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18 BLEPHEX, LLC

19 **UNITED STATES DISTRICT COURT**
20 **SOUTHERN DISTRICT OF CALIFORNIA**

22 BLEPHEX, LLC,
23 Plaintiff,
24 vs.
25 NULIDS, LLC,
26 Defendant.

Case No. '23CV0578 BEN AHG

**COMPLAINT FOR PATENT
INFRINGEMENT**

DEMAND FOR JURY TRIAL

1 Plaintiff BlephEx, LLC (“BlephEx” or “Plaintiff”) files this Complaint against
2 Defendant NuLids, LLC (“NuLids” or “Defendant”) and alleges as follows.

3 **NATURE OF THE ACTION**

4 1. This is a civil action for patent infringement.

5 2. BlephEx is the legal owner by assignment of all rights, including all
6 rights to seek and collect damages, in and to United States Patent No. 11,083,621
7 (“the ’621 Patent”), which was duly and legally issued by the United States Patent
8 and Trademark Office (“USPTO”) on August 10, 2021.

9 3. Upon information and belief, NuLids has infringed, and continues to
10 infringe, one or more claims of BlephEx’s ’621 Patent in violation of 35 U.S.C.
11 § 271(a). Further, upon information and belief, NuLids has actively induced, and
12 continues to actively induce, others to infringe the ’621 Patent in violation of 35
13 U.S.C. § 271(b). Upon information and belief, NuLids’ direct and indirect
14 infringement has been, and continues to be, willful, making this an exceptional case.

15 4. BlephEx seeks judgment that NuLids has directly and indirectly
16 infringed one or more claims of the ’621 Patent, literally or under the doctrine of
17 equivalents, and that its infringement has been willful. BlephEx seeks preliminary
18 and permanent injunctive relief against NuLids and any agents, sales representatives,
19 distributors, servants, employees, associates, attorneys, parents, successors, assigns,
20 or any persons or entities in active concert or in participation with any of them,
21 enjoining such persons or entities from infringing or inducing infringement of the
22 ’621 Patent. BlephEx further seeks damages adequate to compensate BlephEx for the
23 harm caused by NuLids, and requests that all such damages be trebled under 35 U.S.C.
24 § 284 given NuLids’ willful infringement. BlephEx further requests that this case be
25 declared an exceptional case under 35 U.S.C. § 285, and that BlephEx be awarded its
26 reasonable attorney fees and costs.

27 **THE PARTIES**

28 5. BlephEx is a limited liability company organized under the laws of the

1 State of Delaware, with its principal place of business at 119 South East Parkway
2 Court, Suite 250, Franklin, TN 37064.

3 6. Upon information and belief, NuLids is a corporation organized and
4 existing under the laws of the State of Delaware, with its principal place of business
5 at 1835A S. Centre City Parkway, #401, Escondido, California.

6 **JURISDICTION AND VENUE**

7 7. This action arises under the patent laws of the United States, Title 35 of
8 the United States Code, 35 U.S.C. §§ 1 *et seq.* This Court has subject matter
9 jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10 8. This Court has general personal jurisdiction over NuLids in this judicial
11 District because, upon information and belief, NuLids' principal place of business is
12 in Escondido, San Diego County, California and NuLids regularly conducts business
13 in the State of California, including in this District. This Court also has specific
14 personal jurisdiction over NuLids in this District because, upon information and
15 belief, NuLids offers its accused products and services in this District, and has
16 committed acts of patent infringement and/or induced acts of patent infringement by
17 others in this District and elsewhere in California, including at NuLids' principal place
18 of business in Escondido, California.

19 9. Venue as to NuLids is proper in this District pursuant to 28 U.S.C.
20 § 1400(b). Venue is appropriate in this District at least because NuLids, upon
21 information and belief, has committed acts of direct and indirect infringement in this
22 District and has a regular and established place of business in this District. NuLids'
23 acts of infringement include performing the claimed method of one or more claims of
24 the '621 Patent in this District, and inducing others to do so in this District.

25 **BLEPHEX'S NOVEL TREATMENT**

26 10. Disorders relating to the eyelid margin are particularly common
27 pathological conditions, especially among the elderly. Examples of such disorders
28 include blepharitis, meibomitis, and dry eye syndrome. Blepharitis is a chronic,

1 inflammatory disease of the eyelids and eyelid margins caused by the presence of an
2 overgrowth of normal bacteria along the lid and the base of the eyelashes. This
3 overgrowth of bacteria produces a “biofilm” (e.g., scurf and debris) on the eyelid
4 margin that builds up over the years and allows the bacteria to greatly increase in
5 density. See J. Rynerson, *et al.*, *DEBS – a unification theory for dry eye and*
6 *blepharitis*, *Clinical Ophthalmology*; 10: 2455–2467 (2016 Dec. 9) (hereinafter
7 “Rynerson *et al.*, DEBS”). Once the bacteria reach a certain density, genes activate
8 to allow the bacteria to produce toxins. *Id.* Because the eyelid margin is difficult to
9 clean, this overgrowth of bacteria, biofilm, and toxins can worsen over time and
10 eventually cause significant damage. *Id.*

11 11. Despite advances in ophthalmology, and other medical treatments in
12 general, the recommended treatments for disorders such as blepharitis had remained
13 essentially unchanged for decades prior to Dr. Rynerson’s novel treatment methods.
14 Historically, treatment began and ended with the patient, who would first begin to
15 notice symptoms including eyelid redness, flaking of skin on the eyelids, crusting
16 and/or cysts at the eyelid margins, and a gritty sensation of the eye culminating in
17 irritation, burning, and reduced vision. Patients were generally prescribed a hygienic
18 home treatment procedure that sometimes included antibiotics and/or topical steroid
19 application. The goal of the home treatment procedure was to remove debris from
20 the eyelid margin, which is critical to healing the eyelid and margin, and associated
21 tear glands, and preventing reoccurrence of the disorder. To that end, the patient was
22 generally required to attempt to remove debris from the eyelid and eyelid margin
23 using a cotton swab, a fingertip, or a scrub pad placed over the fingertip.
24 Unfortunately for many patients, such home treatment generally achieved limited
25 success due to the practical difficulties of cleaning one’s own eyelid and eyelid margin
26 with an imprecise and insufficient instrument such as a fingertip or cotton swab.

27 12. Seeking to address the problems with prior art treatments, James M.
28 Rynerson, MD, (“Dr. Rynerson”), a board-certified ophthalmologist and President

1 and Founder of BlephEx developed a unique treatment for cleaning the eyelids and
2 eyelid margins. Dr. Rynerson’s novel method involves a protocol that uses an
3 electromechanical device (called the BlephEx®) with a soft and resilient tip that
4 safely contacts and removes debris from the eyelids and eyelid margin—encouraging
5 healing and preventing reoccurrence of disorders involving the eyelids and eyelid
6 margin.

7 13. Dr. Rynerson’s treatment protocol revolutionized the treatment of eye
8 disorders such as blepharitis. Within two years of its introduction to the market in
9 2013, it had already been adopted by over 1,000 ophthalmic practices. Today,
10 BlephEx® procedures are performed in doctors’ offices all over the world, including
11 in all 50 states. BlephEx has sold thousands of its novel devices to date, and received
12 widespread recognition and industry praise. For example, in 2017, the Association of
13 Optometrists selected the BlephEx® device as a finalist for “Product of the Year,”
14 noting that it “provid[es] blepharitis sufferers with immediate relief and results.”
15 [https://www.aop.org.uk/education-and-events/aop-awards/previous-](https://www.aop.org.uk/education-and-events/aop-awards/previous-years/2017/product-of-the-year)
16 [years/2017/product-of-the-year](https://www.aop.org.uk/education-and-events/aop-awards/previous-years/2017/product-of-the-year). Moreover, studies evaluating the effects of
17 treatments using BlephEx® have shown significantly positive results for patients.

18 14. In addition to his work inventing the BlephEx® device, Dr. Rynerson
19 has developed groundbreaking theories regarding the origins of dry eye and
20 blepharitis syndrome that have been published in the peer-reviewed journal *Clinical*
21 *Ophthalmology*. See generally, Rynerson *et al.*, *DEBS*.

22 15. Given the success of the BlephEx® device, others have attempted to sell
23 copies or near-copies of the device at cut-rate prices—having not had to invest in the
24 research and development of the invention, yet seeking to profit from Dr. Rynerson’s
25 hard work and ingenuity. BlephEx in the recent past has had to file patent
26 infringement lawsuits to protect its invention.

27 16. In *BlephEx, LLC v. Myco Indus., Inc.*, No. 19-13089, 2020 WL 5951504
28 (E.D. Mich. Oct. 8, 2020), the district court issued a preliminary injunction in favor

1 of BlephEx, barring sales in the United States of a device that the Court found to be a
2 “near copy” of the BlephEx. 2020 WL 5951504, at *8. There, the court found that
3 BlephEx had shown “a strong likelihood of success on the merits of its direct
4 infringement claim” because the BlephEx patent-at-issue was “necessarily infringed
5 when the [accused device] is used in accordance with the [device’s] instruction
6 manual.” *Id.* at *4. The court also found that the defendants there failed to show any
7 substantial question of invalidity created by the asserted prior art, specifically the
8 Nichamin patent publication.

9 17. The Federal Circuit affirmed the district court’s preliminary injunction
10 order, finding “no clear error in the district court’s determination that [defendant]
11 failed to show a substantial question of validity and that BlephEx showed a strong
12 likelihood of success on the merits.” *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th
13 1391, 1395 (Fed. Cir. 2022).

14 18. The defendant in the *Myco* litigation had also filed a petition for *inter*
15 *partes* review, asserting that the patent-in-suit there was invalid in view of the
16 Nichamin patent publication. *See* IPR2020-01738, Paper No. 1. But, after the district
17 court determined that Nichamin did not even raise a substantial question of invalidity,
18 the defendant filed a Joint Motion to Terminate Proceeding with the PTAB. The
19 PTAB granted that motion and terminated IPR2020-01738 prior to a decision on
20 institution.

21 19. The *Myco* district court litigation concluded with entry of a consent order
22 that permanently enjoined the defendant from selling, distributing, or offering for sale
23 anywhere in the United States the accused products. *BlephEx, LLC v. Myco Industries*
24 *et al.*, 2:19-cv-13089, Dkt. No. 106 (May 6, 2022).

25 20. The ’621 patent-in-suit here is in the same patent family as the BlephEx
26 patent at issue in the *Myco* litigation. Specifically, the ’621 patent issued from a
27 continuation application from the patent-in-suit in the *Myco* litigation.

1 THE PATENT-IN-SUIT

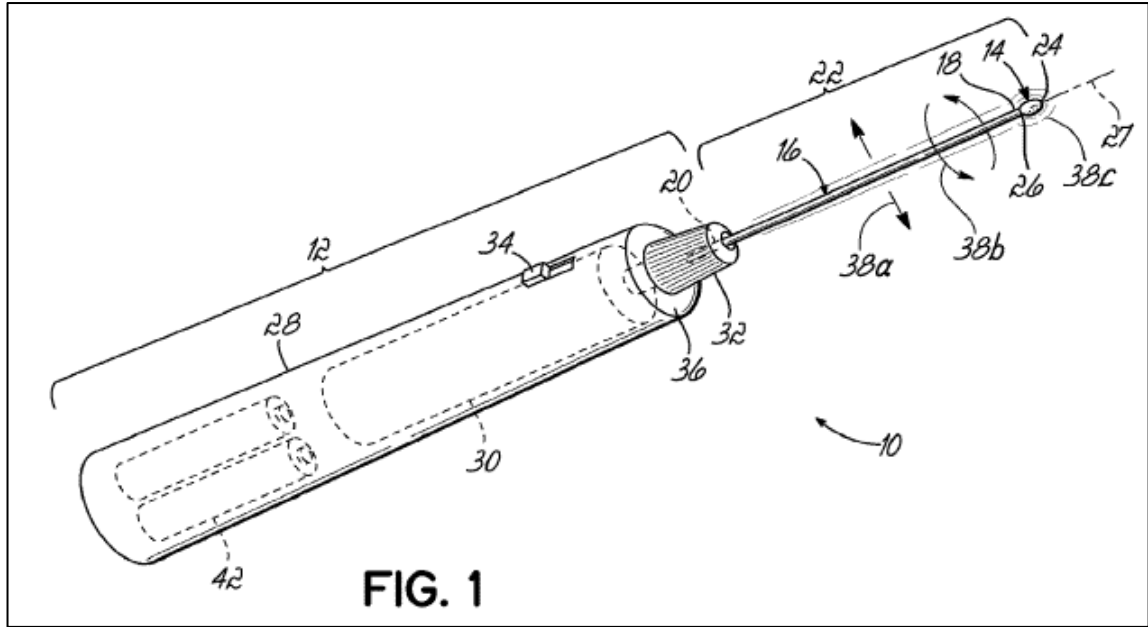
2 21. The patent application that issued as the '621 Patent (Serial No.
3 16/590,228) was filed October 1, 2019, and claims priority to U.S. App. No.
4 13/556,729 ("729 Application"), filed on July 24, 2012. On August 10, 2021, the
5 USPTO duly and legally issued the '621 Patent, titled "Instrument for Treating an
6 Ocular Disorder," to Dr. Rynerson. A copy of the '621 Patent is attached as **Exhibit**
7 **A**.

8 22. BlephEx is, and has at all times relevant to the claims herein been, the
9 owner of all right, title, and interest in the '621 Patent, including the right to sue and
10 to recover damages for any infringement of the '621 Patent.

11 23. The '621 Patent discloses "[a]n instrument for removing debris from an
12 eye during the treatment of an ocular disorder." '621 Patent, Abstract. As discussed
13 in the '621 Patent specification, prior art methods of treating such ocular disorders
14 included antibiotics and/or steroids in combination with patient home treatment. Such
15 home treatment would include the patient "physically scrubbing the eyelid margin,
16 the base of the eyelashes, and the pores of the meibomian glands" with a generic
17 cotton swab, fingertip, or scrub pad. *Id.* at 1:58-60. Such prior art methods were
18 plagued with problems, including that patients "routinely fail to totally cleanse the
19 margin of the eyelid, the base of the eyelashes, and the meibomian glands." *Id.* at
20 2:13-15.

21 24. The inventive methods of the '621 Patent address these problems by
22 providing healthcare providers and patients with a novel electromechanical device
23 and method for safely cleaning the eyelid margin and eyelashes. *Id.*, Abstract. An
24 exemplary embodiment of the device of the '621 Patent is shown in Figure 1 therein,
25 reproduced below:
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25. As shown in Figure 1, the electromechanical device includes at its tip an element (14) that rotates, reciprocates, or vibrates to clean the eyelid margin. '621 Patent at 4:54-56. In the example embodiment of Figure 1, element 14 is made of a “soft” and “resilient” material. *Id.* at 4:3.

26. The '621 Patent discloses that the inventive methods may be practiced by, for example, a physician and/or a patient, who “may treat his or her own ocular disorder with the electromechanical device in periodic intervals” in a “home treatment” embodiment. *Id.* at 5:19; 8:43-47.

27. The '621 Patent contains 18 claims, with Claims 1 and 12 being the independent claims.

28. The BlephEx® device is used to practice the methods of cleaning the eyelid margin claimed in the '621 Patent.

29. BlephEx sold its first BlephEx® device on July 3, 2013.

NuLids’ Awareness Of BlephEx’s Novel Methods And Launch Of Its NuLids Systems

30. Upon information and belief, Dr. John Olkowski is the founder of NuLids’ predecessor company, Teeny Clean, LLC, which previously did business under the trade name “NuSight Medical.” Upon information and belief, Teeny Clean,

1 LLC changed its name to NuLids, LLC on August 19, 2021.

2 31. Dr. Olkowski was an early adopter of the BlephEx® device and method
3 in his ophthalmic practice. On or about September 23, 2014, Dr. Olkowski placed an
4 order for a BlephEx® device, which BlephEx shipped to him. On September 30,
5 2014, Dr. Olkowski emailed Dr. Rynerson expressing how Dr. Olkowski was looking
6 forward to using the BlephEx® device.

7 32. In or around June 2018, upon information and belief, Teeny Clean, LLC
8 (d/b/a NuSight Medical) began selling in the United States a competing
9 electromechanical device for cleaning the eyelid margin using the methods described
10 in the '729 Application. This device, named the “NuLids” device, was, and still is,
11 marketed for at-home use by patients (hereinafter this device is referred to as the “At-
12 Home NuLids Device”). The At-Home NuLids Device uses disposable tips that are
13 soft silicone disks with projections therefrom, which are configured to contact and
14 remove debris from the eyelid margin. The electromechanical device rotates the disks
15 back and forth around an axis, to effect cleaning of the eyelid margin.

16 33. According to NuLids, as early as January 5, 2023, NuLids launched the
17 NuLids Pro product. *See* NuLids’ January 5, 2023 tweet posted on its official twitter
18 account (available at
19 <https://twitter.com/getnulids/status/1611060509066858514?s=20>). The NuLids Pro
20 is substantially the same as the At-Home NuLids Device for purposes of the
21 infringement allegations herein. The NuLids Pro is, however, marketed for use by
22 healthcare providers in their practices rather than for use by patients at home.

23 34. According to NuLids, the NuLids Pro “provides every eyecare practice
24 (large and small) with the ability to provide professional in-office eyelid hygiene,”
25 for eyelid conditions including “meibomian gland dysfunction, blepharitis, demodex,
26 collarettes, excess biofilm.” NuLids Pro’s product webpage on NuLids’ website (the
27 “NuLids Pro Webpage,” available at <https://nulids.com/nulids-pro/>). According to
28 NuLids, with the NuLids Pro, “practitioners or technicians can provide a new value

1 added treatment, that benefits the patient in real-time as part of a regular eye exam.”

2 *Id.*

3 35. On or about January 22, 2023, the self-proclaimed “founder and inventor
4 of NuLids, Dr. John Olkowski” appeared on a YouTube video titled “Introducing
5 Nulids Pro - An In-Office Eyelid Hygiene Device” (the “NuLids Pro Promotional
6 Video,” available at <https://youtu.be/sbitrimNH0>) to promote the NuLids Pro
7 product. *See* NuLids Pro Promotional Video. The video description states that
8 “NuLids [Pro] opens clogged meibomian glands and removes pathogens embedded
9 in crust and biofilm.” *Id.* at video description.

10 36. Like the BlephEx® device, both the NuLids Pro and At-Home NuLids
11 Device use electromechanical rotation of a soft and resilient tip to clean a patient’s
12 eyelid margin.

13 37. Based at least on Dr. Olkowski’s use of the BlephEx® device,
14 discussions with BlephEx, and development of competing devices, NuLids, upon
15 information and belief, was and is aware of BlephEx’s patent portfolio and continuing
16 prosecution thereof.

17 38. At no point has BlephEx granted a license, either express or implied,
18 under any BlephEx patent to Teeny Clean, LLC or its successor, NuLids.

19 **NuLids’ Infringement Of The ’621 Patent**

20 39. The NuLids Pro and At-Home NuLids Device, when used as intended
21 and instructed by NuLids, perform the method of treating an eye for an ocular disorder
22 claimed in one or more claims of the ’621 Patent, including but not limited to Claim
23 1.

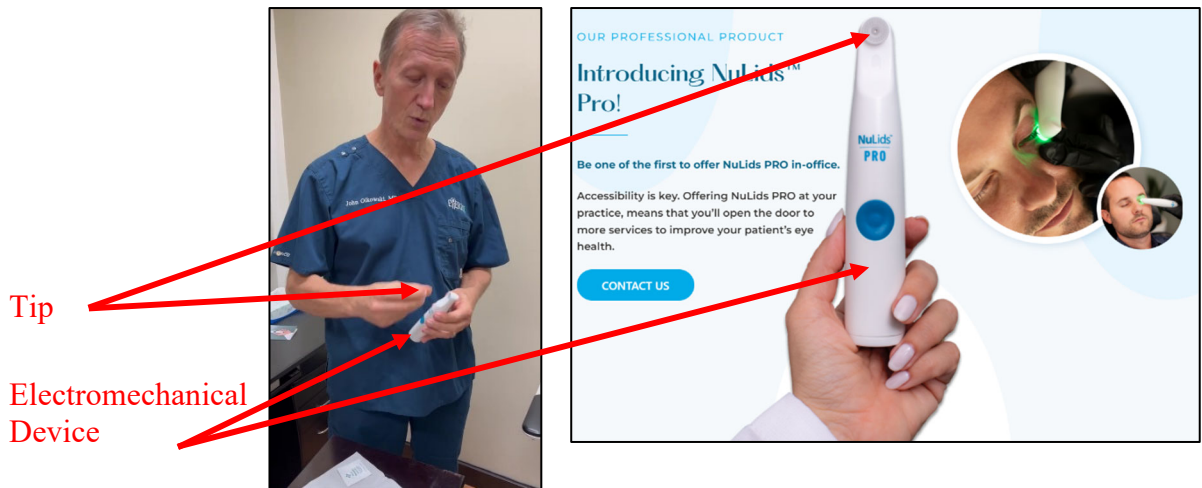
24 **i) Claim 1, preamble.**

25 40. The preamble to Claim 1 recites “[a] method of treating an eye for an
26 ocular disorder with a contact member comprising a soft and resilient material
27 operably connected to an electromechanical device, wherein the eye has an eyelid
28 margin and an eyeball and includes a removable debris.”

a. NuLids Pro

41. To the extent the preamble is limiting, the NuLids Pro Webpage, NuLids’ instructional video titled “Using NuLids PRO In Office - Dr. John Olkowski” uploaded to NuLids’ official YouTube channel and available directly on the NuLids Pro Webpage (the “NuLids Pro Instructional Video,” available at <https://youtu.be/YCDkNNVKK10>), and NuLids’ Pro Promotional Video featuring Dr. Olkowski show that the NuLids Pro device meets this limitation when used as instructed by NuLids.

42. The NuLids Pro includes a tip operably connected to an electromechanical device, as shown by the NuLids Pro Instructional Video and NuLids Pro Webpage:



NuLids Pro Webpage (emphasis added).

“So first off, the [NuLids] Pro comes with **individually wrapped tips** and gel, and we’ll get that set up right here. ... We use the single-use disposable Pro tips and **we apply a pro tip onto the device.**”

NuLids Pro Instructional Video at 0:39-1:07 (emphasis added).



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8 NuLids Pro Webpage; *see also* NuLids Pro Instructional Video at 1:06 and
9 1:44.

10 43. The NuLids Pro’s tip removes debris from the eyelid margin by
11 contacting the eyelid margin with such tip. The NuLids Pro tip is a “contact member.”

12 “NuLids Pro is an in-office version of our very popular NuLids
13 At-Home Device, and this is to be used in the office on patients to
14 help to breathe the lid margins, **clean the lid margins**, and
stimulate the meibomian glands.”

15 NuLids Pro Instructional Video at 0:07-24 (emphasis added).

16 44. The NuLids Pro Instructional Video further shows that the tips of NuLids
17 Pro are contact members made of a soft and resilient material:

18 “The differences between the Pro and the at-home version is that,
19 the Pro is a bit more robust of a device, and **the soft tips used for**
20 **the pro** are a little stiffer – so it gives them deeper cleaning that
21 patients can appreciate and will give a lasting effect.”

22 *Id.* at 0:39-1:07 (emphasis added).

23 45. The tips are made of a resilient silicone material.

24 46. That the NuLids Pro tips are “soft and resilient” is also evident upon
25 inspection of the physical tips.

26 47. The NuLids Pro Webpage further shows that NuLids instructs healthcare
27 providers to use the NuLids Pro to treat ocular disorders, providing “new value added
28 treatment” for at least meibomian gland dysfunction, blepharitis, demodex,

1 collarettes, and excess biofilm:

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3 Limited quantity available. Every purchase comes with

4 support from our expert team of concierges to ensure you

5 receive the most out of your NuLids PRO

6 NuLids Pro is a new product that provides every eyecare practice (large and small) with the ability to provide

7 professional in-office eyelid hygiene that is comfortable, fast, effective and highly affordable. About 25% of

8 patients present with some form of eyelid condition (meibomian gland dysfunction, blepharitis, demodex,

9 collarettes, excess biofilm, etc). In many cases these conditions will appear before symptoms of dry eye or other

10 diseases develop. With NuLids PRO, practitioners or technicians can provide a new value added treatment,

11 that benefits the patient in real-time as part of a regular eye exam. While patients will appreciate how they

12 look and feel, practices will benefit from competitive differentiation and a significant new revenue source.

10 NuLids Pro Webpage (blue highlighting added).

11 48. The eye, having an eyelid margin and an eyeball, to be treated with the
12 NuLids Pro includes removable debris. For example, the NuLids Pro Webpage shows
13 before and after NuLids Pro treatment comparison photos, which depict removable
14 debris on the eyelid margin:

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The screenshot shows a webpage layout. At the top, it says 'Before & After NuLids™ Pro Treatment'. Below this are two pairs of circular images, each labeled 'Before' and 'After', showing the eyelid margin. The 'Before' images show significant debris on the eyelid margin, while the 'After' images show a much cleaner margin. Below the images is a section titled 'Testimonials' with a quote from Brooks Wood, OD Patient: "I always just thought it was allergies. But the doctor noticed I had too much bacteria on my eyelids and recommended a cleaning. After a simple procedure I'm already feeling improvement and the doctor said he could see improvement after just the first treatment. I'm looking forward to the additional treatments." At the bottom of the testimonial section, there is a navigation bar with a blue dot indicating the current slide.

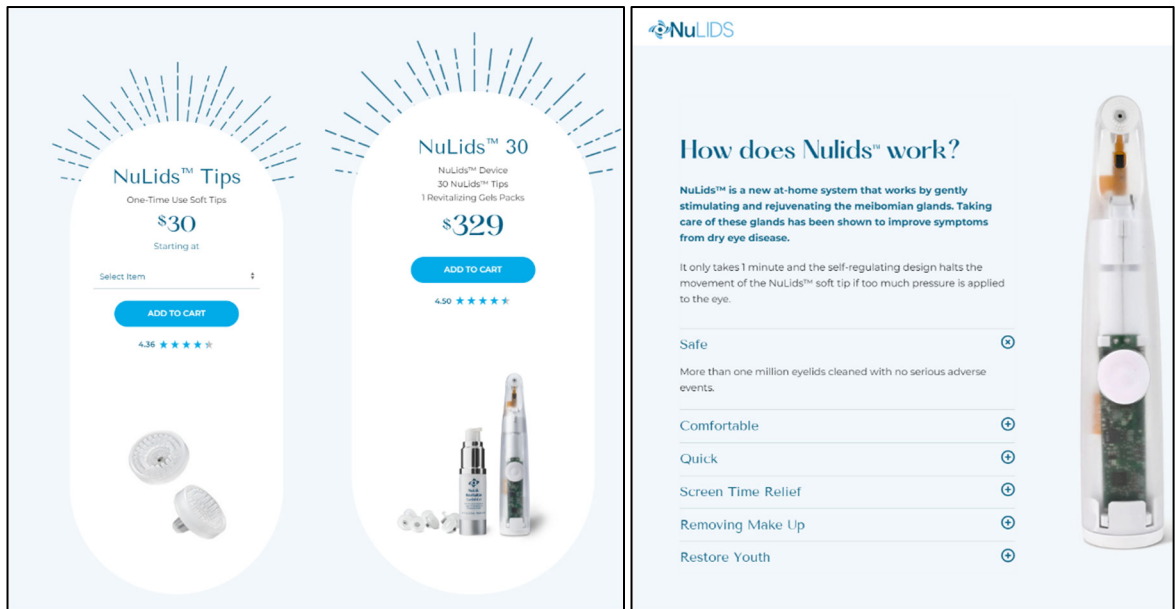
24 NuLids Pro Webpage.

25 **b. At-Home NuLids Device**

26 49. To the extent the preamble is limiting, the product webpage for the At-
27 Home NuLids Device on the NuLids website (the “At-Home NuLids Device
28 Webpage,” available at <https://nulids.com/>), a manual titled “User Manual for the

1 NuLids System” provided by NuLids online (the “NuLids System User Manual,”
2 available at [https://nulids.com/wp-content/uploads/2021/10/NuLids-System-User-
4 Manual.pdf](https://nulids.com/wp-content/uploads/2021/10/NuLids-System-User-
3 Manual.pdf)), and a video titled “How To Use Your NuLids Device” uploaded to
5 NuLids’ official YouTube channel and available directly on the At-Home NuLids
6 Device Webpage (the “At-Home NuLids Device Instructional Video,” available at
7 <https://youtu.be/cYE8FrMZMs0>) show that the At-Home NuLids Device meets this
8 limitation when used as instructed by NuLids.

9 50. The At-Home NuLids Device includes a tip operably connected to an
10 electromechanical device:



20 At-Home NuLids Device Webpage.

21 51. The At-Home NuLids Device removes debris from the eyelid margin by
22 contacting the eyelid margin with such tip as shown above. The At-Home NuLids
23 Device tip is a “contact member.”



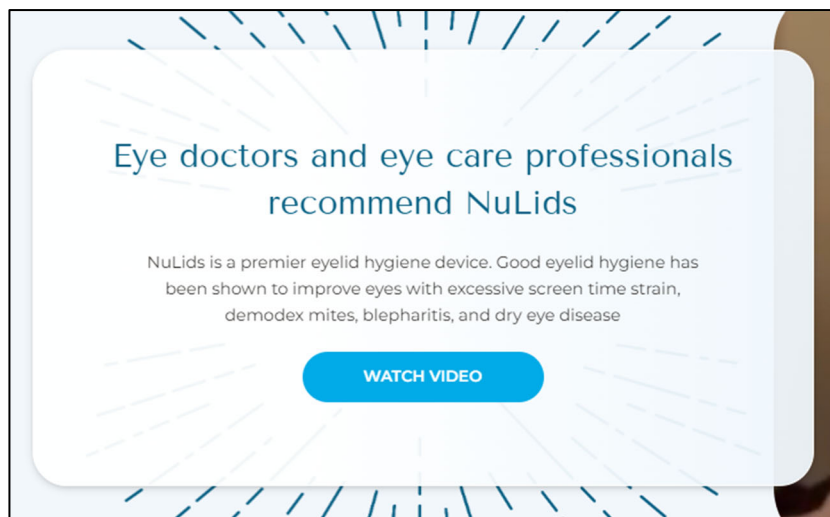
At-Home NuLids Device Instructional Video at 1:36-48.

52. The At-Home NuLids Device tips are made of a soft and resilient material. They are described by NuLids as “soft tips” as shown above.

53. The tips are made of a resilient silicone material.

54. That the At-Home NuLids Device tips are “soft and resilient” is also evident upon inspection of the physical tips.

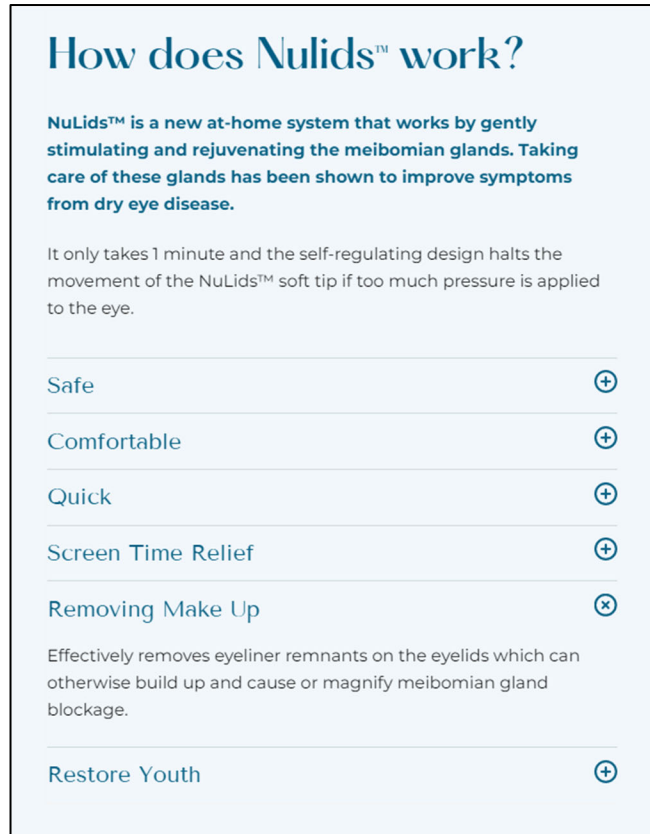
55. The At-Home NuLids Device, when used as intended and instructed by NuLids, treats the eye for an ocular disorder:



At-Home NuLids Device Webpage.

56. The At-Home NuLids Device Webpage further shows that the eye has an eyelid margin and an eyeball and includes a removable debris:

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At-Home NuLids Device Webpage.

ii) Claim 1, limitation [1.a]

57. Claim 1, limitation [1.a] recites “effecting movement of the contact member relative to the electromechanical device, the contact member having at least a portion thereof configured to access a portion of the eyelid margin, wherein the movement comprises electromechanical rotation of the contact member”

58. When used as intended and instructed by NuLids, the NuLids Pro and At-Home NuLids Device perform this step of the claimed method.

a. NuLids Pro

59. The NuLids Pro Webpage, NuLids Pro Instructional Video, and NuLids Pro Promotional Video show that the tip of NuLids Pro (contact member) moves relative to the handpiece when the device is turned on and used on a patient’s eyelid margin. The movement comprises electromechanical rotation. Specifically, the tip (a disk) rotates back and forth in the directions illustrated by the red arrows below.

1 This alternating rotational movement is rapidly repeated during operation to create an
2 oscillatory effect.



13 NuLids Pro Webpage (red arrows and black line added).

14 “Why I think it works really well with MGD, I think is the
15 massaging action makes a difference. **It’s got the massaging, it’s**
16 **got the oscillation**, I think that loosens up meibum and makes it,
you know, more accessible and more easy to flow.”

17 NuLids Pro Promotional Video at 14:22-37 (emphasis added).

18 60. The tip is configured to access a portion of the eyelid margin because, as
19 shown above, it is designed to and does access a patient’s eyelid margin to remove
20 debris therefrom.

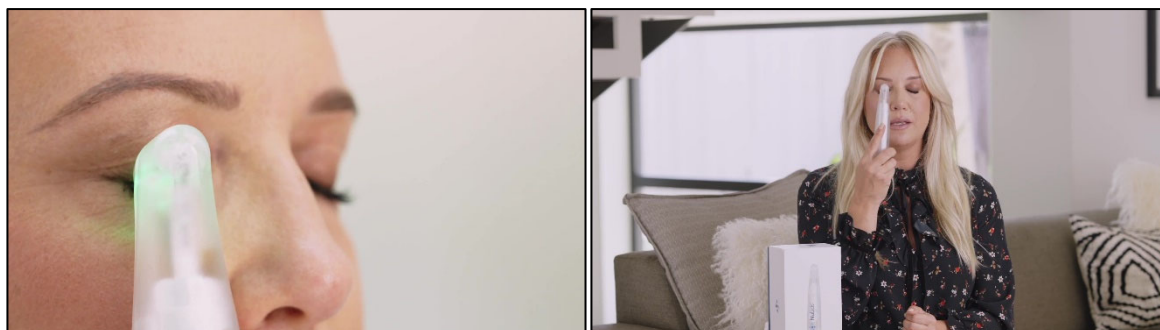
21 **b. At-Home NuLids Device**

22 61. The At-Home NuLids Device Webpage and NuLids System User
23 Manual show that the tip of the At-Home NuLids Device (contact member) moves
24 relative to the handpiece when the device is turned on and used on a patient’s eyelid
25 margin. The movement comprises electromechanical rotation. Specifically, the tip
26 (a disk) rotates back and forth in the directions illustrated by the red arrows below.
27 This alternating rotational movement is rapidly repeated during operation to create an
28 oscillatory effect.

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NuLids webpage (red arrows and black line added).



At-Home NuLids Device Instructional Video at 1:36-48.

Daily Operations - Instructions for Use

RECOMMENDED TREATMENT METHOD: Treating the lower & upper eyelids simultaneously.



1. Disconnect the NuLids handpiece from the electrical outlet via the charger plug. If connected, the handpiece will not operate.
2. Wash hands and face.
3. Select a new / unused Soft Tip from the package.
4. Press the On/Off button on the handpiece so that the white illumination light activates.
5. Bring the face of the handpiece head close to the Soft Tip until it magnetically snaps into position.
6. Confirm that the Soft Tip fits snugly into the head of the handpiece.
7. Apply thick lubricant gel onto the Soft Tip at the 12 o'clock position.

IMPORTANT: *If using a foam, spray, or oil, do not apply product to the Soft Tip. Instead, apply lubricant product directly onto the closed eyelid and/or eyelid margin.*
8. Hold the handpiece in your dominant hand and experiment to determine the most comfortable hand position.
9. Gently close one eye and place the edge of the Soft Tip at the intersection of the upper and lower lids.
10. Press the On/Off button to start the handpiece. The green LED light at the head of the handpiece will illuminate and the Soft Tip will oscillate.
11. Move from one corner of the eyelid to the other with slow, steady, even pressure for 30 seconds. [The handpiece pauses after each 15 second interval and starts again to give guidance on when 30 seconds has passed.]
12. Transition to the opposite eye and treat it in the same manner for 30 seconds.
13. Press the On/Off button to stop the handpiece.
14. Remove and dispose of the used Soft Tip **NEVER SHARE OR REUSE ANY SOFT TIP**

NuLids System User Manual at 11 (*see* step 10 describing the oscillatory effect).

62. The tip is configured to access a portion of the eyelid margin because, as shown above, it is designed to and does access a patient's eyelid margin to remove debris therefrom.

iii) Claim 1, limitation [1.b]

63. Claim 1, limitation [1.b] recites “while the contact member is being moved by the electromechanical device, contacting the eyelid margin with the contact member without lifting the eyelid margin from the eye so as to scrub the portion of the eyelid margin that includes the removable debris with the contact member thereby impacting the debris with the contact member to remove debris from the eye.”

64. When used as intended and instructed by NuLids, the NuLids Pro and

1 At-Home NuLids Device perform this step of the claimed method.

2 **a. NuLids Pro**

3 65. The NuLids Pro Webpage and NuLids Pro Instructional Video both
4 show that Defendant instructs healthcare providers to use the NuLids Pro to perform
5 this step. As shown below, NuLids instructs healthcare providers to contact the
6 rotating tip (as indicated by the green light) with a portion of the eyelid margin that
7 includes removable debris, in order to scrub this portion of the eyelid margin by
8 impacting the debris and removing it:



18 NuLids Pro Webpage.

19 66. NuLids also instructs healthcare providers to scrub the eyelid margin
20 “without lifting the eyelid margin from the eye.” For example, the above image
21 displayed on the NuLids Pro Webpage demonstrates the use of the NuLids Pro device
22 on a patient with his eyes closed and without the healthcare provider taking any step
23 to lift the eyelid margin from the eye. This is also demonstrated in the NuLids Pro
24 Instructional Video where Dr. Olkowski uses the device to clean a patient’s eyelid
25 margin without lifting it away from the eye:

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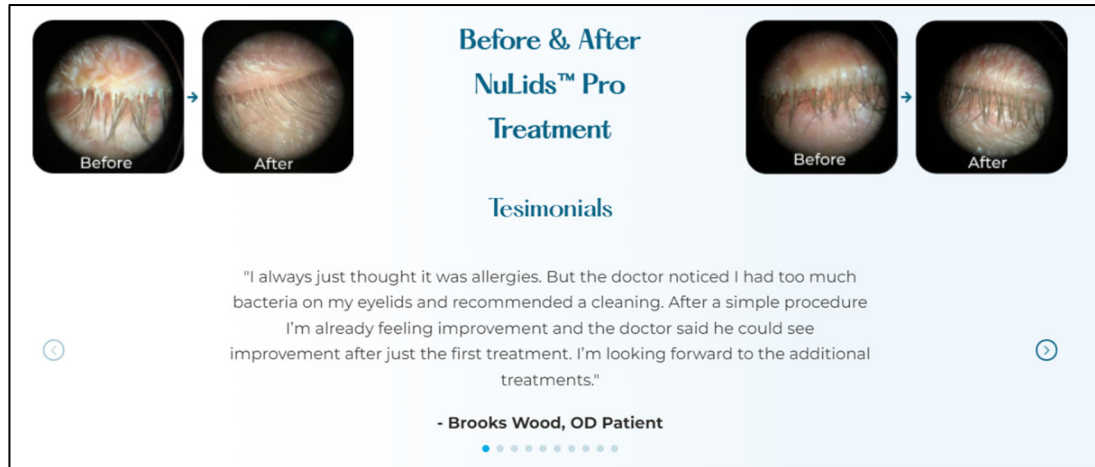


NuLids Pro Instructional Video at 1:44.

“And then, **turn the device on. We’ll have the patient close her eyes gently and we begin the treatment.** We do this for one minute per lid.”

Id. at 1:23-1:44 (emphases added).

67. Further, NuLids has repeatedly stated that the NuLids Pro may be used to treat blepharitis. A patient with blepharitis will, in the ordinary course, have debris that is located on “a portion of the eyelid margin.” This is evident in the very pictures NuLids posted on the NuLids Pro Webpage that demonstrate a real-world example of the condition to be treated thereby. As shown below, the debris to be removed is located at a portion of the eyelid margin:



NuLids Pro Webpage.

68. Accordingly, when used as intended and instructed by NuLids, the NuLids Pro product performs the method of at least Claim 1 of the '621 Patent.


b. At-Home NuLids Device

69. The At-Home NuLids Device Webpage, At-Home NuLids Device Instructional Video, and NuLids System User Manual show that Defendant instructs users to use the At-Home NuLids Device to perform this step. As shown below, NuLids instructs users to contact the rotating tip with a portion of the eyelid margin that includes removable debris, in order to scrub this portion of the eyelid margin by impacting the debris and removing it:

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Daily Operations - Instructions for Use

RECOMMENDED TREATMENT METHOD: Treating the lower & upper eyelids simultaneously.



1. Disconnect the NuLids handpiece from the electrical outlet via the charger plug. If connected, the handpiece will not operate.
2. Wash hands and face.
3. Select a new / unused Soft Tip from the package.
4. Press the On/Off button on the handpiece so that the white illumination light activates.
5. Bring the face of the handpiece head close to the Soft Tip until it magnetically snaps into position.
6. Confirm that the Soft Tip fits snugly into the head of the handpiece.
7. Apply thick lubricant gel onto the Soft Tip at the 12 o'clock position.

IMPORTANT: If using a foam, spray, or oil, do not apply product to the Soft Tip. Instead, apply lubricant product directly onto the closed eyelid and/or eyelid margin.
8. Hold the handpiece in your dominant hand and experiment to determine the most comfortable hand position.
9. Gently close one eye and place the edge of the Soft Tip at the intersection of the upper and lower lids.
10. Press the On/Off button to start the handpiece. The green LED light at the head of the handpiece will illuminate and the Soft Tip will oscillate.
11. Move from one corner of the eyelid to the other with slow, steady, even pressure for 30 seconds. [The handpiece pauses after each 15 second interval and starts again to give guidance on when 30 seconds has passed.]
12. Transition to the opposite eye and treat it in the same manner for 30 seconds.
13. Press the On/Off button to stop the handpiece.
14. Remove and dispose of the used Soft Tip **NEVER SHARE OR REUSE ANY SOFT TIP**

NuLids System User Manual at 11 (see steps 10-13).



At-Home NuLids Device Instructional Video at 1:36-48.

70. As shown above, NuLids also instructs users to clean the eyelid margin “without lifting the eyelid margin from the eye,” as the above excerpt from the NuLids System User Manual (see steps 9-11) instructs the user to close his or her eyes during

1 the cleaning. The images captured from the At-Home NuLids Device Instructional
2 Video instruct use of the At-Home NuLids Device by a user with her eyes closed and
3 without the user taking any step to lift the eyelid margin from the eye.

4 71. Accordingly, when used as intended and instructed by NuLids, the At-
5 Home NuLids Device performs the method of at least Claim 1 of the '621 Patent.

6 **COUNT I**

7 **DIRECT INFRINGEMENT**

8 72. BlephEx incorporates by reference each of the prior paragraphs.

9 73. 35 U.S.C. § 271(a) provides that “[w]hoever without authority makes,
10 uses, offers to sell, or sells any patented invention, within the United States or imports
11 into the United States any patented invention during the term of the patent therefor,
12 infringes the patent.”

13 74. In violation of § 271(a), NuLids has and continues to infringe one or
14 more claims of the '621 Patent, literally or under the doctrine of equivalents, by
15 performing the patented method. As set forth in Paragraphs 39-71, the NuLids Pro
16 and At-Home NuLids Device, when used as directed and instructed by NuLids,
17 performs the method of treating an eye for an ocular disorder claimed in one or more
18 claims of the '621 Patent, including at least Claim 1.

19 75. NuLids has, in the United States, advertised the NuLids Pro and At-
20 Home NuLids Device, used these devices, offered them for sale, sold them, and
21 continues to sell them. Moreover, healthcare providers have used and continue to use
22 the NuLids Pro and At-Home NuLids Device, and customers have used and continue
23 to use the At-Home NuLids Device.

24 76. Upon information and belief, NuLids, or its agents, or others acting in
25 active concert and jointly with them, have performed and continue to perform, without
26 authority, the claimed method of one or more claims of the '621 Patent in the United
27 States by using the NuLids Pro and NuLids products on patients. For example, the
28 NuLids Pro Instructional Video shows Dr. Olkowski using the NuLids Pro device on

1 a patient, and the At-Home NuLids Device Instructional Video on the At-Home
2 NuLids Device Webpage shows an instructor using the At-Home NuLids Device on
3 her own eyelid margin. Upon information and belief, NuLids used, or engaged others
4 to use, the NuLids Pro and At-Home NuLids Device on patients—thereby infringing
5 the '621 Patent—in connection with offering it for sale.

6 77. BlephEx has no adequate remedy at law for NuLids's acts of
7 infringement.

8 78. As a direct and proximate result of NuLids's acts of infringement,
9 BlephEx has suffered and continues to suffer damages and irreparable harm including,
10 but not limited to, lost sales, lost market share, price erosion, damage to its goodwill,
11 and reputational harm. Unless NuLids's acts of infringement are enjoined by this
12 Court, BlephEx will continue to be damaged and irreparably harmed.

13 79. NuLids had knowledge of the '621 Patent – including at least Claim 1 of
14 the patent – since at least the filing date of this Complaint. Further, upon information
15 and belief, NuLids actively monitors and is aware of BlephEx's patent portfolio,
16 including the '621 Patent, as evidenced by NuLids' citation of multiple BlephEx
17 patent publications in its own patent applications filed with the USPTO, its mention
18 of BlephEx on the NuLids website, Dr. Olkowski's discussions with BlephEx, and
19 NuLids' design of devices competing with the BlephEx®, where the BlephEx®
20 device is marked with the '621 patent. Thus, upon information and belief, NuLids
21 knew of, or was willfully blind to, the '621 on or about its issuance date.

22 80. Upon information and belief, NuLids' past and continuing infringement
23 has been deliberate and willful, and this case is therefore exceptional, warranting an
24 award of treble damages pursuant to 35 U.S.C. § 284 and attorney fees pursuant to 35
25 U.S.C. § 285.

26 **COUNT II**

27 **INDUCED INFRINGEMENT**

28 81. BlephEx incorporates by reference each of the prior paragraphs.

1 82. 35 U.S.C. § 271(b) provides “[w]hoever actively induces infringement
2 of a patent shall be liable as an infringer.”

3 83. When the NuLids Pro and At-Home NuLids Device are used as intended
4 and instructed by NuLids, their use infringes one or more claims of the ’621 Patent,
5 including Claim 1.

6 84. NuLids has and continues to actively induce infringement of the claims
7 of the ’621 Patent, including, but not limited to, Claim 1, in violation of 35 U.S.C. §
8 271(b).

9 85. NuLids had knowledge of the ’621 Patent – including at least Claim 1 of
10 the patent – since at least the filing date of this Complaint. Further, upon information
11 and belief, NuLids actively monitors and is aware of BlephEx’s patent portfolio
12 including the ’621 Patent, as evidenced by NuLids’ citation of multiple BlephEx
13 patent publications in its own patent applications filed with the USPTO, its mention
14 of BlephEx on the NuLids website, Dr. Olkowski’s discussions with BlephEx, and
15 NuLids’ design of devices competing with the BlephEx®, where the BlephEx®
16 device is marked with the ’621 patent. Thus, upon information and belief, NuLids
17 knew of, or was willfully blind to, the ’621 on or about its issuance date.

18 86. NuLids has, in the United States, advertised the NuLids Pro and At-
19 Home NuLids Device, used the devices, offered them for sale, sold them, and
20 continues to sell them. Moreover, healthcare providers have used and continue to use
21 the NuLids Pro and At-Home NuLids Device, and customers have used and continue
22 to use the At-Home NuLids Device.

23 87. NuLids has and continues to encourage and instruct healthcare providers
24 to use the NuLids Pro product to perform each and every step of the methods claimed
25 in the ’621 Patent, including but not limited to the method of Claim 1. On information
26 and belief, NuLids has done so and continues to do so with the knowledge that so
27 instructing and directing will induce acts that constitute patent infringement. On
28 information and belief, NuLids has acted affirmatively and with specific intent to

1 encourage healthcare providers to commit acts of direct infringement, including using
2 the NuLids Pro in an infringing manner, based on NuLids' instructions for use of the
3 NuLids Pro device as set forth in, for example, the NuLids Pro Webpage, NuLids Pro
4 Instructional Video, NuLids Pro Promotional Video, and NuLids' official social
5 media posts discussed above in Paragraphs 39-71. Upon information and belief,
6 NuLids's affirmative acts have in fact caused or led to acts of direct infringement.

7 88. NuLids has and continues to encourage and instruct patients to use the
8 At-Home NuLids Device to perform each and every step of the methods claimed in
9 the '621 Patent, including but not limited to the method of Claim 1. Upon information
10 and belief, NuLids has done so and continues to do so with the knowledge that so
11 instructing and directing will induce acts that constitute patent infringement. Upon
12 information and belief, NuLids has acted affirmatively and with specific intent to
13 encourage patients to commit acts of direct infringement, including using the At-
14 Home NuLids Device in an infringing manner, based on NuLids' instructions for use
15 of the At-Home NuLids Device as set forth in, for example, At-Home NuLids Device
16 Webpage, At-Home NuLids Device Instructional Video, NuLids' official social
17 media posts, and NuLids System User Manual discussed above in Paragraphs 39-71.
18 Upon information and belief, NuLids's affirmative acts have in fact caused or led to
19 acts of direct infringement.

20 89. BlephEx has no adequate remedy at law for NuLids's acts of
21 infringement.

22 90. As a direct and proximate result of NuLids's acts of inducing
23 infringement, BlephEx has suffered and continues to suffer damages and irreparable
24 harm including, but not limited to, lost sales, lost market share, price erosion, damage
25 to its goodwill, and reputational harm. Unless NuLids's acts of inducing infringement
26 are enjoined by this Court, BlephEx will continue to be damaged and irreparably
27 harmed.

28 91. Upon information and belief, NuLids's past and continuing inducing of

1 infringement has been deliberate and willful, and this case is therefore exceptional,
2 warranting an award of treble damages pursuant to 35 U.S.C. § 284 and attorney fees
3 pursuant to 35 U.S.C. § 285.

4 **PRAYER FOR RELIEF**

5 WHEREFORE, BlephEx prays for judgment in its favor and against NuLids
6 as follows:

- 7 A. That the Court enter judgment that NuLids has infringed one or more
8 claims of the '621 Patent, directly and indirectly, literally or under the
9 doctrine of equivalents;
- 10 B. That the Court enter an award of damages to BlephEx, including pre-
11 judgment and post-judgment interest and supplemental damages for any
12 continuing post-verdict infringement up until entry of the final judgment
13 with an accounting, as needed, in an amount adequate to compensate for
14 NuLids' infringement of the '621 Patent;
- 15 C. That the Court find the actions by NuLids complained of herein were
16 willful and intentional and treble all damages for patent infringement;
- 17 D. That the Court deem this an exceptional case under 35 U.S.C. § 285 and
18 award BlephEx its reasonable costs and reasonable attorney fees;
- 19 E. That the Court enter an order preliminarily and permanently enjoining
20 NuLids from infringing or inducing infringement of the '621 Patent; and
- 21 F. That the Court award BlephEx any and all other and further relief that
22 the Court deems just and proper.
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1 Dated: March 31, 2023

Respectfully submitted,

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/s/ Jason F. Lake

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Attorneys for Plaintiff
BLEPHEX, LLC

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

BLEPHEX, LLC

(b) County of Residence of First Listed Plaintiff Williamson County, TN (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Jason F. Lake (SBN 254147) QUINN EMANUEL URQUHART & SULLIVAN LLP 865 S. Figueroa St., 10th Floor, Los Angeles, CA 90017

DEFENDANTS

NULIDS, LLC

County of Residence of First Listed Defendant San Diego County (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, PRISONER PETITIONS, TORTS, PERSONAL INJURY, PERSONAL PROPERTY, LABOR, IMMIGRATION, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District (specify), 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 35 U.S.C. §271. Brief description of cause: Patent Infringement

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: [X] Yes [] No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

DATE: 3/31/2023 SIGNATURE OF ATTORNEY OF RECORD: /s/ Jason F. Lake

FOR OFFICE USE ONLY: RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I. (a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

- II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 - United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 - Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 - Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

- III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

- IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).

- V. **Origin.** Place an "X" in one of the seven boxes.
 - Original Proceedings. (1) Cases which originate in the United States district courts.
 - Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
 - Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 - Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 - Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 - Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 - Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.

PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

- VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 - Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 - Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

- VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.