

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: SOCLEAN, INC., MARKETING,
SALES PRACTICES AND PRODUCTS
LIABILITY LITIGATION**

Master Docket: No. 22-mc-152
MDL No. 3021

This document relates to: *SoClean, Inc. v.
Koninklijke Philips N.V., et al.*, 2:22-cv-542

KONINKLIJKE PHILIPS N.V.,
PHILIPS NORTH AMERICA LLC,
PHILIPS RS NORTH AMERICA LLC,

Counterclaim-Plaintiffs,

v.

SOCLEAN, INC., and DW MANAGEMENT
SERVICES, LLC,

Counterclaim-Defendants.

DEFENDANTS' COUNTERCLAIMS

Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively, “Counterclaim-Plaintiffs”) hereby assert the following counterclaims against Counterclaim-Defendants SoClean, Inc. (“SoClean”) and DW Management Services, LLC (d/b/a DW Healthcare Partners (“DWHP”)) (collectively, the “SoClean Entities”). Counterclaim-Plaintiffs’ allegations are on knowledge as to themselves and, for the conduct of others, on information and belief following a reasonable inquiry.

INTRODUCTION

1. Since 2014, and up until its 2023 FDA recall, SoClean has recklessly and unlawfully promoted the fiction that its ozone cleaning devices are “compatible” with the CPAPs and BiPAPs (collectively, “PAPs”) designed and manufactured by Philips RS North America LLC (“Philips RS”) when the reality is precisely the opposite. Contrary to SoClean’s repeated representations of compatibility, SoClean knew that its ozone cleaners had the potential to eat away at Philips Respironics’ PAPs from the inside.

2. Ozone consists of 3 oxygen atoms. EPA has labeled it a “toxic gas.”¹ As EPA explains, ozone “cleans” by shedding one of its three oxygen atoms, which bonds with the molecules of other substances, altering their chemical compositions.² EPA warns that exposure to even “relatively low amounts” of ozone can cause harm to the human body, damaging the lungs, and causing chest pain, coughing, shortness of breath, throat irritation, worsened asthma, and compromised respiratory immunity.³ Putting aside its health impact, ozone can also cause many common materials to degrade, including polyester-based polyurethane (“PE-PUR”) foam found in the Philips Respironics’ PAPs that are subject to the current Philips Respironics recall.

3. SoClean has known all about the destructive properties of ozone for years. By no later than 2015, SoClean was already writing internally that its ozone cleaners [REDACTED] [REDACTED] when injected into a PAP machine—the only question was [REDACTED]

¹ *Ozone Generators that are Sold as Air Cleaners*, U.S. ENV'T PROTECTION AGENCY, <https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#:~:text=of%20manufacturers%27%20claims.,How%20is%20Ozone%20Harmful%3F,ozone%20can%20damage%20the%20lungs> (last visited Jan. 1, 2024).

² *Id.*

³ *Id.*

5. In June 2021, Philips RS voluntarily elected to recall devices because of degradation issues with PE-PUR sound-abatement foam inside some Philips Respironics PAPs. As part of the recall, FDA instructed Philips RS to “[REDACTED]” to alert consumers that the “use of ozone cleaners to disinfect or sanitize the Recalled Products may exacerbate the breakdown of the foam.” Accordingly,

⁵ *Id.*

Philips RS informed shareholders and provided consumers with actionable information regarding the potential for degradation caused by ozone cleaners. SoClean responded not by studying whether Philips might be right—i.e., whether its ozone-based cleaners might be causing degradation inside CPAP machines—but instead by suing Philips for making it “a scapegoat.” SoClean’s Second Amended Complaint (“SAC”) 7.

6. But SoClean’s lawsuit has a stunning omission. Nowhere in its 256-paragraph Second Amended Complaint—or in the prior two versions—did SoClean actually allege that its devices do not cause PE-PUR foam to degrade. SoClean could not make this allegation, because its devices *do* cause PE-PUR foam to degrade.

7. Following the recall, Philips RS undertook an expansive testing program with a number of independent certified laboratories. That testing confirmed the conclusion previously reached from visual inspections and other testing: that ozone dramatically increases the risk that the PE-PUR foam will degrade in the recalled devices.

8. The reality is that SoClean recklessly brought to market an illegal product that uses a “toxic gas” to clean medical equipment without first confirming that its product would not harm that medical equipment. Underscoring that recklessness, SoClean never even established a Complaint Handling System (a safety mechanism legally required for all manufacturers of medical devices to receive, document, and monitor feedback from the field) for its products until late-2020. Still, for years, continuing through today, SoClean falsely advertised that its products were “compatible” with Philips Respironics PAP machines.

9. SoClean made these claims in its advertisements without required FDA approval or clearance. Nevertheless, SoClean alleged in its lawsuit against Counterclaim-Plaintiffs that it “legally markets its ozone cleaner products with the knowledge of FDA, without a requirement for

premarket authorization.” (SAC ¶ 71.) And SoClean represented before this Court that “FDA never expressed any concerns about the marketing or distribution of SoClean’s products” (ECF No. 271 at 4), and that “FDA has never told SoClean that the company cannot market its products without FDA approval, despite ample opportunity to do so” (ECF No. 339 at 7). None of this was true.

10. Rather, FDA repeatedly told SoClean that its promotion and sale of ozone-based PAP cleaners violated federal law. For instance, far from “never express[ing] any concerns,” FDA told SoClean in 2019 that [REDACTED] including use with medical devices such as PAPs. (emphasis added.) FDA also warned SoClean: [REDACTED] (emphasis added.)

11. To date, FDA has not approved or cleared for legal marketing a single ozone-based PAP cleaning device—not one. To the contrary, SoClean recently announced a recall of its SoClean 2 and SoClean 3 devices so that “adapters” can be installed to ensure no ozone reaches the inside of a PAP (where the foam is).

12. SoClean’s strategy of skipping pre-market compatibility testing, FDA compliance, and post-market surveillance made it a high-risk business opportunity when it was acquired in 2017 by its private equity owner, DWHP. DWHP esteems itself as specializing in investments in the healthcare sector. As such, during its acquisition diligence of SoClean, it undoubtedly discovered that SoClean—a promoter and seller of medical devices—had never obtained FDA approval or clearance for any of its PAP cleaners. Seeing this potential ticking time bomb, DWHP

left SoClean undercapitalized and underinsured after the acquisition, even as it assumed management responsibilities.

13. Counterclaim-Plaintiffs have suffered profound reputational harm and economic losses from SoClean's and DWHP's conduct. By falsely marketing its products as "compatible" with Philips Respironics PAP machines while being undercapitalized and underinsured by DWHP, SoClean deceived consumers and PAP distributors, tarnishing their experience with Philips Respironics' products and their impressions of the world-famous Philips brand owned by KPNV. Both SoClean and DWHP are liable for false advertising and trademark dilution under the Lanham Act at 15 U.S.C. § 1125(a), and deceptive trade practices in violation of New Hampshire state law.

THE PARTIES

14. Plaintiff Koninklijke Philips N.V. ("KPNV") is a Dutch holding company with its principal place of business located in Amsterdam, the Netherlands.

15. Plaintiff Philips North America LLC ("Philips NA") is a Delaware company with its principal place of business in Andover, Massachusetts.

16. Plaintiff Philips RS North America LLC ("Philips RS") is a Delaware company headquartered in Pittsburgh, Pennsylvania.

17. Counterclaim Defendant SoClean, Inc. ("SoClean") is a Delaware corporation with its principal place of business in Peterborough, New Hampshire.

18. Counterclaim Defendant DW Management Services, LLC, d/b/a DW Healthcare Partners ("DWHP"), is a Delaware company with its principal place of business in Park City, Utah. DWHP acquired SoClean in December 2017.

JURISDICTION AND VENUE

19. These counterclaims arise under the federal Lanham Act at 15 U.S.C. § 1125(a) and (c), and New Hampshire’s Regulation of Business Practices for Consumer Protection, N.H. Rev. Stat. Ann. § 358 (“New Hampshire Consumer Protection Act”).

20. This Court has subject matter jurisdiction over the counterclaims pursuant to 28 U.S.C. §§ 1331 as they present a federal question under 15 U.S.C. § 1125. This Court has supplemental jurisdiction over the New Hampshire Consumer Protection Act claim pursuant to 28 U.S.C. § 1367.

21. This Court has personal jurisdiction over the SoClean Entities because they (i) have contacts within this judicial district, (ii) have purposefully availed themselves of the privileges of conducting business in this judicial district, and (iii) each regularly conduct business within this judicial district. In addition to having regular sales in this district, SoClean is suing Counterclaim-Plaintiffs in this district in the underlying case. Finally, DWHP is subject to personal jurisdiction due to its control over, and undercapitalization of, SoClean.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c).

FACTUAL ALLEGATIONS

Nature of the Products and False Claims at Issue

23. KPNV is a health technology holding company that, through its investments, develops products and services focused on improving people’s health and wellbeing through innovation. Founded in 1891, the Philips brand is one that consumers have come to know, value, and trust based on over 120 years of investment and innovation.

24. By virtue of over a century of substantially exclusive use and millions of dollars in annual advertising, the name and mark PHILIPS is a household brand and is famous within the meaning of 15 U.S.C. § 1125(c). The Philips brand ranked 59th on the 2022 Interbrand Best

Global Brands Ranking, placing higher than brands like FedEx, LEGO, and Nestle, among others.⁶ Moreover, the Philips entities have built significant goodwill towards the Philips brand and marks. The Philips group ranked 22nd on Global RepTrack's annual ranking of most reputable companies.⁷

25. In addition to its extensive and longstanding common law rights, KPNV owns the following United States Federal trademark registration: 7110031. KPNV has continuously used this trademark in commerce since at least its date of first use and has not abandoned. A true and correct copy of documents retrieved from the United States Patent and Trademark Office's online Trademark Status & Document Retrieval database ("TSDR") evidencing the current status and Philips' ownership of the registered mark are attached hereto as **Exhibit 1**.

26. Philips RS develops, manufactures, markets, and sells medical devices. Its portfolio includes breathing and respiratory care products, including PAP machines. PAP machines include both CPAP (continuous positive airway pressure) machines and BiPAP (bilevel positive airway pressure) machines. Both treat sleep-related breathing disorders, including sleep apnea, by using mild air pressure to keep breathing airways open during sleep. Philips RS was one of the most successful suppliers of PAP machines.

27. Philips NA is a leading provider of innovative medical solutions and services. Among its products are diagnostic imaging machines, patient monitoring equipment, and sleep and respiratory care products. Its sleep and respiratory care products include PAP machines, which are manufactured by Philips RS and sold by Philips NA into the hospital channel.

⁶ Interbrand, *Interbrand Launches Best Global Brands 2022*, <https://interbrand.com/newsroom/interbrand-launches-best-global-brands-2022/> (last visited Jan. 4, 2024).

⁷ Reptrak, *2023 Global RepTrak® 100 Rankings*, <https://www.reptrak.com/rankings/#ranking-list> (last visited Jan. 4, 2024).

28. Philips NA and Philips RS sell or have sold PAP machines under and in connection with the Philips brand (the “Philips Respironics PAPs”), including the sub-brand Philips Respironics. Philips Respironics PAPs have a clear association with the Philips brand. The Philips logo, marks, and tradenames—including, among others, the KPNV-owned trademark “Philips”—are featured prominently on the products’ advertising and promotional materials, consumer packaging, instructions for use, and the devices themselves.

29. PAP devices contain foam used to reduce the sound and vibration of the sleep equipment machines, known as “sound abatement foam.” The devices sold by Philips NA and Philips RS that were the subject of the recall contained PE-PUR sound-abatement foam.

30. SoClean manufactures and markets ozone-based cleaning products that it holds out to the market as safe and effective for cleaning PAP machines, including, by name, Philips Respironics PAP machines. Among these SoClean products are automated cleaning devices, device filters, and adapters used to connect the cleaning devices to PAP machines. SoClean sells its products in New Hampshire, as well as in interstate commerce throughout the United States.

31. SoClean’s technology over a series of ozone-based PAP cleaners—the SoClean 1, the SoClean 2, the SoClean 3, and the SoClean 3+—has remained relatively constant. As SoClean describes it in its lawsuit:

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, 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 converts it back into common oxygen. SAC ¶ 58.

32. Conveniently left out from this description are the facts that (1) ozone can leak into the ambient air during this process and (2) when foam inside the PAP is exposed to ozone, ozone can eat the foam.

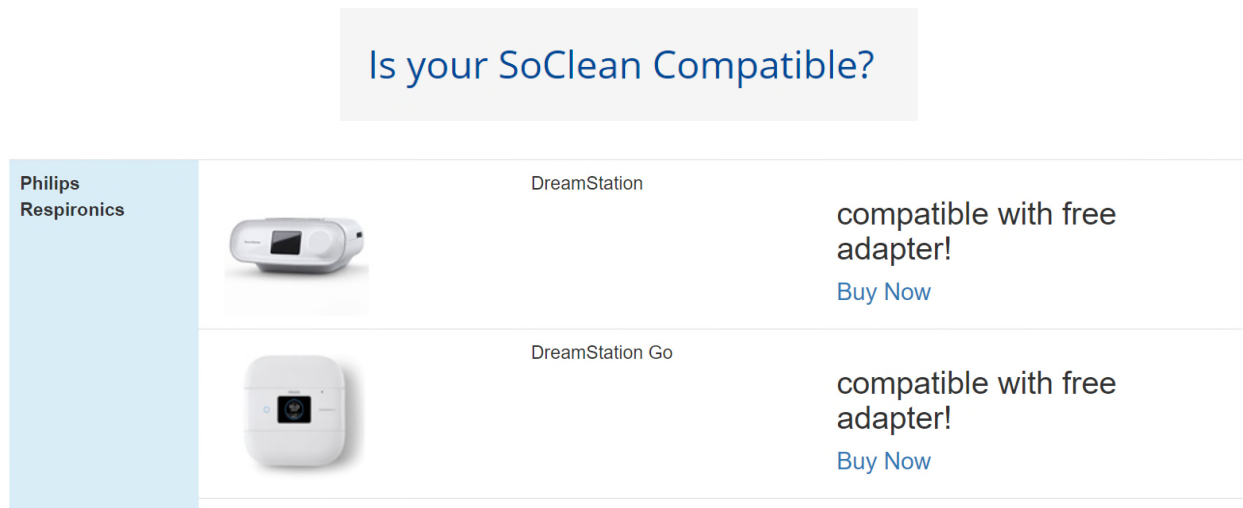
***SoClean Recklessly Ignored Evidence of Foam Degradation and Continued on
with Its False and Harmful Claims of Compatibility***

33. SoClean sells its devices through multiple channels, including direct sales to consumers, online Durable Medical Equipment suppliers (“DMEs”) and other DMEs, as well as indirect sales through distributors. SAC ¶ 204.

34. SoClean placed its false and misleading statements in interstate commerce by promoting its products through various means of advertising, including on its website (the avenue by which SoClean sells directly to consumers), television advertising (such as commercials featuring William Shatner), direct-to-consumer advertising (such as emails and text messages), content supplied to its DMEs, and other online advertising. SoClean’s promotions to U.S. consumers have contained pictures of the Philips RS devices, bearing the Philips logo, marks, and tradenames, which KPNV owns. In addition to the use of images, SoClean has repeatedly and continuously used the KPNV-owned Philips marks and tradenames in the text of its marketing materials, including “Philips,” “Respironics,” and “DreamStation,” among others.

35. From their inception, despite all evidence to the contrary, SoClean’s promotions have included false claims that its ozone cleaning devices are compatible with, approved by, or otherwise have some association or connection with Philips RS products when no such compatibility or association exists. These false compatibility claims were necessary to make SoClean’s ozone-based products attractive to consumers. And, SoClean offers a 30-day risk free trial for its devices, providing consumers with a money-back guarantee within that time period.

36. SoClean, for example, created and posted on its website a compatibility chart that included Philips trademarks and identified multiple Philips Respironics PAP machines, including the DreamStation, DreamStation Go, and other Philips RS models, as “compatible with free adapter!” with SoClean products:⁸



37. SoClean also created and posted on its website a “SoClean CPAP Compatibility Tool” that allows consumers to search for compatibility by brand and model. The tool identified various Philips CPAP products, including the DreamStation 1 model, as appropriate for use with a SoClean device:⁹

⁸ SoClean UK, *CPAP Machine & SoClean Compatibility Chart / SoClean CPAP Cleaning Solutions*, <https://web.archive.org/web/20190621210744/https://www.soclean.com/support/soclean-support/soclean-compatibility/> (accessed Jan. 4, 2024, archived June 21, 2019).

⁹ *Id.*

SoClean CPAP Compatibility Tool

<p>CPAP brand:</p> <div style="border: 1px solid #ccc; padding: 2px;">Philips Respironics ▾</div>	<p>Model:</p> <div style="border: 1px solid #ccc; padding: 2px;">DreamStation ▾</div>	<div style="background-color: #f4a460; color: white; padding: 5px 10px; border-radius: 3px;">Go</div>	 <p>The Philips Respironics DreamStation is compatible with adapter!</p> <div style="background-color: #f4a460; color: white; padding: 5px 10px; border-radius: 3px;">Buy Now</div>
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38. Even after FDA demanded that SoClean remove from its website and other promotional channels any statement that its products were intended for use with PAPs, SoClean ensured that U.S. consumers can still see SoClean’s assertions that its products are meant to be used with Philips Respironics’ PAPs. An online search for “SoClean” currently yields results containing compatibility claims expressly prohibited by FDA. For example, portions of the current SoClean.com website still provide the above-referenced compatibility chart and compatibility tool characterizing SoClean as compatible for use with Philips Respironics PAP devices, including the DreamStation models. SoClean’s site asks: “Is your SoClean Compatible?” The site then provides only two choices with respect to each pictured “Philips Respironics” model listed: “Compatible!” or “Compatible with free adapter!”¹⁰ SoClean easily could limit U.S. consumers’ access to these foreign-hosted websites through geolocation of users’ IP addresses, as many other companies do. But it is not in SoClean’s financial best interest to acknowledge its incompatibility with Philips Respironics PAPs.

¹⁰ SoClean UK, *CPAP Machine & SoClean Compatibility Chart / SoClean CPAP Cleaning Solutions*, <https://www.soclean.com/uk/support/soclean-support/soclean-compatibility> (last visited Jan. 4, 2024).

SoClean CPAP Compatibility Tool

<p>CPAP brand: <div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">Philips Respironics ▾</div></p> <p>Model: <div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">DreamStation ▾</div></p> <p style="text-align: right;">Go</p>	 <p>The Philips Respironics DreamStation is compatible with adapter!</p> <p>Buy Now</p>
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39. Even today, following a FDA-supervised recall based upon SoClean’s incompatibilities with certain PAPs, SoClean’s U.S. website currently states that its SoClean 3 devices work with “all popular sleep equipment brands & models.”¹¹ Philips Respironics PAP is a “popular” sleep equipment brand, as reflected not only on SoClean’s website, but in industry reports as well such as the Sleep Apnea Devices Global Market Report 2023, which names Philips as among the “major players” in the market.¹² In fact, SoClean’s “compatibility” chart lists eight Philips Respironics PAP models, two times as many as the next manufacturer and eight times more than several other manufacturers. And when describing the SoClean 3 device’s “Compatibilities with PAP Equipment,” SoClean stated, “SoClean 3 will be interfaced with most popular PAP devices currently on the market: the ResMed AirSense 10 PAP unit and the Philips Respironics DreamStation PAP unit.”

¹¹ SoClean, *SoClean 3 - Save \$50 / SoClean Sleep Equipment Maintenance*, <https://www.soclean.com/soclean3/product/soclean-3> (last visited Jan. 4, 2024) (*emphasis in original*).

¹² See ReportLinker, *International Forecast 2023: Sleep Disorder Equipment Industry*, https://www.reportlinker.com/p06479788/Sleep-Apnea-Devices-Global-Market-Report.html?utm_source=GNW (last visited Jan. 4, 2024) (providing overview of the December 2023 market report).

SoClean 3 works with all popular sleep equipment brands & models.

Get the peace of mind that you're taking the best possible care of your sleep equipment and yourself, with SoClean 3.

Save \$50 today!

~~\$398~~ \$348

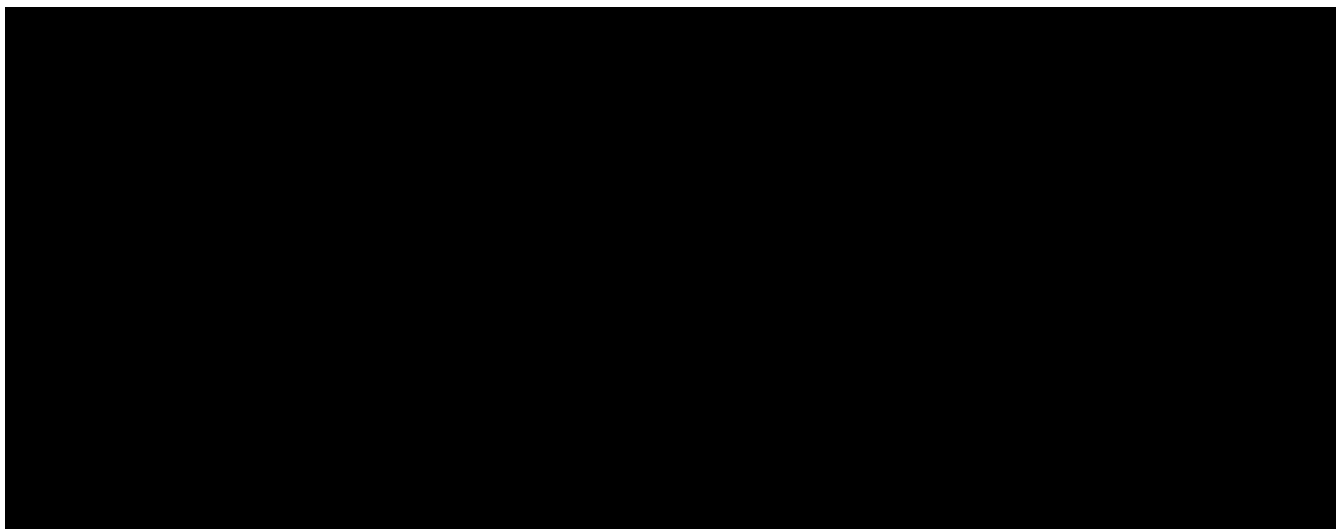
SoClean 3 - No fuss, no mess, no worry.

Add to Cart

Special Offer Ends 12/21/2023

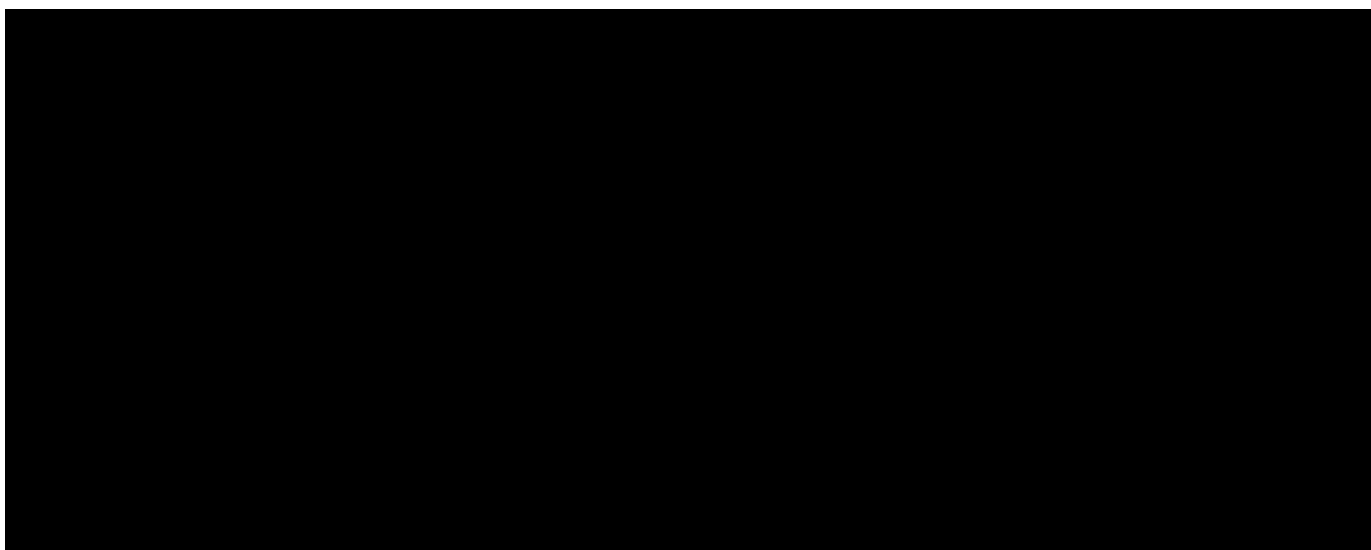
40. Separate and apart from its online advertising bearing a “no fuss, no mess, no worry” tagline designed to give false assurances that there was nothing to worry about with use of its product, SoClean’s user manuals also include false claims of compatibility with Philips Respironics PAP products. For example, the 2019 version pictured below, identifies multiple Philips Respironics PAP devices as among the SoClean 2 [REDACTED] PAP machines and [REDACTED]:

■



■

41. Later user manuals also included unsubstantiated and false claims of compatibility with Philips Respironics PAP products. User manuals are available online and also are included in the product packaging, allowing customers the opportunity to view the information before deciding whether to purchase and/or return the device. The SoClean 2 user manual current as of at least June 2022 identified four Philips Respironics PAP products subject to recall for PE-PUR foam degradation as ■■■■■ by SoClean devices: ■

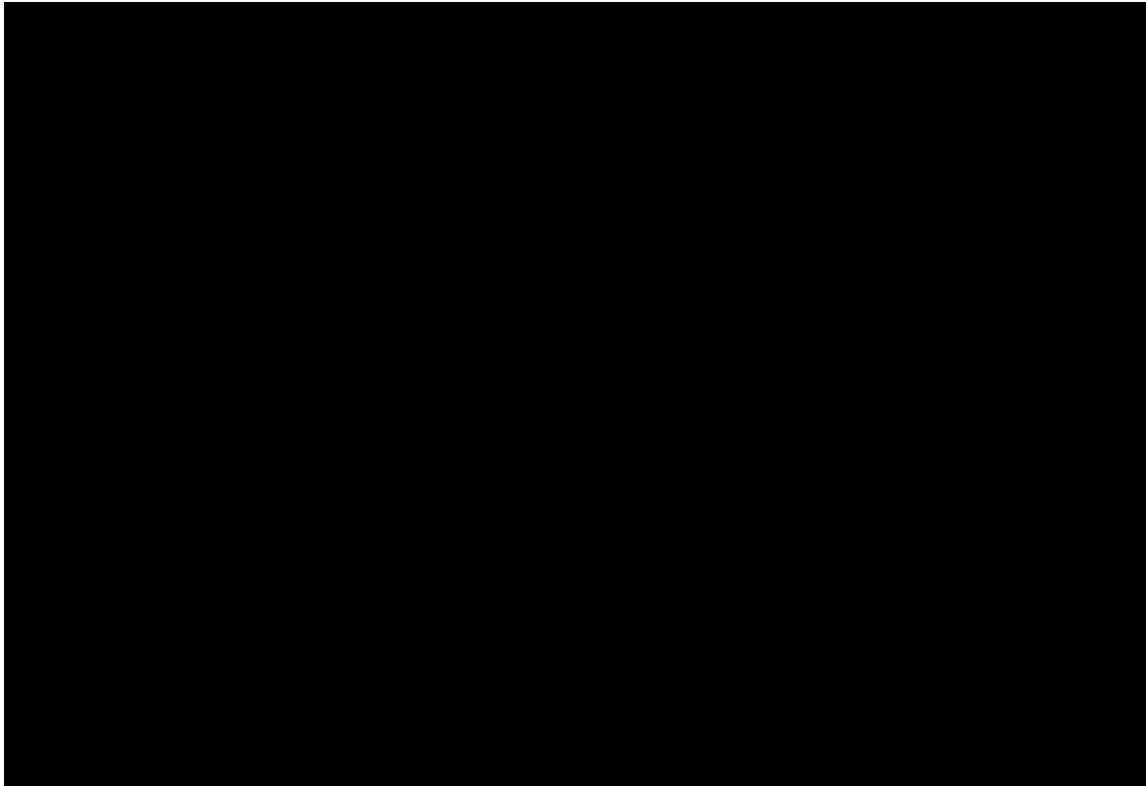


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42. SoClean eventually did start to include completely vague and deliberately uninformative warnings in the user manuals for its SoClean 2 and SoClean 3 product models, but only as to “memory foam” and other non-foam materials. For example, the SoClean 2 user manual current as of at least November 2020 stated that [REDACTED] (emphasis added.) Similarly, the SoClean 3 user manual current as of at least April 2021 advised users to [REDACTED] (emphasis added.) At no time did SoClean ever identify that the Philips Respironics PAP devices had “memory foam” in them or clarify that PE-PUR foam is a type of memory foam. To the contrary, SoClean simultaneously promoted compatibility with the Philips Respironics PAPs.

43. The SoClean 3 manual also states, immediately beneath the chart of [REDACTED] devices, that the [REDACTED] This is intentionally misleading insofar as it suggests that those machines listed in the manual *were* in fact subjected to, and passed, compatibility tests showing that SoClean did not harm those devices or their components. Again, no such testing has established SoClean’s compatibility with any Philips Respironics PAP machine.

44. Confusingly, SoClean’s manuals advise users to follow the PAP manufacturers’ cleaning instructions, which of course never call for the use of an ozone-based device to clean a PAP. Worse still, in these very same user manuals, SoClean identified Philips Respironics’ DreamStation model among SoClean’s [REDACTED] This would have led reasonable consumers to believe that SoClean’s devices were compatible with the Philips Respironics DreamStation. [REDACTED]



45. SoClean recognized the importance of product compatibility to its consumers' purchasing decisions and DMEs' distribution decisions. So, rather than confirming compatibility by testing SoClean products with Philips Respironics PAP devices, SoClean barreled ahead with prominent, false or unfounded claims of compatibility to consumers, distributors, and resellers. SoClean's purpose in doing so was to capitalize on the Philips brands' reputation and goodwill for the purpose of selling its own products.

***SoClean Has Known for Years That Ozone Degrades
Foam Used in PAP Machines***

46. Since at least as early as 2015, SoClean was aware of the potential for harm, and actual harm, caused by ozone when used with various materials including foam and other materials found in PAP machines. In 2015, results from a test of a SoClean device with another manufacturer's medical device showed [REDACTED]

[REDACTED] In a December 2015 email forwarding those results, a

SoClean employee noted that the test [REDACTED]

[REDACTED] adding that [REDACTED]

[REDACTED] (emphasis

added.)

47. In 2017, SoClean prepared a [REDACTED] based on a

[REDACTED] The

results of the review underscored SoClean's earlier findings: namely, that [REDACTED]

48. In April 2018, following DWHP's acquisition of SoClean, SoClean investigated degradation affecting sound-abatement foam inside ResMed PAPs. Incredibly (given SoClean is suing Counterclaim-Plaintiffs for saying the same thing), SoClean's CEO wrote internally, [REDACTED]

[REDACTED] (emphasis added.)

49. In February 2020, FDA issued a Safety Communication informing patients and health care providers that devices claiming to clean, disinfect, or sanitize PAP devices or accessories using ozone "are not legally marketed for this use by FDA in the U.S., and as such, their safety and effectiveness for use with CPAP devices and accessories is unknown."¹³ SoClean nonetheless continued illegally marketing of ozone-cleaning devices for PAPs, and also began

¹³ U.S. Food and Drug Admin., *FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized* (Feb. 27, 2020), <https://www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or>.

looking for new uses of ozone, perhaps to clean keys, change, jewelry, or smart phones. In connection with that review,

50. SoClean's Director of Engineering circulated a [REDACTED] [REDACTED] report discussing potential messaging around ozone's impact on various materials based on internal testing of a device used to disinfect items like cell phones and keys. SoClean confirmed again in the report that ozone could degrade foam. The report was circulated in April 2020, long before any Philips entity had made any public statement regarding degradation. The report listed a number of materials for which ozone had [REDACTED] after just [REDACTED] [REDACTED]

[REDACTED]

51. This was yet another obvious confirmation that SoClean's ozone-based cleaners could degrade the product they were intended to clean. This is especially true for PAPs, which SoClean's manual recommended cleaning with ozone for 5-10 minutes per day (with the device having a pre-set cycle of seven minutes)—much more than the “few cycles” that resulted in degradation of polyurethane foam during the tests of the Device Disinfector.

52. The SoClean 2020 report went on to consider consumer messaging based on the effects of these [REDACTED] cycles. Among the potential messaging options considered was the following guidance: [REDACTED]

53. Incredibly, SoClean did not adopt a warning not to use any of its ozone-based cleaning devices with the above materials, including [REDACTED]. Instead, SoClean continued to promote and sell its ozone-based cleaning devices as compatible with sleep equipment including Philips Respironics PAP machines even while under scrutiny from FDA to conduct additional testing for materials degradation.

54. In a November 2020 email between SoClean engineers regarding testing for the SoClean 3 device, one noted that FDA [REDACTED]

[REDACTED] She then quoted an FDA comment that read, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (emphasis added.) SoClean never did this.

55. In September 2021—a month before suing Philips for allegedly “scapegoating” SoClean—SoClean’s Vice President of Business Operations echoed FDA’s concerns about compatibility with Philips Respironics DreamStation 2 device due to the lack of testing. During an exchange about the SoClean 3 device’s Instructions for Use (“IFU”) and Quick Reference

Guide (“QRG”), he stated that [REDACTED]

[REDACTED]

[REDACTED] (emphasis added.) Again, SoClean never did this.

56. Unable to prove compatibility, that same month, SoClean stopped selling the SoClean 2 device altogether and adopted an FDA-compliance strategy that sought to abandon the need to prove compatibility through testing. SoClean’s new strategy is to only seek FDA approval to clean ResMed PAPs (not Philips Respironics PAPs), and then only the masks and hoses attached to those devices. Not surprisingly (given SoClean’s evidence that ozone degrades foam), SoClean determined not to seek FDA approval to have its ozone touch the inside of a PAP, where the foam is.

57. Still, SoClean allowed its existing products to remain on the market—promoted and sold to be used to clean PAPs from manufacturers including Philips RS—until a November 21, 2023 recall. Through this recall, SoClean ensured that its ozone would never touch the inside of a PAP again by instructing consumers to use an adapter “which facilitates use of the SoClean2 and SoClean3 equipment without ozone entering the CPAP.”

58. Although SoClean has stated at direction of FDA that it no longer holds itself out publicly as selling products that are CPAP cleaners,¹⁴ *to this day*, DWHP identifies and describes

¹⁴ “By [February 28, 2020], SoClean was cooperatively working with the FDA and had already removed any marketing claims about cleaning and disinfecting CPAP machines from its website and promotional materials based on the FDA’s prior guidance” and “SoClean removed its marketing claims related to PAP-device cleaning following the FDA’s September 2019 correspondence, and it no longer markets its products for this purpose.” ECF No. 271 at 11, 23; *see also* Aug. 30, 2022 Hearing Tr. at 30 (“SoClean has not marketed itself as a disinfectant or cleaner for CPAP machines since 2019, and that was in direct response to guidance from the FDA saying that they could not do that.”).

SoClean on its website’s “our companies” page as creator of the “world’s first automated CPAP cleaner and sanitizer.”¹⁵

DWHP’s Domineering Management and Undercapitalization of SoClean

59. DWHP, as owner of SoClean, has acted as SoClean’s alter ego, dominating, managing, and controlling SoClean’s affairs as a shareholder, without regard to the separate existence of the corporate entity by undercapitalizing and underinsuring SoClean while it engaged in illegal conduct (promoting and selling a medical device without FDA approval or clearance) and sold a product that harmed Philips Respironics PAPs.

60. DWHP is a “healthcare-focused private equity firm.” The front page of its website prominently features its sophistication in the sector: “We know healthcare.”¹⁶ According to its website, DWHP is run by “seasoned healthcare executives with more than 120 years of combined industry experience.” And DWHP claims that its “investment focus allows us to better understand and monitor the *regulatory climate*, pending and current reimbursement issues, and *government policies* and trends that impact the healthcare marketplace.”¹⁷

61. Given DWHP’s announced sophistication in healthcare and healthcare regulation, DWHP knew or should have known from even a basic level of diligence at of the time of its SoClean acquisition that SoClean’s ozone-based cleaning machines were not FDA approved or cleared for use with PAPs and therefore illegal to promote or sell for use with PAP machines. In

¹⁵ DW Healthcare Partners, *Our Companies*, <https://www.dwhp.com/companies/#close> (last visited Jan. 4, 2024) (“SoClean Inc. is the creator of the world’s first automated CPAP cleaner and sanitizer, an innovative device that naturally sanitizes CPAP equipment.”).

¹⁶ DW Healthcare Partners, *DWHP Home*, <https://www.dwhp.com/> (last visited Jan. 4, 2024).

¹⁷ DW Healthcare Partners *Adding Value*, <https://www.dwhp.com/adding-value/> (last visited Jan. 4, 2024) (emphases added).

other words, DWHP knew or should have known that SoClean's business and primary source of income was predicated on illegal conduct and could be subject to an enforcement action at any time. Further, DWHP knew or should have known from its diligence that ozone was known to degrade the components of the PAP machines they were meant to clean, further placing SoClean's business at risk. DWHP thus attempted to ensure this risk would only be to SoClean by keeping SoClean on paper as a separate corporation with little capital.

62. Notwithstanding this risk profile, DWHP acquired SoClean from SoClean's original shareholders, including its current management, for \$121 million on December 20, 2017. About \$86.5 million of this went to SoClean's former owners in cash, with another \$32.6 million in newly issued stock. Only \$1.6 million of the purchase price went to SoClean's working capital to operate the business. And the acquisition was accounted for on SoClean's balance sheet by dramatically increasing intangible assets and goodwill overnight, even though both were subject to immediate impairment because both were based on SoClean's illegal business. The accounting for the transaction created two new sizeable assets (i.e., intangible assets and goodwill) to draw down on SoClean's assets while loading the company up with debt. Overnight, with only \$1.6 million invested in SoClean's operations, SoClean supposedly increased dramatically in value. *See* SoClean Financial Statements attached as **Exhibit 2**. But those intangible assets and that goodwill was built upon the premise that SoClean had a viable and lawful business. And, when SoClean's auditors actually evaluated these assumptions, it required management to write down these assets.

63. Further, DWHP structured its acquisition in a manner that saddled SoClean with enormous debt that left SoClean in a precarious financial condition. DWHP financed its acquisition through a senior credit facility that imposed \$60 million in debt on SoClean, with liens

on *all* of SoClean's assets and that of its parent. The creditor, White Oak Healthcare Finance, LLC, required that the \$60 million in financing be secured as senior debt because of SoClean's lack of liquidity, regulatory risk, and other material financial debts and obligations.

64. Less than a year after the acquisition, DWHP increased SoClean's debt by another \$33 million, also borrowed from White Oak Healthcare Finance. Again, the proceeds of this transaction were used to make distributions to SoClean's shareholders (i.e., to DWHP), not to improve the SoClean business, its products, or its financial position. More debt simply allowed more distributions to DWHP, thereby ensuring the quick recoupment of fully half of its investment, no matter whether SoClean survived as a going concern. SoClean received no benefit from this distribution to DWHP; instead, it was only further saddled with 50% more debt, with no offsetting benefit. There was no reason for SoClean's board of directors to approve more debt, just to turn over that amount to its private equity sponsor.

65. By December 2018, DWHP certainly had direct knowledge regarding SoClean's regulatory risks. On December 18, 2018, SoClean provided DWHP (and White Oak) a letter SoClean had received from FDA that day. The letter informed SoClean that FDA was evaluating

Despite this risk, DWHP caused SoClean to take on additional debt, while once again attempting to insulate itself from any exposure.

66. In 2019, DWHP repeated its further leveraging of SoClean, this time by increasing SoClean's debt by another \$5 million, the proceeds from which were used to buy back shares of the company from DWHP. Again, there was no reason for SoClean's board of directors to approve more debt, just to allow the repurchase of DWHP's shares. This further enriched DWHP and SoClean's former owners, who still held a minority stake and received cash for these shares.

67. DWHP did not only enrich itself through these distributions achieved by creating more leverage. DWHP further siphoned funds from SoClean, both in terms of management fees and the receipt of large dividends. DWHP secured annual management fees of about \$1 million, regardless of SoClean's performance. DWHP also distributed to itself large dividends at the expense of SoClean. For example, the year following the assumption of the additional \$33 million of SoClean debt, DWHP paid itself and the other shareholders dividends of \$2.989 million.

68. In addition to DWHP's overt siphoning of funds, DWHP also obtained inadequate insurance coverage for SoClean. As a medical device company operating without FDA approval or clearance to sell a device that uses a toxic gas to clean PAP machines that patients use every day, SoClean's business was fraught with litigation and regulatory risk. Despite this, DWHP opted for minimal insurance coverage for SoClean. For example, when SoClean sought coverage related to the ongoing MDL product liability claims against it, SoClean's insurer informed SoClean its policy did not cover the claims asserted against it. Worse still, even had the insurer deemed the conduct was covered, SoClean's policy had an aggregate coverage limit of only \$10 million—clearly inadequate to cover a company of SoClean's risk profile.

69. In 2021, SoClean's house of cards started to collapse. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In 2021, SoClean wrote down its intangible assets and good will by a staggering \$38.6 million, a write down over 100 times greater than its \$232,000 write down the year prior.

70. SoClean has not provided in discovery its most recent financial statements. But SoClean has regularly represented to the Court that it is under severe financial strain, such as by representing that consumer plaintiffs suing SoClean were “well aware of the financial status of the company,” and by confirming as “accurate” descriptions of SoClean having “very attenuated . . . financial circumstances.”

71. Throughout its ownership, DHWP has dominated SoClean’s management and controlled it for its own benefit. In addition to owning the majority of SoClean stock, SoClean’s board of directors includes senior executives from DWHP. These executives serving on SoClean’s board participate in SoClean’s management beyond what is customary for an investor. In fact, SoClean’s day-to-day management is run by DHWP, as DWHP admits by charging annually its \$1 million management fee.

72. Based on the limited discovery record received to date, it is apparent that DWHP’s involvement in, running of, and control of SoClean’s day-to-day affairs far exceeded that which is typical of or appropriate for a shareholder. DWHP controlled and was intimately involved in the minutiae of SoClean’s operations. The limited produced records to date indicate that, at minimum: (i) DWHP was involved in and exercised authority over personnel decisions at SoClean; (ii) DWHP was involved in and exercised authority over branding decisions at SoClean; (iii) DWHP was involved in and exercised authority over testing and research decisions at SoClean; and (iv) DWHP was involved in and exercised authority over the marketing and advertising decisions at SoClean.

73. At all relevant times, DHWP knew or should have known through, *inter alia*, its heavy presence on SoClean’s board and role in day-to-day management, that SoClean’s flagship ozone machines were neither FDA approved or cleared for use with PAPs, that SoClean’s

promotion and sale of its ozone-based PAP cleaning machines was unlawful and, thus, that nearly 100% of SoClean's revenues were derived from unlawful conduct. Similarly, at all relevant times, DHWP knew or should have known that SoClean ozone machines could cause foam within various PAP devices in the market, including the Philips Respironics PAP, to degrade.

Damages to Counterclaim-Plaintiffs

74. SoClean's and DWHP's continuing deceptive conduct has caused Counterclaim-Plaintiffs ongoing economic harm.

75. The risks and uncertainty posed by foam degradation, determined to be significantly due to ozone exposure, tarnished Philips RS's and Philips NA's reputation, goodwill, and relationships with customers, including DMEs and hospitals. Due to this reputational harm, Philips NA's and Philips RS's sales plummeted, affecting not just those products subject to the recall, but all Philips Respironics PAP products, as well as Philips RS's and NA's broader relationships with their customers. Moreover, SoClean's reckless conduct, promoted by its sponsor, DWHP, contributed in large part to Philips RS's decision to initiate a voluntary recall of potentially affected products in 2021.

76. SoClean's and DWHP's unauthorized use of the Philips name marks and its false statements about product compatibility tarnish the valuable and hard-earned goodwill that KPNV has achieved in its brand, and harmed KPNV by tarnishing its trademark.

CLAIMS FOR RELIEF

COUNT I

(FALSE ADVERTISING UNDER LANHAM ACT § 43(a), 15 U.S.C. § 1125(a))

77. Philips RS and Philips NA incorporate each of the allegations above as if fully set forth herein.

78. Philips RS and Philips NA have standing to pursue these claims because they are within the zone of interest protected by the false advertising provisions of the Lanham Act. The Supreme Court in *Lexmark* found that to determine whether the plaintiff was within the Lanham Act's "zone of interests" of the for a false advertising claim under § 1125(a), "a plaintiff must allege an injury to a commercial interest in reputation or sales." (citations omitted). *See* Opinion on Motion to Dismiss for Failure to State a Claim 36, Dkt. 480.

79. The Philips Respironics PAP products about which the SoClean Entities made these advertising claims are sold in interstate commerce throughout the United States.

80. The SoClean Entities have made and continue to make materially false and misleading statements about SoClean products' compatibility with Philips Respironics PAP devices in their advertising and promotions. Even after their failure to comply with repeated FDA demands to remove unsubstantiated claims that their product can work with PAPs, the SoClean Entities made and continue to make deceptive and false claims about their products' compatibility with the Philips Respironics PAPs.

81. The SoClean Entities marketed their offerings as "compatible" with Philips Respironics PAP devices notwithstanding the SoClean Entities' knowledge that their products harmed the performance and longevity of Philips Respironics PAP devices. The SoClean Entities were aware that their products contributed to the degradation of Philips Respironics PAP devices yet continued to advertise the devices as compatible.

82. The SoClean Entities' false compatibility claims are exacerbated by their false statements and implications that their offerings were safe or legal when, in reality, the SoClean Entities lacked FDA approval or clearance for the promotion, sale, or use of their products for use with any PAP machine, let alone in connection with Philips Respironics PAPs.

83. The SoClean Defendants' advertising claims are designed to influence customers' purchasing decisions and are made readily and widely available to the U.S. public, including, *inter alia*, by publication on SoClean's and its DMEs' websites.

84. The false statements of compatibility and suggested association with Philips Respironics PAP machines are material and would tend to deceive, and actually did deceive the SoClean Entities' target audience, who purchased products they believed were compatible with specifically identified Philips Respironics PAP products, including the DreamStation models and others.

85. Hundreds of thousands of customers have purchased SoClean for use with Philips Respironics PAPs.

86. Philips NA and Philips RS have suffered economic injury as a result of the SoClean Entities' false advertising.

87. Philips NA and Philips RS lost significant sales revenue as a result of SoClean's false and misleading claims.

88. Additionally, Philips RS bore the significant costs associated with the product recall that was driven in part by SoClean's deceptive conduct, including the expense of servicing or replacing PAP machines due to damaged foam.

89. Additional equitable damages are appropriate in this instance, as neither the SoClean Entities' profits nor Philips NA's and Philips RS's actual damages to date will adequately compensate Counterclaim-Plaintiffs. The resulting harm suffered by Philips NA and Philips RS extends far beyond the devices at issue in the Philips product recall. The reputational damage and loss of goodwill has tangibly affected Philips NA's and Philips RS's business and resulted in diminished sales not just for the recalled models, but for their future PAP sales as well. Philips NA

and Philips RS have suffered enormous losses as a result of the SoClean Entities' willfully deceptive conduct and the losses are ongoing.

90. The SoClean Entities ignored the known reality that their illegal products damage the foam in Philips RS PAP equipment, continuing with their false and harmful claims of compatibility. The SoClean Entities' unreasonable conduct was not deterred either by FDA warnings about the need for FDA approval, nor by foam degradation concerns triggering a recall. The SoClean Entities continued—and still continue—to promote their products for use with Philips RS devices.

91. Philips RS and Philips NV have thus suffered substantial damages in an amount to be determined at a trial of this matter.

COUNT II

(FEDERAL TRADEMARK DILUTION UNDER LANHAM ACT § 43(a), 15 U.S.C. § 1125(c))

92. KPNV incorporates each of the allegations above as if fully set forth herein.

93. KPNV expended substantial time and resources building the Philips brand, which is currently valued at approximately \$12.8 billion.¹⁸ As a result of the substantial resources devoted to innovation, investment, advertising and other brand-building efforts, there was significant goodwill associated with the Philips brand and marks. KPNV's United States Federal trademark registration are valid, subsisting, and in full force and effect.

94. To the detriment of KPNV, the SoClean Entities have made commercial use of the Philips marks by, *inter alia*, posting images of Philips Respironics PAP devices bearing the Philips wordmark and logo on its website to promote its own products, and by falsely touting compatibility

¹⁸ Philips, *Our Brand*, <https://www.philips.com/a-w/about/our-brand.html> (last visited Jan. 1, 2024).

with Philips Respironics PAP products in an effort to drive product purchases. As a result, SoClean's reputation has benefitted by improperly associating its illegal products with the Philips name and marks, to the detriment of KPNV.

95. The SoClean Entities' unauthorized use of the Philips name marks, and its false statements about product compatibility as a specific driver of consumer purchases, constitute a threat to the goodwill that Philips has achieved in its brand, which Philips has spent enormous time and financial resources to develop and maintain and is exclusively able to exploit. The SoClean Entities' association of SoClean's devices with Philips when, in fact, such offerings have not been approved by FDA and cause damage to Philips Respironics products, irreparably tarnishes the hard-earned and extraordinarily valuable goodwill in the Philips brand, and will continue to cause harm if SoClean continues its conduct.

96. Philips KPNV has been damaged economically by the SoClean Entities' conduct in an amount to be determined at trial.

COUNT III

(DECEPTIVE TRADE PRACTICES UNDER NEW HAMPSHIRE REVISED STATUTES § 358-A)

97. Philips RS and Philips NA incorporate each of the allegations above as if fully set forth herein.

98. SoClean's principal place of business is in Peterborough, New Hampshire. The SoClean Entities conduct trade and commerce within the state of New Hampshire.

99. The SoClean Entities committed unfair and deceptive acts in the conduct of trade or commerce within the state of New Hampshire.

100. Philips RS and Philips NA suffered harm as a result of the SoClean's unfair and deceptive conduct.

101. The SoClean Entities' repeated and ongoing claims of compatibility with Philips Respironics PAP devices were intended to mislead consumers into mistakenly believing that the SoClean Entities' products have some affiliation, connection, or approval for use with Philips Respironics PAP devices.

102. Customers were in fact confused about whether there was an affiliation between SoClean and Philips Respironics PAP devices.

103. The SoClean Entities' continued assertions about the compatibility of their products even after repeated demands from FDA to cease and remove such claims further underscores SoClean Entities' desire to deceive consumers about the benefits and approved uses of their products.

104. The SoClean Entities' false and deceptive statements were meant to influence customers to purchase their products.

105. The SoClean Entities' misleading statements led reasonable consumers, including consumers in New Hampshire, to erroneously believe that the SoClean Entities' products were safe, effective, and compatible for use with Philips RS sleep equipment machines.

106. Philips NA and Philips RS lost significant sales revenue as a result of SoClean's false and misleading claims.

107. Philips RS also bore the large expense of the product recall, which was driven in part by SoClean's deceptive conduct.

108. The SoClean Entities' unfair and deceptive conduct has confused Philips NA's and Philips RS's customers and negatively affected user experience and perceptions of Philips NA and

Philips RS and their products, and has tarnished the enormous and longstanding goodwill associated with the Philips brands and marks.

109. Philips NA and Philips RS have been damaged economically by the SoClean Entities' misrepresentation in an amount to be determined at trial.

110. Pursuant to N.H. Rev. Stat. Ann. § 358-A:10, Philips NA and Philips RS are entitled to costs and attorney's fees. Philips NA and Philips RS also are entitled to up to treble damages, but no less than double damages, because the SoClean Entities continuously made harmful statements they knew to be false, making their conduct a willful and knowing violation of the law.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs pray for judgment as follows:

a. An order that SoClean Entities have violated the unfair competition laws of the United States and New Hampshire, including the Lanham Act and the New Hampshire Consumer Protection Act;

b. An injunction prohibiting the SoClean Entities' further violation of 15 U.S.C. § 1125(a) and (c), and RSA 358-A;

c. An award of all damages to which Counterclaim-Plaintiffs are entitled as a result of the SoClean Entities' false representations and unfair competition (together with pre- and post-judgment interest), including increased damages for willful infringement of 15 U.S.C. § 1125(a) and RSA 358-A;

d. A holding that this case be declared exceptional in accordance with the meaning of 15 U.S.C. § 1117 and that Counterclaim-Plaintiffs be awarded and the SoClean Entities pay Philips' attorneys' fees; and

e. Such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

A jury trial is requested on all claims and issues triable by jury.

Respectfully submitted,

Dated: January 4, 2024

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EXHIBIT 1

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO Form 1478 (Rev 09/2006)

OMB No. 0651-0009 (Exp 02/28/2021)

Trademark/Service Mark Application, Principal Register

Serial Number: 90375000

Filing Date: 12/11/2020

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	90375000
MARK INFORMATION	
*MARK	PHILIPS
STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	PHILIPS
MARK STATEMENT	The mark consists of standard characters, without claim to any particular font style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
*OWNER OF MARK	KONINKLIJKE PHILIPS N.V.
*MAILING ADDRESS	High Tech Campus 52
*CITY	Eindhoven
*COUNTRY/REGION/JURISDICTION/U.S. TERRITORY	Netherlands
*ZIP/POSTAL CODE (Required for U.S. and certain international addresses)	5656AG
*EMAIL ADDRESS	XXXX
LEGAL ENTITY INFORMATION	
TYPE	a public limited liability company
STATE/COUNTRY/REGION/JURISDICTION/U.S. TERRITORY WHERE LEGALLY ORGANIZED	Netherlands
GOODS AND/OR SERVICES AND BASIS INFORMATION	
INTERNATIONAL CLASS	005
*IDENTIFICATION	Oxygen for medical use; adhesive for application to a respiratory mask for creating an air tight seal between the mask and the face to protect patients and healthcare workers from air-borne pathogens.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	007
*IDENTIFICATION	Oxygen concentrator and compressor for compressing oxygen and for filling oxygen bottles; compressor for compressing oxygen and for filling oxygen bottles; all for domestic use.
FILING BASIS	SECTION 1(b)

INTERNATIONAL CLASS	009
*IDENTIFICATION	Batteries and electric rechargeable batteries; electrical rechargeable battery packs; battery kits; battery chargers; parts of the aforesaid goods in this class only; wrist worn micro-controller based data logger for use to monitor activity, ambient light and physiological parameters in human subjects; computer software for medical purposes, namely, for controlling apparatus for treating breathing disorders, and for controlling and managing patient medical information; computer software for use in the field of healthcare, namely, for collecting, processing and managing sleep and respiratory patient data enabling providers to share and exchange information; computer software for use in diagnosing sleep disorders; computer software for automatically performing sleep study scoring for use in recording and analyzing data during the sleep of patients; computer software programs and application software suited for smart phones for recording, editing and transmitting data; computer software incorporating medical algorithms for controlling positive airway pressure apparatus for the treatment of respiratory disorders; computer software and firmware, namely, operating system programs, data synchronization programs, and application development computer software programs for personal and handheld computers; downloadable and non-downloadable computer software for analyzing data from face and head images and patient questionnaires for use in selecting a respiratory mask or generating a customized respiratory mask design.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	010
*IDENTIFICATION	010 Medical and surgical apparatus, equipment and instruments, namely, apparatus for use in the treatment of breathing disorders and parts and fittings therefor; positive airway pressure equipment for the treatment of sleep apneas and parts and fittings therefor; medical ventilator equipment to assist or replace patient breathing and parts and fittings therefor; medical resuscitators and parts and fittings therefor; respiratory equipment and monitors therefor, and apparatus that provides variable air pressure to a patient and parts therefor; airway clearance systems and parts, fittings and accessories therefor; a mechanical insufflation-exsufflation device used to clear secretions from the lungs by gradually applying positive pressure to the airway and rapidly shifting to negative pressure to produce a high expiratory flow from the lung; airway pressure devices; pulsating garments for providing pulsating pressure or vibration to the upper body of a person; a pulsating garment and an air pulsating unit connected to the garment for providing pulsating pressure to the upper body of a person to assist in loosening and eliminating mucus from the lungs, in muscle and nerve relaxation, and in other bodily functions; oxygen concentrators; portable oxygen concentrators and parts and accessories therefor, for medical applications; capnography sensors; a valved holding chamber for use with metered dose inhalers; compressor-nebulizer for respiration therapy and drug delivery; nebulizers for respiration therapy; respiratory apparatus and instruments in the nature of compressor nebulizers for respiration therapy, drug delivery nebulizers for administering medication in the form of a mist inhaled into the lungs for treatment of asthma and respiratory diseases and parts therefor; compressor

	nebulizer devices for respiratory therapy and parts therefor including nebulizers, compressors, respiratory sensors, mask seals, and masks; nasal masks in the nature of respiratory masks for medical purposes, as well as parts therefor; respiratory masks for sleep therapy, as well as parts therefor; respiratory mask for use with medical breathing devices, as well as parts therefor; masks with gel nasal pillows or with silicone nasal pillows, as well as parts therefor; wrist worn medical device for monitoring physical activity, namely, motion, as an indicator of movement disorders, sleep disorders, or other medical conditions characterized by movement or lack of it such as level of pain, as well as for monitoring other parameters such as ambient light level, noise levels, temperature, or other physiological or environmental parameters that aid in diagnosis and in tracking treatment effectiveness; sleep apnea diagnostic devices for in-home use; medical apparatus for recording and analyzing sleep-related disorders in infants.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	035
*IDENTIFICATION	Compilation and systemization of data in computer databases; data processing services in the nature of data administration using computers.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	038
*IDENTIFICATION	Remote electronic transmission of data via communications network and internet for data processing; communications through a global computer network; communications through the internet; providing access to the internet; providing internet chat rooms; providing user access to computer programs via the internet; providing telecommunications connections to the internet or databases; providing access to computer networks and the internet.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	042
*IDENTIFICATION	Computer software design for data processing and data analysis; scientific research for medical purposes.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	044
*IDENTIFICATION	Services in the field of healthcare, namely, collecting, processing and managing sleep and respiratory patient data enabling providers to share and exchange information for the purpose of medical treatment and diagnosis; medical training and continuing education in the sleep and respiratory care fields; cloud-computing services for processing and analyzing face and head images, retrieving and analyzing patient questionnaires, and selecting a respiratory mask or generating a customized face mask design to fit the patient.
FILING BASIS	SECTION 1(b)
ATTORNEY INFORMATION	
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ATTORNEY BAR MEMBERSHIP NUMBER	XXX
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FEE INFORMATION	
APPLICATION FILING OPTION	TEAS Standard
NUMBER OF CLASSES	8
APPLICATION FOR REGISTRATION PER CLASS	275
*TOTAL FEES DUE	2200
*TOTAL FEES PAID	2200
SIGNATURE INFORMATION	
SIGNATURE	/Kathleen A. Asher/

SIGNATORY'S NAME	Kathleen A. Asher
SIGNATORY'S POSITION	Attorney of Record - DC bar member
SIGNATORY'S PHONE NUMBER	617-613-2452
DATE SIGNED	12/11/2020

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO Form 1478 (Rev 09/2006)

OMB No. 0651-0009 (Exp 02/28/2021)

Trademark/Service Mark Application, Principal Register

Serial Number: 90375000

Filing Date: 12/11/2020

To the Commissioner for Trademarks:

MARK: PHILIPS (Standard Characters, see [mark](#))

The literal element of the mark consists of PHILIPS. The mark consists of standard characters, without claim to any particular font style, size, or color.

The applicant, KONINKLIJKE PHILIPS N.V., a a public limited liability company legally organized under the laws of Netherlands, having an address of

High Tech Campus 52
Eindhoven 5656AG
Netherlands
XXXX

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

International Class 005: Oxygen for medical use; adhesive for application to a respiratory mask for creating an air tight seal between the mask and the face to protect patients and healthcare workers from air-borne pathogens.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 007: Oxygen concentrator and compressor for compressing oxygen and for filling oxygen bottles; compressor for compressing oxygen and for filling oxygen bottles; all for domestic use.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 009: Batteries and electric rechargeable batteries; electrical rechargeable battery packs; battery kits; battery chargers; parts of the aforesaid goods in this class only; wrist worn micro-controller based data logger for use to monitor activity, ambient light and physiological parameters in human subjects; computer software for medical purposes, namely, for controlling apparatus for treating breathing disorders, and for controlling and managing patient medical information; computer software for use in the field of healthcare, namely, for collecting, processing and managing sleep and respiratory patient data enabling providers to share and exchange information; computer software for use in diagnosing sleep disorders; computer software for automatically performing sleep study scoring for use in recording and analyzing data during the sleep of patients; computer software programs and application software suited for smart phones for recording, editing and transmitting data; computer software incorporating medical algorithms for controlling positive airway pressure apparatus for the treatment of respiratory disorders; computer software and firmware, namely, operating system programs, data synchronization programs, and application development computer software programs for personal and handheld computers; downloadable and non-downloadable computer software for analyzing data from face and head images and patient questionnaires for use in selecting a respiratory mask or generating a customized respiratory mask design.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 010: 010 Medical and surgical apparatus, equipment and instruments, namely, apparatus for use in the treatment of breathing disorders and parts and fittings therefor; positive airway pressure equipment for the treatment of sleep apneas and parts and fittings therefor; medical ventilator equipment to assist or replace patient breathing and parts and fittings therefor; medical resuscitators and parts and fittings therefor; respiratory equipment and monitors therefor, and apparatus that provides variable air pressure to a patient and parts therefor; airway clearance systems and parts, fittings and accessories therefor; a mechanical insufflation-exsufflation device used to clear secretions from the lungs by gradually applying positive pressure to the airway and rapidly shifting to negative pressure to produce a high expiratory flow from the lung; airway pressure devices; pulsating garments for providing pulsating pressure or vibration to the upper body of a person; a pulsating garment and an air pulsating unit connected to the garment for providing pulsating pressure to the upper body of a person to assist in loosening and eliminating mucus from the lungs, in muscle and nerve relaxation, and in other bodily functions; oxygen concentrators; portable oxygen concentrators and parts and accessories therefor, for medical applications; capnography sensors; a valved holding chamber for use with metered dose inhalers; compressor-nebulizer for respiration therapy and drug delivery; nebulizers for respiration therapy; respiratory apparatus and instruments in the nature of compressor nebulizers for respiration therapy, drug delivery nebulizers for administering medication in the form of a

mist inhaled into the lungs for treatment of asthma and respiratory diseases and parts therefor; compressor nebulizer devices for respiratory therapy and parts therefor including nebulizers, compressors, respiratory sensors, mask seals, and masks; nasal masks in the nature of respiratory masks for medical purposes, as well as parts therefor; respiratory masks for sleep therapy, as well as parts therefor; respiratory mask for use with medical breathing devices, as well as parts therefor; masks with gel nasal pillows or with silicone nasal pillows, as well as parts therefor; wrist worn medical device for monitoring physical activity, namely, motion, as an indicator of movement disorders, sleep disorders, or other medical conditions characterized by movement or lack of it such as level of pain, as well as for monitoring other parameters such as ambient light level, noise levels, temperature, or other physiological or environmental parameters that aid in diagnosis and in tracking treatment effectiveness; sleep apnea diagnostic devices for in-home use; medical apparatus for recording and analyzing sleep-related disorders in infants.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 035: Compilation and systemization of data in computer databases; data processing services in the nature of data administration using computers.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 038: Remote electronic transmission of data via communications network and internet for data processing; communications through a global computer network; communications through the internet; providing access to the internet; providing internet chat rooms; providing user access to computer programs via the internet; providing telecommunications connections to the internet or databases; providing access to computer networks and the internet.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 042: Computer software design for data processing and data analysis; scientific research for medical purposes.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

International Class 044: Services in the field of healthcare, namely, collecting, processing and managing sleep and respiratory patient data enabling providers to share and exchange information for the purpose of medical treatment and diagnosis; medical training and continuing education in the sleep and respiratory care fields; cloud-computing services for processing and analyzing face and head images, retrieving and analyzing patient questionnaires, and selecting a respiratory mask or generating a customized face mask design to fit the patient.

Intent to Use: The applicant has a bona fide intention, and is entitled, to use the mark in commerce on or in connection with the identified goods/services.

The owner's/holder's proposed attorney information: KATHLEEN A. ASHER. Other appointed attorneys are MARY YAWNEY REDMAN, MICHAEL E. MARION, DAVID SCHREIBER. KATHLEEN A. ASHER of PHILIPS IP&S, is a member of the XX bar, admitted to the bar in XXXX, bar membership no. XXX, and the attorney(s) is located at

465 Columbus Avenue, Suite 340
Valhalla, New York 10595
United States
617-613-2452(phone)
(914) 495-9540(fax)
Lillian.Drumheller@philips.com

The docket/reference number is 2020TF50049.

KATHLEEN A. ASHER submitted the following statement: The attorney of record is an active member in good standing of the bar of the highest court of a U.S. state, the District of Columbia, or any U.S. Commonwealth or territory.

The applicant hereby appoints KATHLEEN A. ASHER of PHILIPS IP&S

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Valhalla New York 10595
United States
617-613-2452(phone)
(914) 495-9540(fax)
Lillian.Drumheller@philips.com

as applicant's representative upon whom notice or process in the proceedings affecting the mark may be served.

The applicant's current Correspondence Information:

KATHLEEN A. ASHER
PRIMARY EMAIL FOR CORRESPONDENCE: Lillian.Drumheller@philips.com

SECONDARY EMAIL ADDRESS(ES) (COURTESY COPIES): Kate.Asher@philips.com

Requirement for Email and Electronic Filing: I understand that a valid email address must be maintained by the applicant owner/holder and the applicant owner's/holder's attorney, if appointed, and that all official trademark correspondence must be submitted via the Trademark Electronic Application System (TEAS).

A fee payment in the amount of \$2200 has been submitted with the application, representing payment for 8 class(es).

Declaration

☒ **Basis:**

If the applicant is filing the application based on use in commerce under 15 U.S.C. § 1051(a):

- The signatory believes that the applicant is the owner of the trademark/service mark sought to be registered;
- The mark is in use in commerce and was in use in commerce as of the filing date of the application on or in connection with the goods/services in the application;
- The specimen(s) shows the mark as used on or in connection with the goods/services in the application and was used on or in connection with the goods/services in the application as of the application filing date; and
- To the best of the signatory's knowledge and belief, the facts recited in the application are accurate.

And/Or

If the applicant is filing the application based on an intent to use the mark in commerce under 15 U.S.C. § 1051(b), § 1126(d), and/or § 1126(e):

- The signatory believes that the applicant is entitled to use the mark in commerce;
 - The applicant has a bona fide intention to use the mark in commerce and had a bona fide intention to use the mark in commerce as of the application filing date on or in connection with the goods/services in the application; and
 - To the best of the signatory's knowledge and belief, the facts recited in the application are accurate.
- ☒ To the best of the signatory's knowledge and belief, no other persons, except, if applicable, concurrent users, have the right to use the mark in commerce, either in the identical form or in such near resemblance as to be likely, when used on or in connection with the goods/services of such other persons, to cause confusion or mistake, or to deceive.
- ☒ To the best of the signatory's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, the allegations and other factual contentions made above have evidentiary support.
- ☒ The signatory being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements and the like may jeopardize the validity of the application or submission or any registration resulting therefrom, declares that all statements made of his/her own knowledge are true and all statements made on information and belief are believed to be true.

Declaration Signature

Signature: /Kathleen A. Asher/ Date: 12/11/2020

Signatory's Name: Kathleen A. Asher

Signatory's Position: Attorney of Record - DC bar member

Payment Sale Number: 90375000

Payment Accounting Date: 12/11/2020

Serial Number: 90375000

Internet Transmission Date: Fri Dec 11 09:06:52 ET 2020

TEAS Stamp: USPTO/BAS-XXX.XXX.XX.XXX-202012110906520

80150-90375000-7506a3d2f93622cc6796b9184

ae175990f43bb86215cd2d8510dd10c49f45c79-

DA-06519253-20201210202819481338

PHILIPS

United States of America

United States Patent and Trademark Office

PHILIPS

Reg. No. 7,110,031

Registered Jul. 18, 2023

Int. Cl.: 9, 10, 35, 38, 41, 42

Service Mark

Trademark

Principal Register

KONINKLIJKE PHILIPS N.V. (NETHERLANDS NAAMLOZE
VENNOOTSCHAP (NV))
High Tech Campus 52
Eindhoven, NETHERLANDS 5656AG

CLASS 9: Batteries and electric rechargeable batteries; electrical rechargeable battery packs; battery kits comprising batteries, battery packs, battery chargers, calibration devices for calibrating rechargeable batteries, battery cables, connection cables, electric adapter cables, power cords, battery cases, and printed instructions; battery chargers; replacement parts of the aforesaid batteries, namely, electrical cables for battery chargers, replacement batteries, replacement battery packs, battery chargers, calibration devices for calibrating rechargeable batteries, battery cables, connection cables, electric adapter cables, power supplies, power cords, battery cases, battery straps and printed instructions; wrist worn micro-controller based electronic data logger for use to monitor activity, ambient light and physiological parameters in human subjects; downloadable and recorded computer software for medical purposes, namely, for controlling apparatus for treating breathing disorders, and for controlling and managing patient medical information; downloadable and recorded computer software for use in the field of healthcare, namely, for collecting, processing and managing sleep and respiratory patient data enabling providers to share and exchange information; downloadable and recorded computer software for use in diagnosing sleep disorders; downloadable and recorded computer software for automatically performing sleep study scoring for use in recording and analyzing data during the sleep of patients; downloadable and recorded computer software programs and application software suited for smart phones for recording, editing and transmitting data; downloadable and recorded computer software incorporating medical algorithms for controlling positive airway pressure apparatus for the treatment of respiratory disorders; downloadable and recorded computer software and firmware, namely, operating system programs, data synchronization programs, and application development computer software programs for personal and handheld computers; downloadable and recorded computer software for analyzing data from face and head images and patient questionnaires for use in selecting a respiratory mask or generating a customized respiratory mask design

FIRST USE 12-31-2016; IN COMMERCE 12-31-2016

CLASS 10: Medical and surgical apparatus, equipment and instruments, namely, apparatus for use in the treatment of breathing disorders and replacement parts and

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office



fittings therefor, positive airway pressure equipment for the treatment of sleep apneas, medical ventilator equipment to assist or replace patient breathing, medical resuscitators, bi-level positive airway pressure devices, continuous positive airway pressure devices and variable positive airway pressure devices, airway clearance systems, comprised of air delivery devices and/or suction devices and patient interfaces therefor; mechanical insufflation-exsufflation devices to clear secretions from the lungs by gradually applying positive pressure to the airway and rapidly shifting to negative pressure to produce a high expiratory flow from the lung, air pulsating units for medical purposes for providing pulsating positive and negative air pressure to the airway of a person to assist in loosening and eliminating mucus from the lungs and in other bodily functions; oxygen concentrators for medical purposes; portable oxygen concentrators for medical applications; capnography sensors being respiratory sensors; valved holding chamber for use with metered dose inhalers; compressor-nebulizer for respiration therapy and drug delivery; nebulizers for respiration therapy; respiratory apparatus and instruments in the nature of compressor nebulizers for respiration therapy; drug delivery nebulizers for administering medication in the form of a mist inhaled into the lungs for treatment of asthma and respiratory diseases; portable medical device for monitoring physical activity, namely, motion, as an indicator of movement disorders, sleep disorders, or other medical conditions characterized by movement or lack of it such as level of pain, as well as for monitoring other parameters such as ambient light level, noise level, temperature, or other physiological or environmental parameters that aid in diagnosis and in tracking treatment effectiveness; sleep apnea diagnostic devices for in-home use, namely, positive airway pressure equipment, diagnostic sleep monitors and sensors, medical apparatus for recording and analyzing physiological data to identify sleep-related disorders; adhesive tape for application to a respiratory mask for creating an air tight seal between the mask and the face to protect patients and healthcare workers from air-borne pathogens; medical tubing and tubing connectors; textile and/or plastic material headgear specially adapted for use with medical mask interfaces; medical masks, mask seals, mask cushions and cannulas for medical purposes; humidification apparatuses for medical purposes, therapeutic mouthpieces, air filters for use in the treatment of breathing disorders, pressure relief valves for medical purposes, control valves for regulating the flow of gases for medical purposes and printed instructions for medical and surgical apparatus, equipment and instruments; positive airway pressure equipment for the treatment of sleep apneas and replacement parts and fittings therefor; positive airway pressure equipment tubing and tubing connectors; textile and/or plastic material headgear specially adapted for use with positive airway pressure equipment mask interfaces and medical insufflation mask interfaces, medical positive airway pressure masks and medical insufflation masks; mask seals for use with positive airway pressure equipment; mask cushions for use with positive airway pressure equipment, medical apparatus for the treatment of respiratory conditions, namely, positive airway pressure equipment for the treatment of sleep apneas and replacement parts and fittings therefor, tubing and tubing connectors for use with positive airway pressure equipment for the treatment of sleep apneas, textile and/or plastic material headgear specially adapted for use with positive airway pressure equipment for the treatment of sleep apneas, medical masks and medical insufflation masks for use with positive airway pressure equipment for the treatment of sleep apneas, mask seals for use with positive airway pressure equipment for the treatment of sleep apneas, mask cushions for use with positive airway pressure equipment for the treatment of sleep apneas, cannulas for use with positive airway pressure equipment for the treatment of sleep apneas; humidification apparatuses for use with positive airway pressure equipment; diagnostic sleep monitors, sensors, and air filters for use with positive airway pressure equipment; medical ventilator equipment to assist or replace patient breathing and replacement parts and fittings therefor; medical ventilator tubing and tubing connectors, textile and/or plastic material headgear specially adapted for use with medical ventilator mask interfaces and medical insufflation mask interfaces, medical ventilator masks, mask seals for use with medical ventilator equipment, mask cushions for use with medical ventilator equipment, cannulas for use with medical ventilator equipment, humidification apparatuses for use with medical ventilator equipment, and air filters for use with medical ventilator equipment; medical

resuscitators and replacement parts and fittings therefor, medical resuscitator tubing and tubing connectors, textile and/or plastic material headgear specially adapted for use with medical resuscitator mask interfaces, medical resuscitator masks, mask seals for use with medical resuscitators, mask cushions for use with medical resuscitators, cannulas for use with medical resuscitators, humidification apparatus for use with medical resuscitators, and air filters for use with medical resuscitators; respiratory equipment and monitors therefor, and medical apparatus that provides variable air pressure to a patient, namely, bi-level positive airway pressure devices, continuous positive airway pressure devices and variable positive airway pressure devices and replacement parts therefor, medical tubing and tubing connectors for use with respiratory equipment and monitors therefor, textile and/or plastic material headgear specially adapted for use with respiratory equipment and monitors therefor, medical masks for use with respiratory equipment and monitors therefor, mask seals for use with medical respiratory equipment; mask cushions for use with medical respiratory equipment, cannulas for use with respiratory equipment, humidification apparatuses for use with respiratory equipment, and air filters for use with respiratory equipment; medical apparatus for the treatment of respiratory conditions, namely, airway clearance systems and replacement parts and fittings therefor; medical tubing and tubing connectors for use with airway clearance systems; medical masks for use with airway clearance systems; mask seals for use with airway clearance systems; mask cushions for use with airway clearance systems; cannulas for use with airway clearance systems; therapeutic mouthpieces for use with airway clearance systems; air filters for use with airway clearance systems; water traps for separating liquid from a breathing gas of a patient; stand brackets and stands for airway clearance systems, foot pedals for airway clearance systems, cases for airway clearance systems, rechargeable battery packs for airway clearance systems, cases and covers for rechargeable battery packs for airway clearance systems, chargers for rechargeable battery packs for airway clearance systems, cables for airway clearance systems, power adapters for airway clearance systems; medical apparatus for the treatment of respiratory conditions, namely, mechanical insufflation-exsufflation device used to clear secretions from the lungs by gradually applying positive pressure to the airway and rapidly shifting to negative pressure to produce a high expiratory flow from the lung; airway pressure devices, namely, bi-level positive airway pressure devices, continuous positive airway pressure devices and variable positive airway pressure devices; medical apparatus for the treatment of respiratory conditions, being an apparatus to dislodge mucus and mobilize secretions in the respiratory system; oxygen concentrators for medical purposes; portable oxygen concentrators and replacement parts therefor, for medical applications, medical tubing and tubing connectors for use with oxygen concentrators, medical masks for use with oxygen concentrators, mask seals for use with oxygen concentrators, mask cushions for use with oxygen concentrators, cannulas for use with oxygen concentrators, therapeutic mouthpieces for use with oxygen concentrators, air filters for use with oxygen concentrators, stands for oxygen concentrators, cases and straps for oxygen concentrators, medical bags designed to hold oxygen concentrators, medical bags designed to hold accessories for oxygen concentrators, pulse oximeters for medical purposes, medical cases for pulse oximeters, carts for oxygen concentrators, carts specially adapted for holding or carrying portable medical oxygen cylinders, peak flow meters, gaskets and gasket tools for use with oxygen concentrators, humidification apparatuses for use with oxygen concentrators, pressure relief valves for use with oxygen concentrators, humidifier pouches for medical humidifiers, rechargeable battery packs for oxygen concentrators, cases and covers for rechargeable battery packs for oxygen concentrators, chargers for rechargeable battery packs for oxygen concentrators, charger stands for oxygen concentrators, cables for oxygen concentrators, power cords for oxygen concentrators, power adapters for oxygen concentrators, and powers supplies for oxygen concentrators; medical devices for use in oxygen therapy, namely, oxygen concentrators for in-home use; medical apparatus for facilitating the inhalation of pharmaceutical preparations, namely, valved holding chamber for use with metered dose inhalers; compressor-nebulizer for respiration therapy and drug delivery; nebulizers for respiration therapy; respiratory apparatus and instruments in the nature of compressor nebulizers for respiration therapy, drug delivery nebulizers for administering medication in the form of a mist inhaled into the lungs for

treatment of asthma and respiratory diseases and replacement parts therefor, medical tubing and tubing connectors for use with drug delivery nebulizers, chambers for use with drug delivery nebulizers, respiratory masks for use with drug delivery nebulizers, control valves for regulating the flow of gases for use with drug delivery nebulizers, medical tubing for administering gases, therapeutic mouthpieces for use with drug delivery nebulizers, respiratory apparatus and instruments; peak flow meters for use with drug delivery nebulizers, respiratory apparatus and instruments; power adapters for use with drug delivery nebulizers, respiratory apparatus and instruments; rechargeable battery packs for use with drug delivery nebulizers, respiratory apparatus and instruments; chargers for rechargeable battery packs for use with drug delivery nebulizers, respiratory apparatus and instruments; power cords for use with drug delivery nebulizers, respiratory apparatus and instruments; power adapters for use with drug delivery nebulizers, respiratory apparatus and instruments; cases for use with drug delivery nebulizers, respiratory apparatus and instruments; air filters for use with drug delivery nebulizers, respiratory apparatus and instruments; compressor nebulizer devices for respiratory therapy and replacement parts therefor including nebulizers, compressors, respiratory sensors, mask seals, and masks; nasal masks in the nature of respiratory masks for medical purposes, as well as replacement parts therefor, medical tubing and tubing connectors for use with nasal masks, control valves for regulating the flow of gases for use with nasal masks, medical tubing for administering gases for use with nasal masks, cannulas for use with nasal masks, humidification apparatus for use with nasal masks; respiratory masks for sleep therapy, as well as replacement parts therefor, medical tubing and tubing connectors for use with respiratory masks for sleep therapy, textile and/or plastic material headgear specially adapted for use with respiratory masks for sleep therapy, masks for sleep therapy, mask seals for use with respiratory masks for sleep therapy, cannulas for use with respiratory masks for sleep therapy, humidification apparatus for use with respiratory masks for sleep therapy, valves for regulating the flow of gases for use with respiratory masks for sleep therapy; respiratory mask for use with medical breathing devices, as well as replacement parts therefor, medical tubing and tubing connectors for use with medical breathing devices, textile and/or plastic material headgear specially adapted for use with medical breathing devices, mask seals for use with medical breathing devices, cannulas for use with medical breathing devices, humidification apparatuses for use with medical breathing devices, control valves for regulating the flow of gases for use with medical breathing devices; respiratory masks for medical purposes with gel nasal pillows or with silicone nasal pillows, as well as replacement parts therefor, medical tubing and tubing connectors for use with respiratory masks for medical purposes, headgear specially adapted for use with respiratory masks for medical purposes, mask seals for use with respiratory masks for medical purposes, cannulas for use with respiratory masks for medical purposes, humidification apparatuses for use with respiratory masks for medical purposes, control valves for regulating the flow of gases for use with respiratory masks for medical purposes; medical apparatus for diagnosing sleeping disorders, namely, sleep apnea diagnostic devices for in-home use; medical apparatus for recording and analyzing physiological data to identify sleep-related disorders

FIRST USE 12-31-2016; IN COMMERCE 12-31-2016

CLASS 35: Data processing services, namely, compilation and systemization of data in computer databases; data processing services in the nature of data administration using computers; data processing services in the field of healthcare, namely, collecting, processing and managing sleep and respiratory patient data enabling providers to share and exchange information for the purpose of medical treatment and diagnosis

FIRST USE 12-31-2016; IN COMMERCE 12-31-2016

CLASS 38: Remote electronic transmission of data via communications network and internet for data processing; communications being recording, storing, editing, analyzing, reporting, sharing and transmitting patient data through transmission of patient data, transmission of voice, transmission of images, voice over IP services, transmission of tutorial videos, transmission of follow-up and diagnostic assessments,

transmission of queries, and transmission of summaries through a global computer network; communications being transmission of patient data, transmission of voice, transmission of images, voice over IP services, transmission of tutorial videos, transmission of follow-up and diagnostic assessments, transmission of queries, and transmission of summaries through the internet; providing access to the internet; providing internet chat rooms; providing user access to computer programs via the internet; providing telecommunications connections to the internet or databases; providing access to computer networks and the internet

FIRST USE 12-31-2016; IN COMMERCE 12-31-2016

CLASS 41: Medical training and continuing education in the sleep and respiratory care fields

FIRST USE 12-31-2016; IN COMMERCE 12-31-2016

CLASS 42: Computer software design for data processing and data analysis; scientific research for medical purposes in the field of sleep analysis and therapy, respiratory care, medical ventilators, oxygen concentrators, oxygen delivery devices, inhalation drug delivery systems, and activity monitoring; providing online non-downloadable software for analyzing data from face and head images and patient questionnaires for use in selecting a respiratory mask or generating a customized respiratory mask design; cloud-computing services featuring software for processing and analyzing face and head images, retrieving and analyzing patient questionnaires, and selecting a respiratory mask or generating a customized face mask design to fit the patient

FIRST USE 12-31-2016; IN COMMERCE 12-31-2016

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

OWNER OF U.S. REG. NO. 0706721

SEC.2(F)

SER. NO. 90-375,000, FILED 12-11-2020

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*

What and When to File:

- **First Filing Deadline:** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.
- **Second Filing Deadline:** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*

What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see <http://www.wipo.int/madrid/en/>.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at <http://www.uspto.gov>.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at <http://www.uspto.gov>.

EXHIBIT 2
FILED UNDER SEAL
REDACTED IN ITS ENTIRETY