UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SOCLEAN, INC., Plaintiff, v. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC, Defendants.	Civil Action No. 1:21-cv-11662-NMG **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

Plaintiff SoClean, Inc. ("SoClean" or "Plaintiff"), by and through its undersigned counsel, brings this action against Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively, "Philips" or "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. This is a case about a multinational corporation deflecting attention away from inexcusable design flaws, misleading the public, creating confusion, and causing hundreds of millions of dollars of damage in the process.

2. A recent inspection by the Food and Drug Administration (FDA) revealed that Philips has known for years that the company's products created a serious risk of harm to consumers. The FDA's report also confirmed that Philips took no corrective action while the company's executives concealed damaging information and problematic test results from the public. In short, Philips engaged in a deliberate cover-up and initiated a dishonest smear campaign against SoClean to shirk responsibility and accountability for its own corporate malfeasance.

3. Philips' Q1 2021 Quarterly Report included a warning: Philips had identified "possible risks" associated with the foam used by Philips for sound abatement in certain sleep and respiratory care devices.

4. Several months later, Philips issued a voluntary product recall of the affected devices, including continuous positive airway pressure (CPAP) machines, bi-level positive airway pressure (BiPAP) machines, and ventilators.

5. Philips provided two independent reasons for the product recall. First, Philips stated that the polyester-based polyurethane foam it chose for sound abatement "may degrade into particles which enter the device's air pathway and be ingested or inhaled by the user." Second, Philips said the foam may "off-gas certain chemicals" that may cause "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects."

6. Without any explanation, Philips suggested to consumers and users of its sleep and respiratory care devices that ozone cleaners were somehow responsible for the product recall: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation."

7. The FDA safety communication cited by Philips (with a hyperlink) had nothing to do with safety issues related to foam degradation or off-gassing. In fact, the document was wholly unrelated to the product recall.

8. Philips continued to mislead consumers and deflect blame to ozone cleaners after the product recall. In a Q&A published on Philips' website, the company referenced ozone cleaners at least nine times, suggesting they were somehow responsible for the issues that led to

the recall. Included among those statements: "Philips is recommending that customers and patients do not use ozone-related cleaning products." Also: "Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods."

9. Philips' Chief Executive Officer and Chairman of the Board, Frans van Houten, condemned the use of ozone cleaners in a series of earnings calls. On April 26, 2021, Philips' CEO said "[w]e don't want to debate culpability," and then, in the same breath, tried to deflect blame and shift responsibility to "certain companies [in the U.S.] that have been very active in marketing that [ozone cleaning] method." He continued: "The FDA observed this and also put out a safety notice to say don't use ozone for sleep ap[nea] machines." This statement by Philips' CEO is demonstrably false. During the next earnings call in July 2021, Mr. van Houten offered an inaccurate assessment of ozone cleaners: "It's a very aggressive cleaning method that should not be used on medical devices at all." This statement has no scientific merit whatsoever.

10. After SoClean filed this lawsuit against Philips, Mr. van Houten attempted to rewrite history concerning Philips' false and misleading statements. During Philips' Q3 Earnings Call, on October 18, 2021, Mr. van Houten said: "I would also like to remind you that, when we announced the recall in June, we acted on the assumption of a worst case clinical impact scenario assessment, related to the PE-PUR foam issue, based on test data and information available at that point time." Contrary to Mr. van Houten's prior statements, which suggested that Philips had conducted robust testing on ozone, he admitted: "When we went out in April and May, it was on a relatively narrow set of data, taking a worst-case scenario, as to potential patient risk." He also admitted that "further research and testing" and "expert assessments" were not expected until the fourth quarter of 2021.

11. Philips' CEO is a material witness in this case.

12. The true reason for Philips' product recall was its own glaring design flaw. Philips chose a material for sound abatement—polyester-based polyurethane foam—known to degrade in the presence of heat and humidity. At the same time, many of the recalled products operate under hot and humid conditions, often with the use of a heated humidifier. Also, by Philips' own admission, polyester-based polyurethane foam off-gasses harmful chemicals right out of the box. Simply put, the safety concerns that led to the recall arose because of Philips' poor choice of foam.

13. Philips published an "update" to the recall notification on its website, in which it told customers: "Products that are not affected [by the recall] may have different sound abatement foam materials, as new materials and technologies are available over time." Philips failed to disclose, however, that alternative materials for sound abatement had existed for years prior to the recall. Included among the alternative materials available to Philips were foams that would not physically break down in the presence of water or off-gas harmful chemicals.

14. In the same "update," Philips admitted that "sound abatement foam in unaffected devices may be placed in a different location due to device design." In other words, Philips could have designed the recalled machines such that the sound abatement foam was not in the direct path of the air being inhaled by users.

15. The safety concerns associated with degradation and off-gassing were easily addressed by replacing the polyester-based polyurethane foam with a more stable material. Indeed, Philips has reassured customers that "Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected" by the recall. Of course, the next-generation DreamStation 2 product uses a different type of foam for sound abatement. In short, replace the problematic foam and the safety concerns go away.

16. The issues that led to the product recall were caused by Philips' flawed product design, including Philips' poor choice of materials for sound abatement, not the use of ozone cleaners to sanitize and disinfect the devices. Degradation of Philips' polyester-based polyurethane foam occurs by hydrolysis, a chemical reaction involving water, without any exposure to ozone. Also, the off-gassing of harmful chemicals by the polyester-based polyurethane foam is wholly unrelated to ozone exposure. If anything, the use of ozone cleaners would help mitigate the off-gassing of harmful chemicals and effectively destroy them through chemical reactions.

17. On November 12, 2021, the FDA issued an update on the Philips recall and a report from an inspection of Philips that took place from August 26 to November 9, 2021. The FDA stated that the purpose of the inspection was to "determine what may have caused or contributed to the foam issues and assess adherence to the agency's requirements for quality manufacturing."

18. The report included eight specific observations with detailed findings in support of each observation. Among other things, the FDA report included the following findings:

- "[T]here were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/ or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices . . . ."
- "[A] query of [Philips'] consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 and 2017 and involved Trilogy devices."

- "No formal investigation, risk analysis, or CAPA [Corrective and Preventative Actions] were initiated, performed, or documented, in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017, prior to the initiation of CAPA INV 0988 in 2018."
- "[E]mail correspondence between your firm and your raw foam supplier beginning 10/30/2015 and forward, document that [Philips] was made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by your foam supplier on 08/05/2016, via email."
- "[Philips] management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021."

19. The FDA report confirmed that Philips had been aware of safety concerns related to the off-gassing of harmful chemicals and foam degradation for years, but it took no corrective action while the company's executives concealed damaging information and problematic results from the public.

20. The FDA report also confirmed that Philips had been receiving customer complaints about its foam long before SoClean machines were even on the market and with respect to ventilator devices for which SoClean is not compatible.

21. The FDA report did not contain a single reference to ozone.

22. The dirty secret of the CPAP industry is that the cleaning instructions provided by the device manufacturers, including Philips, are inadequate to disinfect the entire machine. A superficial cleaning with soap and warm water is not sufficient to kill all pathogens, and it will not

address the inner recesses of the device. As a result, germs and bacteria can accumulate not only in the mask and tubing, but also deep inside the machine—that is, unless an ozone cleaner is used to disinfect the entire device.

23. Worse yet, CPAP and BiPAP machines are often returned within a matter of weeks, only to be refurbished and shipped out to other customers without their knowledge. This cycle can repeat itself up to 5-10 times with "new" CPAP equipment. In the absence of any cleaning standards or regulations for refurbished equipment, no one knows what happens to these devices before they find a permanent home and what, if anything, has been done to sanitize them in between users.

24. Ozone gas is widely recognized in peer-reviewed scientific literature as "one of the safest [biocides] for humans" and a "safe, fast, and economical alternative when compared to other low-temperature sterilization methods for the disinfection and/or sterilization of medical devices and environments."[1] Among the reported advantages of ozone as a sterilant are (i) "[h]igh efficacy," (ii) "[h]igh material compatibility," (iii) "[n]o toxic residues or emissions," (iv) "[n]o manual handling of the sterilant," and (v) "[l]ow temperature process."[2] Applications include "[r]eusable medical devices" made of "materials like stainless steel, titanium, anodized aluminum, ceramic, glass, silica, PVC, Teflon, silicone, polypropylene, polyethylene and acrylics."[3]

25. Plaintiff SoClean is the market leader for ozone cleaners. SoClean's products use ozone gas that flows through CPAP and BiPAP equipment and kills germs, bacteria, or viruses it

[1] Luis Alberto Breda Mascarenhas et al., *Technological Advances in Ozone and Ozonized Water Spray Disinfection Devices*, 11 Appl. Sci. 3081, at 1, 15 (2021).

[2] Meenakshi Sundaram Muthuraman et al., *Systematic Review on Sterilization Methods of Implants and Medical Devices*, 8 Int. J. ChemTech Res. 2, 897-911, at 906-7 (2015).

[3] *Id.*

comes into contact with. SoClean's lead product, the SoClean 3.0, is an automated cleaning device that cleans and sanitizes CPAP and BiPAP machines. Its patent-protected technology kills up to 99.9% of germs and bacteria that can build up in CPAP and BiPAP equipment without having to disassemble the devices.

26. Philips' false and misleading statements regarding ozone cleaners have had a devastating impact on SoClean. As a result of Philips' warning, public statements, statements to SoClean's distributors and customers, and other wrongful conduct, SoClean's sales have plummeted, its brand reputation has been tarnished, and the company has lost an enormous amount of goodwill. Philips has caused damage to SoClean in excess of $200 million.

27. SoClean's ozone cleaners are the only solution on the market capable of effectively cleaning and disinfecting CPAP and BiPAP machines. Nonetheless, Philips has engaged in deliberate misdirection, pointing the finger at SoClean's ozone cleaners to divert attention away from Philips' poor choice of materials and obvious design flaws. Philips only has itself to blame for the product recall. Through this lawsuit, SoClean intends to defend itself against Philips' dishonest attacks, restore its hard-earned reputation, and correct the record for a consuming public that has been intentionally misled by Philips.

PARTIES

28. Plaintiff SoClean is a Delaware corporation with its principal place of business at 12 Vose Farm Road, Peterborough, New Hampshire 03458.

29. Defendant Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands.

30. Defendant Philips North America LLC is a Delaware company with its principal place of business in Andover, Massachusetts.

31. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company headquartered in Pittsburgh, Pennsylvania.

JURISDICTION AND VENUE

32. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because this action arises, in part, under 15 U.S.C. § 1125(a).

33. This Court has personal jurisdiction over Defendants because Defendants have conducted substantial business and have promoted their products, including sleep and respiratory care devices, in the Commonwealth of Massachusetts and in this District. Defendants have purposefully availed themselves of the privilege of conducting business in Massachusetts. Defendants have purposefully directed their activities at Massachusetts residents, and this litigation results from injuries that arise out of and relate to those activities. The assertion of personal jurisdiction over Defendants in this District is reasonable and fair.

34. On the subject of the product recall, Philips has admitted that "[r]elevant documents and witnesses are located in Massachusetts." *See In Re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Liability Litigation*, Case MDL No. 3014, Dkt. No. 47, at 7.

35. Personal jurisdiction over Defendant Philips North America LLC also exists because the company's headquarters and principal place of business are located in the Commonwealth of Massachusetts.

36. Personal jurisdiction over Defendant Philips RS North America LLC also exists because Philips RS North America LLC is a citizen of Massachusetts. Philips RS North America LLC is wholly owned by a single member, Philips RS North America Holding Corporation, which has a principal place of business located at 222 Jacobs Street, Cambridge, MA 02141.

37. Defendant Koninklijke Philips N.V. is the parent company of Defendant Philips North America LLC, its largest subsidiary in the United States.[4] Upon information and belief, Defendant Koninklijke Philips N.V. exercises pervasive control over Philips North America LLC with regard to the day-to-day operations of the subsidiary and the conduct underlying this dispute. The corporate parent appears to claim copyright ownership and maintain control over the website https://www.usa.philips.com, which contains numerous published statements regarding ozone cleaners at issue in this dispute. Upon information and belief, the parent and its largest U.S. subsidiary engage in a common undertaking in a manner that substantially disregards the separate nature of the corporate entities or, at least, creates serious ambiguity about the existence of any such separation. Upon information and belief, the parent the subsidiary have overlapping leadership and personnel on the Executive Committee and Board of Management.

38. To the extent Defendant Koninklijke Philips N.V. contests specific jurisdiction and contends it is not subject to jurisdiction in any state's courts of general jurisdiction, including the Commonwealth of Massachusetts, personal jurisdiction would exist under Federal Rule of Civil Procedure 4(k)(2). SoClean has asserted a claim under federal law. And the exercise of personal jurisdiction satisfies due process requirements. Upon information and belief, Defendant Koninklijke Philips N.V. has previously consented to personal jurisdiction and has affirmatively filed lawsuits in this District on multiple occasions.

39. Venue is proper under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to this action occurred in this District.

[4] Defendant Koninklijke Philips N.V. is also the parent company of Defendant Philips RS North America LLC.

FACTUAL ALLEGATIONS

CPAP and BiPAP Machines

40. Sleep apnea is a potentially dangerous sleep disorder in which a person's breathing is interrupted during sleep. People with untreated sleep apnea stop breathing repeatedly during the night, such that the brain and the rest of the body may not get enough oxygen. If left untreated, serious complications may result, including high blood pressure, diabetes, and heart problems.

41. CPAP machines deliver enough air pressure to keep upper airway passages open, thereby preventing snoring and sleep apnea. The pressurized air is delivered through a mask that seals on the mouth or nose.

42. Sleep apnea can also be treated with BiPAP machines. Like CPAP devices, BiPAP machines generate and deliver positive airway pressure through a system of masks, hoses, and other accessories. The primary difference is that BiPAP machines have two pressure settings for inhalation and exhalation, allowing for lower pressure during exhalation.

43. Philips sells both CPAP and BiPAP machines, as well as ventilator devices for respiratory care. Upon information and belief, Philips has a majority market share for CPAP and BiPAP machines.

44. Philips launched its DreamStation product line in October 2015. Philips' DreamStation products are among the best-selling CPAP machines on the market. A photo of the original DreamStation product is shown below.

SoClean's Cleaning and Sanitizing Products

45. The dirty secret of the CPAP industry is that the manufacturer instructions for keeping the devices clean do not properly sanitize the devices. The Philips website acknowledges that "[i]t is vitally important to keep everything as clean as possible, as hoses/tubing and masks can be a prime breeding ground for bacteria and mold," quoting the Director of Communications for Sleep Apnea Treatment Centers of America.

46. Philips' cleaning instructions recommend that users wipe down any areas that come into contact with skin on a daily basis, using a damp towel with mild detergent and warm water. For devices with a humidifier, Philips also recommends refilling the humidifier with clean, distilled water each day before bed. On a weekly basis, Philips tells users to clean the CPAP tubing, nasal mask, and headgear in "a bathroom sink filled with warm water and a few drops of ammonia-free, mild dish detergent." Philips also instructs users to remove and rinse the filter with warm tap water each week. Last, Philips recommends a weekly cleaning of the humidifier with warm soapy water.

47. Upon information and belief, the cleaning instructions recommended by CPAP device manufacturers, including Philips, are inadequate to properly clean and disinfect the devices. Wiping down the mask and hosing with mild detergent and soapy water is insufficient to kill all bacteria, mold, and other pathogens that may accumulate during the lifespan of the device.

48. Moreover, Philips' cleaning instructions do not address every part of the machine, including internal components that may also serve as a breeding ground for bacteria, mold, and other pathogens. By way of example, Philips' cleaning instructions do nothing to address bacteria that may be growing within the sound abatement foam on the inside of the device. This is notable

because, upon information and belief, microbial enzymes can accelerate degradation of the polyester-based polyurethane foam that Philips used for sound abatement, particularly in the absence of a biocide additive.

49. The lack of cleanliness is compounded by the fact that CPAP machines are often returned, refurbished, and then shipped to other customers, all within a matter of weeks. This cycle could repeat itself up to 5-10 times with "new" CPAP equipment. Absent any cleaning standards or regulations for the refurbished equipment, it is not possible to trace what happens to the devices before they find a permanent home and what, if anything, has been done to sanitize the devices in between users. Upon information and belief, CPAP machines being sold to consumers as "new" could easily have multiple prior owners, without any cleaning or sanitization from one user to the next.

50. Ozone cleaners provide the best available technology on the market to thoroughly clean and sanitize CPAP and BiPAP machines and rid them of bacteria, mold, and viruses.

51. Ozone gas is widely recognized in peer-reviewed scientific literature as "one of the safest [biocides] for humans" and a "safe, fast, and economical alternative when compared to other low-temperature sterilization methods for the disinfection and/or sterilization of medical devices and environments." *See* Luis Alberto Breda Mascarenhas, et al., *Technological Advances in Ozone and Ozonized Water Spray Disinfection Devices*, 11 Appl. Sci. 3081, at 1, 15 (2021). Among the reported advantages of ozone as a sterilant are (i) "[h]igh efficacy," (ii) "[h]igh material compatibility," (iii) "[n]o toxic residues or emissions," (iv) "[n]o manual handling of the sterilant," and (v) "[l]ow temperature process." *See* Meenakshi Sundaram Muthuraman et al., *Systematic Review on Sterilization Methods of Implants and Medical Devices*, 8 Int. J. ChemTech Res. 2, 897-911, at 906-7 (2015). Applications include "[r]eusable medical devices" made of "materials like

stainless steel, titanium, anodized aluminum, ceramic, glass, silica, PVC, Teflon, silicone, polypropylene, polyethylene and acrylics." *Id.* Researchers have also found that ozone can significantly reduce the amount of surrogate viruses that can cause COVID-19. *See*, *e.g.*, G. Franke et al., *An automated room disinfection system using ozone is highly active against surrogates for SARS-CoV-2*, 112 J. Hospital Infection 108-113 (2021).

52. SoClean is the dominant market leader for ozone cleaners. SoClean's lead product, the SoClean 3.0, is an automated cleaning device that cleans and sanitizes CPAP and BiPAP machines within minutes. Its patent-protected technology kills up to 99.9% of germs and bacteria that can build up in CPAP and BiPAP equipment without having to disassemble the device.

53. SoClean products generate and pump ozone through the supply tube and into the humidifier reservoir, cleaning not only the water, but also the inner walls of the reservoir. The ozone then moves through the CPAP hose, reaching every crevice of the device, and eliminating potentially harmful pathogens in the process. Ozone also passes in and out of the mask, cleaning

it in the same manner as the hose and reservoir. When the short cleaning cycle is over, the ozone gas exits the chamber through a special filter that coverts it back into common oxygen.

Philips' "Warning" Coincides with the Launch of Its Next-Generation CPAP Device

54. Philips' Q1 2021 Quarterly Report told the public that the company had identified "possible risks" associated with "the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use." Despite the report's reference to multiple risks, Philips identified only one: a risk that the foam may degrade "under certain circumstances." According to Philips, the degradation was "influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."

55. During Philips' Q1 Earnings Call, the company's CEO, Frans van Houten, was more definitive. On April 26, 2021, Mr. van Houten said that ozone "in fact has an impact on the foam used in the machine, which makes it degrade."

56. The timing of the warning coincided with the launch of Philips' next-generation CPAP device. In fact, Philips issued the warning just two weeks after the launch of the new DreamStation 2 product. The Q1 Quarterly Report reassured consumers that "Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected" by the risks identified in the warning. Philips chose a different foam for sound abatement in the DreamStation 2.

57. During the Q1 Earnings Call, Philips' CEO said: "The good thing is, is that we have launched Dream Station 2. That product is already authorized in the United States and is of a different design and is not affected by this component."

58. Upon information and belief, Philips coordinated the timing of the warning with its product launch to induce customers to switch from the original DreamStation to the new DreamStation 2 product.

59. Upon information and belief, Philips' knowledge of potential safety issues associated with polyester-based polyurethane foam led the company to select a different foam for sound abatement in the DreamStation 2 product.

The Voluntary Product Recall

60. On June 14, 2021, Philips issued a recall notification in the United States for multiple sleep and respiratory care devices, including the original DreamStation CPAP device ("Recall Notice"). The Recall Notice provided two separate, independent reasons for the recall. First, Philips stated that the polyester-based polyurethane foam chosen for sound abatement "may degrade into particles which may enter the device's the [sic] air pathway and be ingested or inhaled by the user[.]" Second, Philips also stated that the foam "may off-gas certain chemicals." Without any explanation, Philips suggested that ozone cleaners were somehow responsible for the recall: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation." Notably, the FDA safety communication cited by Philips (with a hyperlink) had nothing to do with foam degradation.

61. Philips recalled a total of 20 serial numbers for different products, including numerous ventilator products that are not compatible with SoClean's ozone cleaner devices.

Philips Misleads the Public About Off-Gassing

62. The Recall Notice and other statements by Philips misled consumers, distributors, health care providers, and the general public in several important respects.

63. The "off-gassing" of volatile organic compounds (VOCs), which Philips acknowledged "can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment," was unrelated to the use of ozone cleaners.

64. On July 8, 2021, Philips published an update to physicians and health care providers ("July Update"), a statement that received far less attention and publicity than the Recall Notice. In the July Update, Philips acknowledged that the off-gassing of harmful VOCs was "associated with the production process of the foam." Specifically, Philips identified "two compounds of concern" emanating from its devices: dimethyl diazene and phenol 2, 6-bis (1,1-dimethylethyl)-4-(1-methylpropyl). Philips claims its test results suggested that the emission of these two volatile organic compounds dissipated within "the initial days of use of a new device." Nonetheless, the risks associated with the chemical emissions were serious enough to serve as an independent basis for the product recall, separate and apart from any foam degradation.

65. The recall due to the off-gassing of VOCs was unrelated to the use of ozone cleaners.

66. Upon information and belief, the use of ozone cleaners would help mitigate the emission of the VOCs identified by Philips and effectively destroy them through chemical reactions.

67. Upon information and belief, phenol 2, 6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) is an antioxidant that, based on its chemical properties, would not dissipate during "the initial days of use of a new device," as Philips told the public.

Philips Misleads the Public About Degradation

68. Philips also misled the public and caused confusion on the foam degradation issue. Weeks after the recall, Philips clarified in the July Update that the complaint rate was "low." In

fact, Philips received only 486 foam-related complaints out of 1.56 million devices shipped in 2020, representing a complaint rate of 0.03%.

69. In the July Update, Philips clarified that it had determined from a combination of user reports and lab testing that the degradation of the foam was actually caused by "a process called hydrolysis"—*i.e.*, the chemical breakdown of a compound due to a reaction with water. Philips cited a "research study reported in the literature" that identified diethylene glycol (DEG) as one of the "degradative by-products" from a reaction involving polyester-based polyurethane foam and humidity (*i.e.*, water). Importantly, Philips acknowledged that its own "[l]ab analysis of the degraded foam positively confirmed the presence of DEG as well as other compounds."

70. The positive confirmation of DEG in the degraded foam samples established that the degradation observed by Philips was due to hydrolysis—a reaction involving water—not reactions involving ozone.

71. The 2011 study cited by Philips in the July Update concluded in no uncertain terms: "***It is now accepted that hydrolysis predominates for polyester based polyurethane PU(ES)*** whereas oxidation is the principal cause of degradation for polyether-based polyurethane PU(ET) variety." Lattuati-Derieux, A. et al., *Assessment of the degradation of polyurethane foams after artificial and natural ageing by using pyrolysis-gas chromatography/mass spectrometry and headspace-solid phase microextraction-gas chromatography/mass spectrometry*, J. Chromatogr., A 1218, 4498-4508 (2011) (emphasis added). This was true in 2011. It remains true today.

72. In the July Update, Philips belatedly acknowledged what has been well-established in the scientific literature for many years—namely, that hydrolysis is the dominant source of degradation for polyester-based polyurethane foams. Yet, Philips has never corrected or retracted its prior statements regarding ozone cleaners, and it continued to make them publicly and privately.

73. Upon information and belief, Philips knew or should have known about the susceptibility of polyester-based polyurethane foam to hydrolysis long before the Q1 2021 Quarterly Report, the Q1 Earnings Call, and the Recall Notice.

74. Upon information and belief, Philips' knowledge of potential safety issues concerning polyester-based polyurethane foam led Philips to select an alternative foam for sound abatement in the DreamStation 2 product.

75. Despite all evidence to the contrary, and without reference to any testing or data, the July Update repeated Philips' unfounded recommendation that customers and patients should not use ozone-related cleaning products.

76. In a Q&A about the product recall on its public website, Philips referenced ozone cleaners at least *nine* times, suggesting they were responsible for the issues that led to the recall. Included among those statements: "Philips is recommending that customers and patients do not use ozone-related cleaning products." Also: "Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods."

77. During Philips' Q2 Earnings Call, Philips' CEO unilaterally condemned the use of ozone cleaners not only for CPAP machines or Philips' recalled CPAP machines, but for all medical devices. In response to a question from an analyst, who asked if Philips had "any data that shows how ozone is accelerating foam degradation," Philips's CEO responded:

> Yeah, that we do. We have tested that, and we see a 40 times factor of acceleration of degradation when ozone is being used. And that's on an average use of ozone cleaning. And if people do that every day, of course, it goes even faster, right? But the acceleration factor caused by ozone cleaning is very, very significant, right? And otherwise, we would not call it out. It's a very aggressive cleaning method that should not be used on medical devices at all.

78. Upon information and belief, the statements from Philips and its CEO about ozone cleaners are false, misleading, and lack any scientifically-valid evidentiary support. Mr. van Houten's purported 40-fold acceleration factor is a fallacy. To the extent Philips has tested polyester-based polyurethane foams in the presence of ozone, upon information and belief, such testing failed to properly account for (i) the actual concentration of ozone at the surface of the foam during the cleaning cycle, (ii) the short duration of ozone exposure during the cleaning cycle, (iii) confounding variables, including heat, pH, and microbial enzymes, all of which would accelerate degradation of the foam, and/or (iv) the fact that high humidity can reduce ozone generation by as much as 50%.

79. Upon information and belief, Philips' CEO had no good-faith scientific basis for his sweeping statement that ozone cleaners "should not be used on medical devices at all."

80. In stark contrast to the public statements from its CEO, Philips conducted at least six months of testing on SoClean devices in or around late 2017 to April 2018. According to a Philips employee familiar with the testing: "Early signs were favorable that SoClean did not affect our DreamStation devices."

81. During Philips' Q3 Earnings Call on October 18, 2021, Philips revealed that the product recall and the company's prior statements about ozone were actually based on "a relatively narrow set of data, taking a worse-case scenario, as to potential risk." In fact, Philips' CEO announced for the first time that "further research and testing" and "expert assessments" were not expected until the fourth quarter of 2021.

82. The true reasons for the product recall were Philips' poor choice of materials and obvious design flaws. Philips chose a material for sound abatement—polyester-based polyurethane foam—for use in a heated and humid environment, despite the fact that the foam was

known to degrade by hydrolysis in the presence of heat and humidity. Indeed, Philips sold a heated humidifier as an accessory for the recalled DreamStation CPAP devices. Moreover, Philips selected a foam that, by its own admission, emits harmful VOCs right out of the box.

83. Despite this, in April 2021, Philips' CEO pointed the finger at "companies [in the U.S.] that have been very active in marketing that [ozone cleaning] method." While Mr. van Houten did not mention SoClean by name, it is beyond dispute that his statement was a reference to SoClean. SoClean is the dominant market leader for ozone cleaners. Simply put, SoClean is synonymous with ozone cleaning. SoClean had invested heavily in marketing at the time, enlisting the services of William Shatner, a celebrity spokesperson who suffers from a sleep disorder and uses a SoClean device, to appear in commercials and increase brand recognition.

84. Philips' CEO kept talking: "The FDA observed this and also put out a safety notice to say don't use ozone for sleep ap[nea] machines." Contrary to Mr. van Houten's characterization, the FDA safety communication did not say anything of the sort.

85. In fact, the FDA safety communication said: "The FDA is working with manufacturers of products that claim to clean, sanitize or disinfect CPAP machines and accessories with either ozone gas or UV light to submit the recommended testing to support use of these devices as claimed." In addition, the FDA said it "will continue to monitor adverse events associated with the use of ozone gas or UV light" and "[w]hen new information becomes available, [the FDA] will update this communication."

86. The FDA safety communication had nothing to do with the reasons cited by Philips for its product recall. The document related to ozone leakage and inadequate clearance of ozone from the cleaning cycle prior to use. SoClean has patented technology directed at preventing both of these issues. Upon information and belief, the FDA safety communication was a response to

low-end manufacturers and their attempt to utilize ozone cleaning technology while benefiting from SoClean's brand reputation and goodwill.

87. Upon information and belief, the FDA has not updated the safety communication since it came out on February 27, 2020.

88. Upon information and belief, Philips' CEO knowingly misled the public about the FDA's position regarding the use of ozone cleaners.

Philips Creates Confusion Among Customers, Distributors, and the Public

89. Philips' conduct and statements have created widespread confusion in the marketplace, including with SoClean's actual and prospective customers and distributors. SoClean's actual and prospective customers and distributors have been wrongfully led to believe that SoClean devices were the reason for Philips' recall, should not be used to sanitize CPAP machines or other medical devices, and are unsafe.

90. On June 14, 2021, for example, the day after Philips issued the Recall Notice, the Oregon Sleep Association (OSA) issued a notice stating that "[t]here is a slight risk of [the] foam degrading into particles which may be inhaled or ingested during use," and that "[t]he highest risk of exposure appears to be in conjunction with ozone cleaning machines such as SoClean Devices."

91. The OSA later issued another notice stating that "Philips has advised that patients who have reported these rare symptoms may be users of the ozone cleaning systems, such as SoClean. If you are currently using such a system to clean your PAP machine, we suggest you stop doing so . . . ."

92. On June 16, 2021, the Pulmonary and Critical Care of Baltimore (PCCB) issued a notice notifying its patients of the Philips recall. The notice incorrectly stated: "It appears that [the foam degradation issue] has been found predominantly when such machines have been cleaned

with ozone cleaning machine device." The PCCB noted that "Philips is recommending that customers and patients halt use of ozone-related cleaning products." The notice also said that the PCCB "recommends that all of our patients discontinue the use of ozone or UV cleaners until we have learned more about this."

93. The Minnesota Sleep Institute issued a similar notice, instructing patients and members to "stop using ozone cleaning products such as SoClean."

94. The U.S. Department of Veteran Affairs, which had distributed nearly 600,000 recalled Philips devices to veterans for home use and another 2,000 devices used within VA hospitals or clinic settings, issued a similar notice, stating that "Philips Respironics testing indicates that the breakdown [of the foam] is primarily caused by the devices being used in high heat and high humidity environments or using unapproved cleaning methods such as ozone." The notice further stated incorrectly that "[m]ost of the devices found with this issue have been in use for more than three years and have been routinely cleaned with an ozone cleaner."

95. On July 16, 2021, the American Academy of Sleep Medicine—which has a combined membership of 11,000 accredited member sleep centers and individual members, including physicians, scientists, and other health care professionals—issued a notice directing its members to "[i]nform patients that Philips has stated that ozone-related products should not be used to clean PAP equipment."

96. Upon information and belief, many health care providers, associations, agencies, and other groups have issued similar notices or communications to their patients, members, and the broader public. These organizations have wrongfully represented the reason for the product recall and the risks associated with ozone cleaners based on Philips' false and misleading statements.

97. Numerous media outlets and websites have wrongfully represented the reason for the product recall and the risks associated with ozone cleaners based on Philips' false and misleading statements.

98. Upon information and belief, Philips has made false and misleading statements about ozone cleaners to SoClean's distributors and resellers. For example, in July 2021, at Medtrade West, the largest home medical equipment trade show and conference in the United States, Philips cancelled its public booth and invited distributors to private offsite meetings at a nearby hotel. Many of the distributors in attendance service both Philips and SoClean. Upon information and belief, Philips wrongfully told SoClean's distributors during the private meetings that SoClean was to blame for the product recall. Upon information and belief, Philips has made similar statements to SoClean's distributors, which have negatively impacted SoClean's sales.

99. Distributors have specifically cited Philips' false and misleading statements about ozone cleaners as the reason for not placing orders with SoClean.

100. Prior to Philips' wrongful conduct, SoClean enjoyed an exceptionally high customer satisfaction rate, with more than 90% ranking their experience with SoClean as "Very Satisfying" or "Extremely Satisfying."

101. Following Philips' recall and other public statements, however, SoClean has been inundated with messages from customers, distributors, and others who have been misled to believe that SoClean devices are the reason for Philips' recall, should not be used to clean their medical devices, and are unsafe.

102. SoClean has received customer complaints following Philips' false and misleading statements alleging, among other things, that SoClean "ruins" the CPAP machine and that ozone is "not safe."

103. As a result of Philips' wrongful conduct, SoClean has been named in multiple lawsuits wrongfully alleging that its ozone cleaning products are "unhealthy" and "unsafe."

FDA Inspection Report

104. On November 12, 2021, the FDA issued an update on the Philips recall and a report from an inspection of Philips that took place from August 26 to November 9, 2021. The FDA stated that the purpose of the inspection was to "determine what may have caused or contributed to the foam issues and assess adherence to the agency's requirements for quality manufacturing."

105. Among other things, the FDA report confirmed that Philips had been aware of issues related to both the off-gassing of harmful chemicals and foam degradation for years, but took no corrective action while the company's executives concealed damaging information and problematic test results from the public. The report also confirmed that Philips had been receiving customer complaints about its foam long before SoClean machines were even on the market and with respect to ventilator devices for which SoClean is not compatible.

106. The report "lists observations made by the FDA representative(s) during the inspection of [Philips'] facility." The following eight observations describe Philips' conduct with respect to the issues that led to the product recall:

i. Risk analysis is inadequate.

ii. Procedures for corrective and preventative action have not been adequately established.

iii. Design validation did not ensure the device conforms to defined user needs and intended uses.

iv. Procedures for design change have not been adequately established.

v. A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

vi. Management with executive responsibility has not ensured that the quality policy is understood, implemented and maintained at all levels of the organization.

vii. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

viii. Potential consultants were not evaluated and selected based on their ability to meet specified requirements.

107. The FDA report begins with the following statement: "There is no documented investigation, risk analysis, or design failure mode effect analysis to support [Philips'] rationale for which polyester polyurethane foam-containing products were affected, included, or not included in your firm's ongoing recalls."

108. The FDA observed that Philips failed to conduct an appropriate risk analysis when it became aware of concerns regarding either foam degradation or the off-gassing of harmful chemicals: "A risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of [Philips] becoming aware of potential polyester polyurethane foam degradation and/or Volatile Organic Compound (VOC) emission concerns regarding various CPAP, BiPAP, and ventilator devices."

109. The FDA report described numerous instances dating back to April 2016, when Philips became aware of issues and concerns regarding foam degradation and the off-gassing of VOCs: "Specifically, there were at least fourteen instances, assessments, and/or test reports, dated

from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/ or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices . . . ."

110. The FDA found that Philips initiated no formal investigation, risk analysis, or corrective measures in response to at least 222,000 complaints between 2008 and 2017 that "could potentially be related to foam degradation." According to the FDA, over 20,000 of those complaints occurred between 2008 and 2017 and involved Trilogy ventilator devices. This means that many of the consumer complaints related to foam degradation pre-dated SoClean's introduction to the market. Also, Trilogy ventilators are not compatible with SoClean machines, eliminating any possibility that ozone cleaners were somehow responsible for the foam degradation in the Trilogy devices.

111. The FDA reviewed email correspondence between Philips and its raw foam supplier. The email correspondence revealed that Philips was "made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by your foam supplier on 08/05/2016, via email."

112. Philips internal email correspondence from August 2018 describes testing that showed "the affected foam breaks down in high heat and high humidity environments." According to the FDA, these test results "concurred with Trilogy ventilator related complaints" received by Philips. Despite clear evidence of foam degradation, the same email exchange, dated August 24, 2018, revealed that Philips "made the decision not to change the design, and continue to include polyester polyurethane foam, in the Trilogy ventilator platform of devices."

113. Philips initiated a "field correction" of Trilogy 100 and 200 ventilator devices and failed to report the event to the FDA. According to the FDA report, "[t]his field correction was

implemented as a corrective action in response to CAPA INV 0988, which was initiated due to multiple field complaints and at least 1 Trilogy unit failure, caused by polyester polyurethane foam degradation." Again, Trilogy ventilators are not compatible with SoClean devices. Thus, the foam degradation in these Philips machines had nothing whatsoever to do with ozone or ozone cleaners.

114. According to the FDA: "Th[e] affected foam was later found to be mutagenic, cytotoxic, carcinogenic, and non-biocompatible." In short, Philips knew of a potential cancer risk and said nothing.

115. The FDA observed that Philips management, including company executives, concealed known health risks associated with foam degradation from the public: "[F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021."

116. On the issue of off-gassing, the FDA inspection report stated that Philips DreamStation machines failed emissions testing for VOCs as early as 2019, based on compounds not previously or publicly disclosed by Philips. For example, the report revealed that Philips machines failed emissions testing by exceeding tolerable limits of formaldehyde.

117. The FDA inspection report did not contain a single reference to ozone.

Philips Causes Damage to SoClean

118. As a result of Philips' public and private statements and other wrongful conduct, SoClean's sales to distributors, resellers, and end-users have plummeted. SoClean has experienced devastating and potentially irreparable damage to its brand reputation and a loss of goodwill in the immediate aftermath of Philips' wrongful conduct, as well as other substantial harm.

119. Upon information and belief, users of CPAP devices made and sold by companies other than Philips have stopped using SoClean products in response to Philips' false and misleading statements and other wrongful conduct.

120. Upon information and belief, distributors of CPAP devices made and sold by companies other than Philips have stopped distributing SoClean products in response to Philips' false and misleading statements and other wrongful conduct.

121. Upon information and belief, Philips customers have continued using Philips' CPAP devices but have stopped using their SoClean devices in response to Philips' false and misleading statements and other wrongful conduct.

122. Upon information and belief, the damage to SoClean caused by Philips exceeds $200 million.

CLAIM I

(Lanham Act Violation: 15 U.S.C. § 1125(a)(1)(B))

123. SoClean repeats each of the allegations above as if fully set forth herein.

124. Philips made false and misleading descriptions of fact and misrepresented facts about (i) its own sleep and respiratory care products, including Philips' DreamStation CPAP machines, and (ii) ozone cleaners sold by SoClean, in commercial advertising or promotion.

125. Among other statements, Philips has provided false and misleading information and misrepresented facts regarding the cause of degradation and VOC emissions associated with the polyester-based polyurethane foam that Philips used for sound abatement in its sleep and respiratory care products, including the original DreamStation CPAP machine. Philips has also published false and misleading information and misrepresented facts related to SoClean's ozone

cleaner products in communications directed at consumers and distributors of sleep and respiratory care products.

126. Philips' misrepresentations (i) constituted commercial speech, (ii) were made with the intent of influencing customers and potential customers to continue purchasing Philips' sleep and respiratory care products, including the next-generation DreamStation 2, and (iii) were disseminated to the consuming public in such a way to constitute advertising or promotion.

127. Philips' misrepresentations advanced its own economic, business, and commercial interests. Philips had an economic motivation to preserve its own brand reputation, preserve existing customer relationships, and shift responsibility for the safety concerns associated with the sound abatement foam to someone other than Philips. Philips has offered to repair and replace the problematic foam in affected devices at no cost. Philips has also emphasized to different categories of consumers that its next-generation DreamStation 2 device was not affected by the product recall.

128. Philips' misrepresentations were material in that they were likely to influence, and have influenced, the purchasing decisions of distributors and individual consumers. Philips targeted a specific class and category of purchasers or potential purchasers—*e.g.*, CPAP and BiPAP machine users and/or distributors—to deflect blame and responsibility for the recall so that customers would continue to purchase Philips' sleep and respiratory care devices.

129. Philips' misrepresentations deceived a substantial segment of its audience regarding the cause of safety issues specific to Philips' products, including foam degradation and VOC emissions, and the general safety of ozone cleaners. As a result of Philips' actions and misrepresentations, countless distributors and individual users of CPAP and BiPAP devices are under the false impression that SoClean and its ozone cleaners are responsible for the product recall and unsafe for use.

130. Philips placed the false and misleading statements in interstate commerce, for example, through its public website, quarterly reports, earnings calls, and other published statements directed to physicians, health care providers, distributors, and others.

131. Plaintiff SoClean has been severely injured as a result of Philips' misrepresentations, including in the form of a dramatic decline in sales, damage to brand reputation, and a loss of goodwill.

CLAIM II

(M.G.L. Chapter 93A)

132. SoClean repeats each of the allegations above as if fully set forth herein.

133. Philips has engaged in unfair and deceptive practices in the conduct of trade and commerce. Philips misled consumers, acting reasonably under the circumstances, to act differently than they otherwise would have—that is, to continue using and purchasing Philips' sleep and respiratory care products, while discontinuing the use of SoClean's ozone cleaning products. Philips' statements have misled reasonable consumers to mistakenly believe that ozone cleaners were the reason for the product recall and are unsafe for use.

134. Philips' conduct has been immoral, unethical, and unscrupulous.

135. Upon information and belief, the actions constituting unfair and deceptive trade practices by Philips occurred primarily and substantially within the Commonwealth of Massachusetts, the primary location and headquarters of Philips' operations in the United States.

136. Philips' conduct has caused substantial injury to SoClean.

137. SoClean has incurred significant monetary losses and actual damages as the result of Philips' conduct, including in the form of a dramatic decline in sales, damage to brand reputation, and a loss of goodwill.

CLAIM III

(Commercial Disparagement)

138. SoClean repeats each of the allegations above as if fully set forth herein.

139. Philips published numerous false statements to numerous individuals—including customers, potential customers, investors, actual and potential distributors, and health care professionals—of and concerning SoClean's ozone cleaning products. For example, Philips has stated that ozone cleaners were responsible for the degradation of its sound abatement foam. However, Philips' lab testing of the degraded foam found by-products of hydrolysis, a chemical reaction involving water, indicating that humidity, not ozone, was the source of the degradation. Moreover, Philips tested SoClean's ozone cleaners for at least six months in or around 2018 and saw "favorable" results with no undesired effects on the DreamStation products.

140. Philips and its CEO wrongfully claimed that the FDA put out a safety notice "to say don't use ozone," and wrongfully stated that ozone cleaners "should not be used on medical devices at all."

141. Philips has had direct communications with SoClean's distributors, in which Philips has wrongfully stated that SoClean was the reason for the product recall.

142. Without any valid factual or scientific basis, Philips continues to tell its customers not to use ozone cleaning products.

143. Philips made false statements about ozone cleaners and the FDA safety communication with knowledge of their falsity, or at least with reckless disregard of their truth or falsity.

144. Pecuniary harm to SoClean's interests was intended and foreseeable following Philips' statements. SoClean is the market leader for ozone cleaners, accounting for the vast

majority of sales. Accordingly, Philips knew or should have known that false statements about the safety of ozone cleaners, as well as subsequent recommendations to customers and distributors not to use or purchase ozone cleaners, would result in pecuniary harm to SoClean's interests.

145. Philips' publication of false statements about SoClean's ozone cleaning products resulted in special damages to SoClean in the form of pecuniary loss. SoClean has seen a dramatic decline in sales, damage to brand reputation, and a loss of goodwill.

CLAIM IV

(Tortious Interference with Business Relationships)

146. SoClean repeats each of the allegations above as if fully set forth herein.

147. SoClean has business relationships and contemplated contracts of economic benefit with customers and distributors that purchase SoClean's ozone cleaners.

148. Philips has knowledge of SoClean's business relationships.

149. Upon information and belief, Philips has interacted directly with customers and distributors of SoClean devices. Philips also knows that consumers of its CPAP and BiPAP machines use SoClean's ozone cleaners.

150. SoClean is the dominant market leader for ozone cleaners, accounting for the vast majority of sales. Thus, upon information and belief, when Philips and its representatives made public and private statements concerning ozone cleaners to SoClean's customers and distributors, those statements were made with knowledge of SoClean and with reference to SoClean machines.

151. Philips interfered with SoClean's business relationships through improper motive or means. Philips made false and misleading descriptions of fact and misrepresented facts, including those about (i) its own sleep and respiratory care products, including, but not limited to, Philips' DreamStation CPAP machines, and (ii) ozone cleaners sold by SoClean, in commercial

advertising or promotion. Philips' false and misleading statements constitute, among other things, violations of the Lanham Act and commercial disparagement.

152. SoClean has been severely injured as a result of Philips' conduct, including its false and misleading statements about Philips' CPAP machines and SoClean's ozone cleaners, in the form of a dramatic decline in sales, damage to its brand reputation, and a loss of goodwill.

CLAIM V

(Unfair Competition)

153. SoClean repeats each of the allegations above as if fully set forth herein.

154. Philips misled the public and has caused confusion about the product recall and the safety of SoClean's ozone cleaners.

155. Philips repeatedly made false and misleading statements asserting and implying that ozone cleaners were responsible for the foam degradation and VOC off-gassing issues that led to the voluntary recall, and that ozone cleaners were otherwise unsafe.

156. Philips made these false and misleading statements despite knowledge of testing showing that the degraded foam included by-products of hydrolysis—that is, evidence of degradation caused by reactions with water, not ozone.

157. Philips also made these false and misleading statements despite knowledge of testing showing that VOC emissions were due to the production of the foam itself, and not exposure to ozone.

158. Further, Philips made these false and misleading statements despite knowledge of its own internal testing on SoClean machines, which, upon information and belief, showed that the SoClean machines had no adverse effect on Philips' DreamStation CPAP device.

159. Upon information and belief, Philips made these false and misleading statements without any credible evidence that ozone cleaners are unsafe for use.

160. Upon information and belief, Philips made false and misleading statements about ozone cleaners in order to deflect bad press and negative attention away from its design flaw so that customers continued using Philips' sleep and respiratory care products.

161. Also, upon information and belief, Philips timed the recall to induce customers to purchase its next-generation DreamStation 2 CPAP device.

162. SoClean has been damaged as a result of the consumer confusion caused by Philips. SoClean's sales have declined, its brand reputation has been tarnished, and it has lost goodwill as the direct result of Philips' false and misleading statements about ozone cleaners.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff SoClean respectfully requests that the Court enter an Order:

A. That Philips has violated 15 U.S.C. § 1125(a)(1)(B) and M.G.L. Chapter 93A;

B. That Philips is liable for commercial disparagement, tortious interference, and unfair competition;

C. That SoClean be awarded all monetary relief available under the laws of the United States and the Commonwealth of Massachusetts, including, but not limited to, actual damages, pre- and post-judgment interest, enhanced damages, costs, and attorneys' fees pursuant to 15 U.S.C. § 1117(a) and M.G.L. Chapter 93A;

D. That this is an exceptional case under 15 U.S.C. § 1117(a); and

E. For such other and further relief as the Court deems just and proper.

Dated: December 2, 2021

Respectfully submitted,

/s/ Colin Cabral

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