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15 Attorneys for Plaintiff
16 ACCLARENT, INC.

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA
13 SAN JOSE DIVISION

15 ACCLARENT, INC.,

16 Plaintiff,

17 v.

18 ENTELLUS MEDICAL, INC.,

19 Defendant.

Case No.

COMPLAINT

DEMAND FOR JURY TRIAL

21 Plaintiff Acclarent, Inc. ("Acclarent") hereby files this Complaint against
22 Defendant Entellus Medical, Inc. ("Entellus Medical") and alleges as follows:

23 **PRELIMINARY STATEMENT**

24 1. This is an action for damages and injunctive relief to remedy patent
25 infringement by Entellus Medical of multiple method patents assigned to and/or owned by
26 Acclarent. The inventions at issue involve balloon dilation technology-based surgical
27 devices used to treat patients suffering from sinusitis. The infringed Acclarent patents
28 include U.S. Patent Nos. 7,740,642 (Exhibit A hereto), 7,645,272 (Exhibit B hereto)

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1 7,654,997 (Exhibit C hereto), 7,717,933 (Exhibit D hereto), and 7,753,929 (Exhibit E
2 hereto).

3 **PARTIES**

4 2. Plaintiff Acclarent, Inc. is a California corporation with its principal
5 place of business at 1525-B O'Brien Drive, Menlo Park, California 94025.

6 3. Upon information and belief, Defendant Entellus Medical, Inc. is a
7 Minnesota corporation with its principal place of business at 6705 Wedgwood Court
8 North, Maple Grove, Minnesota 55311.

9 4. Upon information and belief, Defendant Entellus Medical is engaged
10 in the marketing, distribution, and/or selling of medical devices, including balloon
11 dilation technology-based surgical devices used to treat patients suffering from sinusitis,
12 in the United States.

13 **JURISDICTION AND VENUE**

14 5. This is an action for patent infringement arising under the United
15 States Patent Laws, 35 U.S.C. § 101 *et seq.*

16 6. This court has subject matter jurisdiction pursuant to 28 U.S.C. §§
17 1331 and 1338(a).

18 7. Personal jurisdiction exists over defendant Entellus Medical because
19 Entellus Medical has continuous, systematic, and substantial contacts with the State of
20 California, including with respect to the marketing, distribution, and selling of medical
21 devices, including balloon dilation technology-based surgical devices used to treat patients
22 suffering from sinusitis in the State of California, and within this judicial district. In
23 addition, this lawsuit arises from Entellus Medical's patent infringement activities
24 believed to be directed towards the State of California, and within this judicial district.

25 8. Upon information and belief, Entellus Medical routinely sells
26 medical devices, including balloon dilation technology-based surgical devices used to
27 treat patients suffering from sinusitis in California and within this judicial district and that,
28 over the past two years Entellus Medical has generated significant revenues from the sales

1 of its products in California and within this judicial district. The marketing and sales of
2 the products at issue in this action infringes Acclarent's patent rights within this State and
3 elsewhere in the United States.

4 9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391
5 (b)-(c) and 1400(b).

6 **ACCUSED PRODUCTS**

7 10. Entellus Medical uses, has used, offers to sell, sells, has sold, imports
8 and/or has imported in the United States the following products:

- 9 • 5mm FinESS Sinus Treatment, either with or without the Entellus
10 Endoscope bundle ("FinESS"); and
11 • XprESS Multi-Sinus Dilation Tool ("XprESS").

12 These Entellus Medical surgical devices, and any related models, are
13 collectively referred to herein as the "Accused Entellus Medical Devices."

14 **COUNT 1**

15 **(Infringement of U.S. Patent No. 7,740,642 (XprESS))**

16 11. Acclarent incorporates by reference the allegations set forth in
17 paragraphs 1-10 above as though fully set forth herein.

18 12. On June 22, 2010, United States Patent No. 7,740,642 for "Method
19 For Treating Naturally Obstructed Paranasal Sinuses" (the "'642 patent") was duly and
20 legally issued by the U.S. Patent and Trademark Office. A true and correct copy of the
21 '642 patent is attached hereto as Exhibit A.

22 13. Acclarent has received an assignment of and holds all rights, title,
23 and interest to the '642 patent, including the right to recover all damages for past
24 infringement.

25 14. As instructed in the XprESS Instructions for Use and XprESS
26 brochure, the XprESS product is used to "access and treat the frontal recesses and
27 sphenoid sinus ostia in adults using a trans-nasal approach. The bony sinus outflow tracts
28 are remodeled by balloon displacement of adjacent bone and paranasal sinus structures."

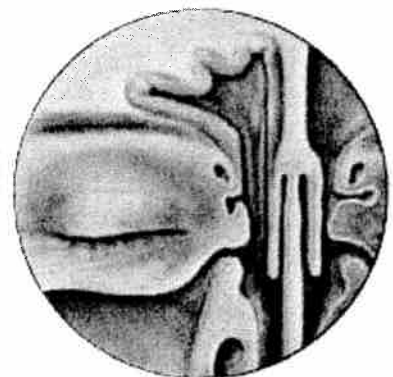
As shown in the brochure, the doctor will push the balloon catheter through the narrowed or obstructed opening, inflate the balloon within the narrowed or obstructed opening to enlarge the opening when the balloon is inflated, and then deflate and remove the balloon, leaving the opening dilated or enlarged. The purpose of this procedure is to enlarge the opening sufficient to treat the patient's sinusitis after removal of the balloon. The brochure includes the following images that demonstrate the procedure:



Locate



Inflate



Dilate

15. Entellus Medical has been and is actively inducing others to infringe the '642 patent through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing XprESS devices in the United States in violation of 35 U.S.C. § 271(b).

16. Entellus Medical has been and is contributing to infringement of the '642 patent by others through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing XprESS devices in the United States in violation of 35 U.S.C § 271(c).

17. Upon information and belief, Entellus Medical has been and continues to be aware of the '642 patent and has willfully infringed the patent.

18. Acclarent has suffered and continues to suffer damages and has been and continues to be irreparably injured.

COUNT 2

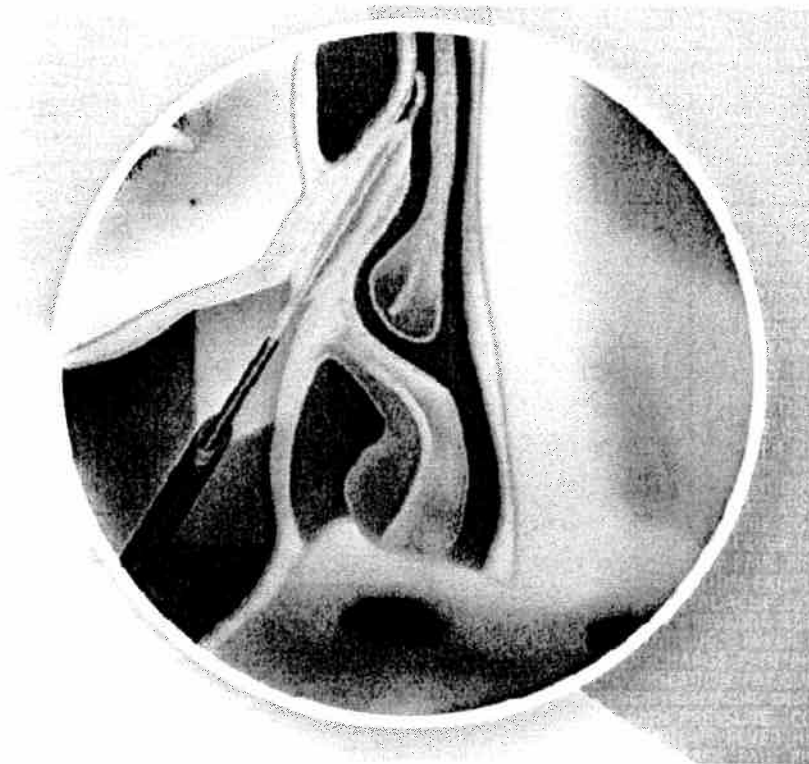
(Infringement of U.S. Patent No. 7,645,272 (FinESS))

19. Acclarent incorporates by reference the allegations set forth in paragraphs 1-18 above as though fully set forth herein.

20. On January 12, 2010, United States Patent No. 7,645,272 for “Devices, Systems And Methods For Treating Disorder Of The Ear, Nose And Throat” (the “‘272 patent”) was duly and legally issued by the U.S. Patent and Trademark Office. A true and correct copy of the ‘272 patent is attached hereto as Exhibit B.

21. Acclarent has received an assignment of and holds all rights, title, and interest to the ‘272 patent, including the right to recover all damages for past infringement.

22. As instructed in the FinESS Instructions for Use and the FinESS brochure, the FinESS product is used to “access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures.” As directed by the Instructions for Use and as shown in the brochure, the doctor will, (1) using a light emitting endoscope for direct visualization, insert the canula (which has a preset shape) to a point at or near the maxillary sinus ostium to allow delivery of a balloon catheter, (2) push a balloon catheter through the canula and then through the narrowed or obstructed opening, (3) inflate the balloon within the narrowed or obstructed opening to enlarge the opening when the balloon is inflated, and (4) then deflate the balloon and remove the balloon catheter through the canula, leaving the opening dilated or enlarged. The purpose of this procedure is to enlarge the opening sufficient to treat the patient’s sinusitis after removal of the balloon. The brochure includes the following image that demonstrates the procedure:



23. Entellus Medical has been and is actively inducing others to infringe the '272 patent through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing FinESS devices in the United States in violation of 35 U.S.C. § 271(b).

24. Entellus Medical has been and is contributing to infringement of the '272 patent by others through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing FinESS devices in the United States in violation of 35 U.S.C § 271(c).

25. Upon information and belief, Entellus Medical has been and continues to be aware of the '272 patent and has willfully infringed the patent.

26. Acclarent has suffered and continues to suffer damages and has been and continues to be irreparably injured.

1 **COUNT 3**

2 **(Infringement of U.S. Patent No. 7,654,997 (FinESS))**

3 27. Acclarent incorporates by reference the allegations set forth in
4 paragraphs 1-26 above as though fully set forth herein.

5 28. On February 2, 2010, United States Patent No. 7,654,997 for
6 “Devices, Systems And Methods For Diagnosing And Treating Sinusitis And Other
7 Disorders Of The Ears, Nose And/Or Throat” (the “‘997 patent”) was duly and legally
8 issued by the U.S. Patent and Trademark Office. A true and correct copy of the ‘997
9 patent is attached hereto as Exhibit C.

10 29. Acclarent has received an assignment of and holds all rights, title,
11 and interest to the ‘997 patent, including the right to recover all damages for past
12 infringement.

13 30. Entellus Medical has been and is actively inducing others to infringe
14 the ‘997 patent through its actions in using, having used, offering to sell, selling, having
15 sold, making, having made, importing, having imported and/or marketing FinESS devices
16 in the United States in violation of 35 U.S.C. § 271(b).

17 31. Entellus Medical has been and is contributing to infringement of the
18 ‘997 patent by others through its actions in using, having used, offering to sell, selling,
19 having sold, making, having made, importing, having imported and/or marketing FinESS
20 devices in the United States in violation of 35 U.S.C § 271(c).

21 32. Upon information and belief, Entellus Medical has been and
22 continues to be aware of the ‘997 patent and has willfully infringed the patent.

23 33. Acclarent has suffered and continues to suffer damages and has been
24 and continues to be irreparably injured.

25 **COUNT 4**

26 **(Infringement of U.S. Patent No. 7,717,933 (FinESS))**

27 34. Acclarent incorporates by reference the allegations set forth in
28 paragraphs 1-33 above as though fully set forth herein.

35. On May 18, 2010, United States Patent No. 7,717,933 for “Balloon Catheters And Methods For Treating Paranasal Sinuses” (the “’933 patent”) was duly and legally issued by the U.S. Patent and Trademark Office. A true and correct copy of the ‘933 patent is attached hereto as Exhibit D.

36. Acclarent has received an assignment of and holds all rights, title, and interest to the '933 patent, including the right to recover all damages for past infringement.

37. Entellus Medical has been and is actively inducing others to infringe the '933 patent through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing FinESS devices in the United States in violation of 35 U.S.C. § 271(b).

38. Entellus Medical has been and is contributing to infringement of the '933 patent by others through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing FinESS devices in the United States in violation of 35 U.S.C § 271(c).

39. Upon information and belief, Entellus Medical has been and continues to be aware of the '933 patent and has willfully infringed the patent.

40. Acclarent has suffered and continues to suffer damages and has been and continues to be irreparably injured.

COUNT 5

(Infringement of U.S. Patent No. 7,740,642 (FinESS))

41. Acclarent incorporates by reference the allegations set forth in paragraphs 1-40 above as though fully set forth herein.

42. On June 22, 2010, United States Patent No. 7,740,642 for “Method For Treating Naturally Obstructed Paranasal Sinuses” (the “‘642 patent”) was duly and legally issued by the U.S. Patent and Trademark Office. A true and correct copy of the ‘642 patent is attached hereto as Exhibit A.

43. Acclarent has received an assignment of and holds all rights, title, and interest to the '642 patent, including the right to recover all damages for past infringement.

44. Entellus Medical has been and is actively inducing others to infringe the '642 patent through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing FinESS devices in the United States in violation of 35 U.S.C. § 271(b).

45. Entellus Medical has been and is contributing to infringement of the '642 patent by others through its actions in using, having used, offering to sell, selling, having sold, making, having made, importing, having imported and/or marketing FinESS devices in the United States in violation of 35 U.S.C § 271(c).

46. Upon information and belief, Entellus Medical has been and continues to be aware of the '642 patent and has willfully infringed the patent.

47. Acclarent has suffered and continues to suffer damages and has been and continues to be irreparably injured.

COUNT 6

(Infringement of U.S. Patent No. 7,753,929 (XprESS))

48. Acclarent incorporates by reference the allegations set forth in paragraphs 1-47 above as though fully set forth herein.

49. On July 13, 2010, United States Patent No. 7,753,929 for “Method For Treating Obstructed Paranasal Sphenoid Sinuses” (the “’929 patent”) was duly and legally issued by the U.S. Patent and Trademark Office. A true and correct copy of the ’929 patent is attached hereto as Exhibit A.

50. Acclarent has received an assignment of and holds all rights, title, and interest to the '929 patent, including the right to recover all damages for past infringement.

51. Entellus Medical has been and is actively inducing others to infringe the '929 patent through its actions in using, having used, offering to sell, selling, having

1 sold, making, having made, importing, having imported and/or marketing XprESS devices
2 in the United States in violation of 35 U.S.C. § 271(b).

3 52. Entellus Medical has been and is contributing to infringement of the
4 '929 patent by others through its actions in using, having used, offering to sell, selling,
5 having sold, making, having made, importing, having imported and/or marketing XprESS
6 devices in the United States in violation of 35 U.S.C § 271(c).

7 53. Upon information and belief, Entellus Medical has been and
8 continues to be aware of the '929 patent and has willfully infringed the patent.

9 54. Acclarent has suffered and continues to suffer damages and has been
10 and continues to be irreparably injured.

11
12 **DEMAND FOR JUDGMENT**

13 WHEREFORE, Acclarent respectfully requests the Court enter judgment
14 against Entellus as follows:

15 A. An order that the '642 patent, the '272 patent, the '997 patent, the
16 '933, and the '929 patents are valid and have been infringed by Entellus;

17 B. Orders preliminarily and permanently enjoining Entellus, its officers,
18 agents, servants, employees, attorneys, and all other persons in active concert or
19 participation with any of them, from making, using, offering for sale, and/or selling
20 within the United States, and/or importing into the United States, the FinESS product
21 and any other product that infringes the '642 patent, the '272 patent, the '997 patent,
22 and the '933 patents;

23 C. Orders preliminarily and permanently enjoining Entellus, its officers,
24 agents, servants, employees, attorneys, and all other persons in active concert or
25 participation with any of them, from making, using, offering for sale, and/or selling
26 within the United States, and/or importing into the United States, the XprESS products
27 and any other product that infringes the '642 patent or the '929 patent;
28

1 D. An order adjudging and decreeing that such infringement has been
2 willful and;

3 E. An award of Acclarent's damages for infringement, with interest and
4 trebled, pursuant to 35 U.S.C. § 284;

5 F. A declaration that this is an "exceptional case" due to the willful
6 nature of Entellus Medical's patent infringement, and an award of attorneys' fees to
7 Acclarent pursuant to 35 U.S.C. § 285, or other applicable law, in connection with this
8 Action;

9 G. An award of the costs and disbursements of this action against
10 Entellus Medical; and

11 H. Such other and further relief as the Court may deem just and proper.

12 **DEMAND FOR JURY TRIAL**

13 Acclarent demands a trial by jury on each of its claims for relief triable
14 before a jury.

15 Dated: July 28, 2010

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