Court File No. 16-69039CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

A. DRIESSEN

Plaintiff

- and -

3M CANADA COMPANY, **3M COMPANY**, AND **ARIZANT HEALTHCARE INC.**

Defendants

Proceeding under the Class Proceedings Act, 1992

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.

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: June 21, 2016

Issued by _____
Local Registrar

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DEFINED TERMS

1. In this Statement of Claim, in addition to the terms that are defined elsewhere herein, the following terms have the following meanings:

(a) "**Forced-Air Warming**" and/or "**Forced-Air Warming Device**" means a convective temperature management system used to maintain a patient's core body temperature before, during, and after surgery to prevent hypothermia and its associated complications including **Surgical Site Infections**, increased hospital length of stay, and higher mortality rates;

(b) The "**3M Bair Hugger Forced-Air Warming Device**", the "**Bair Hugger**", and/or the "**Bair Hugger System**" means the **Forced-Air Warming Device** which is researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold by the **Defendants** and which consists of single-use disposable warming blankets through which warm air is circulated by a reusable warming unit;

(c) "**Design Defect**" means the propensity of the internal air flows of the **3M Bair Hugger Forced-Air Warming Device** to become contaminated with bacteria, fungi, and pathogens which proliferate and incubate and then become expelled onto the patient and into the operating room;

(d) "**Surgical Site Infection(s)**" and/or "**SSI**" means an infection that occurs after surgery in the part of the body where the surgery took place;

(e) "**High-Efficiency Particulate Air Filter(s)**" and/or "**HEPA Filter(s)**" means an air filter that satisfies certain standards of efficiency and which remove, at minimum, 99.97 percent of particles that have a size of 0.3 micrometres[1] from air passing through the filter in order to prevent the spread of airborne bacterial and viral organisms and, therefore, infection;

(f) "**US-FDA**" means the United States Food and Drug Administration;

(g) "**Class**", "**Proposed Class**", and/or **"Class Members**" means all persons residing in Canada who had the **3M Bair Hugger Forced-Air Warming Device** used on them during surgery;

(h) "***Courts of Justice Act***" means the *Ontario Courts of Justice Act*, RSO 1990, c. C-43, as amended;

(i) "***Class Proceedings Act***" means the *Class Proceedings Act*, 1992, SO 1992, c. 6, as amended;

(j) "***Competition Act***" means the *Competition Act*, RSC 1985, c. C-34, as amended;

(k) "***Food and Drugs Act***" means the *Food and Drugs Act*, RSC 1985, c. F-27, as amended;

(l) "***Health Insurance Act***" means the *Health Insurance Act*, RSO 1990, c.11.6, as amended;

[1] The micrometre is represented by the symbol, μm and is commonly known as micron.

(m) "**Defendants**" and/or "**3M**" means 3M Canada Company, 3M Company, and Arizant Healthcare Inc.;

(n) "**Representative Plaintiff**" or "**Plaintiff**" means A. Driessen;

(o) "**Representation**" means the **Defendants'** false, misleading and/or deceptive representations that the Bair Hugger (a) has approval, performance characteristics, uses, benefits and/or qualities which it did not possess, (b) is of a particular standard and/or quality that it is not, (c) is available for a reason that does not exist, and the **Defendants'** (d) use of exaggeration, innuendo and/or ambiguity regarding its safety as well as (e) use of exaggeration, innuendo and ambiguity in failing to disclose that the Bair Hugger had **Dangerous Complications** despite the wealth of existing knowledge; and

(p) "**Dangerous Complications**" means the severe and life-threatening complications, including the risk of serious infection, severe deep joint infection, implant revision surgery, Methicillin-resistant Staphylococcus aureus (MRSA) [2], sepsis or septic hip/knee [3], permanent disability, amputation, death, physical pain and mental anguish, including diminished enjoyment of life, physical impairment and/or disfigurement, as well as the need for lifelong medical treatment, monitoring and/or medications.

[2] Methicillin-resistant Staphylococcus aureus (MRSA) infection is caused by a type of staph bacteria that's become resistant to many of the antibiotics used to treat ordinary staph infections.
[3] Sepsis is the presence in tissues of harmful bacteria and their toxins, typically through infection of a wound.

THE CLAIM

2. The proposed Representative Plaintiff, A. Driessen, claims on his own behalf and on behalf of the members of the Class of persons as defined in paragraphs 4 below (the "Class") as against 3M Canada Company, 3M Company, and Arizant Healthcare Inc. (the "Defendants"):

(a) An order pursuant to the *Class Proceedings Act* certifying this action as a class proceeding and appointing him as Representative Plaintiff for the Class Members;

(b) A declaration that the Defendants are strictly liable for all of the damages suffered by the Class Members;

(c) A declaration that the Defendants were negligent in the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger System;

(d) A declaration that the Defendants breached their express and/or implied warranties relating to their representation regarding the Bair Hugger System's safety, fitness, and merchantability for its intended uses/purposes, its Dangerous Complications and the adequacy of its testing;

(e) A declaration that the Defendants breached their duty to warn the Plaintiff and Class Members of the Dangerous Complications associated with the Bair Hugger System;

(f) A declaration that the Defendants committed a fraudulent and/or negligent misrepresentation when they represented to the medical and health community, to Health Canada, to the Plaintiff, to the Class Members, and to the public in general that the Bair Hugger System had been tested and found to be safe and effective during surgery;

(g) A declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives;

(h) A declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives;

(i) A declaration that the Defendants are jointly and severally liable for any and all damages awarded;

(j) General damages in an amount to be assessed individually or in the aggregate for the Class Members;

(k) Special damages in an amount that this Honourable Court deems appropriate, to be calculated individually or in the aggregate;

(l) Punitive damages in an amount that this Honourable Court deems appropriate;

(m) Aggravated damages in an amount that this Honourable Court deems appropriate;

(n) In the alternative to the claim for damages, a restitutionary remedy disgorging the revenues realized by the Defendants from the sales of the Bair Hugger in Canada, such as: (i) an order for an accounting of revenues received by the Defendants and/or (ii) a declaration that any funds received by the Defendants through the sale of all of the Bair Hugger Systems in Canada are held in trust for the benefit of the Plaintiff and Class Members;

(o) Restitution and/or a refund of all monies paid to or received by the Defendants from the sale of all the Bair Hugger Systems in Canada on the basis of unjust enrichment;

(p) In addition, or in the alternative, restitution and/or a refund of all monies paid to or received by the Defendants from the sale of all the Bair Hugger Systems in Canada on the basis of *quantum meruit* and/or *quantum valebat*;

(q) An order compelling the creation of a plan of distribution pursuant to ss. 23, 24, 25 and 26 of the *Class Proceedings Act*;

(r) An interim interlocutory and permanent order restraining the Defendants from continuing any tortious actions, including those taken in contravention of the *Competition Act* and/or the *Food and Drugs Act*;

(s) An order directing a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

(t) Pre-judgment and post-judgment interest on the foregoing sums in the amount of 2% per month, compounded monthly, or alternatively, pursuant to ss. 128 and 129 of the *Courts of Justice Act*;

(u) Costs of notice and administration of the plan of distribution of recovery in this action, plus applicable taxes, pursuant to s. 26 (9) of the *Class Proceedings Act*;

(v) Costs of this action on a substantial indemnity basis including any and all applicable taxes payable thereon; and

(w) Such further and other relief as counsel may advise and/or this Honourable Court may deem just and appropriate in the circumstances.

THE PARTIES

The Representative Plaintiff

3. The Plaintiff, A. Driessen, is an individual residing in the city of Barrhead, in the province of Alberta. On December 9, 2014, Mr. Driessen underwent knee replacement surgery at the Royal Alexandra Hospital at 10240 Kingsway Avenue NW, in Edmonton, Alberta, during which time the Bair Hugger System was used.

The Class

4. The Plaintiff, Mr. Driessen seeks to represent the following class of which he is a member (the "Proposed Class"):

> All persons residing in Canada who had the 3M Bair Hugger Forced-Air Warming Device used on them during surgery.

The Defendants

5. The Defendant, 3M Canada Company ("3M Canada"), is a Canadian corporation with its principal place of business in London, Ontario. 3M Canada is and was at all relevant times involved in the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger System. It is a wholly-owned subsidiary of Defendant 3M Company that does business throughout Canada, including within the province of Ontario.

6. The Defendant, 3M Company, is an American corporation with its principal place of business in St. Paul, Minnesota. 3M Company is and was at all relevant times involved in the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger System. It is the registrant of the trade-mark (design) which was filed on December 14, 1993. In addition, it filed the trade-mark (design) for the Bair Hugger Logo on October 23, 2015, which was formalized on October 23, 2015 and it filed the trade-mark (word) BAIR HUGGER on December 10, 2015, which was formalized on December 10, 2015, but both have not yet been registered.

7. On October 13, 2010, Defendant 3M Company acquired non-party Arizant Inc., which is the parent company of Defendant Arizant Healthcare Inc. and therefore, 3M Company is the parent company of Defendant Arizant Healthcare Inc., which is termed "Arizant Healthcare Inc., a 3M Company".

8. The Defendant, Arizant Healthcare Inc. ("Arizant"), is an American corporation with its principal place of business in Eden Prairie, Minnesota. Arizant a wholly-owned subsidiary of

Defendant 3M Company. It is a manufacturer and developer of patient temperature management systems, including the 3M Bair Hugger Forced-Air Warming Device, which was the first forced-air warming product line. Arizant is and was at all relevant times involved in the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of all the Bair Hugger Forced-Air Warming Device. It is the owner of the patent for "A Forced Air Warming Unit."

9. Given the close ties between the Defendants and considering the preceding, they are all jointly and severally liable for the acts and omissions of the other.

THE NATURE OF THE CLAIM

10. The Defendants are and, have been at all relevant times, engaged in the business of researching, designing, developing, testing, licensing, manufacturing, producing, supplying, marketing, packaging, promoting, advertising, distributing, labelling and/or selling the 3M Bair Hugger Forced-Air Warming Device which is the subject of the present Statement of Claim.

11. As will be elaborated upon hereinbelow, the 3M Bair Hugger Forced-Air Warming Device is a system that is designed to maintain a patient's core body temperature before, during, and after surgery by producing hot air which accumulates under the surgical drape covering the patient to prevent hypothermia and its related medical complications, including infection.

12. Unfortunately, the Bair Hugger System is defective in that the hot air (produced from the device to warm the patient) accumulates under the surgical drape covering the patient and escapes from under it, gathers bacteria, fungi, and pathogens from the floor of the surgical room and then

rises back up to the surgical site (as hot air inevitably will do) depositing them and contaminating the internal airflow paths of the Bair Hugger air blower.

13. To further exacerbate the situation, these pathogens incubate and proliferate in the internal airflow paths of the Bair Hugger System's blowers and then are expelled through the hose into the disposable blanket and escape into the operating room.

14. Therefore, and quite ironically, while the Bair Hugger System is marketed as a device to prevent infection and other medical complications during surgery, it actually does the opposite; actively increasing the risk of infection and other medical complications due to the Design Defect.

15. The Defendants represented to the medical and healthcare community, to Health Canada, to the US-FDA, and to the Class Members that they researched, designed, developed, tested, licensed, manufactured, and produced the Bair Hugger System and that it had been found to be safe and/or effective for its intended use. In addition, the Defendants concealed their knowledge of the Bair Hugger System's defects from the medical and healthcare community, Health Canada, the US-FDA, and from Class Members.

16. Defendants failed to disclose, despite a wealth of longstanding knowledge, that the Bair Hugger System had Dangerous Complications including, severe and life-threatening complications which are sometimes permanent and lasting in nature, including the risk of serious infection, severe deep joint infection, implant revision surgery, permanent disability, amputation, death, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

17. The Defendants continue to license, supply, market, package, promote, advertise, distribute, label and/or sell the Bair Hugger System throughout Canada, including within the province of Ontario, with inadequate warnings as to its serious and adverse side effects.

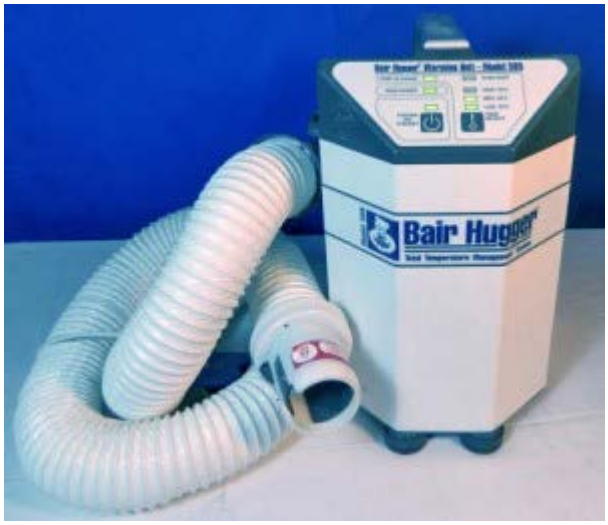
I. Forced-Air Warming Devices – Explained

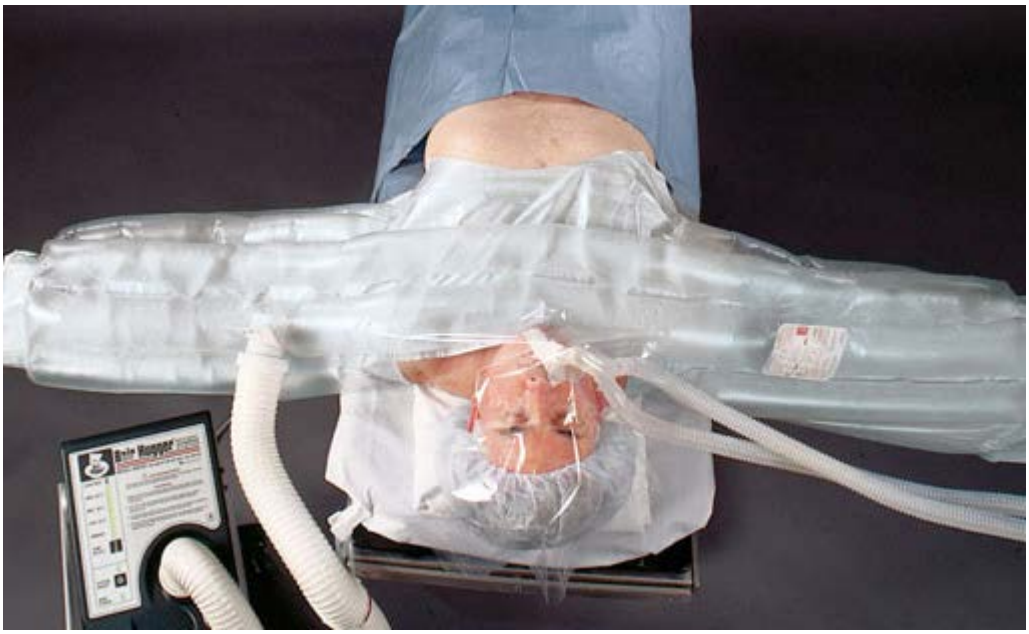
18. Put simply, the idea behind Forced-Air Warming Devices is that anaesthetized patients cannot regulate their own temperature (medically speaking, "anaesthesia-induced thermoregulatory inhibition"). The vast majority of anaesthetics, including opioids, propofol[4], inhalational agents, and spinal/epidural anaesthetics, have been shown to impair the brain's ability to regulate and/or to maintain its temperature. More specifically, the body's physiological response to anaesthesia is to drop its core temperature, placing the patient at risk of hypothermia. Patients, and, in particular, the very young or the elderly, who are exposed to these anaesthetics in combination with a cool operating room are at an increased risk of developing hypothermia.

19. Forced-Air Warming Devices are intended to counter the effects of anaesthesia and prevent hypothermia and its associated post-operative medical complications, including an increased rate of wound infection, increased hospital length of stay, and higher mortality rates.

[4] Propofol, marketed as *inter alia* Diprivan, is a short-acting medication that results in a decreased level of consciousness and lack of memory for events.

II. The 3M Bair Hugger Forced-Air Warming Device





20. As is depicted above, the Bair Hugger consists of a portable heater/blower connected by a flexible hose to a disposable blanket that is positioned over (or in some cases under) surgical patients. The system warms patients during surgery by blowing hot air onto a patient's exposed skin.

21. The 3M Bair Hugger Forced-Air Warming Device was introduced in 1987 and was the first Forced Air-Warming Device. Today it is the market leader.

22. As described above, the Bair Hugger System works is the following manner: hot air accumulates under the blanket covering the patient and it then escapes from under the blanket below the level of the surgical table or at the head end of the surgical table. Unfortunately, this escaped air gathers bacteria, fungi, and pathogens from the floor of the surgical room and then rises back up to the surgical site, depositing bacteria, fungi, and pathogens into the Bair Hugger air blowers from the floor of the surgical room. These bacteria, fungi, and pathogens incubate and proliferate in the internal airflow paths and are then expelled through the hose into the disposable blanket covering the patient and escape into the operating room.

23. For years, the Bair Hugger System was used on patients; however, at some point between 2002 and 2009, the Defendants made the business decision to reduce the efficiency of the air filtration of the Bair Hugger blowers. This action reduced the safety of such blowers.

24. As a result of this business decision, the internal airflow paths of the Bair Hugger blowers become contaminated with pathogens which, because of the heat, multiply and become even more contaminated as described above.

25. The Defendants have been aware of the pathogenic contamination of the airflow paths of the Bair Hugger blowers since at least 2009.

III. The Scientific Studies

26. There have been many publications of peer-reviewed studies documenting the perilous safety shortcomings of the Bair Hugger System; any one of which should have prompted the Defendants to redesign or to discontinue their product. Instead, those criticisms only caused Defendants to amplify their efforts to champion their product as will be elaborated hereinbelow.

27. The various studies and publications constituted a clear indication that Forced-Air Warming and the 3M Forced-Air Warming Devices were defective in that they have the potential to generate airborne contamination and contribute to infection, whereas other alternate methods were more safe. These publications include, but are not limited to, the following:

(a) M. S. Avidan et al. “Convention warmers – not just hot air” Anaesthesia (1997) 52 at 1073;

(b) Y. Matsuzaki et al. “Warming by resistive heating maintains perioperative normothermia as well as forced air heating” British Journal of Anaesthesia 90:5 at 689;

(c) Chiharu Negishi et al. “Resistive-Heating and Forced-Air Warming Are Comparably Effective” Anesthesia & Analgesia (2003) 96 at 1683;

(d) A.T. Bernards et al. “Persistent *Acinetobacter baumannii?* Look Inside Your Medical Equipment” Infection Control & Hospital Epidemiology (2004) 25:11 at 1002;

(e) V. Ng et al. “Comparison of forced-air warming and electric heating pad for maintenance of body temperature during total knee replacement” Anaesthesia (2006) 61 at 1100;

(f) Oliver Kimberger et al. “Resistive Polymer Versus Forced-Air Warming: Comparable Heat Transfer and Core Rewarming Rates in Volunteers” Anesthesia & Analgesia (2008) 107:5 at 1621;

(g) Mark Albrecht et al. “Forced-air warming: a source of airborne contamination in the operating room?” (2009) Orthopedic Reviews 1:28 at 85;

(h) Sebastian Brandt et al. “Resistive-polymer versus forced-air warming: comparable efficacy in orthopedic patients” Anesthesia & Analgesia (2010) 110:3 at 834;

(i) Mark Albrecht et al. “Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room” (2011) 39 American Journal of Infection Control at 321;

(j) P. D. McGovern et al. “Forced-air warming and ultra-clean ventilation do not mix” (2011) The Journal of Bone and Joint Surgery 93-B:11 at 1537;

(k) A. J. Legg et al. “Do Forced-Air patient-warming devices disrupt unidirectional downward airflow?” The Journal of Bone & Joint Surgery (2012) 94-B:2 at 254;

(l) K. B. Dasari et al. “Effect of Forced-Air warming on the performance of operating theatre laminar flow ventilation[5]” (2012) Anaesthesia 67 at 244;

[5] Laminar airflow is defined as air moving at the same speed and in the same direction, with no or minimal cross-over of air streams (or “lamina”). By contrast, turbulent flow creates swirls and eddies that deposit particles on surfaces randomly and unpredictably.

(m) Kumar G. Belani et al. “Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance” Anesthesia & Analgesia (2013) 117:2 at 406; and

(n) A. M. Wood et al. “Infection control hazards associated with the use of forced-air warming in operating theatres” Journal of Hospital Infection (2014) 88 at 132.

28. The 1997 Avidan et al. study, in testing whether Forced-Air Warming Devices could be a source of microbial pathogens (90 percent of which were the Bair Hugger) found that they are a potential source of nosocomial infection[6] and that they should only be used with perforated blankets, have their microbial filters changed regularly and their hoses sterilized.

29. The 2003 Matsuzaki et al. study, in testing Forced-Air Warming with two (2) other warming methods; “circulating heating water mattresses” and resistive heat covers, found that Forced-Air Warming was no better than the resistive heat covers.

30. The 2003 Negishi et al. study, in testing the efficacy of Forced-Air Warming, circulating heating water mattresses, and resistive heating covers, found that Forced-Air Warming was no better than the resistive heat covers.

31. The 2004 Bernards et al. study, in testing the cause of two outbreaks of *Acinetobacter baumannii*[7], found that one of the outbreaks was caused by its presence in dust in the interior the Bair Hugger filter and in a mechanical ventilator. The study concluded the following:

> “The Bair Hugger is designed to create an airflow; dust is sucked into the machine, with filters becoming contaminated and possibly serving as a secondary source of transmission. It was not known how long the filters had been in place, and there was

[6] Nosocomial infections are hospital-acquired infections that are caused by viral, bacterial, and fungal pathogens.
[7] *Acinetobacter baumannii* is a bacterium that affects people with compromised immune systems, and is becoming increasingly important as a hospital-derived (nosocomial) infection

> no protocol for regular replacement of the filters. We believe the outbreak strain was transmitted by being carried on contaminated dust from within the machines to the exterior during operation when a fan created an air current. Thus, the exterior of the machines may have been contaminated and become a secondary source of spread."

32. The 2006 Ng et al. study, in testing the efficacy of the Bair Hugger System with an electric heating pad, found that the Bair Hugger was no better than the electric heating pad;

33. The 2008 Kimberger et al. study, in testing the efficacy of the Bair Hugger System with another device called the "Hot Dog" which uses a conductive warming technology blanket, found that the Bair Hugger was similar to this safer technology.

34. The 2009 Albrecht et al. study, in testing 25 Forced-Air Warming Devices study found that "[m]icroorganisms were detected on the internal air path surfaces of 94% of [Forced-Air Warming Device] blowers" and that "[a]lthough [Forced-Air Warming Devices] [are] one of several methods available for maintaining surgical normothermia[8], it has the potential to mobilize and generate airborne contamination in the operating room from [Forced-Air Warming Device] airflow which other methods of warming do not...Airflow-free alternatives to [Forced-Air Warming Devices], such as resistive-heating technologies, have been shown to be comparably effective to or better than [Forced-Air Warming Devices] for maintaining surgical normothermia."

35. The 2010 Brandt et al. study, in testing the efficiency of the Bair Hugger System with another device called the "Hot Dog" which uses a conductive warming technology blanket, found that the Bair Hugger was no better or no more efficient than this safer technology.

[8] Normothermia is a condition of normal body temperature.

36. The 2011 Albrecht et al. study, in testing out five (5) new filters directly obtained from the Defendants and five (5) different older filters obtained from hospitals, found that "[t]he design of popular [3M Bair Hugger Forced-Air Warming Devices] using the 200708C filter was … inadequate for preventing the internal buildup and emission of microbial contaminants into the operating room. Substandard intake filtration allowed airborne contaminants … to penetrate the intake filter and reversibly attach to the internal surfaces within the [3M Bair Hugger Forced-Air Warming Device] blowers. The reintroduction of these contaminants into the [3M Bair Hugger Forced-Air Warming Device] blower air stream was detected and could contribute to the risk of cross-infection. Given the deficiencies identified with the 200708C intake filter, the introduction of a new filter (model 200708D) with substantially lower retention efficiency is of concern." The study found a wide difference in filtration efficiency between the two (2) filters: the filtration efficiency for the older 200708C model was 93.8 percent, while the filter efficiency for the newer 200708D model was only 61.3 percent.

37. The 2011 McGovern et al. study, in testing the effects of Forced-Air Warming as opposed to air-free conductive fabric warming found "[a] significant increase in deep joint infection, as demonstrated by an elevated infection odds ratio (3.8, $p = 0.024$), was identified during a period when forced-air warming was used compared to a period when conductive fabric warming was used. Air-free warming is, therefore, recommended over forced-air warming for orthopaedic procedures."

38. The 2012 Legg et al. study, in testing Forced-Air Warming Devices as opposed to radiant warming devices and no warming devices, found that "[f]orced air warming resulted in a significant mean increase in the temperature (1.1°C vs 0.4°C, $p < 0.0001$) and number of particles (1038.2 vs

274.8, p = 0.0087) over the surgical site when compared with radiant warming, which raises concern as bacteria are known to require particles for transport."

39. The 2012 Dasari et al. study, in testing the 3M Bair Hugger Forced-Air Warming Device as opposed to air-free conductive fabric warming and an under-body resistive mattress, found that "With forced-air warming, mean (SD) temperatures were significantly elevated over the surgical site vs those measured with the conductive blanket (+2.73 (0.7) ^{o}C; $p < 0.001$) or resistive mattress (+3.63 (0.7) ^{o}C; $p < 0.001$)…the clinical concern is that these currents may disrupt ventilation airflows intended to clear airborne contaminants from the surgical site."

40. The 2013 Kumar et al. study, in testing of Forced-Air Warming as opposed to air-free conductive fabric warming, found that "[e]xcess heat from forced air warming resulted in the disruption of ventilation airflows over the surgical site, whereas conductive patient warming devices had no noticeable effect on ventilation airflows. These findings warrant future research into the effects of forced air warming excess heat on clinical outcomes during contamination-sensitive surgery."

41. The 2014 Wood et al. study, in testing the infection control hazards of Forced-Air Warming, found that Forced-Air Warming "does contaminate ultra-clean air ventilation", that there is a lack of research in the area, and recommended that "surgeons should at least consider alternative patient-warming systems in areas where contamination of the operative field may be critical."

42. As the studies confirm, the Bair Hugger System poses serious health risks to surgical patients; ones which wholly negate its positive elements of maintaining normothermia during

surgery. In addition, the Bair Hugger System is no more effective for its purposes than other safer, alternative methods.

43. Despite these studies, the Defendants have neither done anything to alter the design of the Bair Hugger, nor have they made any efforts to warn physicians or the public about these risks. To do so would be against their economic interests.

IV. The Defendants' Marketing Practices

44. The Defendants have actively and aggressively marketed the 3M Bair Hugger Forced-Air Warming Device as safe for use on patients during surgery, despite their knowledge to the contrary.

45. Further, the Defendants have actually gone so far as to deny the credibility of the results of the various studies indicating that the Bair Hugger System alters the airflow in the operating room. For example, on their website www.fawfacts.com, they make the following representation:

> "No Disruption of Laminar Airflow
>
> Our competitors have raised theoretical questions about the use of forced-air warming in laminar airflow operating rooms. Is it possible, they have asked, that forced-air warming systems could inhibit or alter laminar airflow in operating rooms? Thorough examination by multiple sources has conclusively determined there is no disruption of laminar airflow tied to the use of forced-air warmers."

46. Firstly, it is not 3M's "competitors" which have raised "theoretical" questions – it is peer-reviewed studies which have concluded and documented the dangers associated with the Bair Hugger System, which stem from the fact that the hot air that the device blows out alters the airflow in the operating room. Secondly, the Defendants supposed "[t]hourough examination by multiple sources" was funded by themselves making the results (which run contrary to the basic principles

of physics) clearly biased and unreliable. It is a widely-accepted phenomenon that hot air rises; and therefore, producing and projecting hot air downwards would obviously alter normal air patterns. It is unnecessary to engage in a study of thermodynamics to understand that the Defendants have funded studies to come up with convenient theories for the continued sale of the Bair Hugger.

47. In a pamphlet created by the Defendants, they state that "[t]here is not a single, credible, scientific study that associates the Bair Hugger system with a surgical site infection. On the contrary, there is ample evidence that it actually helps patients." The above section of this Statement of Claim provides ample evidence to the contrary. The pamphlet also states "[c]ontrary to claims from a competitor, the Bair Hugger system does not disrupt the air flow in the operating room…...[b]y raising doubts, the competitor hopes to sell more of his warming devices."

48. The Defendants go on to state "No. There is no evidence that the Bair Hugger system's forced-air warming causes infections."

49. In an advertisement that appeared in multiple medical publications as early as 2010, including the Operating Theatre Journal (April 2010 – Issue No. 235), the Defendants made the following false and misleading claims:

> "…some manufacturers of electric blankets, pads and other conductive warming modalities are attempting to plant fears about the safety of forced air warming. One has even claimed that the country's most prominent method of surgical warming may be contributing to surgical site infections (SSIs) by "blowing air" around the operating theatre, or disrupting laminar air flow."
>
> "It is time to put an end to these baseless claims about forced air warming and set the record straight."

> "While simple logic makes it clear that Forced-Air warming has no impact on laminar conditions, science also supports this. A Forced-Air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems."

50. As published scientific research, both before and after this statement, has demonstrated, this is untrue. The exhaust generated by the Bair Hugger creates convective airflow patterns that do disrupt the laminar flow of the operating theatre.

51. In a letter dated April 8, 1997 entitled "510(k) Summary of Safety & Effectiveness"[9], Dr. Scott Augustine of non-party Augustine Medical, Inc. (a subsidiary of Arizant) requests permission from the US-FDA to market the Bair Hugger System with a different blanket (being model 630), summarizing the related safety issues. In this letter, it is admitted that: "Contamination: air blown intraoperatively across the surgical wound may result in airborne contamination." Defendants countered this flaw in their products by misrepresenting to the US-FDA that the risk of contamination by air flow is obviated because "All Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent air from migrating toward the surgical site." This statement, while attempting to be ameliorative, is false on a number of fronts, including, but not limited to the following:

[9] A 510(k) is a premarket submission made to US-FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to Premarket Approval (PMA). Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process.

(a) A number of the Bair Hugger blankets marketed as safe for use in surgeries do not utilize a taped edge at all. Instead, those blankets blow contaminated air directly toward the surgical field, and

(b) The statement that the taped barrier would contain the contaminated air is false because it ignores the fact that the heated air from the Bair Hugger System rises against the general downward airflow of the operating theatre. The presence of a tape edge would do absolutely nothing to prevent the fact that The Bair Hugger facilitates the movement of pathogens from the floor of the operating room to the surgical site.

When Defendants made these misrepresentations, they had actual knowledge of their falsity.

52. In a communication to the US-FDA in September 2000, the Defendants represented that the Bair Hugger's filtration system meets HEPA ("High Efficiency Particulate Air") Standards. This statement was false at the time that the Defendants made it and it remains false today. To meet HEPA standards, an air filter must be capable of removing 99.97% of all particles 0.3 microns or larger. The filter of the Bair Hugger, which is marketed as HEPA compliant, is only capable of removing less than 65% of all such particles.

53. On their website, www.fawfacts.com, the Defendants make the following misrepresentations:

(a) Contamination mobilized by the convection currents generated by the Bair Hugger cannot reach the surgical site because "[a]ir velocity within the operating theatre is many times stronger than that of the forced-air warming blanket";

(b) "The air emerging from the blanket is directed downward by the surgical drape and emerges under the operating room table and is drawn away through the laminar system's return air inlets";

(c) "It's been suggested that warm air rising above the Bair Hugger blanket could interfere with the downward laminar flow toward the surgical site. It should be noted that the Bair Hugger warming unit delivers less than one percent of the airflow of a laminar flow system and the momentum of the downward air is far greater than the upward momentum imparted to the air above the blanket."

54. These statements are false and intentionally misleading. Through these statements, the Defendants deliberately disguise the fact that the issue is not the strength of the airflow in a laminar system, but instead, the heat of the air generated by the Bair Hugger in order to create confusion. The cold air circulated within the operating room, having a higher density than the air heated by the Bair Hugger, falls to the floor which forces the contaminated air at the floor of the operating room, now warmed by the waste heat from the Bair Hugger, to rise into the sterile field and the surgical site. The heated air rises, it is not "drawn away" as the Defendants' suggest.

55. In a communication that appeared in *Healthcare Purchasing News* in July of 2012, Defendants' public relations and communications specialist Greta Deutsch stated "some conductive-warming manufacturers have alleged that forced-air warming increases bacterial contamination of operating rooms or interrupts laminar airflow. These accusations have no factual basis." Again, this statement ignores numerous published studies documenting the adverse effects the Bair Hugger has on laminar airflow.

56. In a marketing video produced by the Defendants and available online at http://www.youtube.com/watch?v=0j9w5brozV4, the Defendants make the following misrepresentations:

(a) "3M Bair Hugger forced-air warming does NOT influence the effectiveness of a laminar flow system" (at 4:10);

(b) Claims by conductive warming manufacturers that Bair Hugger disrupts laminar flow are "inaccurate and irresponsible" (at 1:28);

(c) "Laminar airflow is stronger than the convective currents" created by the Bair Hugger FAW (at 5:04).

57. These misrepresentations had the effect of misleading healthcare providers about the safety of the Bair Hugger for use in surgical procedures.

58. Physicians' relied upon the above representations and advertisements to the Plaintiff's and Class Members' detriment. Any reasonable and competent physician would not use the Bair Hugger in a surgery if they were fully apprised of the dangers and risks associated with doing so. However, through misrepresentations to the public, the medical community, Health Canada and the US-FDA, Defendants actively concealed the infection-causing propensity of the Bair Hugger in surgery.

59. Through misrepresentations to the public, the medical community, Health Canada, and the US-FDA, the Defendants actively concealed the fact that the Bair Hugger increases the risk of infection in all types of surgeries, especially orthopedic implant surgeries.

60. The Plaintiff and his physician(s) were therefore unaware and could not have reasonably known or have learned through reasonable diligence of the significantly increased risk of infection associated with the Bair Hugger.

V. Summative Remarks

61. The Defendants researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold the 3M Bair Hugger Forced-Air Warming with the Design Defect coupled with active misrepresentations about its safety in Canada, including within the province of Ontario.

62. The Defendants failed to disclose and/or actively concealed, despite a wealth of longstanding knowledge, that the Bair Hugger System is defective and unsafe in order to increase profits.

63. The Defendants continue to research, design, develop, test, license, manufacture, produce, supply, market, package, promote, advertise, distribute, label and/or sell the Bair Hugger System throughout Canada, including within the province of Ontario, with the Design Defect coupled with active misrepresentations about its safety.

64. The Defendants placed the Bair Hugger System into the stream of commerce in Ontario and elsewhere in Canada with the expectation that it would be used on persons, such as the Plaintiff and Class Members.

65. The Class Members have suffered and will suffer injuries, losses or damages as a result of the Defendants' conduct.

66. The Plaintiff and Class Members would not have had the Bair Hugger System used on them were it known they were unsafe.

67. The Defendants concealed material information regarding the truth about the existence and nature of the Design Defect from the medical and health community, Health Canada, US-FDA, the Plaintiff, the Class Members, and the public in general at all times, even though they knew about the Design Defect and knew that information about the Design Defect would be important to a reasonable person.

68. The Defendants were under a duty to disclose the Design Defect and they never disclosed it to the public at any time or place or in any manner.

THE REPRESENTATIVE PLAINTIFF'S EXPERIENCE

69. On December 9, 2014, Mr. Driessen underwent knee replacement surgery at the Royal Alexandra Hospital at 10240 Kingsway Avenue NW, in Edmonton, Alberta, during which time the Bair Hugger System was used.

70. Mr. Driessen believed that all the equipment, medications and other material used during the surgery, which included the Bair Hugger System, were the most appropriate choices for surgery and would provide him with a reasonable standard of care.

71. Within four (4) months of the surgery, in March 2015, Mr. Driessen began suffering from significant night sweats. He also suffered from increasing pain in his knee that interfered with his regular functioning and mobility, which in turn affected his personal life.

72. On July 20, 2015, Mr. Driessen suffered an alarming night sweat and the following day, on July 21, 2015, his knee was swollen and stiff and he was suffering serious pain and increased difficulty in moving it or bending it. He therefore went to the Barrhead Healthcare Centre where he was immediately injected intravenously with antibiotics, and from that point onward, he was injected twice daily until his surgery as will be described hereinbelow.

73. On July 22, 2015, after an analysis of the fluid in Mr. Driessen's knee, it was confirmed that he was suffering from a bacterial infection in his knee. After this discovery, Mr. Driessen was prescribed two (2) antibiotics, to be injected intravenously twice a day. Mr. Driessen suffered discomfort from the injection of the antibiotics because they would cause his veins to become inflamed and damaged, making it necessary to continuously look for new veins for the injections.

74. Mr. Driessen needed to have a first bone scan performed at the Hys Medical Centre, 1.5 hours from his home in Barrhead, and he returned 2.5 hours later the same day for a second scan.

75. On July 24, 2015, following a consultation with the "Infection Control Department" at the Royal Alexandra Hospital in Edmonton, 1.5 hours away from his home, Mr. Driessen was informed that due to the severity of the infection, he had to undergo an immediate surgery to remove the replacement knee. Mr. Driessen then underwent surgery without having the opportunity to see any of his family members prior to even entering the operating room.

76. After the surgery, Mr. Driessen remained in the hospital for two (2) weeks and received intravenous injections of antibiotics three times each day.

77. Because of his distressing condition, Mr. Driessen was forced to cancel his flight to Australia, which had been scheduled for July 28, 2015. Mr. Driessen's family left for Australia while he remained in convalescence in the hospital.

78. Approximately two (2) weeks after his surgery, Mr. Driessen was moved to the Barrhead Healthcare Centre where he stayed for another two (2) weeks and received intravenous injections of antibiotics three times each day.

79. When Mr. Driessen finally returned home, he required homecare assistance in order to receive his intravenous injections of antibiotics and to care for the infected area. Mr. Driessen also needed assistance in taking care of his daily obligations.

80. After the antibiotic intravenous injection treatment ended, Mr. Driessen was prescribed two (2) different painkiller medications which he took on a daily basis so as to ease his pain.

81. At present, Mr. Driessen's mobility is quite limited and, even with the use of crutches or a cane, he still needs to be vigilant with his every move so as to not put pressure onto his knee. Mr. Driessen still frequently experiences a build-up of fluid in his knee which causes rapid swelling.

82. Mr. Driessen has been unable to work and will be unable to return to work for the foreseeable future.

83. In addition, Mr. Driessen has been unable to reasonably take of himself, which has caused him psychological and emotional distress.

84. On November 2, 2015, Mr. Driessen had the fluid in his knee analyzed again at the Royal Alexandra Hospital, which necessitated a whole day of travel.

85. Mr. Driessen has discovered that the Bair Hugger was used during his knee replacement surgery and that the Bair Hugger has been linked to the Dangerous Complications including serious infection, severe deep joint infection, implant revision surgery, permanent disability, amputation and even death.

86. At no time was Mr. Driessen made aware of the risks of infection and related complications associated with the use of the Bair Hugger System.

87. Had the Defendants properly disclosed the risks associated with the Bair Hugger, Mr. Driessen would not have been exposed to the Dangerous Complications.

88. Mr. Driessen is aware that, in addition to the present class action, several lawsuits were filed in the United States for the same product due to the Design Defect associated with the Bair Hugger and due to the Defendant's conduct related thereto.

89. On February 4, 2016, Mr. Driessen underwent a second knee replacement operation; understandably, he requested that the Bair Hugger not be used on him.

90. As a direct and proximate result of the failure of the Bair Hugger to maintain the sterility of the surgical area and the Defendants' wrongful conduct as alleged herein, the Plaintiff sustained and continues to suffer damages, including, but not limited to serious infection, severe physical pain and mental anguish, including diminished quality and enjoyment of life and increased risk of health problems, physical impairment and/or disfigurement, as well as the need for continued

medical treatment, monitoring and/or medications, loss of income and loss of future income, the apportioned cost of the treatments following infection(s) caused by the Bair Hugger, pain, suffering, anxiety, fear, trouble, annoyance, and inconvenience.

CAUSES OF ACTION

A. Strict Liability

91. The Defendants are strictly liable to the Plaintiff and Class Members for the reasons that follow:

(a) The Defendants researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold the Bair Hugger System as hereinabove described;

(b) The Bair Hugger was expected to and did reach the Class Members without substantial change in the condition in which it was researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold by the Defendants;

(c) At those times, the Bair Hugger was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, including, the Plaintiff herein;

(d) The Bair Hugger was suffering from a serious manufacturing and/or design defect in that, when it left the hands of the Defendants, it was unreasonably and

unnecessarily dangerous, and it was more dangerous than an ordinary person would expect;

(e) At all times herein mentioned, the Bair Hugger was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants;

(f) At the time of the Plaintiff's use of the Bair Hugger, the latter was being used for the purposes and in a manner normally intended;

(g) The Defendants, equipped with this knowledge, voluntarily designed the Bair Hugger in a dangerous condition for use on the public, and in particular the Plaintiff;

(h) The Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use;

(i) The Defendants created a product unreasonably dangerous for its normal, intended use;

(j) The Bair Hugger was manufactured defectively in that it left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users;

(k) Class Members were entitled to expect that the Bair Hugger was safe, convenient, and effective;

(l) The researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold a defective product which created an unreasonable risk to the health of Class Members, and the Defendants are therefore strictly liable for the injuries sustained;

(m) The risks inherent in the design of the Bair Hugger, for example, the risk of serious infection, outweigh any possible benefits of its design and such defects were material contributing causes of the injuries and losses of Class Members;

(n) At the time of the injury and loss to Class Members, the Bair Hugger was being used for the purpose and manner for which it was intended and Class Members could not, through the exercise of reasonable care and diligence, have discovered the Bair Hugger's defects herein mentioned and perceived its danger;

(o) The lack of adequate warnings and/or testing on the part of the Defendants materially contributed to the defective nature of the device;

(p) The Bair Hugger was defective due to inadequate post-marketing surveillance and/or warnings because, after the Defendants knew or should have known of the Dangerous Complications of serious side effects related to the use of the Bair Hugger, they failed to provide adequate warnings to the medical and health community, to Health Canada, to the Plaintiff, to the Class Members, and to the public in general, and continued to improperly market, package, promote, advertise, label and/or sell their product;

92. By reason of the foregoing, the Defendants are strictly liable in tort to the Class Members for the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of a defective product, being the Bair Hugger.

93. The Defendants' defective design, manufacturing, and inadequate warnings of the Bair Hugger were acts that amount to wilful, wanton, and/or reckless conduct.

94. The Design Defect was, at minimum, a substantial factor in causing Class Members' and Plaintiff's injuries.

95. As a result of the foregoing acts and omissions, Class Members were exposed to and/or suffered Dangerous Complications including, but not limited to the risk of serious infection, severe deep joint infection, implant revision surgery, Methicillin-resistant Staphylococcus aureus (MRSA), sepsis or septic hip/knee, permanent disability, amputation, death, physical pain and mental anguish, including diminished quality and enjoyment of life, increased risk of health problems, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above- medical consequences.

B. Tort of Civil Negligence

96. The Defendants, at all times, owed a positive legal duty to use reasonable care to perform their legal duty to the Plaintiff and to Class Members, including a duty to assure that the Bair Hugger would not cause Class Members to suffer a risk of unreasonable and Dangerous Complications.

97. The Defendants also failed to exercise reasonable care in their research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger in that the Defendants knew or should have known that using the Bair Hugger created a high risk of unreasonable, Dangerous Complications.

98. In addition, the Defendants were aware that the medical and health community, Health Canada, the Plaintiff, Class Members, and the public relied on them to provide truthful and accurate information regarding the safety and efficacy of the Bair Hugger System.

99. By its acts described herein, the Defendants failed to take reasonable care to ensure that the Bair Hugger was safe and effective.

100. The Defendants breached their duty of care to the Plaintiff and to the Class Members by offering for sale a device that was not fit for the particular purpose for which it was intended.

101. The Defendants failed to meet the standard of care required in all the circumstances and were negligent in the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger in that:

(a) They failed to ensure that the Bair Hugger was fit for its intended and/or reasonably foreseeable use and that they were not dangerous to users;

(b) They failed to properly, adequately, and thoroughly test the Bair Hugger to ensure that it was acceptably safe and free from defects prior to releasing the device into the Canadian marketplace;

(c) They failed to properly, adequately and correctly warn the medical and health community, Health Canada, the Plaintiff, Class Members, and the public in general of the significant and dangerous risks associated with the Bair Hugger, both prior to releasing it into the Canadian marketplace and afterward;

(d) They failed to provide adequate instructions regarding the Dangerous Complications to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, the Bair Hugger;

(e) They failed to conduct sufficient post-market testing and surveillance of the Bair Hugger to determine the safety of the Bair Hugger;

(f) They knew or should have known that the Bair Hugger exposed the Plaintiff and Class Members to the Dangerous Complications;

(g) They negligently represented that the Bair Hugger was safe and that it had equivalent safety and efficacy as other forms of treatment for preventing and treating hypothermia in patients during surgery;

(h) They improperly concealed and/or misrepresented information from the medical and health community, Health Canada, the Plaintiff, the Class Members, and the

public in general, concerning the severity of risks and dangers of the Bair Hugger compared to other forms of treatment for preventing and treating hypothermia in patients during surgery;

(i) They consistently under-reported, underestimated, withheld, and downplayed the serious dangers of the Bair Hugger and misrepresented its efficacy and safety to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general;

(j) They failed to properly inform and/or to warn the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general of the severity and duration of the significant and Dangerous Complications associated with the Bair Hugger, including at minimum, accompanying their product with accurate warnings;

(k) They continue to negligently research, design, develop, test, license, manufacture, produce, supply, market, package, promote, advertise, distribute, label and/or sell the Bair Hugger after Defendants knew or should have known its significant and Dangerous Complications (particularly so from increasing reports thereof);

(l) They failed to monitor, investigate, evaluate and follow-up on adverse reactions to the use of the Bair Hugger,

(m) They failed to timely recall the Bair Hugger Systems, publicize the problems and otherwise act properly and in a timely manner to alert the public of the inherent dangers associated therewith, including, the Dangerous Complications;

(n) They failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

(o) They placed their commercial interests over the Plaintiff and Class Members' safety; and

(p) In all of the circumstances of this case, they applied callous and reckless disregard for the health and safety of the Plaintiff and Class Members.

102. The circumstances of the Defendants being in the business of researching, designing, developing, testing, licensing, manufacturing, producing, supplying, marketing, packaging, promoting, advertising, distributing, labelling and/or selling the Bair Hugger and placing the Bair Hugger into the Canadian stream of commerce are such that the Defendants were in a position of legal proximity to the Class Members and were therefore under an obligation to be fully aware of and disclose adequate information about its safety and efficacy.

103. It was certainly reasonably foreseeable that if the Defendants were negligent in their duty to provide accurate information regarding the safety of the Bair Hugger System, that the Plaintiff and Class Members could and would sustain injury and damages and this, in fact, did materialize.

104. It was reasonably foreseeable that failure by the Defendants research, design, develop, test, license, manufacture, produce, supply, market, package, promote, advertise, distribute, label and/or

sale of the Bair Hugger System, and to thereafter to monitor its performance following market introduction (and to take corrective measures when required) would cause harm to the Plaintiff and the members of the Class.

105. By virtue of the acts, omissions and misrepresentations described above, the Defendants were negligent and caused damage to the Plaintiff and to the Class Members.

C. Breach of Express Warranty

106. The Defendants expressly warranted to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the Bair Hugger was safe, effective and fit for use for the intended purposes; i.e. on patients during surgery such as the Plaintiff and Class Members.

107. The Defendants expressly represented that the Bair Hugger was of merchantable quality, that it did not pose any Dangerous Complications in excess of those risks associated with other forms of treatment for preventing and treating hypothermia in patients during surgery and that it was adequately tested and fit for its intended use.

108. The Bair Hugger does not conform to these express representations because it suffers from the Design Defect which poses Dangerous Complications, all of which were not disclosed by the Defendants and further, were actively denied.

109. The Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Bair Hugger was not safe and fit for the intended use and, in fact, caused serious injuries including the Dangerous Complications.

110. The medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general relied upon the representations and express warranties of the Defendants with regards to the Bair Hugger.

111. As a result of the foregoing acts and omissions, the Plaintiff and Class Members suffered serious and Dangerous Complications including, serious infection, severe deep joint infection, implant revision surgery, Methicillin-resistant Staphylococcus aureus (MRSA), sepsis or septic hip/knee, permanent disability, amputation, death, physical pain and mental anguish, including diminished quality and enjoyment of life, increased risk of health problems, as well as the need for lifelong medical treatment, monitoring and/or medications and pain, suffering, anxiety, fear, trouble, annoyance, and inconvenience.

D. Breach of Implied Warranties

112. At all times herein mentioned, the Defendants researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold the Bair Hugger to maintain normothermia in patients undergoing surgery.

113. At the time that the Defendants researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold the Bair Hugger for use on Class Members, they knew of the use for which the Bair Hugger was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

114. The Defendants represented and warranted to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the Bair Hugger was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

115. Said representations and warranties aforementioned were false, misleading, and inaccurate in that the Bair Hugger was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

116. The medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

117. Class Members and their physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether the Bair Hugger was of merchantable quality and safe and fit for its intended use.

118. The Bair Hugger was placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition.

119. The Defendants breached the aforesaid implied warranties and the Bair Hugger was not fit for its intended purposes and uses.

120. As a result of the foregoing acts and omissions, Class Members suffered serious and Dangerous Complications including, but not limited to serious infection, severe deep joint infection, implant revision surgery, Methicillin-resistant Staphylococcus aureus (MRSA), sepsis or septic hip/knee, permanent disability, amputation, death, physical pain and mental anguish,

including diminished quality and enjoyment of life, increased risk of health problems, as well as the need for lifelong medical treatment, monitoring and/or medications and pain, suffering, anxiety, fear, trouble, annoyance, and inconvenience.

E. Failure to Warn

121. Defendants researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold the Bair Hugger and therefore had a duty to warn of the risks associated with the use of the Bair Hugger.

122. The Defendants failed to warn the medical and health community, Health Canada, the US-FDA, the Plaintiff, the Class Members, and the public in general of the risks associated with the Bair Hugger. These risks include that the Bair Hugger would circulate contaminated air in the operating room and that the vented heat from Bair Hugger would mobilize floor air contaminated with pathogens into the surgical site causing a serious risk of Dangerous Complications.

123. The Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Bair Hugger. Had they done so, proper warnings would have been heeded and no health care professional, including the Plaintiff's and Class Members' physicians, would have used Bair Hugger, and no patient, including the Plaintiff and Class Members, would have allowed any use of the Bair Hugger.

124. The failure to provide timely and reasonable warnings, instructions, and information regarding the Bair Hugger to the Plaintiff and to Class Members and/or to their physicians rendered the Bair Hugger unreasonably dangerous.

125. The Plaintiff states that his damages and the damages of other Class Members were caused by the Defendants' failure to warn, which includes, but is not limited to, the following:

a) They failed to provide the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general with proper, adequate, and/or fair warning of the increased risks associated with the use of the Bair Hugger, including the Dangerous Complications;

b) They failed to provide any or any adequate updated and/or current information to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general respecting the Dangerous Complications associated with the Bair Hugger as such information became available from time to time;

c) They failed to provide adequate warnings of the potential increased risks associated with the Bair Hugger on package labels, in the product certificate, and/or on the information pamphlets in Canada;

d) They failed to issue adequate warnings, timely recall of the device, publicize the problem and otherwise act properly and in a timely manner to alert the public, including adequately warning persons having used and/or about to use the Bair Hugger and their physicians or other health care providers of the device's inherent dangers;

e) They failed to perform or otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, and/or selectively and misleadingly revealed and/or analyzed testing and research data of the Bair Hugger;

f) They failed to provide complete and accurate clinical and non-clinical data to Health Canada throughout the approval process for the Bair Hugger and subsequent to its approval, including when they submitted to Health Canada for premarket approval of the Model 630 Blanket for the Bair Hugger and subsequent to the issuance by Health Canada of the approval thereof;

g) They failed to promptly to report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to the Bair Hugger subsequent to its approval in Canada;

h) They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians or other health care providers respecting the increased risks associated with using the Bair Hugger; and

i) They failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, RSC 1985, c F-27 and its associated regulations.

126. The propensity of the Bair Hugger's internal air flow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens, makes the Bair Hugger unreasonably dangerous when used in the way it is ordinarily used and is dangerous to an extent beyond that which would be contemplated by the ordinary, reasonable person, with the ordinary knowledge common to the community as to its characteristics.

127. At all times relevant to this action, an economically and technologically feasible safer alternative design existed, which in reasonable medical probability:

a) Would have prevented or significantly reduced the risk of the Plaintiff's and Class Member's risk of Dangerous Complications (including additional surgical procedures to clean the infected area and/or remove the implant); and

b) Would not have impaired the utility of the device.

128. Had the Defendants adequately warned the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general, proper warning would have been heeded and no health care professional, including the Plaintiff's physicians, would have used the Bair Hugger and no patient, including the Plaintiff, would have allowed use of the Bair Hugger during surgery.

129. The failure to provide timely and reasonable warnings, instructions, and information regarding the Bair Hugger to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general, rendered the Bair Hugger unreasonably dangerous. As a direct result of Defendants' conduct, the Plaintiff has suffered and continues to suffer serious and permanent injuries.

F. Tort of Fraudulent Misrepresentation

130. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, to Class Members, to Health Canada, and the public in general, that the Bair Hugger had been tested and was found to be safe and/or effective for preventing hypothermia and maintaining normothermia in patients during surgery. The Defendants further

misrepresented that that patients, Class Members, the Plaintiff, and/or the medical and healthcare community could safely use the Bair Hugger without the Dangerous Complications.

131. The representations made by the Defendants were, in fact, false.

132. When said representations were made by the Defendants, they knew those representations to be false or, at a minimum, they wilfully, wantonly and recklessly disregarded whether the representations were true.

133. These representations were made by the Defendants with the intent of deceiving the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general and were made with the intent of inducing them to recommend, purchase, and/or use the Bair Hugger during surgery, all of which evinced a callous, reckless, wilful, depraved indifference to the health, safety and welfare of Class Members.

134. Based on said representations, the Bair Hugger was used on the Plaintiff and Class Members, thereby causing them to be exposed to the Dangerous Complications.

135. The Defendants knew and were aware or should have been aware that the Bair Hugger had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

136. The Defendants knew or should have known that the Bair Hugger had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings and misleading instructions.

137. The Defendants brought the Bair Hugger to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff and Class Members.

G. Tort of Negligent Misrepresentation

138. The tort of negligent misrepresentation can be made out as:

(a) There was a relationship of proximity in which failure to take reasonable care might foreseeably cause loss or harm to the Plaintiff and to the Class;

(b) The Defendants made a Representation that was untrue, inaccurate and/or misleading;

(c) The Defendants acted negligently in making the Representation;

(d) The Representation were relied upon reasonably; and

(e) The Plaintiff and the Class sustained damages as a result of their reliance.

139. The Defendants represented the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the Bair Hugger had been tested and had been found to be safe and effective for preventing hypothermia and maintaining normothermia in patients during surgery – this Representation was untrue as set forth herein.

140. The Defendants represented that the Bair Hugger was safer than other patient warming systems – this Representation was untrue as set forth herein.

141. The Defendants failed to exercise ordinary care in the representation of the Bair Hugger and instead, negligently misrepresented the Bair Hugger's unreasonable, Dangerous Complications.

142. At the time that the Defendants made the misrepresentations herein alleged, they had no reasonable grounds for believing the Representation to be true, as there was ample evidence to the contrary set forth in detail above.

143. The Defendants made the Representation herein alleged with the intention of inducing the Bair Hugger to be used on the Plaintiff and the Class Members.

144. The Representation was relied upon and, in reliance upon it, the Bair Hugger was used on the Plaintiff and on Class Members. Said reliance was reasonable.

145. By reason of the foregoing, Plaintiff and each member of the Class are entitled to recover damages and other relief from the Defendants.

CAUSATION

146. The Defendants knew or should have known that Class Members would foreseeably suffer injury as a result of their failure to exercise ordinary care and there is therefore a sufficient relationship of proximity.

147. The Plaintiff and Class Members, being patients undergoing surgery in Canada, were reasonably in a position to be harmed by the Bair Hugger's use.

148. The acts, omissions, wrongdoings, and breaches of legal duties and obligations of the Defendants directly and proximately caused the Plaintiff's and Class Members' injuries and damages.

149. The Plaintiff pleads that by virtue of the acts, omissions and breaches of legal obligations as described herein, they are entitled to legal and/or equitable relief against the Defendants, including damages, consequential damages, attorneys' fees, costs of suit and other relief as appropriate in the circumstances.

DAMAGES

Special Damages (Pecuniary Damages)

150. By reason of the acts, omissions and breaches of legal obligations of the Defendants, the Plaintiff and Class Members have suffered injuries, economic loss and damages, the particulars of which include:

(a) Out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of the Dangerous Complications;

(b) Loss of income and loss of future income; and

(c) Such further and other damages the particulars of which will be particularized prior to trial.

General Damages (Non-Pecuniary Damages)

151. By reason of the acts, omissions and breaches of legal obligations of the Defendants, the Plaintiff and Class Members have suffered injury, non-economic loss and damages, the particulars of which include:

(a) Serious infection;

(b) Severe physical pain and mental anguish;

(c) Diminished quality and enjoyment of life;

(d) Increased risk of health problems

(e) Pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increased risk of health problems; and

(f) Physical impairment and/or disfigurement.

152. As a result of the Defendants' negligence, putative class members are entitled to damages pursuant to, *inter alia*, the *Tort-feasors Act*, RSA 2000 c T-5, the *Fatal Accidents Act*, RSA 2000, c F-8, the *Civil Code of Quebec* (1991) art 1457 (1991), *The Fatal Accidents Act*, CSSM c F50, the *Fatal Accidents Act*, RSNB 1973, c F-7, as repealed by *Fatal Accidents Act*, SNB 2012, c 104, the *Fatal Accidents Act*, RSNL 1990, c F-6, the *Fatal Injuries Act*, RSNS 1989, c 163, the *Fatal Accidents Act*, RSPEI 1988, c F-5, as amended by SPEI 2008, c 8, s II, *The Fatal Accidents Act*, RSS 1978, c F-11, the *Fatal Accidents Act*, RSNWT 1988, c F-3, the *Fatal Accidents Act*, RSNWT

(Nu) 1988, c F-3, the *Fatal Accidents Act*, RSY 2002, c 86, the *Family Compensation Act*, RSBC 1996, c 126, and the regulations thereunder and amendments thereto.

153. Some of the expenses related to the medical treatment that Class Members have undergone, and will continue to undergo, have been borne by the various provincial health insurers, including the Ontario Ministry of Health and Long-Term Care ("MOHLTC").

154. As a result of the Defendants' negligence, the various provincial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services. A claim is hereby advanced for the cost of such services under the applicable Provincial and Territorial Legislation including the *Health Care Costs Recovery Act*, SBC 2008, c 27, the *Health Services Insurance Act*, CCSM c H35, the *Health Services Act*, RSNB 1973, c H-3, the *Health Services and Insurance Act*, RSNS 1989, c 197, the *Health Insurance Act*, RSO 1990, c H-6, the *Health Insurance Act*, RSQ c A-29, and *The Department of Health Act*, RSS 1978, c D-17, the *Health Care Insurance Plan Act*, RSY 2002, c I 07, the *Hospital Insurance and Health and Social Services Administration Act*, RSNWT 1988, c.T-3, the *Hospital insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c.T-3, the *Crown's Right of Recovery Act*, SA 2009, c C-35, the *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8, the *Hospital Insurance Agreement Act*, RSNL 1990, c H-7, and the regulations thereunder and amendments thereto.

Punitive and Aggravated Damages

155. The Defendants has taken a cavalier and arbitrary attitude to their legal and moral duties to the Class Members.

156. At all material times, the conduct of the Defendants as set forth was deliberate and oppressive and the Defendants conducted themselves in a wilful, wanton and reckless manner, without regard for public safety as to warrant a claim for punitive damages. Defendants' acts or omissions described above, when viewed from the standpoint of the Defendants at the time of the act or omission, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to the Plaintiff, Class Members and the community at large.

157. Defendants' acts or omissions, as described herein, were performed with a realization of the imminence of danger and were performed with reckless disregard or complete indifference to the probable result.

158. Defendants had actual, subjective awareness of the risks involved in the above described acts or omissions, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiff, Class Members and the community at large.

159. In addition, it should be noted since the Defendants are part of highly revered, multi-billion dollar corporation, it is imperative to avoid any perception that they can evade the law without impunity. Should the Defendants only be required to disgorge monies which should not have been retained and/or withheld, such a finding would be tantamount to an encouragement to other businesses to commit wrongdoings as well. Punitive and aggravated damages are necessary in the

case at hand to be material in order to have a general deterrent effect on other corporations as well as a specific deterrent to the Defendants themselves.

STATUTORY REMEDIES

160. The Defendants are in breach of the federal *Competition Act* and the *Food and Drugs Act*.

161. The Plaintiff pleads and relies upon trade legislation and common law, as it exists in this jurisdiction and the equivalent/similar legislation and common law in other Canadian provinces and territories. The Class Members have suffered injury, economic loss and damages caused by or materially-contributed to by the Defendants' inappropriate and unfair business practices.

A. Breach of the *Competition Act*

162. At all times relevant to this action, the Defendants' businesses were "business(es)" and the Bair Hugger was a "product" within the meaning of that term as defined in s. 2 of the *Competition Act*.

163. The Defendants' acts are in breach of s. 52 of Part VI of the *Competition Act*, were and are unlawful, and render the Defendants liable to pay damages and costs of investigation pursuant to s. 36 of the *Competition Act*.

164. The Defendants made the Representation to the public and in so doing breached s. 52 of the *Competition Act* because the Representation:

(a) Was made for the purpose of promoting, directly or indirectly, the use of a product or for the purpose of promoting, directly or indirectly, the business interests of the Defendants;

(b) Was made to the public;

(c) Was false and misleading in a material respect; and

(d) Stated approval, performance characteristics, uses, benefits and/or qualities of the Bair Hugger that were false and not based on adequate and proper testing and stated a particular standard and/or quality that was not based on adequate and proper testing.

165. The Representation was relied upon and the Plaintiff and Class Members suffered damages and loss.

166. Pursuant to s. 36 of the *Competition Act*, the Defendants are liable to pay the damages which resulted from the breach of s. 52.

167. Pursuant to s. 36 of the *Competition Act*, the Plaintiff and Class Members are entitled to recover their full costs of investigation and substantial indemnity costs paid in accordance with the *Competition Act*.

168. The Plaintiff and Class Members are also entitled to recover as damages or costs, in accordance with the *Competition Act*, the costs of administering the plan to distribute the recovery in this action and the costs to determine the damages of each Class Member.

B. Breach of the *Food and Drugs Act*

169. At all times relevant to this action, the 3M Bair Hugger Forced-Air Warming Device was a "device" within the meaning of that term as defined in s. 2 of the *Food and Drugs Act*.

170. At all times relevant to this action, the Design Defect caused "unsanitary conditions" within the meaning of that term as defined in s. 2 of the *Food and Drugs Act*.

171. At all times relevant to this action, the Defendants' representations were "advertisement(s)" within the meaning of that term as defined in s. 2 of the *Food and Drugs Act*.

172. Section 19 of the *Food and Drugs Act* prohibits the sale of any device, such as the Bair Hugger, that when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

173. Section 20 of the *Food and Drugs Act* prohibits the packaging, sale or advertisement of any device, such as the Bair Hugger, in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

174. At material times, the Defendants violated section 19 of the *Food and Drugs Act* by selling the Bair Hugger that, when used under regular conditions creates the risk of the Dangerous Conditions.

175. At material times, the Defendants violated section 20 of the *Food and Drugs Act* by packaging, selling, and advertising the Bair Hugger in a false, misleading or deceptive manner or

in a manner that is likely to create an erroneous impression regarding its design, performance, intended use, character, merit and/or safety.

176. As a result of violating the *Food and Drugs Act*, the Defendants caused the Bair Hugger to be used on the Plaintiff and Class Members, thereby causing severe injuries and damages, as previously described herein.

WAIVER OF TORT, UNJUST ENRICHMENT AND CONSTRUCTIVE TRUST

177. The Plaintiff pleads and relies on the doctrine of waiver of tort and states that the Defendants' conduct, including the alleged torts as well as breaches of the *Competition Act* and/or the *Food and Drugs Act* constitutes wrongful conduct which can be waived in favour of an election to receive restitutionary or other equitable remedies in the amount of the Defendants' gain therefrom.

178. The Plaintiff reserves the right to elect at the Trial of the Common Issues to waive the legal wrongs and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, the net income received by the Defendants, or a percentage of the sales of the Bair Hugger.

179. The Defendants have been unjustly enriched as a result of the revenues generated from the sale of the Bair Hugger and as such, *inter alia*, that:

(a) The Defendants have obtained an enrichment through revenues and profits from the sale of the Bair Hugger;

(b) The Plaintiff and Class Members have suffered harm; and

(c) The benefit obtained by the Defendants and the harm experienced by the Plaintiff and Class Members has occurred without juristic reason. Since the monies that were received by the Defendants resulted from the Defendants' wrongful acts, there is and can be no juridical reason justifying the Defendants retaining any portion of such monies.

180. Further, or in the alternative, the Defendants are constituted as constructive trustees in favour of the Class Members for all of the monies received because, among other reasons:

(a) The Defendants were unjustly enriched by receipt of the monies paid for the Bair Hugger;

(b) The Class Members suffered harm by having the Bair Hugger used on them and by having been exposed to the Dangerous Complications;

(c) The monies were acquired in such circumstances that the Defendants may not in good conscience retain them;

(d) Equity, justice and good conscience require the imposition of a constructive trust;

(e) The integrity of the market would be undermined if the court did not impose a constructive trust; and

(f) There are no factors that would render the imposition of a constructive trust unjust.

181. Further, or in the alternative, the Plaintiff claims an accounting and disgorgement of the benefits which accrued to the Defendants.

COMMON ISSUES

182. Common questions of law and fact exist for the Class Members and predominate over any questions affecting individual members of the Class. The common questions of law and fact include:

(a) Does the Bair Hugger cause, exacerbate and/or contribute to an increased risk of Dangerous Complications?

(b) Was the Bair Hugger researched, designed, developed, tested, licensed, manufactured, produced, supplied, marketed, packaged, promoted, advertised, distributed, labelled and/or sold with defects that increase a patient's risk of Dangerous Complications?

(c) Are the Defendants strictly liable for the damages suffered by Class Members?

(d) Do the Defendants owe the Class Members a duty to use reasonable care?

(e) Did the Defendants act negligently in failing to use reasonable care to perform their legal obligations, to, *inter alia*, properly research, design, develop, test, license, manufacture, produce, supply, market, package, promote, advertise, distribute, label, and/or sell safe medical devices, including the Bair Hugger?

(f) Were the Defendants negligent in the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger?

(g) Were the Defendants negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as researchers, designers, developers, testers, licensers, manufacturers, producers, suppliers, marketers, packagers, promoters, advertisers, distributers, labellers and/or sellers of the Bair Hugger?

(h) Did the Defendants fail to take reasonable care to ensure that the Bair Hugger would be safe and effective?

(i) Did the Defendants breach their duty of care to the Plaintiff and to the Class Members by offering for sale a device that was not fit for the particular purpose for which it was purchased?

(j) Did the Defendants breach their express and/or implied warranties that the Bair Hugger was safe when, in fact, it was not?

(k) Did the Defendants intend or foresee that the Plaintiff and/or other Class Members would have the Bair Hugger used on them based on their unfair practices and/or tortious conduct?

(l) Did the Defendants' negligence proximately cause loss or injury and damages?

(m) Did the Defendants fail to warn the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general, of the Dangerous Complications associated with the Bair Hugger?

(n) Did the Defendants misrepresent the Bair Hugger as safe or fail to adequately disclose in a timely manner, if at all, its dangerous nature?

(o) Did the Defendants engage in unfair, false, misleading, or deceptive acts or practices regarding the research, design, development, testing, licensing, manufacturing, production, supply, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of the Bair Hugger?

(p) Did the Defendants fail in their duty to provide accurate information regarding the safety of the Bair Hugger?

(q) Did the Defendants' acts or practices breach the *Competition Act* and/or the *Food and Drugs Act*?

(r) Have Class Members been damaged by the Defendants' conduct and, if so, what is the proper measure of such damages?

(s) Were the Defendants unjustly enriched?

(t) Should an injunctive remedy be ordered to prohibit the Defendants from continuing to perpetrate their unfair, false, misleading, and/or deceptive conduct?

(u) Are the Defendants responsible to pay punitive and/or aggravated damages to Class Members and in what amount?

EFFICACY OF CLASS PROCEEDINGS

183. The members of the proposed Class potentially number in the thousands, if not more. Because of this, joinder into one action is impractical and unmanageable. Conversely, continuing with the Class Members' claim by way of a class proceeding is both practical and manageable.

184. Members of the proposed Class have no material interest in commencing separate actions. In addition, given the costs and risks inherent in an action before the courts and the amounts being claimed by each person, many people will hesitate to institute an individual action against the Defendants. Even if the Class Members themselves could afford such individual litigation, the court system could not as it would be overloaded. Further, individual litigation of the factual and legal issues raised by the conduct of the Defendants would increase delay and expense to all parties and to the court system.

185. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory and inconsistent judgments on questions of fact and law that are similar or related to all members of the class.

186. In these circumstances, a class action is the only appropriate procedure for all of the members of the class to effectively pursue their respective rights and have access to justice.

187. The Plaintiff has the capacity and interest to fairly and fully protect and represent the interests of the proposed Class and has given the mandate to his counsel to obtain all relevant

information with respect to the present action and intends to keep informed of all developments. In addition, class counsel is qualified to prosecute complex class actions.

LEGISLATION

188. The Plaintiff pleads and relies on the *Class Proceedings Act*, the *Courts of Justice Act*, the *Negligence Act*, the *Competition Act*, the *Food and Drugs Act*, the *Health Insurance Act*, and other legislation.

JURISDICTION AND FORUM

Real and Substantial Connection with Ontario

189. There is a real and substantial connection between the subject matter of this action and the province of Ontario because:

(a) Defendant 3M Canada Company has its head office in Ontario;

(b) The Defendants engage in business in Ontario;

(c) The Defendants derive substantial revenue from carrying on business in Ontario; and

~~(d)~~ The damages of Class Members were sustained in Ontario and in Canada.

190. The Plaintiff proposes that this action be tried in the City of Ottawa, in the Province of Ontario as a proceeding under the *Class Proceedings Act*.

DEFENDANTS' JOINT AND SEVERAL LIABILITY

191. The Plaintiff plead that by virtue of the acts and omissions described above, the Defendants are liable in damages to himself and to the Class Members and that each Defendant is responsible for the acts and omissions of the other Defendants for the following reasons:

(a) Each was the agent of the other;

(b) Each companies' business was operated so that it was inextricably interwoven with the business of the other as set out above;

(c) Each company entered into a common advertising and business plan to research, design, develop, test, license, manufacture, produce, supply, market, package, promote, advertise, distribute, label, and/or sell the Bair Hugger;

(d) Each owed a duty of care to the other and to each Class Member by virtue of the common business plan to research, design, develop, test, license, manufacture, produce, supply, market, package, promote, advertise, distribute, label, and/or sell the Bair Hugger; and

(e) The Defendants intended that their businesses be run as one global business organization.

192. The Plaintiff and Class Members are entitled to legal and equitable relief against the Defendants, including damages, consequential damages, attorneys' fees, costs of suit and other relief as appropriate.

193. The Plaintiff and Class Members are entitled to recover damages and costs of administering the plan to distribute the recovery of the action.

SERVICE OUTSIDE ONTARIO

194. The originating process herein may be served on the foreign Defendants *ex juris* pursuant to subparagraphs (g), (h) and (p) of Rule 17.02 of the *Rules of Civil Procedure*. Specifically, the originating process herein 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) The claim is authorized by statute; including the *Competition Act* and the *Food and Drugs Act* (rule 17.02(n)); and

(d) Against a person carrying on business in Ontario (rule 17. 02(p)).

Date: June 21, 2016

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Plaintiff

3M CANADA COMPANY *et alii.*
Defendants

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED IN OTTAWA

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

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