and all resulting medical treatments or testing of the Plaintiff and the Patient Class;

(u) Punitive, aggravated and exemplary damages in the amount of $250,000,000.00;

(v) An Order directing a reference, or as otherwise directed by the common issues trial judge for the assessment of the damages and special damages suffered by the Patient Class Members, if required;

(w) The future cost of monitoring those Members of the Class who are still in the bacterial latency period and remain at risk further to the alleged bacterial exposure.

On behalf of the *FLA* Class:

(x) Non-pecuniary damages for loss of care, guidance and companionship, including damages for wrongful death of the Patient Class Members who have died as a result of the failure of the HCU, in the amount of $250,000.00 per Patient Class Member or such other amount as fixed by the Court, and special damages in an amount to be assessed pursuant to Section 61 of the *Family Law Act*, R.S.O. 1990 c. f.3 s.61 and similar legislation in other provinces, where applicable, in an amount to be assessed in the aggregate or individually for each *FLA* Member; and,

(y) An Order directing a reference for the assessment of the special damages suffered by the *FLA* Class Members, if required.

REPRESENTATIVE PLAINTIFF

2. Bruno Nardi ("Bruno") is an individual who resides in the Town of Markham, in the Province of Ontario. Bruno brings this action on his own behalf and on behalf of the Patient Class and FLA Class.

3. Bruno underwent a quintuple bypass surgery at Southlake Regional Health Centre in Newmarket, Ontario on November 28, 2014.

4. Bruno received a letter from Southlake Regional Health Centre dated April 24, 2017 indicating that he is among a group of patients who underwent heart surgery using the HCU. This was described in the letter as, "a device used to heat and cool the blood during open heart surgery...". The letter indicates that the use of this HCU has been linked to a rare bacterial infection caused by Mycobacterium Chimaera, a type of bacteria known as non-tuberculosis mycobacterium (NTM). The letter advises that many hospitals across the country as well as in the United States and Europe, use the HCU during open heart surgeries and they are experiencing the same concerns.

5. Bruno is aware of the risks and responsibility associated with acting as the representative of the proposed Class. He has no interest adverse or different than any other putative Class Member.

CLASS MEMBERS

6. This action is brought on behalf of (a) All persons in Ontario and elsewhere in Canada, ~~except Quebec~~, who underwent surgery during which the Sorin 3T Heater-Cooler System (the Sorin 3T System) was used, excluding all persons who were subject to open heart cardiac surgery at the Institut de cardiologie de Montreal after January 1,

2012, (the "Patient Class") ~~and were exposed to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium ("NTM")~~ during the period between January 1, 2010 and the date of certification of this action as a class proceeding (the "Class Period"); and (b) all dependents of Members of the Patient Class as defined by Section 61 of the *Family Law Act* R.S.O. 1990 s.F.3 s.61 and similar legislation in other provinces as listed in ~~Schedule "A"~~ paragraph 71 where applicable (the *FLA* Class).

THE DEFENDANTS

~~7. The Defendant, LivaNova PLC, (hereinafter referred to as "LivaNova"), is a foreign company domiciled in England, and principally located at 20 Eastbourne Terrace, London, England W2 6LG.~~

~~8. The Defendant, Sorin Group USA, Inc., (hereinafter referred to as "Sorin Group"), is a foreign company domiciled in Delaware, and principally located at 14401 West 65th Way, Arvada, Colorado.~~

7. The Defendant, Sorin Group Deutschland GMBH (SGD) is a foreign corporation organized under the laws of Germany with its principal place of business at Lindberghstrasses 25, D-80939, Munich, Germany.

8. The Defendant, LivaNova Canada Corp., (LivaNova Canada) is a domestic corporation with its head office in Halifax, Nova Scotia, and with its principal place of business in Ontario located at 280 Hillmount Road, Suite #8, Markham.

9. The Defendant~~s~~ LivaNova Canada and SGD are hereinafter referred to as "LivaNova".

10. The Defendants are engaged in the common enterprise business of research, developing, designing, licensing, manufacturing, distributing, supplying, selling and marketing, either directly or indirectly through third parties or related entities, its medical devices and products, including the Sorin 3T Heater-Cooler System.

EVIDENTIARY BASIS FOR THE CLAIM

11. The Plaintiff and the Class Members were exposed to non-tuberculous mycobacterium through a Sorin 3T Heater-Cooler System (the "Sorin 3T System"), manufactured by SGD and sold to hospitals by LivaNova Canada, which was used to regulate their blood temperature during open chest surgeries when the heart is stopped and regulation of blood flow is required. The medical device uses a closed-water circuit to regulate the temperature of equipment that keeps the patient at an optimal temperature.

12. The Sorin 3T System is a medical device regulated in Canada pursuant to the *Medical Devices Regulation*, SOR/98-282, which is a Regulation to the *Food and Drugs Act*, RSC 1985, c F-27.

13. The Sorin 3T System used during the Plaintiff's surgery regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. As the water passes through the water tanks and other areas it is aerosolized into a vapor ~~containing NTM~~ which exits from the device and is pushed into the ambient air of the operating room through the System's exhaust fan. When placed in an operating room, the ~~contaminated~~ vapor from the System directly enters the sterile surgical field and the patient's open body through their open surgical site.

14. The Defendants were responsible for the research, development, pre-market testing, ~~and~~ manufacturing, distribution and sale of the Sorin 3T System.

15. The Defendants were responsible for making representations to Canadian and foreign regulators with respect to the design, manufacturing, use and safety of the Sorin 3T System.

16. The Defendants were responsible for conducting post-market monitoring and surveillance of the Sorin 3T System.

17. The claim pertains to the Defendants' negligent research, development, pre-market testing, manufacturing, representation to regulators and medical practitioners, post-market monitoring and surveillance, as well as the negligent failure to give timely warning and recall of the HCU when the defendants knew or ought to have known that use of the HCU during surgery exposed the Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium ("NTM").

18. SGD was negligent in manufacturing of the HCUs sold in Canada during the Class Period. In particular, during the manufacture of the HCUs the equipment was infected with NTM, specifically M. Chimaera and M. Abscessus, as particularized below.

19. Long before the Plaintiff Bruno Nardi underwent his surgery in November 2014, the Defendants knew or should have known of the unreasonable and potentially lethal safety risks associated with their 3T System, but failed to provide any warning to the Canadian users of the HCUs.

20. According to the Medical Journal, The Lancet[1], since 2013, over 100 cases of Mycobacterium chimaera prosthetic valve endocarditis and disseminated disease were ~~notified~~identified in Europe and the USA, linked to contaminated heater–cooler units (HCUs) used during cardiac surgery. The authors concluded that HCU contamination with M chimaera at the ~~LivaNova~~SGD factory seems a likely source for cardiothoracic surgery-related severe M chimaera infections diagnosed in Switzerland, Germany, the Netherlands, the UK, the USA, and Australia.

21. The primary bacteria at issue, inter alia, M. Chimaera and M. Abscessus, are subspecies of Nontuberculous Mycobacterium ("NTM") that occurs naturally in the environment and rarely causes illness. NTM poses a unique risk to patients whose organs and chest

[1] Global outbreak of severe Mycobacterium chimaera disease after cardiac surgery: a molecular epidemiological study, Published online July 12, 2017 http://dx.doi.org/10.1016/S1473-3099(17)30324-9

cavities are directly exposed to the bacteria during surgery. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to five years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease.

22. Symptoms of NTM infection are frequently non-specific and may include any of the following: fever, pain, heat or pus around a surgical incision, wound healing issues, night sweats, joint and muscle pain, weight loss, and fatigue. The diagnosis of an NTM infection requires targeted culturing and/or molecular diagnostic testing. While an NTM infection diagnosed early on may be successfully treated with a series of antibiotics, there is a significant risk of death in cases with delayed diagnoses and/or in individuals with considerably weakened immune systems.

23. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011[2]. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified M. Chimaera contamination in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for M. Chimaera when the units were running, but negative when they were turned off.

24. In April 2011, the FDA visited the ~~Defendant, LivaNova Deutschland GmbH (formerly Sorin Group Deutschland GmbH)~~ SGD in Munchen, Germany for a plant inspection and to discuss safety concerns with several products, including the 3T System. The FDA advised the company that its 3T Systems harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to avoid bacterial infections in patients exposed in the operating room. During this inspection, the FDA advised the company that the bacterial growth charts it used to justify the original

[2] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infectionassociated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed June 5, 2017)

instruction for device disinfection every 14 days allowed bacterial overgrowth well in excess of safe standards in just one and a half days. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no information to support the cleaning methods it disseminated to U.S. purchasers.

25. In January 2014, ~~Sorin~~ LivaNova was made aware of cases of non-tuberculous mycobacteria ("NTM") infections following open heart surgery during which the Sorin 3T Heater-Cooler System ("Sorin 3T") was used.

26. In May 2014, ~~Sorin~~ LivaNova created a task force to mitigate the identified risk of potential NTM infections.

27. In July 2014, ~~Sorin~~ LivaNova's task force confirmed the presence of mycobacteria in the water circuit of devices returned from the field. ~~Sorin~~ LivaNova sent an "Important Information" letter to all Sorin 3T users informing them about the risk and reminding them of the importance of performing the water disinfection procedures according to the manufacturer's instructions.

28. In May 2015, ~~Sorin~~ LivaNova offered a deep disinfection service for contaminated devices at their Munich facilities.

29. In June 2015, ~~Sorin~~ LivaNova sent a Field Safety Notice to all Sorin 3T users and regulatory authorities about the risk of infection. The notice included new instructions for use and for cleaning and disinfection.

30. On July 15, 2015, the Defendants issued a Class 2 Recall of the 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

31. On October 21, 2015, following an NTM outbreak in Pennsylvania, the U.S. Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication to raise awareness among health departments, healthcare facilities and

providers of the association between NTM infections and the use of heater-cooler devices.

32. On December 29, 2015, the FDA sent LivaNova a warning letter advising the company that its 3T Systems were subject to refusal of admission into the U.S. until it resolved several FDA violations, including the FDA's determination that the 3T Systems were adulterated and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions. The FDA's findings were based on its inspections of the company's Munchen, Germany and Arvada, Colorado production facilities. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been documented, validated and/or submitted to the FDA for approval. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

33. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain 3T Systems manufactured at LivaNova's Munich, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

34. A June 1, 2016 FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the M. Chimaera to which European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model - the 3T." The FDA cautioned U.S. purchasers of the 3T that if they purchased their units before September 2014, they may have been shipped from Defendants' factory contaminated with M. Chimaera.[3]

[3] June 1, 2016 FDA Safety Communication, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm (last accessed on June 5, 2017).

35. In June 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via 3T Systems due to the ability of the System's exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study, aerosolization from the 3T carried M. Chimaera particles a distance of up to five (5) meters from the device.

36. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the 3T System. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports (MDR) it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the 3T System. During this Panel, a LivaNova representative admitted that the company was in the process of retrofitting existing 3T Systems with new design features, including, *inter alia*, changing tubing materials from PVC to polyethylene to limit biofilm formation and introducing plugs in the water circuit to prevent standing water.

37. On October 13, 2016, the CDC released the results of genome sequencing studies confirming that patient infections in Pennsylvania and Iowa shared an "identical fingerprint" and were directly linked to Defendants' Munich, Germany manufacturing site.[4]

38. On October 13, 2016, the FDA issued an updated Safety Communication instructing hospitals throughout the United States to discontinue using 3T Systems manufactured before September 2014 because of evidence of "point source contamination at the production site."[5]

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[4] See CDC Morbidity and Mortality Weekly Report for October 14, 2016, available online at https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid'mm6540a6_w (last accessed on June 5, 2017).

[5] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infectionassociated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed on June 5, 2017).

39. On October 21, 2016, Health Canada issued an Alert titled “Heater-Cooler Devices - Risk of Nontuberculous Mycobacteria Infections” in which it warned that:

(a) There are international reports of nontuberculous mycobacteria (NTM) infections associated with heater-cooler devices used in cardiothoracic surgery; a small number of possible Canadian cases are under investigation.

(b) The infection could result from the transfer via aerosolization of NTM-contaminated water contained in the heater-cooler devices into the operating room and into patients during surgery.

(c) NTM infections potentially associated with heater-cooler devices have been diagnosed months to years after cardiothoracic surgery.

(d) Healthcare professionals should consider testing for NTM in ill patients with signs of infection who have a history of cardiothoracic surgery.

(e) At this time, Health Canada is reminding healthcare facilities to strictly follow the cleaning and disinfection procedures recommended by the manufacturers of the devices.

(f) Health Canada is working with heater-cooler device manufacturers to determine additional measures to further mitigate the risk of NTM infections.

40. On February 17, 2017, Health Canada issued a further Alert titled “LivaNova Stöckert 3T Heater-Cooler Device - Risk of Mycobacterium chimaera Infections” in which it warned that:

(a) Stöckert 3T heater-cooler devices (3T HCDs) manufactured by LivaNova prior to September 2014 are at an increased risk of contamination with Mycobacterium chimaera, a type of nontuberculous mycobacterium, and should be removed from service.

(b) If it is not possible to remove these devices from service, facilities should consider interim risk mitigation measures, such as positioning the device as far as possible from the surgical field or sending the devices to the manufacturer for deep disinfection.

(c) To date, cases of M. chimaera infection in Canada and internationally have been reported only with 3T HCDs manufactured by LivaNova before September 2014. Health Canada is not aware of any cases of M. chimaera infection with 3T HCDs manufactured after this date.

(d) The currently available testing methods to detect M. chimaera in water samples collected from HCDs are not reliable. The benefit of routine testing has not been established at this time.

(e) The cleaning and disinfection procedures recommended by LivaNova should be strictly followed for all 3T HCDs.

CAUSES OF ACTION

41. The Plaintiff and Class Members plead and rely upon the following causes of action:

(a) Negligent breach of duty to properly design and manufacture the HCU;

(b) Negligent breach of duty to warn;

(c) Negligent breach of duty to withdraw the HCU from use in Canada;

(d) Breach of Statutory Regulation(s);

(d) Waiver of Tort.

42. The Defendants were negligent because they knew or should have known that the design and/or manufacturing defects in their Sorin 3T System caused bacterial colonization to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death.

43. The Defendants were negligent in their research, development, pre-market testing, manufacturing, representations to regulators, post-market monitoring and surveillance, warning and failure to recall the HCU because the HCU was manufactured by the Defendants in a manner that allowed for, permitted and/or failed to prevent point source contamination at the Defendants' production site. The Defendants knew or ought reasonably to have known that the HCU was contaminated with Mycobacterium chimaera, leaving the Patient Class vulnerable to exposure to bacterial infection, injury and death as a direct result of this negligence.

44. Additionally, the Defendants knew or should have known of proper disinfectant and sterilization procedures to clean the Sorin 3T System to prevent the colonization and spreading of NTM bacteria.

45. Once the Defendants knew of the dangerous and life-threatening defect in the HCU, they failed to warn Health Canada, medical practitioners, the Plaintiffs and the Class of the defect, failed to recall the HCU and continued to sell their existing stock of HCUs into the stream of commerce, callously putting the Patient Class at risk of infection, serious and permanent injury or death.

46. There have, in fact, been deaths associated with the use of HCUs in cardiac care surgeries with resulting infection caused as a result of the use of the HCU.

47. The Defendants were negligent in their research, development, pre-market testing, manufacturing, representations to regulators, post-market monitoring and surveillance, warning and failure to recall the HCU. Particulars of their negligence include failure:

(a) to properly design, develop, test, manufacture, licence, assemble and distribute the HCU;

(b) to ensure the HCU was safe and free from defects prior to its distribution;

(c) to ensure that the HCU was fit for its intended or reasonably foreseeable use;

(d) not to use inappropriate materials and processes to manufacture the HCU;

(e) to properly train their employees who were responsible for the design, testing, assembly and manufacturing of the HCU;

(f) to properly supervise their employees and consultants;

(g) to conduct adequate tests and clinical trials to determine the degree of risk associated with using the HCU prior to their manufacture, assembly and distribution;

(h) to monitor, investigate, evaluate and follow up on adverse reactions to the use of the HCU throughout the world;

(I) to warn the Plaintiff and Patient Class that the use of the HCU during surgery exposed the Plaintiff and Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium;

(j) to ensure that physicians and surgeons were kept fully and completely informed of all risks associated with using the HCU, including the risk of exposing the Plaintiff and Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium;

(k) to conduct ongoing clinical trials with long term follow up to determine the long term effects and risks of continued use of the HCU;

(l) to fix the defects in the HCU as soon as possible after they became aware of the defects and the injuries and risks associated with their use; and,

(m) to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage during the use of the HCU.

48. The Defendants owed to the Plaintiff and the class a duty of care:

(a) to properly design, develop, test, manufacture, licence, assemble and distribute the HCU;

(b) to ensure the HCU was safe and free from defects prior to its distribution;

(c) to ensure that the HCU was fit for its intended or reasonably foreseeable use;

(d) not to use inappropriate materials and processes to manufacture the HCU;

(e) to properly train their employees who were responsible for the design, testing, assembly and manufacturing of the HCU;

(f) to properly supervise their employees and consultants;

(g) to conduct adequate tests and clinical trials to determine the degree of risk associated with using the HCU prior to their manufacture, assembly and distribution;

(h) to monitor, investigate, evaluate and follow up on adverse reactions to the use of the HCU throughout the world;

(I) to warn the Plaintiff and Patient Class that the use of the HCU during surgery exposed the Plaintiff and Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium;

(j) to ensure that physicians and surgeons were kept fully and completely informed of all risks associated with using the HCU, including the risk of exposing the Plaintiff and Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium;

(k) to conduct ongoing clinical trials with long term follow up to determine the long term effects and risks of continued use of the HCU;

(l) to fix the defects in the HCU as soon as possible after they became aware of the defects and the injuries and risks associated with their use; and,

(m) to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage during the use of the HCU.

49. The Defendants breached their duty of care to the Plaintiff and the Patient Class with respect to the design of the HCU as follows:

(a) they improperly designed the HCU, which allowed for, permitted and/or failed to prevent point source contamination at the Defendants' production site;

(b) they failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine whether the design of the HCU was defective, thereby increasing the risks of injury and harm associated with the use of the HCU;

(c) they were aware or ought to have been aware that the HCU was unfit and defective and ought not to have been introduced into the marketplace;

(d) they failed to provide proper long term investigations of the effects and risks of continued use of the HCU; and

(e) they failed to fix the defects in the HCU or to withdraw the HCU from the marketplace as soon as possible after they became aware of the defects and the injuries and risks associated with the use of the HCU.

50. The Defendants breached their duty of care to the Plaintiff and the Patient Class with respect to the manufacturing and assembly of the HCU as follows:

(a) they improperly manufactured and assembled the HCU, which allowed for, permitted and/or failed to prevent point source contamination at the Defendants' production site;

(b) they failed to assemble and manufacture the HCU so they would operate safely and effectively without exposing their consumers to undue risks;

(c) they used inappropriate materials or processes to manufacture the HCU;

(d) they failed to properly train their employees who were responsible for the assembly and manufacturing of the HCU; and

(e) they failed to properly supervise their employees and consultants involved in the assembly and manufacture of the HCU.

51. The Defendants breached their duty of care to the Plaintiff and the Patient Class with respect to their duty to warn of the defects in the design, manufacturing and assembly of the HCU as follows:

(a) they failed to ensure that the HCU was safe and free from defects prior to selling or distributing it;

(b) they failed to ensure that the HCU was fit for its intended or reasonably foreseeable use prior to marketing, distributing and selling it;

(c) they were aware or ought to have been aware that the HCU was unfit and defective and ought not to have been introduced into the marketplace;

(d) they marketed, distributed and sold the HCU without adequately disclosing the risks associated with using the HCU;

(e) they failed to give Health Canada complete and accurate information concerning the HCU by failing to disclose the problems with the HCU on a timely basis or at all;

(f) they failed to adequately warn the Plaintiff, the Patient Class and their physicians and surgeons of the risks then known or which were reasonably foreseeable in using the HCU;

(h) with full knowledge that the HCU posed significant risk of exposing the Plaintiff and Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium, they failed to warn the Plaintiff and the Patient

Class and instead continued to sell, market and distribute the HCU throughout Canada and the world;

(l) they failed to warn the Plaintiff, the Patient Class and their physicians and surgeons about the need to properly and appropriately clean the HCU to avoid bacterial infections in patients exposed in the operating room;

(j) they failed to adequately monitor, evaluate and act promptly upon adverse reactions and high contamination rates in the HCU in Canada and throughout the world;

(k) they failed to undertake comprehensive regular monitoring to ensure early discovery of complications from the use of the HCU;

(l) they failed to establish any adequate procedures to educate their sales representatives respecting the risks associated with the HCU; and

(m) they failed to provide clear and proper instructions to physicians and surgeons, including precautions to be taken, so as to avoid injury or damage from the expected use of the HCU.

52. The defects and risks associated with the HCU were in the Defendants' exclusive knowledge and control. The extent of the defects and risks was not known and could not have been known to the Plaintiff or the Patient Class. The injuries of the Plaintiff and the Patient Class would not have occurred but for the negligence of the Defendants in failing to ensure that the HCU was safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with the HCU to the Plaintiff, the Patient Class and to their physicians and surgeons.

53. The Plaintiff pleads and relies upon the following statutes and regulations which were breached by the Defendants:

(a) *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 20(1); and

(b) the *Medical Devices Regulations*, SOR/98-282, s. 9, 10-13, 15-18, 59- 61.1 and 64-65.1

54. The Defendants' common law duties are informed by the *Medical Devices Regulations*, SOR/98-282. Pursuant to those regulations, each of the Defendants is a "manufacturer". They designed and assembled the HCU, attached their trade name to it, labeled it and assigned it a purpose.

55. The regulations impose continuous obligations on the Defendants, commencing at licensing and continuing thereafter. They require the Defendants to ensure the safety of the HCU before selling it, and to continuously monitor the safety of the HCU thereafter, monitoring any complaints from doctors, hospitals and patients, keeping up with any new developments in the scientific literature, conducting further testing as necessary, and promptly taking corrective actions, including issuing a warning or recall, if new information becomes available which later alters the medical device's risk profile.

56. Pursuant to s. 9 of the *Medical Devices Regulations*, the Defendants were required to maintain objective evidence to establish the safety of the HCU. The Defendants breached this section. They failed to adequately obtain such information before licencing and they failed to promptly update such information thereafter.

57. Pursuant to s. 10 of the *Medical Devices Regulations*, the Defendants were required to identify the risks associated with the intended use of the HCU, to eliminate or reduce those risks if possible, and to provide safety information with the HCU concerning those risks which remained. The Defendants breached this section. They failed to eliminate the significant risk that the intended use of the HCU exposed the Plaintiff and Patient Class to invasive cardiovascular infections identified as NTM, specifically M. Chimaera and M. Abscessus, which are subspecies of Nontuberculous Mycobacterium.

58. Pursuant to s. 11 of the *Medical Devices Regulations*, the Defendants were required to assess the risks of the HCU against its benefits, and to not sell a medical device whose risks outweigh its benefits. The Defendants breached this section. The risk of the HCU outweighed its benefits.

59. Pursuant to s. 12 of the *Medical Devices Regulations*, the Defendants were required to ensure that the HCU was effective for the uses for which it was represented. The Defendants breached this section. The Product was not effective.

60. The Plaintiff and Class Members are entitled to waive the tort and require the Defendants to account for all the revenue they received from the sale of the HCU medical device in Canada during the Class Period.

61. The Plaintiff and Class Members plead that waiver of tort may be appropriate for the following reasons, among others:

(a) Such revenue was acquired in such circumstances that the Defendants cannot in good conscience retain it:

(b) The integrity of the medical device regulations and marketplace would be undermined if the court did not require an accounting:

(c) The Defendants' HCU could not have been marketed, and the Defendants would not have received any revenue from its sale in Canada, absent the Defendants' egregious and negligent conduct;

(d) The Defendants engaged in wrongful conduct by putting into the marketplace a medical device which causes or has the potential to cause increased risks of injury and death; and

(e) The Defendants would be unjustly enriched if they were permitted to retain revenues realized from the sale of the HCU device.

62. The Defendants voluntarily accepted and retained profits and benefits, derived from the sale of the HCU, with full knowledge and awareness that as a result of the Defendants' conscious and intentional wrongdoings, the Plaintiff and putative Class Members were exposed to NTM during open chest surgery.

~~61. By virtue of the conscious wrongdoings alleged, the Defendants have been unjustly enriched at the expense of harm to the Plaintiff and other Class Members.~~

~~62. There is no juristic reason for the Defendants' enrichment.~~

DAMAGES

63. NTM poses a unique risk to patients whose organs and chest cavities are directly exposed to the bacteria during surgery. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to five years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease.

64. Symptoms of NTM infection are frequently non-specific and may include any of the following:

(a) fever;

(b) pain;

(c) heat or pus around a surgical incision;

(d) wound healing issues;

(e) night sweats;

(f) joint and muscle pain;

(g) weight loss;

(h) fatigue.

65. The diagnosis of an NTM infection requires targeted culturing and/or molecular diagnostic testing. While an NTM infection diagnosed early on may be successfully

treated with a series of antibiotics, there is a significant risk of death in cases with delayed diagnoses and/or in individuals with considerably weakened immune systems.

66. The Plaintiff and Class Members have been exposed to NTM as a direct result of the Defendants' negligence, breach of duty and breach of regulatory duty. They must all now undergo rigorous and invasive testing and monitoring.

67. The Plaintiff and the Class Members have suffered and will continue to suffer damages as a direct result of the Defendants' negligence including, but not limited to:

(a) enduring or having to endure painful medical procedures to test for NTM infection;

(b) enduring or having to endure painful medical procedures to treat NTM infection;

(c) for those infected with NTM, personal injury, pain, inflammation, swelling, scarring, weight loss, fatigue, and other adverse effects and complications associated with NTM;

(d) severe emotional distress related to the pain and suffering associated with exposure to and/or infection by NTM;

(e) psychological injury and illness;

68. The Plaintiff and the Class members have suffered and will continue to suffer damages as a direct result of the Defendants' negligence including, but not limited to, damages for personal injuries, mental anguish, pain and suffering, loss of employment income and benefits, loss of enjoyment of life, possibly death, and special damages and expenses.

69. Members of the Class who do not actually contract NTM will nonetheless suffer damages from the cost of additional monitoring including but not limited to frequent physician visits, blood tests, diagnostic imaging and will suffer psychiatric and psychological injuries as well.

70. The Plaintiff and the Class Members have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring and/or medications.

71. The Plaintiff and Class Members plead and rely upon the following statutes:

(a) *Family Law Act*, R.S.O. 1990, c. F.3, s. 61;

(b) *The Fatal Accidents Act*, C.C.S.M. c. F50, ss.3(2), 3.1(2);

(c) *Fatal Accidents Act*, R.S.S. 1978, c.F-11, s.4.1(2);

(d) *Fatal Accidents Act*, R. S.A. 2000, c F-8, s. 8(2);

(e) *British Columbia Family Compensation Act*, R.S.B.C. 1996, c. 126;

(f) *Fatal Accidents Act*, R.S.N.L. 1990, c.F-6, s.6;

(g) *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, s.5;

(h) *Fatal Accidents Act*, R.S.P.E.I. 1988, c.F-5, s. 6(3);

(I) *Fatal Accidents Act*, S.N.B. 2012, c 104, s. 10.

72. As a result of the Defendants' actions, the FLA Class Members have suffered damages recoverable pursuant the statutes referred to above, where applicable, including:

(a) loss of care, guidance and companionship;

(b) provision of nursing and housekeeping services to affected family members; and,

(c) out-of-pocket expenses, including travel, parking and telephone expenses, loss of present and future income and funeral expenses.

73. The Plaintiff and Class Members claim punitive, aggravated and exemplary damages as a result of the egregious, outrageous and unlawful conduct of the Defendants and, in particular, their callous disregard for the health and lives of vulnerable patients in Canada. In particular, the Defendants' conduct in continuing to manufacture and/or

market, sell and distribute the HCU after obtaining knowledge that the HCU devices had been subject to point source contamination at the Defendants' production site. This information was known or ought to have been known by the Defendants months or years before the Plaintiff and Patient Class Members underwent open-chest surgery during which the contaminated HCU devices were used. This failure to act showed a complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages in a sum which will serve to deter the Defendants from similar conduct in the future.

74. The Plaintiff and Class Members have a claim for the recovery of health care costs incurred by provincial health ministries on their behalf. The Plaintiff pleads the *Health Insurance Act*, R.S.O. 1990, c. 11-6, and comparable legislation in other provinces.

REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

75. The Plaintiffs plead that this action has a real and substantial connection with Ontario because, among other things:

(a) the Defendants distribute and sell their products in Ontario and derive substantial revenue from such sales;

(b) the application to Health Canada for permission to market the HCU in Canada was made in Ottawa, Ontario;

(c) the Defendants hold the licence to patents for the HCU which patents are registered with the Canadian Intellectual Property Office in Ottawa;

(d) the trademarks for the HCU were registered with the Canadian Intellectual Property Office in Ottawa;

(e) the Defendants advertised their products, including the HCU, in Ontario;

(f) the tort was committed in the province;

(g) the Plaintiffs and other Patient Class Members underwent surgery in Ontario during which the HCU was used, and sustained consequent damages in Ontario; and

(h) the Defendants, are necessary and proper parties to the action.

76. The Plaintiff pleads and relies upon the following health care statutes with respect to those subrogated claims of Class members:

(a) *Health Insurance Act*, R.S.O. 1990, c. 11-6;

(b) *Health Care Cost Recovery Act*, S.B.C. 2008, c.27

(c) *Alberta Health Care Insurance Act*, R.S.A. 200, c.A-20;

(d) *Hospitals Act*, R.S.A. 2000, c. 11;

(e) *Department of Health Act*, R.S.S. 1978, D-17;

(f) *Health Services Insurance Act*, C.C.S.M., C.1135;

(g) *Hospital Services Act*, R.S.N.B. 1973, c.11-9;

(h) *Health Services and Insurance Act*, R.S.N.S. 1989, c.197;

(I) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;

(j) *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7;

(k) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c.T-3; and

(l) *Hospital Insurance Services Act*, R.S.Y. 2002, c.112.

SERVICE OUTSIDE ONTARIO

77. The Plaintiffs plead and rely on s. 17.02(g), (h), (o) and (p) of the *Rules of Civil Procedure* permitting service outside Ontario in respect of the foreign Defendants.

78. This originating process may be served without court order outside Ontario in that the claim is:

(a) In respect of a tort committed in Ontario (Rule 17.02(g));

(b) In respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (Rule 17.02(h));

(c) In respect of property in Ontario (Rule 17.02 (a));

(d) Against a person outside Ontario who is a necessary or proper party to a proceeding properly brought against another person served in Ontario (Rule 17.02 (o)); and

(e) Against a person carrying on, business in Ontario (Rule 17.02 (p)).

GENERAL

79. ~~The Plaintiff and Class Members plead that.~~ By virtue of the acts described herein, each of the defendants is vicariously liable for the act and omissions of the other~~s~~ for the following reasons:

(a) Each was the agent of the other;

(b) Each defendant's business was operated so that it was inextricably interwoven with the business of the other;

(c) Each defendant entered into a common advertising and business plan with the other to distribute and sell the HCU device;

(d) Each defendant operated pursuant to a common business plan to distribute and sell the HCU device;

(e) Each defendant intended that the businesses be run as one business organization or common enterprise; and

(f) ~~All or some of the~~The defendants are related, associated or affiliated.

80. The Plaintiffs and Class Members individually lacked the information, knowledge or ability to determine that they had been exposed to NTM ~~through~~ as a result of the

regular and intended use of the Defendants' HCU device. This information only became known to the Plaintiff and each putative Class Member when they were informed by the hospital where they underwent surgery that, in the course of their surgery, the Defendant's HCU device exposed them to NTM. As such, the Plaintiff and putative Class Members were unable to commence the herein action before this time.

81. Relative to any applicable limitations statutes or any applicable common law limitation periods, the Plaintiff ~~and putative Class Members~~ pleads and relies on the doctrine of discoverability.

82. The Plaintiff ~~and putative Class Members~~ pleads and relies upon the following:

(a) the *Class Proceedings Act, 1992,* S.O. 1992, c.6, as amended;

(b) the *Courts of Justice Act*, R.S.O. 1990, c.43:

(c) the Ontario *Rules of Civil Procedure*;

(d) the *Consumer Protection Act*, 2002 S.0. 2002, c.30, Sched. A;

(e) *Family Law Act*, R.S.0. 1990, c. F.3;

(f) *Health Insurance Act*, R.S.0.1990, c. 11.6;

(g) *Negligence Act*, R.S.0. 1990, c. N.1;

(h) *Sale of Goods Act*, R.S.0. 1990, c. S.l;

(l) *Trustee Act*, R.S.0. 1990; c. T.23

PLACE OF TRIAL

83. The Plaintiff proposes that the trial in this action take place in the City of Toronto, in the Province of Ontario.

Date of Issue:

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