Form 4.02A
2021

Hfx. No.
507852

SUPREME COURT OF NOVA SCOTIA

Between:

BEVERLY MOORE

PLAINTIFF

and

KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, PHILIPS RS NORTH AMERICA LLC, RESPIRONICS INC., PHILIPS ELECTRONICS LTD., and **PHILIPS CANADA LTD.**

DEFENDANTS

Proceeding under the *Class Proceedings Act*, S.N.S. 2007, c. 28

NOTICE OF ACTION

TO:

Action has been started against you
The Plaintiff takes action against you.

The Plaintiff started the action by filing this notice with the court on the date certified by the Prothonotary.

The Plaintiff claims the relief described in the attached Statement of Claim. The claim is based on the grounds stated in the Statement of Claim.

Deadline for defending the action
To defend the action, you or your counsel must file a Notice of Defence with the court no more than the following number of days after the day this Notice of Action is delivered to you:

- 15 days if delivery is made in Nova Scotia
- 30 days if delivery is made elsewhere in Canada
- 45 days if delivery is made anywhere else.

Judgment against you if you do not defend
The court may grant an order for the relief claimed without further notice, unless you file the Notice of Defence before the deadline.

You may demand notice of steps in the action
If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a Demand for Notice.

If you file a Demand for Notice, the Plaintiff must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

Rule 57 - Action for Damages Under $150,000
Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the Plaintiff states the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the Plaintiff.

This action is not within Rule 57.

Filing and delivering documents
Any documents you file with the court must be filed at the office of the Prothonotary located on 1815 Upper water Street, Halifax, Nova Scotia (telephone # 902-424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

Contact information
The Plaintiff designates the following address:

Michael Dull
Valent Legal
1741 Brunswick Street
Suite 401
Halifax, NS B3J 3X8

Documents delivered to this address are considered received by the Plaintiff on delivery.

Further contact information is available from the Prothonotary.

Proposed place of trial
The Plaintiff proposes that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Signature
Signed this 21st day of July, 2021

Michael Dull
Valent Legal
Solicitor for the Plaintiff
Telephone: (902) 443 – 4488

Prothonotary's certificate
I certify that this Notice of Action, including the attached Statement of Claim, was filed with the court on July 21, 2021.

Prothonotary

AMY HARRISON
Deputy Prothonotary

Form 4.02B

STATEMENT OF CLAIM

Proceeding under the *Class Proceedings Act,* S.N.S. 2007, c. 28

I. Overview

1. The Defendants, Koninklijke Philips N.V., Philips North America LLC, Philips RS North America LLC, and Respironics Inc., Philips Electronics Ltd., and Philips Canada Ltd. (collectively referred to as the "Philips"), form a global healthcare group engaged in the development, marketing, and sale of sleep and respiratory care products.

2. This action is brought by the Plaintiff, Beverly Moore, on behalf of herself and a proposed Class of purchasers and users of Philips Continuous Positive Airway Pressure ("CPAP") and Bi-Level Positive Airway Pressure ("BiPAP") devices, typically used to treat Sleep Apnea, and mechanical ventilator devices, typically used to treat respiratory failure. The nature of these treatments is such that users rely on the Defendants' devices daily. For some individuals, their lives and well-being are dependent on these devices.

3. Absent the sleep or respiratory treatment provided by these devices, there exists a possibility that one can incur a heart attack, stroke, or death by asphyxiation. The cessation of treatment can be highly prohibitive to the normal functioning of an individual. In some cases, employment or licensing to drive is preconditioned on the fact that an individual is receiving CPAP or BiPAP treatment.

4. On April 26, 2021, Philips disclosed that there were serious health risks associated with the polyester-based polyurethane sound abatement foam ("PE-PUR Foam") used in certain CPAP, BiPAP and mechanical ventilator devices.

5. On June 14, 2021, Philips issued a recall of all sleep and respiratory care devices containing the PE-PUR Foam (the "Recall").

6. On June 23, 2021, Health Canada issued a recall of all devices containing PE-PUR Foam and sold in Canada.

7. All CPAP, BiPAP and mechanical ventilator devices recalled by Philips and Health Canada will be referred to collectively as the "Recalled Devices".

8. The Defendants knew or ought to have known of the health risks associated with their CPAP, BiPAP, and mechanical ventilator devices before the Recall. Users have complained of black debris/particles in the air pathway of their devices for years prior to the Recall. Despite these complaints, the Defendants continued to manufacture, market and sell these products to their own benefit and profit.

9. Further, the Recall did not provide for the immediate replacement of the device. Rather, it recommended that users outside of their warranty buy the next generation Philips device, which does not contain PE-PUR Foam, at their cost.

10. Most users rely on these devices daily. The cessation of usage of the Defendants devices may result in life-threatening or permanently altering symptoms. In many cases, users are unable to cease their usage of the affected devices due to the serious health implications. These users are forced to continue their usage of the Recalled Devices until they can locate and pay for an alternative.

11. Sudden replacement of a Recalled Device is cost-prohibitive for many users. One device can be thousands of dollars. Further, there is a general shortage of available replacement machines.

II. The Proposed Representative Plaintiff and Class

12. The Plaintiff, Beverly Moore, is a resident of Nova Scotia.

13. The Plaintiff was diagnosed with Obstructive Sleep Apnea and recommended CPAP treatment by her family physician. She was referred to a registered respiratory therapist at a Philips retailer to purchase and obtain a device for CPAP treatment.

14. The Plaintiff purchased two of the Defendants' Recalled Devices prior to June 14, 2021.

15. The Plaintiff purchased a Philips REMstar Auto A-Flex machine in 2011, and a Philips DreamStation Heated Humidifier in 2016. She used these machines nightly to treat her Obstructive Sleep Apnea.

16. Every five years, the Plaintiff is reassessed by her family physician and referred to a registered respiratory therapist for the purpose of continuing her CPAP treatment.

17. The Plaintiff is eligible for a new device under her insurance policy every five years. Five years is also the recommended time period for the replacement of a sleep or respiratory care device by Philips.

18. Despite the Recall, the Plaintiff has had to continue to use her CPAP device. She has been unable to locate a reasonably fit alternative.

19. The Plaintiff seeks to certify this action as a Class Proceeding and pleads the *Class Proceedings Act, S.N.S.* 2007, c. 28, as providing the basis for such certification. The Plaintiff, as the Representative Plaintiff, does not have any interest adverse to any of the members of the proposed Class. The Plaintiff states that there is an identifiable class that would be fairly and adequately represented by the Plaintiff; that the Plaintiff's; that the Plaintiff's claim raises common issues; and that a Class Proceeding would be the preferable procedure for the resolution of such common issues.

20. The Plaintiff brings this action on behalf of herself, and a proposed Class of other Canadians who have purchased the Recalled Devices. The proposed Class will be further defined in the Motion for Certification.

III. The Defendants

21. The Defendant Koninklijke Philips N.V. ("Royal Philips") is a conglomerate corporation, registered pursuant to the laws of the Netherlands, with its principal address located in Amsterdam, the Netherlands. The Defendant Royal Philips holds itself out as a healthcare technology corporation.

22. The Defendant Philips North America LLC ("Philips NA LLC") is a body corporate registered pursuant to the laws of Delaware, with its principal address located at 222 Jacobs Street, Cambridge, Massachusetts 02141. The Defendant Philips North America LLC holds itself out as doing business as Philips Healthcare. It is a wholly-owned subsidiary of Royal Philips.

23. The Defendant Philips RS North America LLC ("Philips RS") is a body corporate, registered pursuant to the laws of Delaware, with its principal address located at 6501 Living Place, Pittsburgh, Pennsylvania 15296.

24. The Defendant Respironics Inc. ("Respironics") is a body corporate registered pursuant to the laws of Pennsylvania, with its principal address located at 1010 Murry Ridge Lane, Murrysville, Pennsylvania 15668-8617.

25. The Defendant Philips Electronic Ltd. and Philips Canada Ltd. (collectively referred to as "Philips Canada") are bodies corporate registered pursuant to the laws of Ontario, with their principal address located at 281 Hillmount Road, Markham, Ontario L6C 2S3.

26. Royal Philips, Philips NA LLC, Philips RS, Respironics, and Philips Canada are collectively referred to as "the Defendants"; and hereinafter references to the Defendants are intended to include the above-mentioned corporations, their officers, employees, representatives, agents and associates acting on behalf of Philips.

27. Philips are wholly responsible for all the acts and omissions of their subsidiary companies by virtue of having succeeded or acquired those companies and by virtue of having assumed obligations of those companies.

28. Further, and in the alternative, the Plaintiff pleads that, by virtue of the acts described herein, each of the companies comprising Philips, as set out above, is vicariously liable for the acts and omissions of the others for the following reasons:

    (a) Each was the agent of the other;

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

(c) Each Defendant entered into a common advertising and business plan with the other to distribute and sell the Recalled Devices;

(d) Each Defendant operated pursuant to a common business plan to distribute and sell the Recalled Devices;

(e) Each Defendant intended that the business be run as one business organization; and

(f) The Defendants are related, associated or affiliated.

29. At all material times, the Defendants designed, researched, developed, tested, manufactured, marketed, packaged, promoted, distributed, licenses, and sold the Recalled Devices containing the PE-PUR Foam material for users throughout the world, including Nova Scotia and the rest of Canada. At all material times, the Defendants designed, researched, developed, tested, manufactured, marketed, packaged, promoted, distributed, licensed and sold the Recalled Devices throughout Nova Scotia and in Canada under the names CPAP, BiPAP, and mechanical ventilator devices.

30. The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the designing, testing, researching, formulation, development, manufacturing, production, labelling, advertising, promoting, distribution and/or sale of the Recalled Devices in Canada, and elsewhere.

IV. Factual Allegations

A) CPAP and BiPAP Devices, and Mechanical Ventilator Devices

31. Sleep Apnea is a sleep disorder involving the repeated interruption to an individual's breathing throughout their sleep cycle. The interruptions are due to the collapse of the individual's airway, preventing oxygen from accessing the lungs and causing a build-up of carbon dioxide that will wake him or her from sleep in order to reopen the airway.

32. The cycle of sleep interruption due to collapse of the airway will repeatedly occur throughout the night without treatment. Untreated Sleep Apnea can, therefore, result in symptoms such as low energy and daytime sleepiness, headaches, vertigo, obstructed mental ability, mood changes, high blood pressure and other long-term health effects. There is also an acute possibility of heart attack, stroke, or death by asphyxiation.

33. CPAP devices are commonly used as treatment for Sleep Apnea. It delivers pressurized air to the airway of the user in order to prevent its collapse, and thus prevents the interruption of sleep. CPAP users wear a facemask attached to the device that delivers the pressurized air.

34. BiPAP devices are a common alternative to CPAP treatment. BiPAP devices also deliver pressurized air to the airways of users; however, a BiPAP device differs in that it delivers two levels of pressurized air. One level is an inspiratory positive airway pressure delivered to the air pathway as the user inhales. The second level is an expiratory positive airway pressure expelled as the user exhales.

35. Philips also develops, markets, and sells other mechanical ventilator devices to assist with and treat respiratory failure. Mechanical ventilators, in combination with the CPAP and BiPAP devices, make up Philips' "Sleep & Respiratory Care" portfolio. One of these devices can cost thousands of dollars.

36. CPAP, BiPAP, and mechanical ventilator devices are recommended by physicians, respiratory therapists, and other medical treatment providers. One must obtain a referral from a physician in order to purchase a device from a retailer. Continued usage requires reassessment of one's condition every five years.

B) The Defect and Recall

37. On or about April 26, 2021, Philips first publicly disclosed the health risks associated with the usage of their CPAP, BiPAP, and other mechanical ventilator devices constructed with PE-PUR Foam.

38. PE-PUR Foam is used as a sound abatement material. It is integrated to certain Philips' devices as a method of minimizing the noise of the machines.

39. In Philips' Quarterly Report for Q1 of 2021, under the section titled "Regulatory Update", the Defendants' disclosed that PE-PUR Foam "may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."

40. On or about June 14, 2021, Philips issued a recall of all CPAP, BiPAP and other mechanical ventilator devices containing the PE-PUR Foam, targeting between three and four million devices.

41. In the recall notice, Philips reported that "PE-PUR Foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation."

42. The recall notice lists the potential risks of particulate exposure to degrading PE-PUR Foam as: headache, irritation (skin, eye, and respiratory tract), inflammation, respiratory issues, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic and carcinogenic effects ("Adverse Health Effects").

43. Philips lists the potential risks due to the inhalation of chemical emissions from PE-PUR Foam as: headache, dizziness, nausea/vomiting, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, and toxic and carcinogenic effects ("Adverse Health Effects").

44. Philips acknowledged that they received several complaints regarding the presence of black debris/particles within the airpath circuit of their devices (extended from the device outlet, humidifier, tubing, and mask). They received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection by users.

45. On or about June 23, 2021, Health Canada recalled all CPAP, BiPAP, and mechanical ventilator devices manufactured with PE-PUR Foam and sold within Canada. The recall notice states:

> Philips has become aware of two (2) issues that may pose a risk for patients or users of Philips Respironics branded Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BIPAP), and Mechanical Ventilators:
>
> 1. Philips has determined from user reports and testing that the Polyester-Based Polyurethane (PE-PUR) sound abatement foam used in Philips continuous and non-continuous ventilators may degrade under certain circumstances, and the degraded particles could potentially enter the air pathway of the device. This issue affects Philips Respironics branded CPAP's, Bi-Levels, and Mechanical Ventilators.
>
> 2. The results of testing performed by Philips indicate that the PE-PUR sound abatement foam used in these devices may emit certain chemicals. Our investigation to date indicates that this emission occurs during initial operation and may possibly continue throughout the device's useful life.
>
> These issues impact all device product platforms manufactured with Polyester Polyurethane (PE-PUR) sound abatement foam. There is no specific population of device serial numbers which are impacted.

C) The Recalled Devices

46. The CPAP and BiPAP devices recalled by Philips include:

Continuous Ventilator, Minimum Ventilatory Support, Facility Use

- Philips E30 (Emergency Use Authorization)

Continuous Ventilator, Non-life Supporting

- Philips DreamStation ASV
- Philips DreamStation ST, AVAPS
- Philips SystemOne ASV4
- Philips C Series ASV, S/T, AVAPS
- Philips OmniLab Advanced Plus In-Lab Titration Device

Non-continuous Ventilator

- Philips SystemOne (Q Series)
- Philips DreamStation CPAP, Auto CPAP, BiPAP
- Philips DreamStation GO CPAP, APAP
- Philips Dorma 400, 500 CPAP
- REMStar SE Auto CPAP

47. The mechanical ventilator devices recalled by Philips include:

Continuous Ventilator

- Philips Trilogy 100 Ventilator
- Philips Trilogy 200 Ventilator
- Philips Garbin Plus, Aeris, LifeVent Ventilator

Continuous Ventilator, Minimum Ventilatory Support, Facility Use

- Philips A-Series BiPAP Hybrid A30
- Philips A-Series BiPAP V30 Auto Ventilator

Continuous Ventilator, Non-life Supporting

- Philips A-Series BiPAP A40
- Philips A-Series BiPAP A30

48. The CPAP, BiPAP, and mechanical ventilator devices recalled by Health Canada include:

- BiPAP AutoSV with Smartcard Int
- BiPAP AutoSV with Smartcard Int, Core Pkg
- BiPAP Synchrony Ventilatory Support System with Smartcard

- BiPAP Synchrony Ventilatory Support System with Smartcard-Core Pack
- Trilogy 100 Ventilator, Canada
- Trilogy 100 Ventilator-International
- BiPAP AVAPS Core Package, North America
- BiPAP AutoSV Advanced/Encore Smartcard
- BiPAP AutoSV Advanced/Encore Smartcard/Hearted Humidifier
- Trilogy 200, Canada
- BiPAP A30 System-Ventilator
- BiPAP A30 System-Ventilator & System One A-Series Heated Humidifier
- BiPAP A40 Canada
- BiPAP A40 Canada
- BiPAP A40, Canada, Core Package

D) The Replacement Program

49. Philips advised the following in respect to the Recalled Devices:

> "**For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks.
>
> **For patients using life-sustaining mechanical ventilator devices:** DO NOT DISCONTINUE OR ALTER PRESCRIBED THERAPY, without consulting physicians to determine appropriate next steps."

50. Philips has also announced that, as a part of their "projected correction", they will be replacing Recalled Devices with a new or refurbished unit that incorporates a new material unaffected by the issue, or they will replace PE-PUR Foam. This program has yet to be implemented.

51. All Recalled Devices are subject to a two-year warranty upon sale. Philips announced that they will repair those Recalled Devices still within their warranty period.

V. Substantive Allegations

52. The Plaintiff and proposed Class Members allege that the Defendants engaged in tortious conduct in the designing, researching, developing, testing, packaging,

licensing, manufacturing, marketing, promotion, distributing and selling of Respiratory Devices in complete disregard for the health and safety of the Plaintiff and the Class.

53. The Plaintiff and proposed Class alleges that the Defendants knew or ought to have known of the Adverse Health Effects of PE-PUR Foam.

54. The Plaintiff and proposed Class Members further allege that the Defendants were wholly and grossly negligent.

55. The Plaintiff and proposed Class Members further allege that the Defendants failed to warn the Plaintiff and proposed Class Members of the serious complications and problems that would ensue with the use of the Recalled Devices. These individuals were not given warning or, in the alternative, clear, complete, and current warning of the Adverse Health Effects associated with the degradation and chemical emission of the PE-PUR Foam used in the Recalled Devices.

56. The Plaintiff and proposed Class Members further allege that the Defendants expressly and impliedly breached warranties.

57. The Plaintiff and proposed Class Members further allege that they and thousands of other Canadians have sustained physical, mental, and economic harm through the usage of the Recalled Devices as a result of the wholly and grossly negligent actions of the Defendants.

58. The actions of the Defendants have caused damage to the physical and mental health of the Plaintiff and proposed Class. The Plaintiff and proposed Class have also suffered pure economic loss.

59. The Plaintiff alleges on behalf of proposed Class Members that the continued use or abrupt discontinued use of the Recalled Devices creates ongoing risks to the health of the proposed Class.

60. None of the Defendants took any steps to prevent harm to the Plaintiff and proposed Class Members or to protect their health and safety.

VI. Causes of Action

(a) Negligent design, development and testing

61. The Defendants owed the Plaintiff and proposed Class Members a duty of care as follows:

a) to ensure that the Recalled Devices were thoroughly and appropriately tested so as to determine if there were any potential defects associated with the product;

b) to ensure that the Recalled Devices were fit for their intended or reasonably foreseeable use;

c) to design, develop and test the Recalled Devices using methods and processes that conform to industry standards and regulations; and

d) to conduct appropriate follow-up studies on the efficacy and safety of the Recalled Devices.

62. The Defendants were negligent in the design, development and testing of the Recalled Devices. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

a) inappropriately tested the Recalled Devices to determine the magnitude of the risks associated with their use, including but not limited to the risk of Adverse Health Effects;

b) conducted inadequately powered studies and testing to determine the potential for risk of degradation or chemical emission of PE-PUR Foam in the Recalled Devices;

c) designed and developed the Recalled Devices in a manner that caused an increase the potential for risk of Adverse Health Effects, when they knew or ought to have known that the usage of PE-PUR Foam significantly increases the risk of Adverse Health Effects;

d) designed and developed the Recalled Devices in a manner that caused an increased propensity for degradation and chemical emission of PE-PUR Foam;

e) conducted inadequate or no follow-up studies on the efficacy and safety of the Recalled Devices;

f) chose not to conform to industry standards, practices and regulations in the design, development and testing of the Recalled Devices;

g) chose not to conform with applicable disclosure and reporting obligations;

h) inappropriately monitored the post-market effects of the Recalled Devices;

i) conducted no or inappropriate follow-up studies when the risks associated with the Recalled Devices became known to them;

j) disregarded reports of Adverse Health Effects among users of the Recalled Devices, and reports of the presence of black debris/particles within the airpath circuit of certain devices extending from the device outlet, humidifier, tubing and mask;

k) instructed their employees to improperly monitor and record complaints associated with the Recalled Devices;

l) hired incompetent personnel and failed to adequately supervise the personnel conducting the design, development and testing of the Recalled Devices; and

m) took unreasonable steps to ensure that the Recalled Devices were fit for their intended or reasonably foreseeable use.

63. There existed alternative designs which were safer and economically feasible to manufacture.

64. The negligence of the Defendants in the design, development and testing of the Recalled Devices created a substantial likelihood of damage and loss for users of the Recalled Devices. The Plaintiff and proposed Class have suffered loss and damages as a result of the Defendants' negligence.

(b) Negligent Manufacturing

65. The Defendants owed the Plaintiff and proposed Class Members a duty of care as follows:

a) to conform to industry standards, practices and regulations in the manufacturing of the Recalled Devices;

b) to conduct adequate and routine inspections of the plants manufacturing the Recalled Devices; and

c) to have adequate and appropriate quality control methods in place at the plants manufacturing the Recalled Devices.

66. The Defendants were negligent in the manufacturing of the Recalled Devices. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

a) did not meet industry standards, practices and regulations in the manufacturing of the Recalled Devices on a routine bases;

b) inadequately inspected the plants manufacturing the Recalled Devices;

c) manufactured the Recalled Devices without having in place adequate quality control protocols, or in disregard of those protocols;

d) hired incompetent personnel and failed to adequately supervise the personnel manufacturing the Recalled Devices; and

e) continued to manufacture the Recalled Devices when they knew or ought to have known that the Defect caused or would cause Adverse Health Effects in users.

67. The Plaintiff and proposed Class Members have suffered harm and damages as a result of the Defendants' negligence in the manufacturing of the Recalled Devices.

(c) Negligent Distribution, Marketing and Sale

68. The Defendants owed the Plaintiff and proposed Class Members a duty of care as follows:

a) to warn the Plaintiff and Class Members that the Recalled Devices carried a significant risk of Adverse Health Effects due to the degradation and chemical emission of the PE-PUR Foam used in the Recalled Devices;

b) to take reasonably necessary and appropriate steps to ensure that medical practitioners and clinicians were appraised and fully and regularly informed of all the health risks associated with the Recalled Devices; and

c) to inform Health Canada and other regulating agencies fully, properly, and in a timely manner of the health risks and complaints associated with the Recalled Devices.

69. The Defendants were negligent in the distributing, marketing, and sale of the Recalled Devices. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

a) misinformed Health Canada by providing it with incomplete and inaccurate information concerning the Recalled Devices;

b) concealed or misled the Plaintiff, Class Members and medical practitioners and clinicians concerning the risks associated with the Recalled Devices;

c) provided the Plaintiff, Class Members and medical practitioners and clinicians with inadequate and inappropriate warnings concerning the Adverse Health Effects associated with the Recalled Devices;

d) provided the Plaintiff, Class Members and medical practitioners and clinicians with inadequate and incomplete updates and current information on the risks and efficacy of the Recalled Devices as such information became available from time to time;

e) provided inappropriate warnings of the Adverse Health Effects associated with the use of the Recalled Devices on package labels, product monograph or customer information pamphlets in Canada;

f) provided no or inadequate warnings to the Plaintiff and Class Members and their physicians and health regulators about the need for comprehensive regular medical monitoring necessary to assist in the early discovery of Adverse Health Effects, including forms of cancer, associated with the use of the Recalled Devices;

g) after receiving actual and constructive notice of the health risks associated with the Recalled Devices, failed to issue adequate warnings, recall the product in a timely manner, publicize the risks and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff and Class Members and Health Canada of the Devices' inherent risks;

h) engaged in a system of improper and inadequate direction to their sales representatives, and medical practitioners and clinicians respecting the correct usage safety and efficacy of the Recalled Devices;

i) represented that the Recalled Devices were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

j) misrepresented the state of research, opinion and literature pertaining to the safety and efficacy of the Recalled Devices;

k) continued to manufacture, market and promote the selling and/or distribution of the Recalled Devices when they knew or ought to have known that the Recalled Devices caused or could cause serious Adverse Health Effects;

m) continued to manufacture, distribute, and sell the Recalled Devices notwithstanding the fact that that:

i) they had received many credible complaints of Adverse Health Effects, including, but not limited to, the presence of black debris/particles within the airpath circuit of certain devices, extending from the device outlet, humidifier, tubing and mask; and

ii) their own research and analysis demonstrated the health risks of the Recalled Devices.

70. The Plaintiff and proposed Class Members have suffered harm and damages as a result of the Defendants' negligence in the distribution, marketing and sale of the Recalled Devices.

(d) Breach of Express Warranty

71. The Defendants expressly warranted, in the user manual, that the Recalled Devices "shall be free from defects of workmanship and materials and will perform in

accordance with the product specifications for a period of two (2) years from the date of sale".

72. The Defendants breached this express warranty because they knew or ought to have known that the Recalled Devices were defective and could cause Adverse Health Effects at the time of their sale to purchasers. The Defendants sold the Recalled Devices to purchasers without fully informing the purchasers of the risk of Adverse Health Effects related to the Recalled Devices.

73. The warranty was effectively unenforceable by the Plaintiff and proposed Class Members because the Defendants knowingly concealed the defect in the Recalled Devices for the two-year period. At the point of sale, the Recalled Devices appeared safe and in good working order, as should be reasonably expected. The acceptance of the offer was based on the assurance that the materials will perform in accordance with product specifications for a period of two years. In reality, the Recalled Devices contained defects rendering them unsafe and unusable. The Plaintiff and Class Members would not have accepted the offer and purchased the Recalled Devices had they been fully informed.

74. The two-year warranty time period was constructed based on a relationship of unequal bargaining power. The Defendants determined the two-year warranty period without any meaningful consultation with the purchasers of the Recalled Devices.

75. In the alternative, if the Defendants did not know about the defectivity of the Recalled Devices at the time of their sale to the purchasers, the Defendants gave inadequate notice of the Defect to the purchasers within the two-year warranty period. As such, the Plaintiff and proposed Class Members have been forced to bear the cost of replacement or repair of their Recalled Device.

76. Further, the Defendants failed to repair or replace the Recalled Devices, or portions of the Recalled Devices, outside of the two-year warranty period despite their knowledge of the defect at the time of sale and issuance of the two-year warranty.

77. Further, the warranty fails to fulfill its intended purpose. The PE-PUR Foam serves the purpose of sound abatement. The Recalled Devices are characterized and differentiated from other similar products on the market based on their superior sound abatement technology. The removal, replacement or repair of the PE-PUR Foam is an inadequate remedy to make the purchaser whole again.

78. As a result of the Defendants' express breach of warranty, the Plaintiff and Class have suffered harm and damages.

(e) Breach of Implied Warranty

79. The Defendants warranted to the Plaintiff and proposed Class Members that the Recalled Devices were of merchantable quality and fit for use. The Defendants

breached the implied warranties to the Plaintiff and the proposed Class Members by designing, testing, researching, formulating, developing, manufacturing, producing, labelling, advertising, promoting, distributing and/or selling the Recalled Devices, which were inherently dangerous to users and which the Defendants knew or ought to have known would lead to Adverse Health Effects.

80. Further, it was an implied term of the warranty that the repair or replacement of the Recalled Device would occur within a reasonable time period. The Defendants have provided inadequate warranty relief in an unreasonably lengthy manner thus breaching this implied warranty.

81. As a result of the Defendants' implied breach of warranty, the Plaintiff and Class have suffered harm and damages.

(f) Negligent and Fraudulent Misrepresentation

82. "Representation" means the representation made expressly and impliedly, by the Defendants, that the Recalled Devices were safe and fit for use, and effective and preferable to other similar devices on the market due to the Defendants' incorporation of PE-PUR Foam for the purpose of sound abatement in their Recalled Devices.

83. The Defendants made this Representation directly to the proposed Class Members by using the name Philips, and by labelling of the package and the manual of the Recalled Devices. The Defendants also made the Representation in their print and electronic advertising, in their brochures, and in their point-of-purchase displays.

84. The Defendants made their Representation repeatedly and in all manner of ways, including the following:

a) by their conduct in seeking approval from Health Canada and in offering the Recalled Devices for use and/or use by the Class Members; and

b) by their express words, stating the following:

- That the Defendants were a "global leader in Sleep Diagnostic and Therapy solutions";
- That the Defendants were a "global leader in health technology" and a "health technology company improving health and well-being through meaningful innovation";
- That the Defendants provided "patient-driven designed products that help patients lead healthy lives and, for providers, solutions designed to increase patient adoption, long-term use and enhanced efficiencies that help them attend to patient's needs";

- That the Recalled Devices had been "thoroughly tested";
- That the Recalled Devices provided "safe, effective therapy";
- That the Defendants' sleep therapy systems were "guided by nearly 700 interview and surveys of patients in order to produce a high quality product";
- That the Recalled Devices "are designed to be as comfortable and easy to experience as sleep is intended to be. Connecting patients and care teams [the Recalled Devices] empower users to embrace their care with confidence, and enable care teams to practice efficient and effective patient management";
- That the Defendants had 30 years of innovation and expertise in sleep therapy systems and therefore produced a safe and effective product";
- Such further and other representations as may be evidenced at trial.

85. The Defendants, as manufacturers of the Recalled Devices, owe a duty of care to consumers.

86. The Representation made by the Defendants is untrue, inaccurate and misleading.

87. The Defendants made the Representation negligently and fraudulently, knowing it was false and misleading or, failing to take adequate steps to ensure its accuracy or, recklessly caring not whether it was true or false. The Defendants intended that the Plaintiff and each proposed Class Member rely upon the Representation, and that the Plaintiff and each proposed Class Member would act on the Representation and purchase the Recalled Device.

88. The Plaintiff and each other proposed Class Member relied on the Representation to their detriment by using a Recalled Device and, in doing so, increased the Defendants' revenues from their distribution network.

89. The reliance upon the Representation by the Plaintiff and each other proposed Class Member is established by his or her purchase and/or use of a Recalled Device. Had the Plaintiff and each other proposed Class Member known that the Representation was false or misleading, he or she would not have purchased and/or used the Recalled Device.

90. As a result of the Defendants' negligent and fraudulent misrepresentation, the Plaintiff and proposed Class suffered harms and damages.

(g) Unjust Enrichment

91. Substantial benefits have been conferred on the Defendants by the Plaintiff and the proposed Class by their purchasing of the Recalled Devices. The Defendants have knowingly and willingly accepted and enjoyed these benefits.

92. The Defendants either knew or should have known that the payments rendered by the Plaintiffs and the Class were given and received with the expectation that the Recalled Devices would perform as represented and warranted. For the Defendants to retain the benefit of the payments under these circumstances in inequitable.

93. The Defendants' acceptance and retention of these benefits under the circumstances make it inequitable for the Defendants to retain the benefit without payment of the value to the Plaintiff and the proposed Class.

94. The Plaintiff and the proposed Class are entitled to recover from the Defendants all amounts wrongfully collected and improperly retained by the Defendants, plus interest thereon.

95. As a direct and proximate result of the Defendants' wrongful conduct and unjust enrichment, the Plaintiff and the proposed Class are entitled to an accounting, restitution from, and institution of, a constructive trust disgorging all profits, benefits, and other compensation obtained by the Defendants.

(h) Breach of Section 52 of the *Competition Act*

96. The Defendants made the Representation to the public as particularized in paragraphs 82 to 84. In doing so, the Defendants breached section 52 of the *Competition Act*, R.S., 1985, c. C-34, s.1, because the Representation:

a) was made for the purpose of promoting, directly or indirectly, the use of the Recalled Devices and/or the business interests of the Defendants;

b) was made to the public;

c) was made knowingly or recklessly; and

d) was false and misleading in a material respect.

97. The Plaintiff and every other Class Member relied upon the Representation by using the Recalled Devices and suffered damages and loss.

98. Alternatively, the Plaintiff and Class Members rely upon section 52 (1.1) of the *Competition Act* and plead that it is unnecessary for any Plaintiff or Class Member to show actual reliance on the misleading statements of the Defendants for the purposes of establishing a breach of the *Competition Act*.

99. Pursuant to section 36 of the *Competition Act*, the Defendants are liable to pay the damages that resulted from the breach of section 52.

(i) Breach of the *Consumer Protection Act*

100. The Plaintiff pleads and relies upon the *Consumer Protection Act,* R.S.N.S, 1989, c. 92, s. 26, and equivalent legislation in other provinces and territories. The marketing, advertisement, promotion, labelling, distribution, and sale of the Recalled Devices to the Plaintiff and Class constitute a "consumer sale" under section 26.

101. The Defendants breached the implied conditions or warranties set out in section 26 the *Consumer Protection Act*. In particular, the Defendants breached:

a) the implied condition that the Recalled Devices shall correspond with the description in the contract for sale of goods;

b) the implied condition that the goods shall be reasonably fit for the particular purpose for which the Recalled Devices are required, as it was made known by the Plaintiff and Class Members to the Defendants, and as the Plaintiff and Class Members relied upon the skill or judgement of the Defendants that the Recalled Devices were fit for the description which is in the course of the Defendants' business to supply; and

c) the implied condition that the Recalled Devices shall be of merchantable quality.

(j) Breach of the *Sale of Goods Act*

102. The Plaintiff pleads and relies upon the *Sale of Goods Act*, R.S., 1989, c. 408, s. 17 and equivalent legislation in other provinces and territories. The Recalled Devices were purchased by the Plaintiff and proposed Class Members pursuant to consumer agreements within the meaning of the *Sale of Goods Act*. The Defendants represented that the Recalled Devices were safe, an effective Sleep Apnea treatment or an effective respiratory failure treatment, and a more effective device than other similar devices manufactured by the Defendants' competitors. These representations were in fact false, misleading or deceptive.

103. The Plaintiff pleads that the Recalled Devices were neither fit for their intended purpose nor of merchantable quality as an effective treatment for Sleep Apnea or respiratory failure, or as a more effective treatment for Sleep Apnea or respiratory failure than other comparable devices. In making contrary representations, the Defendants acted in breach of section 17 of the *Sale of Goods Act*.

VII. Damages

104. The Plaintiff and Class Members' injuries and damages were caused by the Defendants, their servants and agents.

105. The Defendants have caused injury to the Plaintiff and to the Class Members including:

(a) personal injury;

(b) out-of-pocket expenses including, but not limited to, those connected with medical care and treatment, and the cost of the Recalled Devices paid for directly by Class Members;

(c) cost of past and future medical and other care and services;

(d) past and future loss of income; and

(e) a loss of support, guidance, care and companionship.

106. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiff and Class Members have been placed in a position where they have sustained or will sustain serious personal injuries and damages.

107. As a result of the conduct of the Defendants, the Plaintiff and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

108. Some of the expenses related to the medical treatment that the Plaintiffs and Class Members have undergone and will continue to undergo have been borne by provincial health insurers including the Nova Scotia Medical Services Insurance Plan. As a result of the negligence of the Defendants, the provincial health insurers have suffered and will continue to suffer damages.

109. The subrogated interests of the Provincial and Territorial health insurers include the cost of all past and future insured services for the benefit of the Plaintiffs and Class Members on account of their usage of the Recalled Devices.

110. Class Members who paid for their own Recalled Device seek a full refund of the purchase price. The Class Members are entitled to recover from the Defendants as special damages the cost of purchasing the Recalled Device.

(a) Manifest Harm and Injuries:

111. In addition, the past and ongoing use of Recalled Devices has resulted in the Plaintiff and Class Members' physical and mental health injuries pleaded above, and have

further led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, and out of pocket expenses.

112. The Plaintiff and Class Members assert a claim for each of the types of damages listed above.

(b) Medical Monitoring: Responding to Material Risk of Illness

113. Further, the past and ongoing use of the Recalled Devices have also caused or materially contributed to increased health risks to the Plaintiff and other Class Members. As a result of the use, the Plaintiff and Class Members have already and will continue to experience illness, anxiety, loss of amenities and enjoyment of life.

114. There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will detect at an early stage the serious problems which may result from the use of the Recalled Devices by the Class Members. However, not all of these tests are generally available or being administered to the Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm and risk of death therefrom.

115. The Class Members seek to recover damages in the form of the total funds required to establish a 'medical monitoring' process to be made available to the Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Class Members.

116. The damages referred to above may have been incurred directly by the Plaintiff and Class Members or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.

117. The Plaintiffs further allege that the establishment of a medical monitoring process is a necessary and appropriate step for all of the Defendants to take in the course of fulfilling their obligation to minimize the damages suffered by Class Members.

VIII. Aggravated, Punitive and Exemplary Damages

118. The Defendants manufactured, marketed, promoted and sold the Recalled Devices with full knowledge of the fact that they were adversely impacting the physical and psychological health of the Plaintiff and the Class Members. Knowledge of the risks associated with the use of the Recalled Devices was not released to the Plaintiff and Class Members. Despite having specific information that the Plaintiff and Class Members were at risk of serious problems associated with the use of the Recalled Devices, the Defendants continued or permitted the continuation of the manufacturing, marketing, promoting and selling of the Recalled Devices without any or reasonable controls.

119. These activities were carried out with reckless, callous and wanton disregard for the health, safety and pecuniary interests of the Plaintiff and other Class Members. The Defendants knowingly compromised the interests of the Plaintiff and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that the Recalled Devices posed to the Plaintiff and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.

120. The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety or welfare of the Plaintiff and Class Members.

121. Consequently, the Plaintiff and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.

122. The Plaintiffs and Class Members plead that, by virtue of the acts described herein, the Defendants are liable to them in damages. Each of the Defendants is vicariously liable for the acts and omissions of the others for the following reasons:

(a) each was the agent of the other;

(b) each Defendants' business was operated so that it was inextricably interwoven with the business of the other;

(c) each Defendant entered into a common advertising and business plan with the other to distribute and sell the Recalled Devices;

(d) each Defendant owed a duty to the other and to the Plaintiff and Class Member by virtue of the common business plan to distribute and sell the Recalled Devices; and

(e) each Defendant intended that the businesses be run as one global business organization.

IX. General Provisions

123. The Plaintiff states that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiff and other Class Members.

124. The Plaintiff pleads the doctrine of *respondeat superior* and states that the Defendants are vicariously liable to the Plaintiff and Class Members for the acts, omissions, deeds,

misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.

X. Statutes

125. The Plaintiff pleads and relies, inter alia, upon the following legislation:

Newfoundland

- *Consumer Protection Act, R.S.N.L. 1990 c. C-31*
- *Trade Practices Act,* R.S.N.L., 1990, c. T-71
- *Fatal Accidents Act, R.S.N.L. 1990, c. F-6*
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990, c. H-7
- *Medical Care Insurance Act*, 1999 S.N. 1999, c. 5.1
- *Sale of Goods Act*, R.S.N.L. 1990, c.S-6
- *Current to Gazette Vol. 81:46 (November 17, 2006)*

Nova Scotia

- *Consumer Protection Act, R.S.,* 1989, *c.92*
- *Fatal Injuries Act, R.S.N.S. 1989, c. 163, amended 2000, c. 29, ss 9-12*
- *Health Services and Insurance Act, R.S.N.S. 1989, c. 197*
- *Sale of Goods Act, R.S., 1989, c. 408*
- *Current to Gazette Vol. 30:21 (November 10, 2006)*

Prince Edward Island

- *Consumer Protection Act, R.S.P.E.I. 1988, c. C-19*
- *Business Practices Act, R.S.P.E.I., 1998, c. B-7;*
- *Fatal Accidents Act, R.S.P.E.I. 1988, c. F-5, as amended*
- *Hospital and Diagnostic Services Insurance Act, R.S.P.E.I. 1988, c H-8*
- *Sale of Goods Act, R.S.P.E.I. 1988, c. S-1*
- *Current to Gazette Vol. 132:47 (November 25, 2006)*

New Brunswick

- *Consumer Product Warranty and Liability Act*, S.N.B., 1978, c. C-18.1
- *Fatal Accidents Act,* R.S.N.B. 1973, c. F-7
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9
- *Sale of Goods Act, R.S.N.B. 1973, c.S-1*
- *Current to Gazette Vol. 164:1901 (November 29, 2009)*

Quebec

- *Civil Code of Quebec* Book 5
- *Consumer Protection Act*, R.S.Q., c. P-40-1

Ontario

- *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;
- *Consumer Protection Act*, 2002 S.O. 2002, c.30, Sched. A;
- *Courts of Justice Act*, R.S.O. 1990, c.43;
- *Health Insurance Act*, R.S.0. 1990, c. 11.6;
- *Negligence Act*, R.S.O. 1990, c. N.1;
- *Family Law Act*, R.S.O. 1990, C. F.3;
- *Sale of Goods Act*, R.S.0. 1990, c. S.1;
- *Trustee Act*, R.S.O. 1990,c.T.23

Manitoba

- *Fatal Accidents Act*, C.C.S.M. c. F50, as amended
- *Manitoba Public Insurance Corporation Act*, C.C.S.M. c. P215
- *Sale of Goods Act*, C.C.S.M. c. 51O
- *The Consumer Protection Act*, C.C.S.M. c. C200
- *The Business Practices Act*, S.M., 1990-91, c. 6
- *The Health Services Insurance Act*, R.S.M. 1987, c. H35
- *Trustee Act*, C.C.S.M. c.T160
- *CurrenttoGazetteVol.135:44(November4,2006)*

Saskatchewan

- *Department of Health Act*, R.S.S. 1978, c. D-17
- *Fatal Accidents Act*, R.S.S. 1978, c. F-11 as amended
- *The Consumer Protection Act,* S.S., 1996, c. C-30-1
- *The Sale of Goods Act*, R.S.S. 1978, c. S-1
- *CurrenttoGazetteVol.102:44(November3,2006)*

Alberta

- *Alberta Health Care Insurance Act*, R.S.A., 2000, C.A-20
- *Fair Trading Act,* R.S.A., 2000, c. F-2
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8
- *Hospital's Act*, R.S.A. 2000, c. H-12
- *Sale of Goods Act*, S-2 R.S.A 2000
- *Tort Feasors Act*, R.S.A. 2000, c. T-5
- *Domestic Relations Act,* R.S.A. 2000, c. D10.5, was repealed by R.S.A. 2003, c. F-4.5 [*Family Law Act*]

British Columbia

- *Businesses Practices and Consumer Protection Act*, S.B.C., 2004, c. 2
- *Hospital's Insurance Act*, R.S.B.C. 1996, c. 204 [en. 1994, c. 37, s. 4; am. 1996, c. 24, s. 1(3)]

- *Sale of Goods Act*, R.S.B.C. 1996, c.410
- *Current to Gazette Vol. 49:19 (October 20, 2006)*

Nunavut

- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- *Current to Gazette Vol. 8:10 (October 31, 2006)*

Northwest Territories

- *Consumer Protection Act*, R.S.N.W.T. 1988, c. C-17
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c.T-3
- *Sale of Goods Act*, R.S.N.W.T. 1988, c. S-2
- *Trustee Act*, R.S.N.W.T. 1988, C.S-2
- *Current to Gazette Vol. XXVII:10 (October 31, 2006)*

Yukon

- *Consumers Protection Act*, R.S.Y. 2002, c.40
- *Hospital Insurance Services Act*, R.S.Y. 2002, c.112
- *Sale of Goods Act*, R.S.Y. 2002, c.198
- *Current to Gazette Vol. 25:10 (October 15, 2006)*

Canada

- *The Competition Act,* R.S., 1985, c. C-34

XI. Relief Sought

126. The Plaintiff repeats the foregoing paragraphs and states that the Defendants are jointly and severally liable for the following:

(a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;

(b) general damages, including aggravated damages for personal injuries;

(c) special damages for medical expenses and other expenses related to the use of the Recalled Devices;

(d) aggravated, punitive, and exemplary damages;

(e) further or alternatively, the Plaintiff claims, on his own behalf and on behalf of the Class Members:

(i) a declaration that the benefits which accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;

(ii) an accounting of the benefits which accrued to the Defendants as a result of their wrongful acts;

(iii) a declaration that the Defendants hold in trust for the Class the benefits which accrued to the Defendants as a result of their wrongful acts;

(iv) disgorgement of the benefits which accrued to the Defendants as a result of their wrongful acts;

(f) damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Class Member, and to make recommendations about their treatment;

(g) subrogated claims on behalf of the Provincial and Territorial providers of medical services;

(h) interest pursuant to the *Judicature Act*;

(i) costs; and

(j) such further and other relief as this Honourable Court Deems just.

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Halifax, in the County of Halifax, Province of Nova Scotia, this 21st day of July, 2021.

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