

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

-----X  
SOCLEAN, INC.

Case No. 1:21-cv-10131-IT

Plaintiff,

**FIRST AMENDED COMPLAINT**

- against -

SUNSET HEALTHCARE SOLUTIONS, INC.

Defendant.

-----X

Plaintiff SoClean, Inc., (“SoClean” or “Plaintiff”), by its attorneys, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., as and for its Complaint against Defendant Sunset Healthcare Solutions, Inc. (“Sunset” or “Defendant”), alleges and states as follows:

**NATURE OF THE ACTION**

1. This is an action for patent and trademark infringement arising under the laws of the United States. Sunset is not only selling a knockoff sanitizing device that infringes SoClean’s patent rights covering its flagship product, but Sunset is further undermining SoClean’s hard-fought market share and customer base by selling knockoff replacement filters designed to be used twice annually for the life of the flagship product, thus infringing SoClean’s trademark rights.

2. In an earlier and ongoing related action, *SoClean, Inc. v. Sunset Healthcare Solutions, Inc.*, 1:20-cv-10351-IT (D. Mass.), SoClean filed claims against Sunset for patent infringement, breach of contract, tortious interference with business relations, unjust enrichment, and breach of the covenant of good faith and fair dealing. One of the patents asserted in this action is part of the same family as the patents asserted in the related action.

3. Since January 2020, Sunset has sold a product called the “Zoey.” The Zoey is an automated continuous positive airway pressure (“CPAP”) sanitizing device and is a knock-off of SoClean’s “SoClean 2” product.

4. Sunset served as a distributor of SoClean products, including the flagship SoClean 2 device, from 2014 until late 2019.

5. During this time Sunset used its position as distributor to obtain information regarding SoClean’s customers, products, pricing models, and marketing and product development strategies. This allowed Sunset to quickly develop a copycat product of the SoClean 2 and then launch it into the market for automated CPAP sanitizing devices, a market that SoClean had built from scratch and cultivated for almost a decade.

6. In sum, while purporting to act as SoClean’s distributor, Sunset was in fact surreptitiously developing its own competing product, which runs afoul of SoClean’s patent rights.

7. Both the SoClean 2 and Zoey devices use ozone to sanitize a CPAP machine and its associated hose and mask. More specifically, both devices generate ozone and then allow for a closed system wherein the ozone can penetrate the CPAP reservoir, the hose, and the mask in a very short period of time before being exhausted.

8. In both devices, the mask is placed inside an ozone-generating box, and then the hose is used to complete the closed system between the box, the CPAP machine, and the mask.

9. In both devices, the ozone (O<sub>3</sub>) is converted back into molecular oxygen (O<sub>2</sub>) before being released from the closed system into the atmosphere.

10. The Zoey shares not only the patented features of the SoClean 2, but also the same look and feel, which Sunset has copied to take advantage of SoClean's recognized market popularity.

11. An image of the SoClean 2 device is shown below:



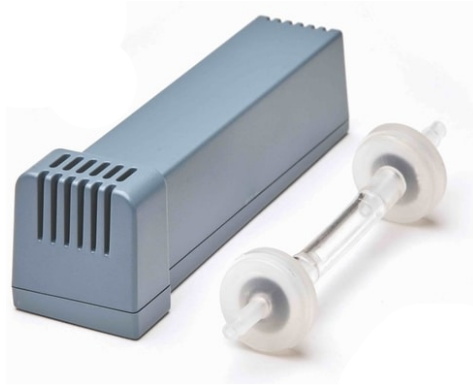
12. An image of the accused Zoey device is shown below:



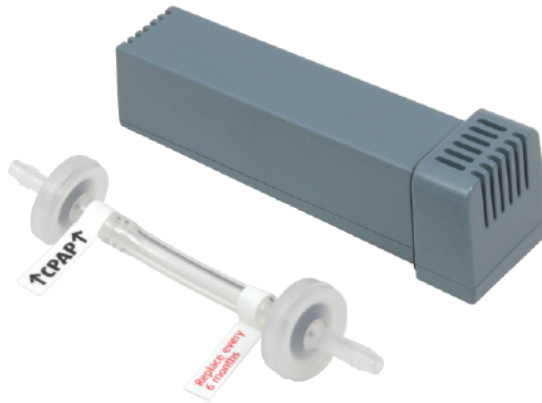
13. Sunset used its distributor relationship with SoClean to improperly copy the SoClean 2 device as a whole.

14. Sunset also used its relationship with SoClean to improperly copy the replacement filters for the SoClean 2 device, thus infringing SoClean's trade dress rights in these filters.

15. Sunset now sells a “*CAP1007S-KIT Filter and Check Valve Kit for SoClean 2 CPAP Cleaning Device,*” which is a knockoff of the filter kit for the SoClean 2 device. The two filter kit sets are shown below for comparison:



**SoClean 2 Filter Kit**



**Sunset Knockoff of SoClean 2 Filter Kit**

16. The SoClean 2 filter is a component of the SoClean 2 device. It serves to convert ozone back to oxygen once the ozone has been used to sanitize the CPAP device.

17. Sunset’s knockoff replacement filter shares the same ornamental designs as SoClean’s protected trade dress.

18. Sunset's infringing actions are irreparably and permanently damaging SoClean through lost sales, lost future sales, price erosion, brand erosion, loss of goodwill, and other damage.

**THE PARTIES**

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

20. SoClean designs, markets, and sells the SoClean 2, an automated ozone-based CPAP sanitizing device, along with related components such as filter kits.

21. Defendant Sunset is a corporation organized and existing under the laws of the Illinois with its principal place of business at 180 N Michigan Avenue, Suite 2000, Chicago, Illinois 60601.

22. Sunset designs, markets, and sells the Zoey, an automated ozone-based CPAP sanitizing device, along with related components.

23. Sunset also markets and sells replacement filter kits for the SoClean 2, along with other SoClean 2 compatible products.

24. Sunset also distributes numerous other medical products not related to this litigation.

**JURISDICTION AND VENUE**

25. This is an action for patent infringement arising under 35 U.S.C. §§1 *et seq.*, and for trademark infringement arising under 15 U.S.C. §§ 1114, 1125 *et seq.* and the common law. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

26. The amount in controversy exceeds the sum of \$75,000, exclusive of interest and costs. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332, based on the diversity of citizenship of the parties and the amount in controversy.

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

28. Venue is also proper in the District pursuant the Distributor Agreement between SoClean and Sunset, which states that “the Parties consent to the venue and jurisdiction of the state or federal courts located in Suffolk County, Massachusetts and Cook County, Illinois.” *See* attached Exhibit A, ¶39. Sunset has violated, and continues to violate, the intellectual property provisions of the Agreement by infringing SoClean’s patents covering the SoClean 2. *Id.* ¶26. These intellectual property provisions survive the termination of the Agreement. *Id.* ¶31.

29. Sunset is subject to personal jurisdiction in this judicial district for at least the same reasons that venue is appropriate here.

30. Sunset is also actively defending a related patent infringement case against SoClean in this District, involving two patents from the same family as one of the patents asserted here and alleging the same background pattern of Sunset’s misuse of the distributor relationship that it had with SoClean to develop the infringing Zoey device. *See SoClean, Inc. v. Sunset Healthcare Solutions, Inc.*, 1:20-cv-10351-IT (D. Mass.).

### **FACTUAL BACKGROUND**

#### **Background on Sleep Apnea and CPAP Devices**

31. Sleep apnea is a common sleep disorder characterized by abnormal breathing during sleep. Pauses in breathing for people with sleep apnea can last from a few seconds to

minutes during sleep, often resulting in significant levels of sleep disturbance, which can in turn result in daytime fatigue, vision problems, and impaired daytime cognition.

32. Sleep apnea is often treated with a continuous positive airway pressure (“CPAP”) device. CPAP devices operate by pressurizing room air and then pumping it through a hose and into a facemask worn by the user. By delivering pressurized air, the CPAP device keeps the user’s air passages open during sleep, thus preventing reduction in oxygen levels. CPAP devices may also come with a humidifier (or reservoir) which can be used to add moisture to the air as the air is pressurized and delivered to the user.

33. An estimated 8 million people in the United States use a CPAP device to treat respiratory illnesses, most commonly sleep apnea. Proper use of a CPAP device can lead to reduced sleep disturbance, improved sleep, and the additional health benefits that flow therefrom.

34. Germs and bacteria can breed in a CPAP device, mask, or hose, and then be passed to the user. Most manufacturers of CPAP devices therefore recommend that users perform daily and weekly maintenance on their machines to prevent bacteria and mold buildup.

35. Each part of the CPAP device needs to be sanitized individually—including the mask, the hose, and the CPAP machine itself (including the reservoir). CPAP users hand wash their CPAP devices with water, soap, and/or chemicals. Such sanitizing can be difficult, messy, and time consuming for CPAP users while still leaving bacteria and other pathogens behind.

36. The ineffective hand-washing approach to sanitizing CPAP devices is what SoClean sought to supplement with its patented, automated, ozone-based sanitizing machine.

### **SoClean's CPAP Sanitizing Device**

37. SoClean currently sells the SoClean 2 automated CPAP sanitizing machine.

38. Timothy Leyva, the lead inventor listed on the face of the asserted patents, came up with the idea for an ozone-based automated CPAP sanitizing machine after experiencing the burden of taking apart and sanitizing his CPAP device on a daily basis.

39. Mr. Leyva first built a prototype of his machine, which made use of an ozone generator to thoroughly, quickly, and easily sanitize a CPAP device—including the reservoir, tubing, and mask. He wanted the user to not have to disassemble their CPAP device to use his invention, and he wanted his sanitizing device to fit aesthetically in the bedroom so that the CPAP could be quickly and conveniently sanitized following each overnight use.

40. The company that Mr. Leyva worked for—which was the predecessor in interest to SoClean—filed several patent applications to protect Mr. Leyva's invention.

41. After the company conducted market research revealing that there was an unmet need for an automated CPAP sanitizing device, the company launched the first iteration of the SoClean in 2012 (now known as the "SoClean 1"), which was followed about 18 months later by the launch of the SoClean 2.

42. Prior to Mr. Leyva's invention, the market for automated CPAP sanitizing devices did not exist. SoClean effectively created this market over the course of many years, through extensive research and development, marketing research, and advertising about the importance of sanitizing CPAP devices and the advantages of doing so in "automated" fashion (as opposed to by taking apart the machine and its components, and then washing by hand). SoClean invested tens of millions of dollars in this effort.



43. By virtue of its patented technology, superior design, and strong marketing and advertising, SoClean became and remains the market leader in sales of automated CPAP sanitizing devices. Today, due to SoClean's marketing and research efforts, advertising, and investment in intellectual property, millions of CPAP users utilize such automated or semi-automated sanitizing devices. As a result, user compliance with sanitizing CPAP devices has significantly improved.

44. The SoClean 2 device operates as follows: the mask and hose from the CPAP device are placed into the SoClean and the lid is closed. Ozone is then generated from within the SoClean and circulates from the SoClean through a tube into and through the CPAP reservoir, the CPAP hose, and the mask, thereby sanitizing all of the components in a closed system. The process takes less than 15 minutes, usually on the order of 7 minutes. Throughout the process, excess ozone is converted to oxygen by way of a filter inside the device. An image of the SoClean 2, configured for operation with a CPAP machine, hose, and mask, is shown below:



**SoClean's Patents Covering Automated CPAP  
Sanitizing Devices Using Ozone**

45. SoClean's patent applications on its technology were originally filed in 2011. The first U.S. patent was granted in 2015, and others have continued to be granted since.

46. In a related action filed earlier this year, *SoClean, Inc. v. Sunset Healthcare Solutions, Inc.*, 1:20-cv-10351-IT (D. Mass.), SoClean accused Sunset of infringing United States Patent numbers 10,434,205 and 10,456,492.

47. On July 28, 2020, United States Patent Number 10,722,603 ("the '603 patent"), entitled "Systems, Methods, and Devices for Ozone Sanitization of Continuous Positive Airway Pressure Devices," issued to SoClean. The '603 patent is part of the same patent family as the previously asserted '205 and '492 patents.

48. The '603 patent is a continuation U.S. Pat. Appl. No. 15/444,916, filed February 28, 2017, which is a continuation of U.S. Pat. Appl. No. 15/142,060 (now U.S. Pat. No. 9,616,147), U.S. Pat. Appl. No. 15/142,085 (now U.S. Pat. No. 10,052,397) and U.S. Pat. Appl. No. 15/142,111 (now U.S. Pat. No. 9,610,373). U.S. Pat. Appl. No. 15/142,060 is a divisional and U.S. Pat. Appl. No. 15/142,085 and U.S. Pat. Appl. No. 15/142,111 are continuations of U.S. Pat. Appl. No. 14/232,773 (now U.S. Pat. No. 9,358,316) filed June 7, 2016, which is a 35 U.S.C. § 371 application of International Appl. No. PCT/US12/46593 filed July 13, 2012, which claims priority to U.S. Provisional Appl. No. 61/508,341, filed July 15, 2011.

49. On November 24, 2020, United States Patent Number 10,842,898 ("the '898 patent"), entitled "Devices, Systems and Methods for Treating Medical Devices Having Passageways with Ozone Gas," issued to SoClean.

50. The '898 patent is a continuation of U.S. Pat. Appl. No. 15/873,506, filed January 17, 2018, which is a continuation of U.S. Pat. Appl. No. 15/481,919 (now U.S. Pat. No.

9,895,461), filed April 7, 2017, which is a continuation of U.S. Pat. Appl. No. 15/141,216 (now U.S. Pat. No. 9,669,124), filed April 28, 2016, which is a continuation-in-part of PCT/US2015/029418, filed May 6, 2015. U.S. Pat. Appl. No. 15/141,216 (now U.S. Pat. No. 9,669,124), filed April 28, 2016, is also a continuation-in-part of U.S. Pat. Appl. No. 14/232,773 (now U.S. Pat. No. 9,358,316), filed January 14, 2014, which is a 35 U.S.C. § 371 application of International Patent Appl. No. PCT/US2012/046593, filed July 13, 2012, which claims the benefit of U.S. Provisional Appl. No. 61/508,341, filed July 15, 2011.

### **The SoClean-Sunset Distribution Agreement**

51. On April 20, 2019, the parties entered into a Distribution Agreement whereby Sunset agreed to act as a distributor to advertise, market, and sell SoClean's products to subdistributors, resellers, and end users in the United States. *See generally*, Exhibit A.

52. By executing the Agreement, Sunset acknowledged and agreed, among other things, that SoClean owned and retained (a) all rights, title, and interest in and to all intellectual property rights embodied in its products, including the manufacture and/or production of its products or any "copies" thereof, and (b) all copyrights, patent rights, trade secret rights, and other proprietary rights in or relating to SoClean's products. *Id.* ¶26.

53. The Agreement did not grant to Sunset any intellectual property rights in the SoClean products. *Id.*

54. At the time the Agreement was executed, Sunset did not sell its own automated CPAP sanitizing device. It simply distributed the SoClean 2, just as it distributed many other products in the healthcare space.

55. As a distributor for SoClean, Sunset was fully aware that the SoClean 2 device was protected by various forms of intellectual property, including U.S. patents.

56. The Agreement was terminated by SoClean in December of 2019, but certain provisions of the Agreement, including the intellectual property provisions, were expressly designed to survive termination. *Id.* ¶31.

### **Sunset's Infringing Device**

57. No sooner than the Distribution Agreement between the parties had been terminated, Sunset began selling a knock-off version of the SoClean 2, which Sunset calls the "Zoey."

58. Sunset could not have moved with such celerity without improperly taking advantage of its position as a distributor of the SoClean 2 for over five years to gain information to help it introduce the Zoey into the market as a direct competitor of the SoClean 2.

59. The Zoey comprises, among other components, a main unit, which is depicted below:

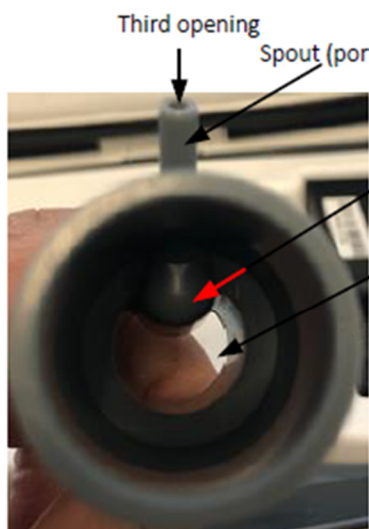
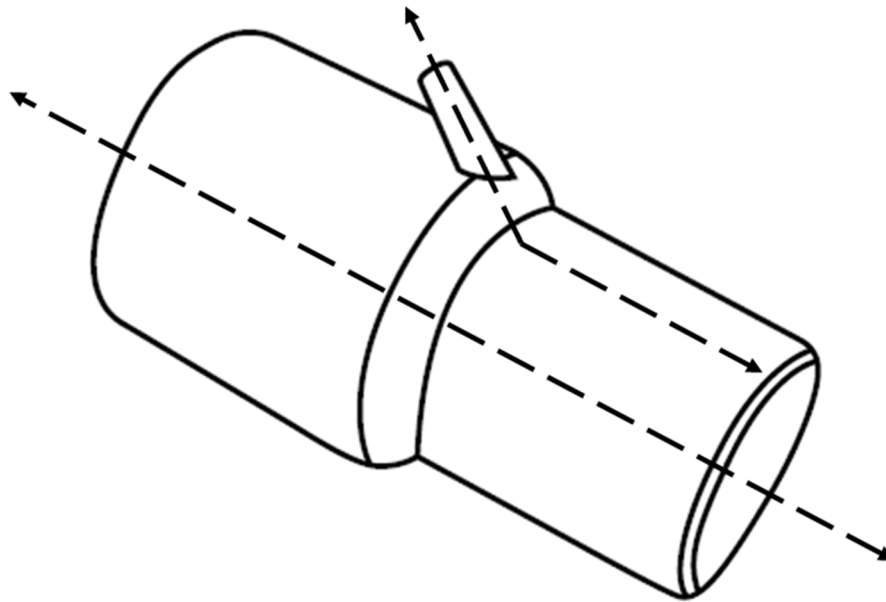


60. The main unit includes an ozone generator and an interior chamber for storing the mask of a CPAP device, just as in the SoClean 2.

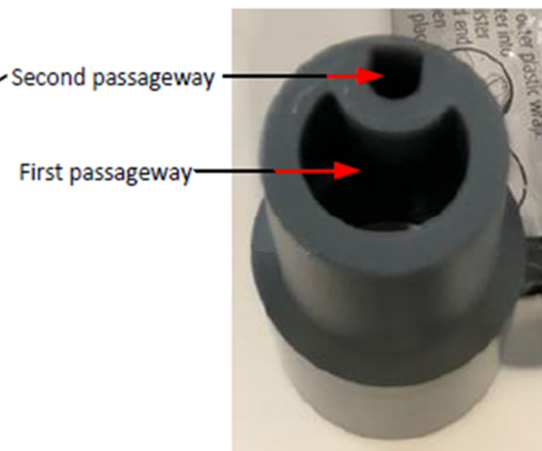
61. The main unit may be connected to a CPAP machine via the user's CPAP hose, thus creating a closed system, just as in the SoClean 2.

62. The Zoey is sold with a connector unit that allows the ozone generated by the main unit to flow seamlessly into the CPAP reservoir, the hose, and the mask, just as in the SoClean 2.

63. When the Zoey was first launched in January 2020, it was sold with the connector unit depicted below (the “1.0 Connector”):



First end comprising a first opening



Second end comprising a second opening

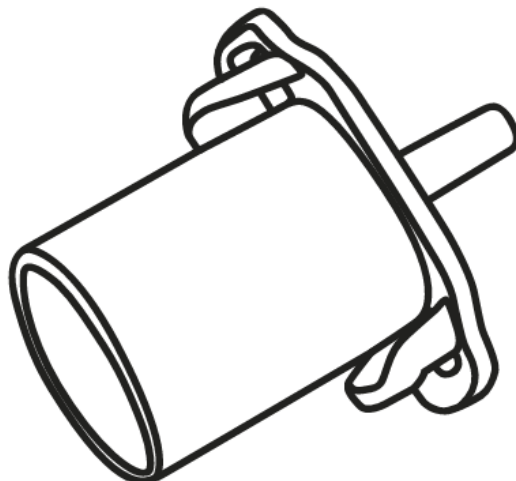
64. The Zoey was sold at launch with an instruction manual for the end user. *See* Exhibit B [1/22/20 Instruction Manual].

65. In the earlier related action, SoClean accused the Zoey of infringing United States Patent Nos. 10,434,205 and 10,456,492, and sought a preliminary injunction against the Zoey. *See SoClean, Inc. v. Sunset Healthcare Solutions, Inc.*, 1:20-cv-10351-IT (D. Mass.).

66. Following a hearing on the motion for preliminary injunction, the district court ruled that (a) SoClean had met its burden to show a likelihood of infringement of at least one of the asserted claims, but (b) SoClean had not met its burden to show irreparable harm. Exhibit C, at 7 (“[T]he court finds that SoClean has a substantial likelihood of succeeding on its claim that Sunset has infringed Claim 1 of the ’205 patent.”); *id.* (“Here, SoClean has not provided a ‘clear showing’ that money damages will not be able to make SoClean whole after a trial on the merits has concluded and, thus, the court cannot issue a preliminary injunction at this time.”). The district court thus denied the motion for preliminary injunction.

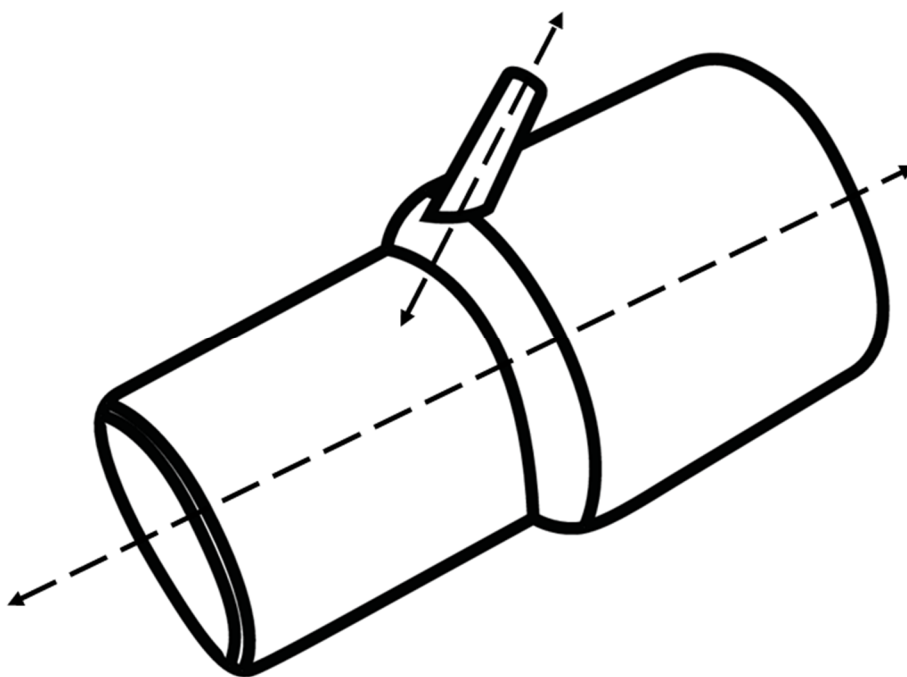
67. Shortly after the district court’s ruling finding a likelihood of infringement, Sunset purported to stop selling the Zoey with the 1.0 Connector.

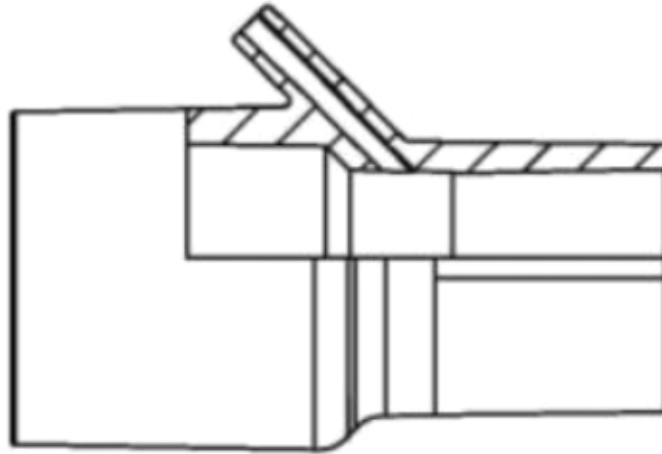
68. Then, starting on or after March 20, 2020, Sunset started selling at least some Zoeyes with a new connector unit (the “2.0 Connector”). A picture of the 2.0 Connector is depicted below:



69. Sunset also revised the Zoey instruction manual, presumably to reflect this change in connector unit. *See* Exhibit D [3/25/20 Instruction Manual].

70. Starting on or after August 21, 2020, Sunset started selling at least some Zoeyes with yet another new connector unit (the “3.0 Connector”). The 3.0 Connector is depicted below:





71. Sunset further revised the Zoey instruction manual, again presumably to reflect this change in connector unit. *See* Exhibit E [8/21/20 Instruction Manual].

72. In all iterations, when configured for use, the main unit of the Zoey operates in conjunction with the connector units, as well as other components, to sanitize a CPAP machine, reservoir, hose, and mask.

73. In operation, the Zoey’s ozone generator generates ozone gas from oxygen in the ambient air.

74. In the Zoey, ozone gas flows through the injection tube and into the connector unit.

75. In the Zoey, ozone gas can then flow into the CPAP machine and its reservoir, through a CPAP hose, and into the mask placed in the main unit.

76. Operation of the Zoey is currently described in the 8/21/20 “Instruction Manual Zoey CPAP Cleaner” that is provided to end users. *See* Exhibit E.

### **SoClean’s Filter Kits for the SoClean 2**

77. SoClean also sells Replacement Cartridge Filter Kits (the “Filter Kits”) for its SoClean 2 device. *Cartridge Filter Kit - SoClean 2*, SoClean, <https://www.soclean.com/soclean2/product/cartridge-filter-kit-soclean-2> (last visited Mar. 9, 2021) (attached as Exhibit F).



78. The Filter Kits facilitate the conversion of ozone to oxygen after the ozone has been used to sanitize the CPAP machine, hose, and mask.

79. If the SoClean 2 is used daily, the Filter Kits should be replaced approximately every six months.

80. The SoClean 2 Filter Kits have a distinctive and ornamental design, as depicted below:



81. SoClean owns two U.S. Trademark Registrations for the non-functional elements of its Filter Kit design in IC Class 11, U.S. Reg. Nos. 6,080,195 and 6,286,680.

82. The distinctive trade dress of the SoClean 2 Filter Kits is protected under the Lanham Act. It is both inherently distinctive and has acquired secondary meaning by virtue of SoClean's extensive use and marketing of the Filter Kits throughout the United States prior to Sunset's infringement.

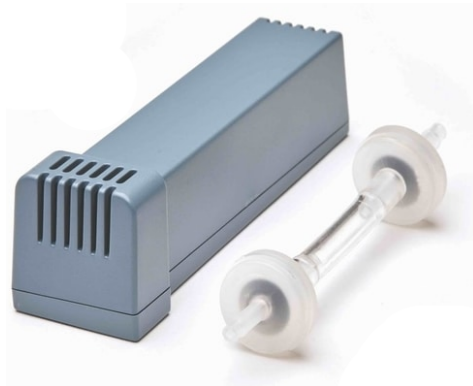
### **Sunset's Infringing Filter Kits for the SoClean 2**

83. Sunset sells a replacement filter kit for the SoClean 2 device, which Sunset markets on its website. *CAP1007S-KIT Filter and Check Valve Kit for SoClean 2 CPAP Cleaning Device*, Sunset Healthcare Solutions, [https://sunsethcs.com/index.php?option=com\\_virtuemart&view=](https://sunsethcs.com/index.php?option=com_virtuemart&view=)

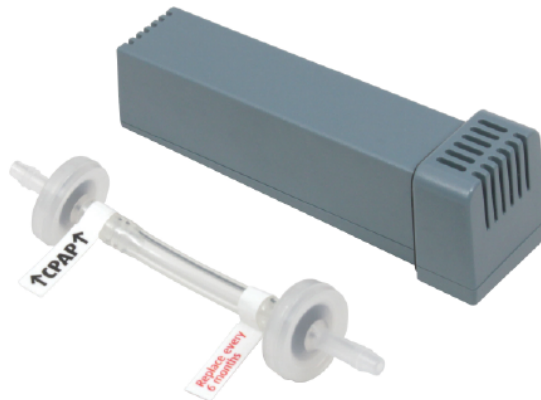
[productdetails&virtuemart\\_product\\_id=694&virtuemart\\_category\\_id=94&Itemid=64](#) (last visited Mar. 9, 2021) (attached as Exhibit G).

84. On information and belief, Sunset began openly marketing and selling these SoClean 2 replacement filter kits on or after February 2021.

85. Just like the Zoey is a knockoff of the SoClean 2, Sunset's replacement filter kit is a knockoff of the SoClean 2 Filter Kit. The two filter kit sets are shown below for comparison:



**SoClean 2 Filter Kit**



**Sunset Knockoff of SoClean 2 Filter Kit**

86. On its website, Sunset has pictures showing how the end user should use the replacement filters with the SoClean 2 device, and then states: *"This product is not made,*

*authorized, or endorsed by SoClean, Inc., but is warranted by Sunset Healthcare Solutions, Inc. to fit and work in the SoClean 2 CPAP cleaning device.” See Exhibit G.*

87. The Sunset replacement filter kit has the exact same design as SoClean’s trademarked trade dress, which Sunset has copied to take advantage of SoClean’s recognized market popularity.

88. On information and belief, Sunset markets and sells its knockoff filter kits to customers and end users at a lower price than the SoClean 2 authentic filters, thus undermining SoClean brand loyalty and undercutting SoClean’s consumable filter business.

89. Sunset’s actions are irreparably and permanently damaging SoClean through lost sales, lost future sales, price erosion, brand erosion, loss of goodwill, and other damage.

90. SoClean will be significantly and irreparably harmed if Sunset is able to continue to market and sell its infringing Zoey product and infringing SoClean 2 replacement filters.

### **FIRST CLAIM FOR RELIEF**

#### **INFRINGEMENT OF U.S. PATENT NO. 10,722,603**

91. SoClean realleges and incorporates by reference the allegations of the paragraphs of this Complaint as though fully set forth herein.

92. On July 28, 2020, United States Patent Number 10,722,603 (“the ’603 patent”) entitled “Systems, Methods, and Devices for Ozone Sanitization of Continuous Positive Airway Pressure Devices,” was duly and legally issued.

93. A true and correct copy of the ’603 patent is attached as Exhibit H and incorporated herein by reference.

94. Sunset is liable for patent infringement pursuant to 35 U.S.C. § 271, because Sunset has literally, and/or under the doctrine of equivalents, directly and willfully infringed, and

continues to infringe, at least claim 1 of the '603 patent by at least using, selling, offering for sale, and/or importing Sunset's Zoey device (the "Accused Product"). Sunset also indirectly infringes by encouraging end users and durable medical equipment ("DME") providers to make, sell, offer for sale, and/or use the Accused Product.

95. Sunset sells and offers for sale the Accused Product in the United States at least to DME providers, who sell the Zoey to end users. *See, e.g.*, Exhibit I.

96. Sunset has previously sold and offered for sale, and may continue to sell or offer for sale, the Accused Product with different connector units or combinations of connector units. *See* Exhibits B, D.

97. Sunset encourages the infringing sale and use of the Zoey through at least the "Instruction Manual" that it currently provides for end users. *See* Exhibit E.

98. A claim chart explaining in detail the manner in which Sunset is infringing representative claim 1 of the '603 patent is attached as Exhibit J.

99. Sunset's infringement of the '603 patent has caused and continues to cause immediate and irreparable damage to SoClean in an amount to be determined at trial. SoClean is entitled to its damages, including without limitation, lost business opportunities, reasonable royalties, lost profits, future lost profits, price erosion, and/or damage to goodwill.

100. Sunset's infringement of the '603 patent has caused and will continue to cause immediate and irreparable harm to SoClean for which there is no adequate remedy at law, unless this Court enjoins and restrains such activities.

101. Sunset received actual notice of the '603 patent, and, as a result, its infringement of the '603 Patent is and continues to be willful and deliberate, since at least the filing of this Complaint.

102. Alternatively, since at least the filing of this Complaint Sunset's infringement of the '603 patent was objectively reckless due to the fact that its actions constituted infringement of a valid patent, and Sunset knew or should have known of this objectively-defined risk because the risk was so obvious: SoClean's intellectual property is publicly searchable, is posted on SoClean's website, and further was known to Sunset by virtue of its distributor relationship with SoClean.

103. SoClean is entitled to enhanced damages pursuant to 35 U.S.C. § 284, and costs, including attorneys' fees pursuant to 35 U.S.C. § 285, incurred prosecuting this action.

### **SECOND CLAIM FOR RELIEF**

#### **INFRINGEMENT OF U.S. PATENT NO. 10,842,898**

104. SoClean realleges and incorporates by reference the allegations of the paragraphs of this Complaint as though fully set forth herein.

105. On November 24, 2020, United States Patent Number 10,842,898 ("the '898 patent"), entitled "Devices, Systems and Methods for Treating Medical Devices Having Passageways with Ozone Gas," was duly and legally issued.

106. A true and correct copy of the '898 patent is attached as Exhibit K and incorporated herein by reference.

107. Sunset is liable for patent infringement pursuant to 35 U.S.C. § 271, because Sunset has literally, and/or under the doctrine of equivalents, directly and willfully infringed, and continues to infringe, at least claim 1 of the '898 patent by at least using, selling, offering for sale, and/or importing Sunset's Zoey device (the "Accused Product"). Sunset also indirectly infringes by encouraging end users and DME providers to make, sell, offer for sale, and/or use the Accused Product.

108. Sunset sells and offers for sale the Accused Product in the United States at least to DME providers, who sell the Zoey to end users. *See, e.g.*, Exhibit I.

109. Sunset has previously sold and offered for sale, and may continue to sell or offer for sale, the Accused Product with different connector units or combinations of connector units. *See Exhibits B, D.*

110. Sunset encourages the infringing sale and use of the Zoey through at least the “Instruction Manual” that it currently provides for end users. *See Exhibit E.*

111. A claim chart explaining in detail the manner in which Sunset is infringing representative claim 1 of the ’898 patent is attached as Exhibit L.

112. Sunset’s infringement of the ’898 patent has caused and continues to cause immediate and irreparable damage to SoClean in an amount to be determined at trial. SoClean is entitled to its damages, including without limitation, lost business opportunities, reasonable royalties, lost profits, future lost profits, price erosion, and/or damage to goodwill.

113. Sunset’s infringement of the ’898 patent has caused and will continue to cause immediate and irreparable harm to SoClean for which there is no adequate remedy at law, unless this Court enjoins and restrains such activities.

114. Sunset received actual notice of the ’898 patent, and, as a result, its infringement of the ’898 Patent is and continues to be willful and deliberate, since at least the filing of this Complaint.

115. Alternatively, since at least the filing of this Complaint Sunset’s infringement of the ’898 patent was objectively reckless due to the fact that its actions constituted infringement of a valid patent, and Sunset knew or should have known of this objectively-defined risk because the risk was so obvious: SoClean’s intellectual property is publicly searchable, is posted on

SoClean's website, and further was known to Sunset by virtue of its distributor relationship with SoClean.

116. SoClean is entitled to enhanced damages pursuant to 35 U.S.C. § 284, and costs, including attorneys' fees pursuant to 35 U.S.C. § 285, incurred prosecuting this action.

### **THIRD CLAIM FOR RELIEF**

#### **TRADEMARK INFRINGEMENT**

117. SoClean realleges and incorporates by reference the allegations of the paragraphs of this Complaint as though fully set forth herein.

118. SoClean owns the U.S. Trademark Registration for the non-functional elements of the SoClean 2 Cartridge Filter Kit design, U.S. Reg. No. 6,080,195. *See* Exhibit M.

119. SoClean also owns the U.S. Trademark Registration for the non-functional elements of the SoClean 2 Cartridge Filter Kit design, U.S. Reg. No. 6,286,680. *See* Exhibit N. Collectively, these trademark registrations are referred to herein as "the Marks."

120. SoClean is owner of the SoClean 2 Filter Kit design, including by virtue of its ownership of the above-noted registrations and its extensive use of the Marks in interstate commerce so as to enjoy market penetration to a substantial customer base across the United States.

121. The distinctive features of the Marks constitute protectable trade dress of SoClean.

122. The features of the Marks are inherently distinctive and have acquired secondary meaning by virtue of their extensive use in SoClean's CPAP sanitizing machine, the SoClean 2, which has been sold to hundreds of thousands of CPAP users throughout the United States, fueled by SoClean's extensive spend in advertising to promote the SoClean 2 product and filter kits.

123. Sunset's replacement filter design was adopted after the Marks were in the market and the trade dress filings were issued or publicly searchable. Sunset's replacement filter design is

likely to confuse consumers, including because the two designs are virtually identical, are used for the exact same type of registered goods, and are advertised and sold through the same or similar channels.

124. Sunset's infringing use of the Marks was done willfully and with knowledge that such use would or was likely to cause confusion and deceive others. Moreover, Sunset continued to use the Mark despite previously being a distributor of SoClean 2 devices and components and knowing of SoClean's valuable intellectual property rights.

125. Sunset's use of its replacement filter kits in interstate commerce infringes SoClean's registered and common law trademark rights and constitutes trademark infringement under 15 U.S.C. §§ 1114 and 1125 *et seq.*

126. As a result of the similarities between the Sunset replacement filters for the SoClean 2, and the Marks for the same product, consumers are likely to be confused into incorrectly believing there is an association, affiliation, or sponsorship between SoClean and Sunset and their replacement filters. Sunset has thus engaged in trademark infringement.

127. As a direct and proximate result of Sunset's trademark infringement, SoClean has been damaged and Sunset has enjoyed resulting sales and profits, in an amount to be established after proof at trial or in the statutory amount of up to \$2 million per infringing good.

128. SoClean is further entitled to disgorge Sunset's profits for its willful sales, unjust enrichment, and to deter future infringement.

129. This case qualifies as an "exceptional case" within the meaning of 15 U.S.C. § 1117(a) in that Sunset's acts were malicious, fraudulent, deliberate, and willful, and taken in bad faith.



130. SoClean's remedy at law is not adequate to compensate it for injuries inflicted by Sunset. Accordingly, SoClean is entitled to preliminary and permanent injunctive relief.

**PRAYER FOR RELIEF**

WHEREFORE, SoClean prays for relief as follows:

1. Judgment on all Counts of this Complaint;
2. An award of no less than a reasonable royalty for Sunset's patent and trademark infringement, along with pre-judgment and post-judgment interest according to proof;
3. Damages in an amount to be determined at trial, including Sunset's unjust enrichment and profits;
4. An order finding that Sunset's patent infringement has been willful, and that the circumstances presented justify trebling the damages awarded to SoClean, as provided by 35 U.S.C. § 284;
5. A declaration that this is an exceptional case under the patent laws, awarding SoClean its attorneys' fees incurred in prosecuting this action, as provided by 35 U.S.C. § 285, or as otherwise provided by law, whether by statute, common law, or the Court's inherent power;
6. Statutory damages for trademark infringement up to \$2 million per type of good or service;
7. Attorney's fees under, among others, 15 U.S.C. § 1117(a) as an exceptional case and § 1117(b) for willful use of a counterfeit mark;
8. A preliminary and/or permanent injunction prohibiting Sunset and its parents, subsidiaries, officers, directors, agents, employees, licensees, and any persons acting in concert with Sunset, along with any distributors, sub-distributors, or resellers, from manufacturing, marketing, or selling (a) the Zoey or any product which infringes SoClean's patents for automated CPAP sanitizing devices, or (b) SoClean 2 replacement filters, or any product which infringes SoClean's trademarks covering the SoClean 2 Cartridge Filter Kits;

9. Pre- and post-judgement interest at the maximum legally allowable rate, according to proof;
10. Costs, expenses, and fees; and
11. All other and further relief deemed just and proper by the Court.

**DEMAND FOR JURY**

SoClean demands trial by jury on all issues so triable.

Boston, Massachusetts  
March 9, 2021

MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY AND POPEO, P.C.

*/s/ Thomas H. Wintner*

---

Thomas H. Wintner (BBO No. 667329)  
Clancy Galgay (BBO No. 673116)  
Matthew S. Galica (BBO No. 696916)  
One Financial Center  
Boston, MA 02111  
Tel: (617) 542-6000  
TWintner@mintz.com  
CGalgay@mintz.com  
MGalica@mintz.com

Andrew D. Skale (*pro hac vice* to be  
submitted)  
3580 Carmel Mountain Road, Suite 300  
San Diego, CA 92130  
Tel: (858) 314-1500  
ADSkale@mintz.com

*Attorneys for Plaintiff SoClean, Inc.*