

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PUREWICK CORPORATION)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-1508-MN
)	
SAGE PRODUCTS, LLC,)	JURY TRIAL DEMANDED
)	
Defendant.)	

SECOND AMENDED COMPLAINT

Plaintiff PureWick Corporation (“PureWick” or “Plaintiff”), hereby demands a jury trial and alleges the following against Defendant Sage Products, LLC (“Sage” or “Defendant”):

NATURE OF ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*

2. Plaintiff has filed this lawsuit to stop Defendant’s unlawful infringement of Plaintiff’s patented inventions and to obtain damages, an injunction, and other relief.

THE PARTIES

3. PureWick Corporation is a corporation organized and existing under the laws of the State of California with its principal place of business located at 2030 Gillespie Way, Suite 109, El Cajon, CA 92020. PureWick is a wholly owned subsidiary of C.R. Bard, Inc.

4. On information and belief, Sage is incorporated under the laws of Delaware, and has a place of business at 3909 Three Oaks Road, Cary, IL 60013.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. §1, et. seq., including 35 U.S.C. § 271. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Sage based at least on Sage's incorporation in the State of Delaware.

7. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Sage is incorporated in, and therefore resides in, the State of Delaware.

FACTUAL BACKGROUND

PureWick™ FEC Solution

8. PureWick developed and patented a groundbreaking female external catheter, the PureWick™ FEC Solution. PureWick's female external catheter provides an incontinence solution for women, designed to reduce catheter-associated urinary tract infections ("CAUTI") and skin damage caused by urine-soaked diapers and bedding. The PureWick™ FEC Solution has shown an ability to consistently capture and take away urine, while improving users' sleep quality as they do not have to be awakened for diaper changes.

9. PureWick has received industry recognition for its innovation of the PureWick technology, including MedTech Dare to Dream Design Challenge (Finalist, 2014); Most Innovative New Product Award, Medical Devices and Pharmaceutical Products Category (Winner, 2015, connect.org); Athena Pinnacle Award (Winner, 2016).

The Patents-in-Suit

10. On October 16, 2012 the United States Patent and Trademark Office ("the USPTO") duly and legally issued U.S. Patent No. 8,287,508 ("the '508 patent), titled "Using Moisture-Wicking Article Wrapped Over Openings In An Elongated Urine Collecting Container

For Drawing Urine From A Region Surrounding An Urethral Opening.” PureWick is the owner by assignment of the ’508 patent. A true and accurate copy of the ’508 patent is attached hereto as Exhibit 1.

11. On March 12, 2019 the USPTO duly and legally issued U.S. Patent No. 10,226,376 (“the ’376 patent”), titled “Apparatus And Methods For Receiving Discharged Urine.” PureWick is the owner by assignment of the ’376 patent. A true and accurate copy of the ’376 patent is attached hereto as Exhibit 2.

12. On August 27, 2019, the USPTO duly and legally issued U.S. Patent No. 10,390,989 (“the ’989 patent”), titled Apparatus And Methods For Receiving Discharged Urine.” PureWick is the owner by assignment of the ’989 patent. A true and accurate copy of the ’989 patent is attached hereto as Exhibit 3.

13. On August 13, 2019, the USPTO duly and legally issued U.S. Patent No. 10,376,407 (“the ’407 patent”), titled “Using Wicking Material To Collect Urine From A Male For Transport.” PureWick is the owner by assignment of the ’407 patent. A true and correct copy of the ’407 patent is attached hereto as Exhibit 7.

Defendant’s Accused Products

14. The success of the PureWick™ FEC Solution did not go unnoticed by competitors in the medical device industry, including Sage. In June 2016, representatives from Sage met with PureWick and were given a presentation about PureWick’s business and intellectual property. In July 2016, Sage entered into a Mutual Confidentiality Agreement with PureWick in order for Sage to evaluate a potential acquisition of PureWick.

15. Through multiple meetings, phone calls and other correspondence, Sage received information about PureWick’s business, products, patents and patent applications. In connection

with these discussions, Sage learned of the '508 patent and the applications to which the '376 and '989 patents claim priority. Sage's discussions with PureWick ended when PureWick was acquired by C.R. Bard, Inc. in June 2017.

16. In or around October 2017, Sage introduced a competing product to the PureWick™ FEC called the PrimaFit™, which is identified at <https://sageproducts.com/prima-fit-external-urine-management-system-for-females/>. On information and belief, Sage makes, uses, offers to sell, and/or sells the PrimaFit™ in the United States, and/or imports the PrimaFit™ into United States.

17. Literature describing the PrimaFit™ is available at <https://sageproducts.com/prima-fit-external-urine-management-system-for-females/>.

18. Provided herewith as Exhibit 4 is a true and correct copy of the "PrimaFit Brochure" at <https://sageproducts.com/wp-content/uploads/Sage-PrimaFit-Brochure.pdf>.

19. Provided herewith as Exhibit 5 is a true and correct copy of the "Patient Education Card" at <https://sageproducts.com/wp-content/uploads/PrimaFit-Patient-Education-Card.pdf>.

20. Provided herewith as Exhibit 6 is a true and correct copy of the "Instructions for Use" at <https://sageproducts.com/wp-content/uploads/PrimaFit-Instructions-for-Use.pdf>.

21. The PrimaFit™ is "an external urine management system designed to help manage urinary incontinence in female patients." Exhibit 4. The Instructions for Use manual, instructs how to use the PrimaFit™ product for "non-invasive, non-sterile collection of urine for female patients" with a vacuum. Exhibit 6 at e.g. Step 11.

22. The image below from Sage's product brochure further illustrates the main features of the PrimaFit™ product.



Exhibit 4.

23. Sage recently announced that it is making a male external catheter product called the Primofit™.

24. Provided herewith as Exhibit 8 is a true and correct copy of the Primofit™ product brochure available at

<https://www.stryker.com/content/dam/stryker/sage/products/primofit/resources/Sage-PrimoFit-Brochure.pdf>.

25. The Primofit™ provides “External Urine Management for the Male Anatomy” and “serves as an alternative to external collection devices or, when appropriate, indwelling catheters.” Exhibit 8.

26. The image below from Sage’s product brochure further illustrates the main features of the Primofit™ product.



COUNT I

INFRINGEMENT OF THE '508 PATENT

27. The allegations in the preceding paragraphs are incorporated by reference as if fully set forth herein.

28. Defendant has directly infringed, and continues to directly infringe, claims 1-19 of the '508 patent by making, using, offering for sale, selling, and/or importing into the United States the PrimaFit™ product, and contributed to and/or induced infringement of the '508 patent by others, including hospitals, patients and other customers.

29. For example, and without limitation, on information and belief the PrimaFit™ product meets every limitation of at least independent claim 1 of the '508 patent and Defendant's making, using, offering for sale, selling, and/or importing the PrimaFit™ product into the United States directly infringes claim 1 of the '508 patent under 35 U.S.C. § 271(a).

30. The PrimaFit™ product is "[a] urine collection device for use in a system for transporting urine voided from a person or an animal." Exhibit 1 at 6:59-60. Defendant's product information states "PrimaFit is an external urine management system designed to help manage urinary incontinence in female patients and promote early catheter removal, addressing the #1 risk factor of catheter-associated urinary tract infections (CAUTI). PrimaFit serves as an alternative to incontinence pads, diapers, or at times, catheters, while transitioning patients to independent continence." Exhibit 4.

31. The PrimaFit™ product acts "by drawing the urine into a moisture-wicking article that is disposed in contact with a region of the person or animal surrounding an urethral opening." Exhibit 1 at 6:60-63. Defendant's product information states "[w]hen properly positioned, PrimaFit's ultra-soft wicking fabric absorbs and diverts urine away from the patient's skin. Urine is then absorbed into the system's core and suctioned into a collection canister,

helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” Exhibit 4. The annotated illustration below, included in Defendant’s product information, also depicts these features of the PrimaFit™ product:

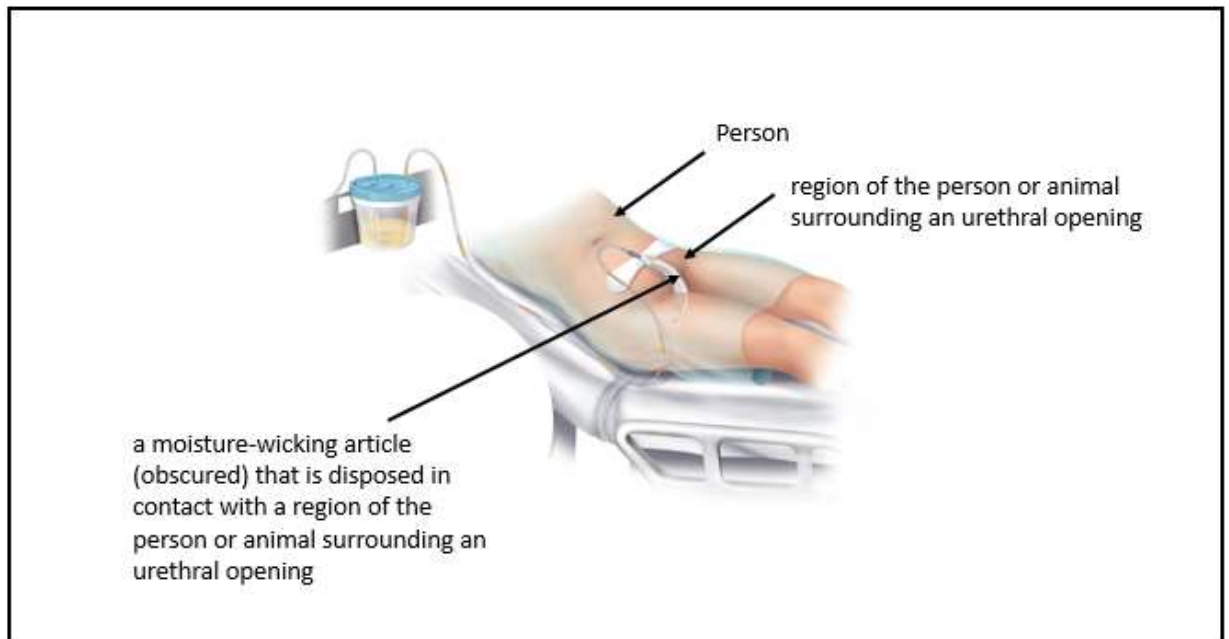
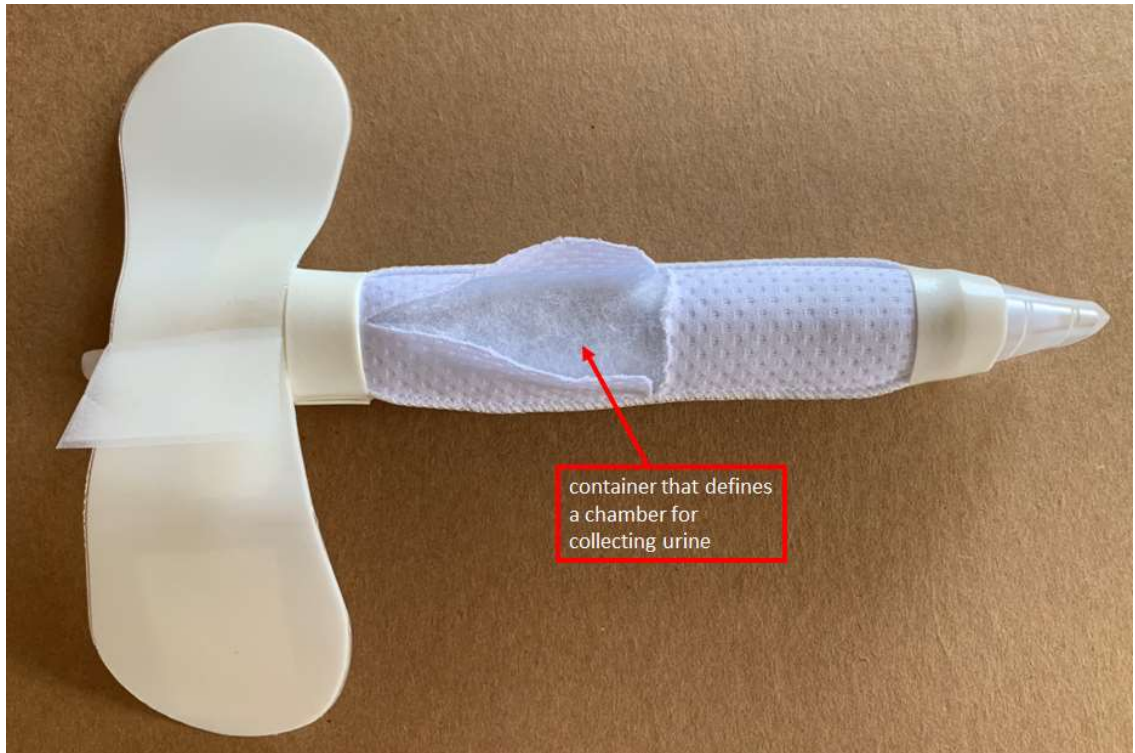


Exhibit 4.

32. The PrimaFit™ product “further draw[s] the urine into the collection device from the moisture-wicking article.” Exhibit 1 at 6:63-64. Defendant’s product information states “[w]hen properly positioned, PrimaFit’s ultra-soft wicking fabric absorbs and diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister, helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” Exhibit 4.

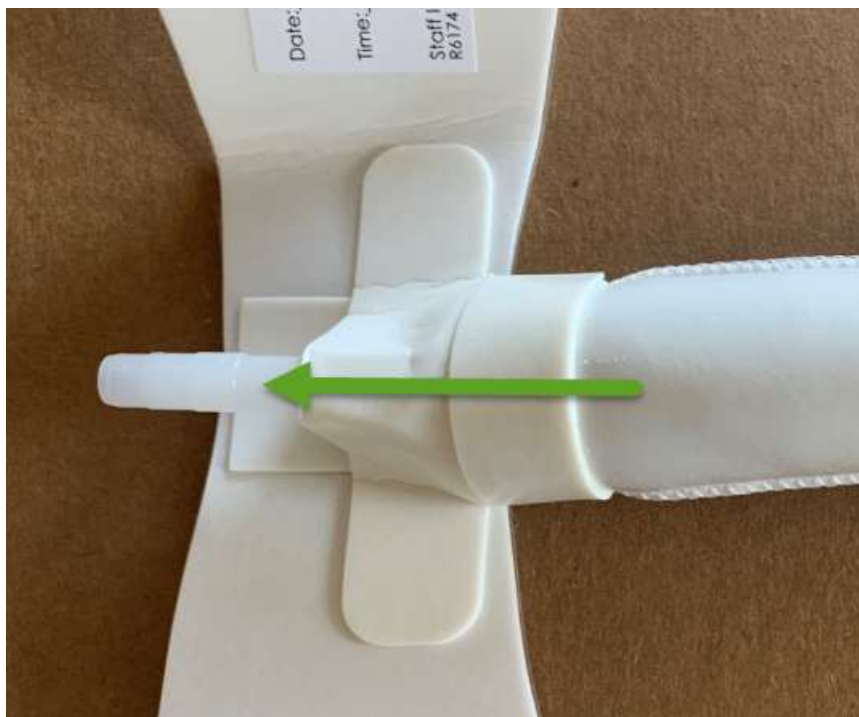
33. The PrimaFit™ product comprises “a container,” where the container defines “a chamber for collecting urine.” Exhibit 1 at 6:65. As shown in the photograph below, the PrimaFit™ product includes a container comprising at least a spun-fiber material that defines a chamber for collecting urine.



34. The PrimaFit™ product container “is closed, except for having an array of openings through which urine can be drawn into the chamber and at least one outlet port through which urine can be drawn away from the chamber.” Exhibit 1 at 6:66-7:2. As shown in the photograph below, the spaces between the fibers of the container create an array of openings through which urine can be drawn:



35. The container also includes an outlet port at one end through which urine can be drawn away from the chamber:



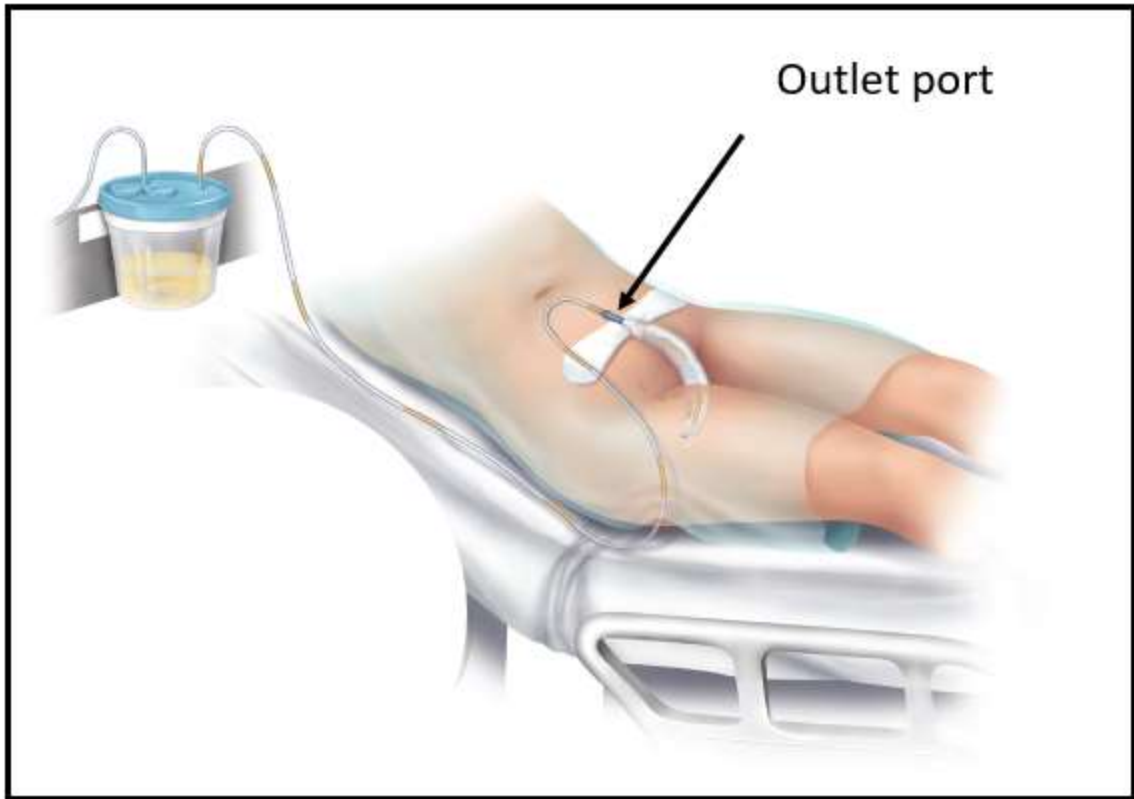
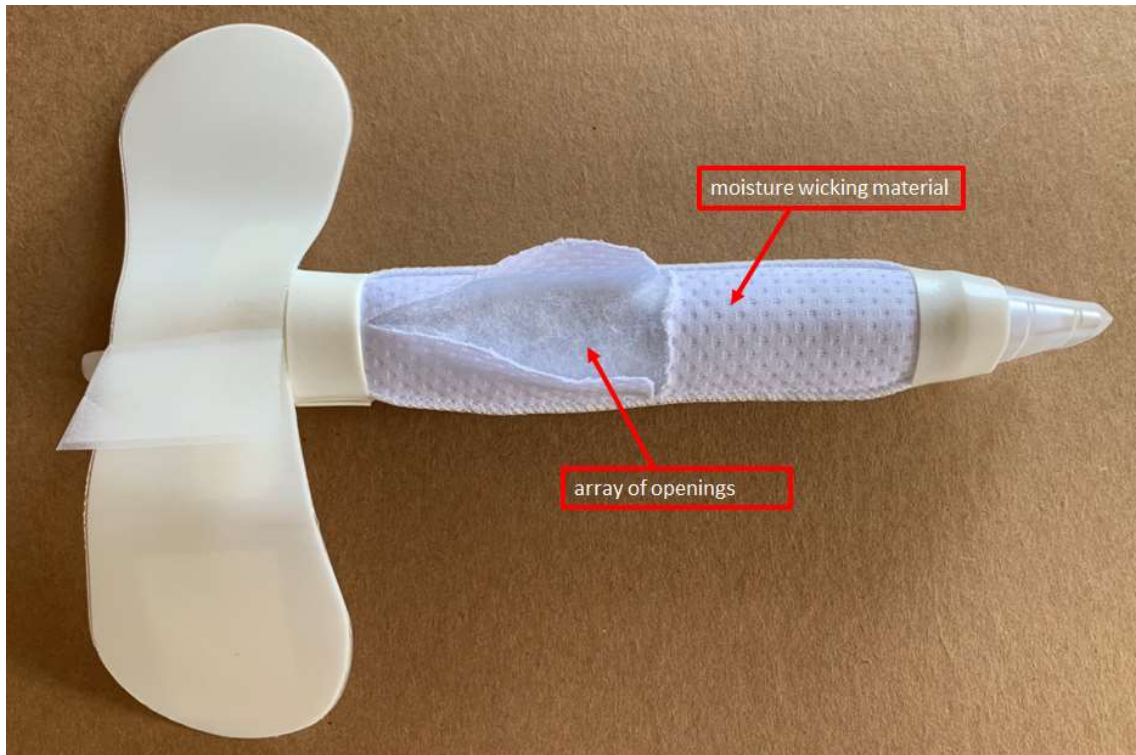
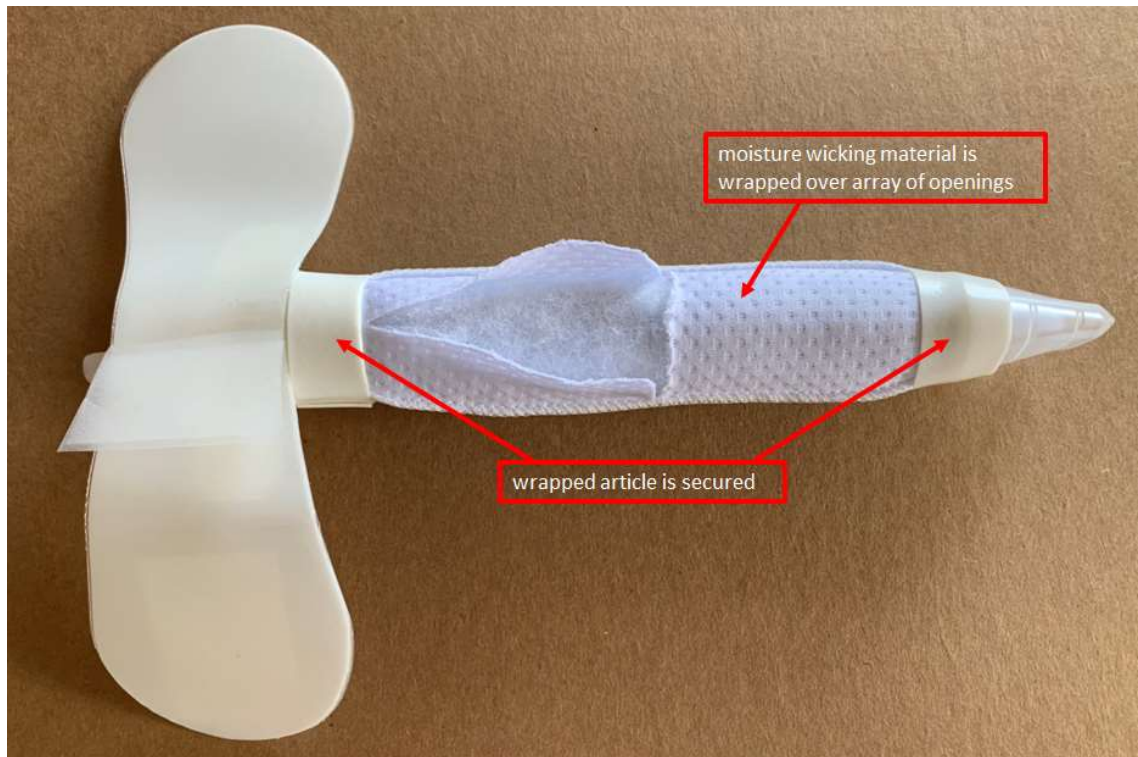


Exhibit 4.

36. The PrimaFit™ product includes “an elongated exterior of the container [that] is configured and dimensioned for enabling a moisture-wicking article to be secured over the array of openings of the container.” Exhibit 1 at 7:3-6. As shown in the photograph below, a moisture wicking material is secured over the array of openings in the container:



37. As shown in the photograph below, the moisture-wicking article on the PrimaFit™ product is secured over the array of openings of the container “by wrapping the article over the array and securing the wrapped article.” Exhibit 1 at 7:6-7.



38. As shown in the PrimaFit™ product materials below, the elongated exterior of the container of the PrimaFit™ product is configured and dimensioned “for enabling said secured moisture-wicking article to be disposed in contact with the region of a female body surrounding the urethral opening.” Exhibit 1 at 7:7-10. Defendant’s product information states “[w]hen properly positioned, PrimaFit’s ultra-soft wicking fabric absorbs and diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister, helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” Exhibit 4. The illustration below, included in Defendant’s product information, also describes these features of the PrimaFit™ product:

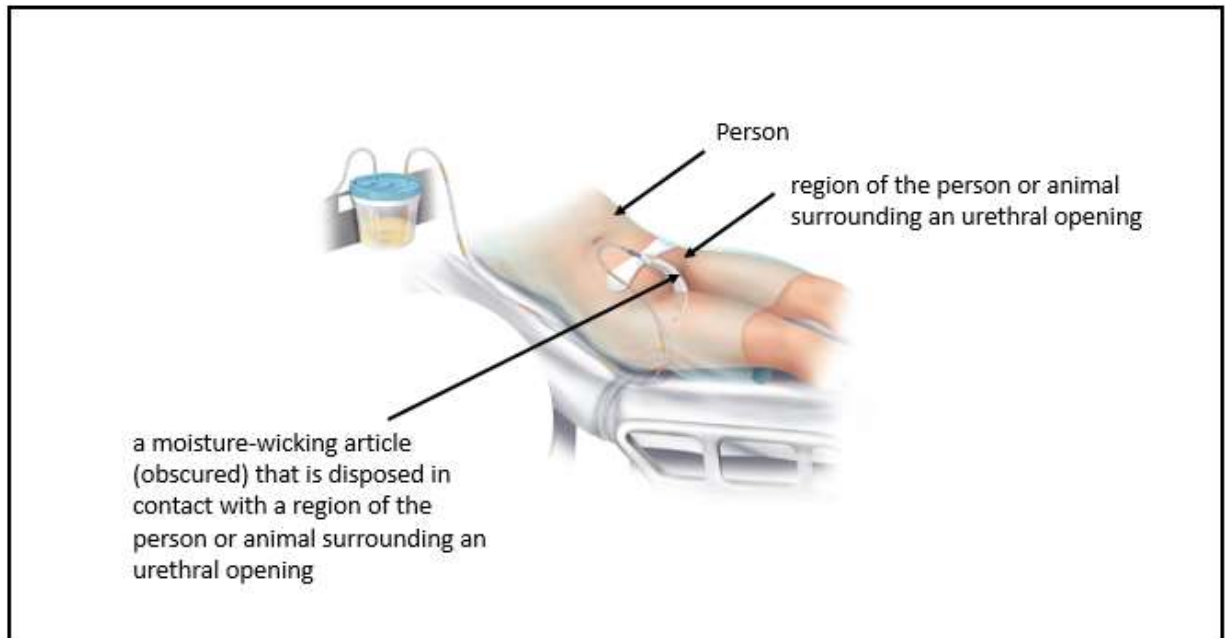


Exhibit 4.

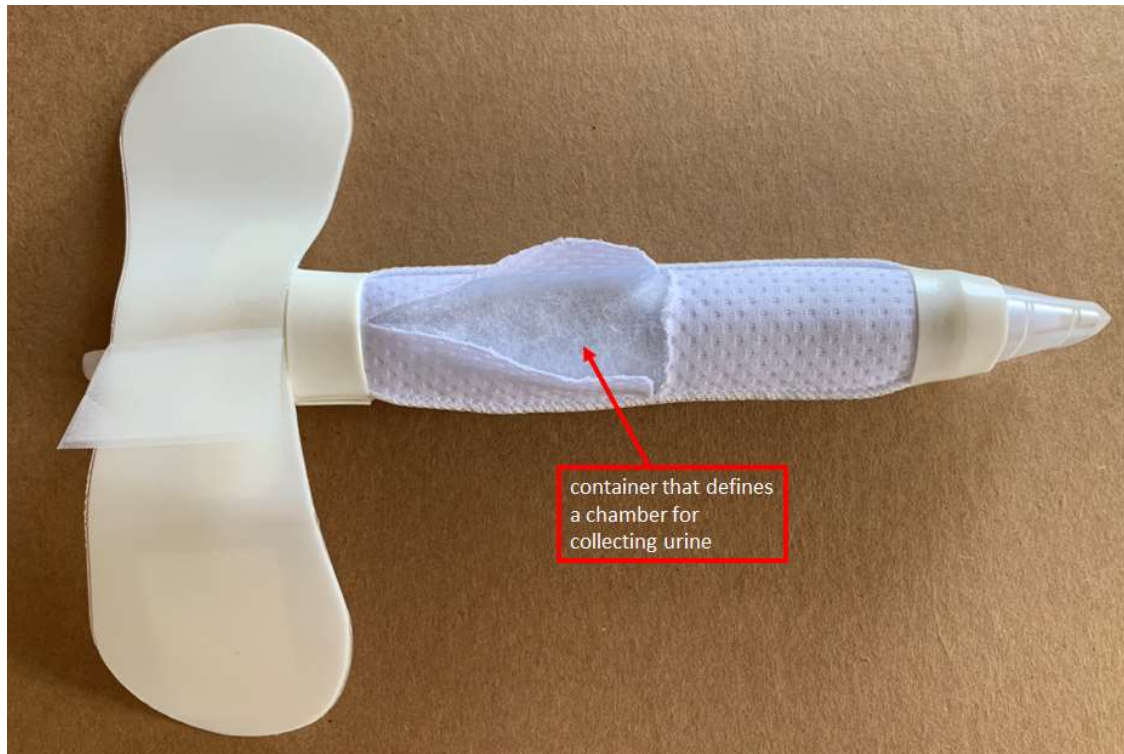
39. Thus, the PrimaFit™ product meets every limitation of at least independent claim 1 of the '508 patent and Defendant directly infringes at least claim 1 in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling, and/or importing the PrimaFit™ product into the United States.

40. The use of the PrimaFit™ product meets each and every limitation of at least independent method claim 10 and Defendant's testing of the product directly infringes claim 10 of the '508 patent under 35 U.S.C. § 271(a).

41. The use of the PrimaFit™ product practices "[a] method of transporting urine voided from a person or an animal." Exhibit 1 at 7:37-38. Defendant's product information states "PrimaFit is an external urine management system designed to help manage urinary incontinence in female patients and promote early catheter removal." Exhibit 4.

42. The use of the PrimaFit™ product includes "providing a urine collection device that includes a container defining a chamber for collecting urine." Exhibit 1 at 7:40-41. As

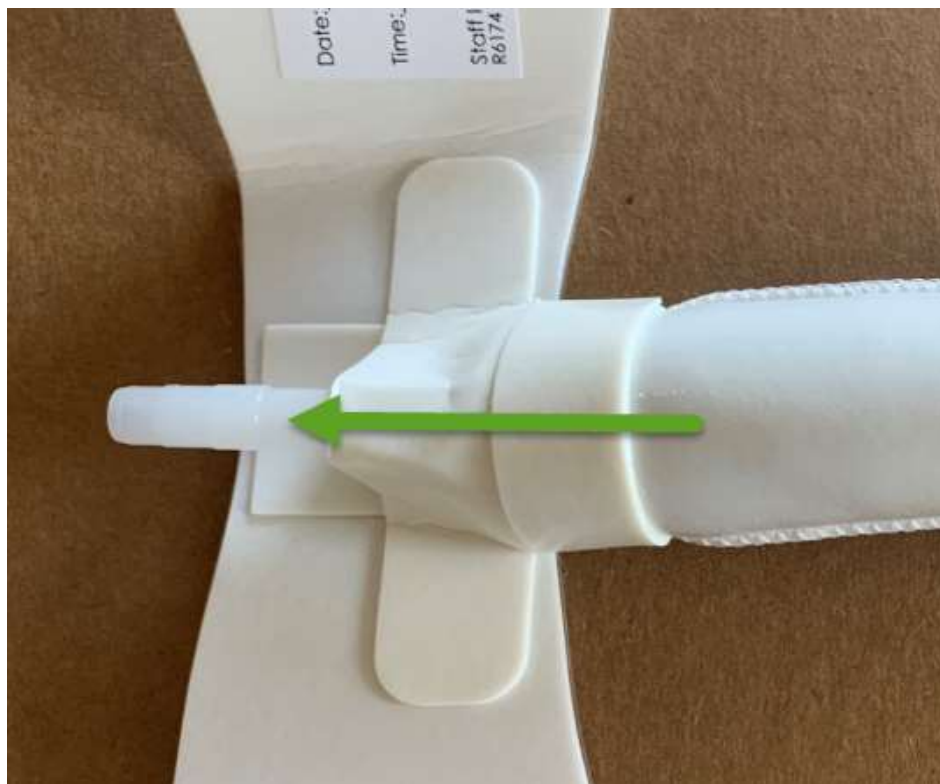
shown in the photograph below, the interior of the PrimaFit™ product includes a spun-fiber container that defines a chamber for collecting urine.



43. The use of the PrimaFit™ product includes a “container [that] is closed, except for having an array of openings through which urine can be drawn into the chamber and at least one outlet port through which urine can be drawn away from the chamber.” Exhibit 1 at 7:40-44. As shown in the photograph below, the spaces between the fibers of the container create an array of openings through which urine can be drawn:



44. The container also includes an outlet port at one end through which urine can be drawn away from the chamber:



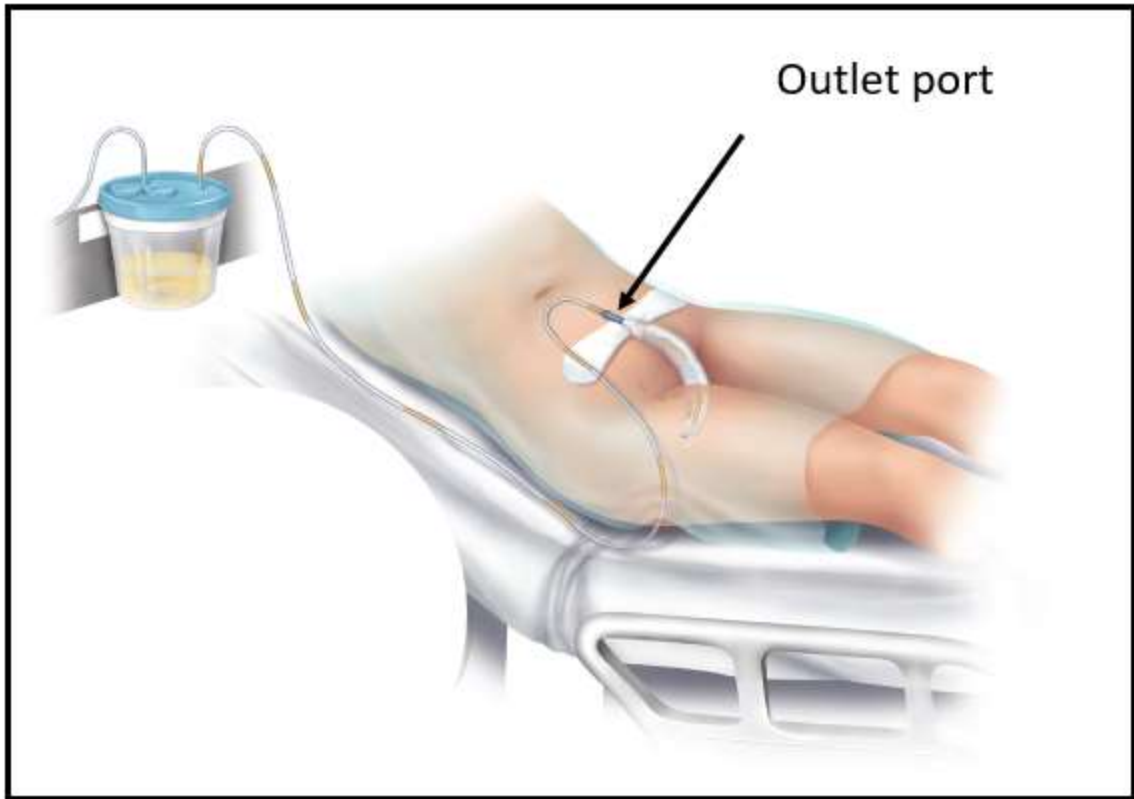
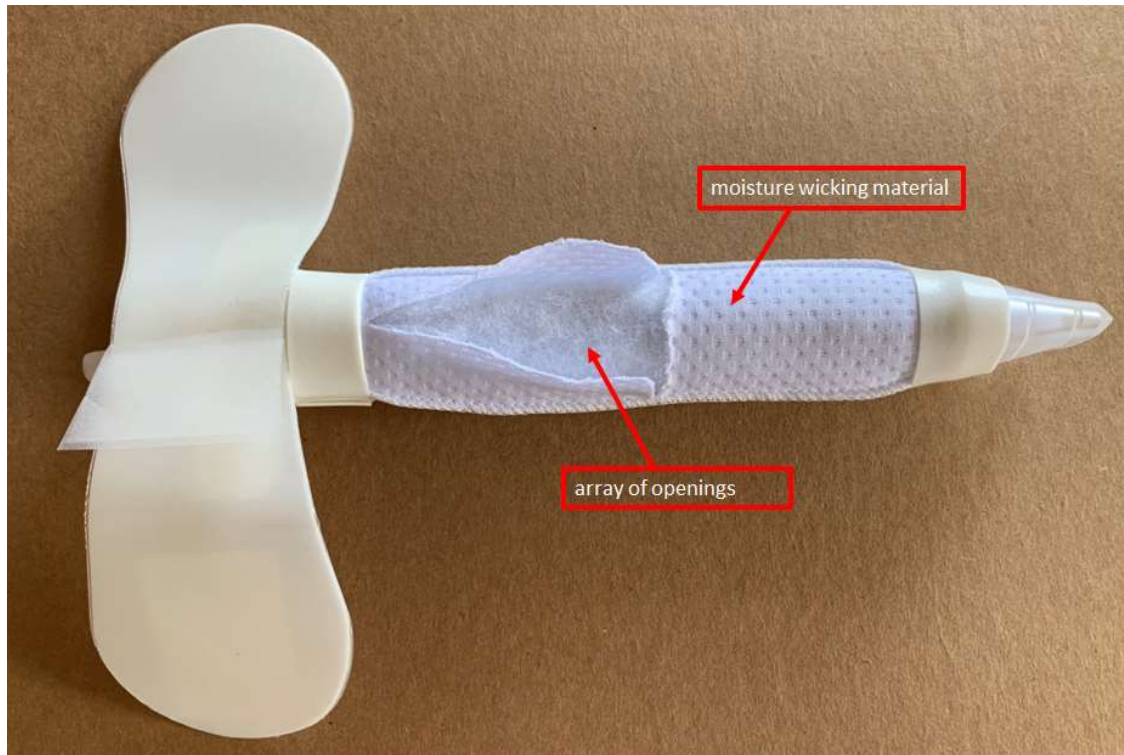


Exhibit 4.

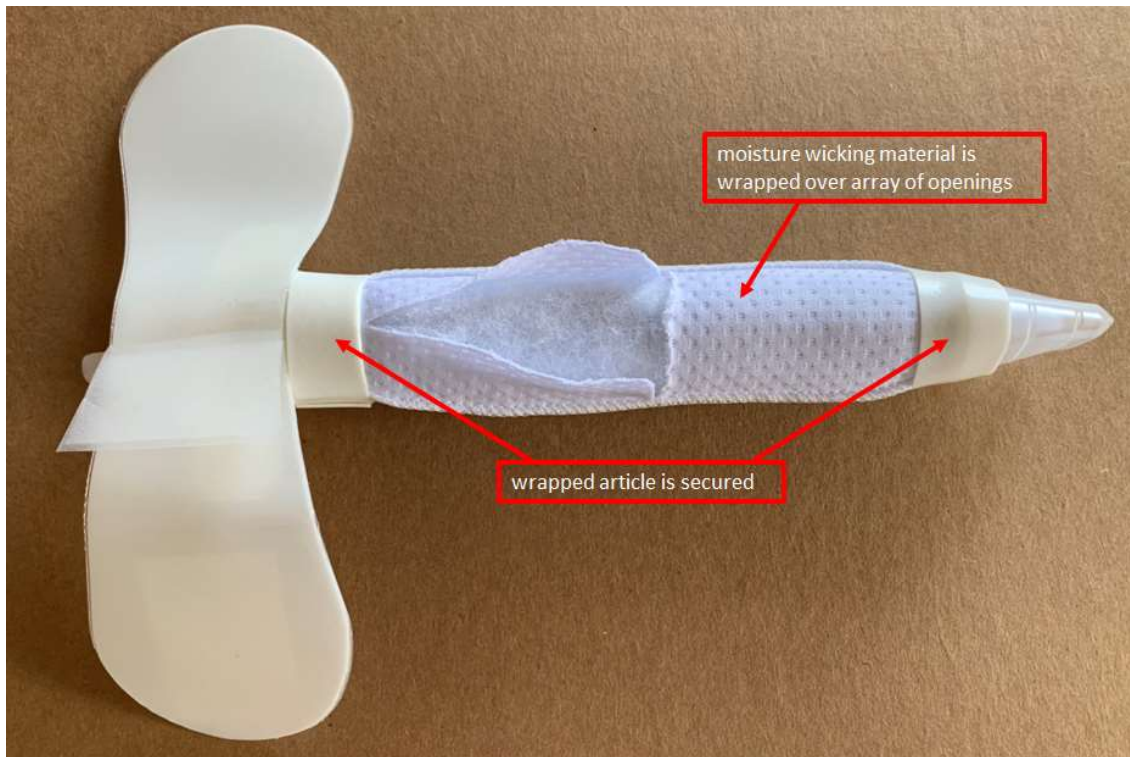
45. The use of the PrimaFit™ product includes an “exterior of the container [that] is configured for enabling a moisture-wicking article to be secured over the array of openings.”

Exhibit 1 at 7:44-47. As shown in the photograph below, a moisture wicking material is secured over the array of openings in the container:



46. The use of the PrimaFit™ product includes “securing a moisture-wicking article over the array of openings by wrapping the article over the array and securing the article.”

Exhibit 1 at 7:48-50.



47. The use of the PrimaFit™ product includes “disposing the secured moisture-wicking article in contact with a region of the person or animal surrounding an urethral opening so that urine from the urethral opening is drawn into the moisture-wicking article.” Exhibit 1 at 7:52-55. Defendant’s product information states “[w]hen properly positioned, PrimaFit’s ultra-soft wicking fabric absorbs and diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister, helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” Exhibit 4. The illustration below, included in Defendant’s product information, also describes these features of the PrimaFit™ product:

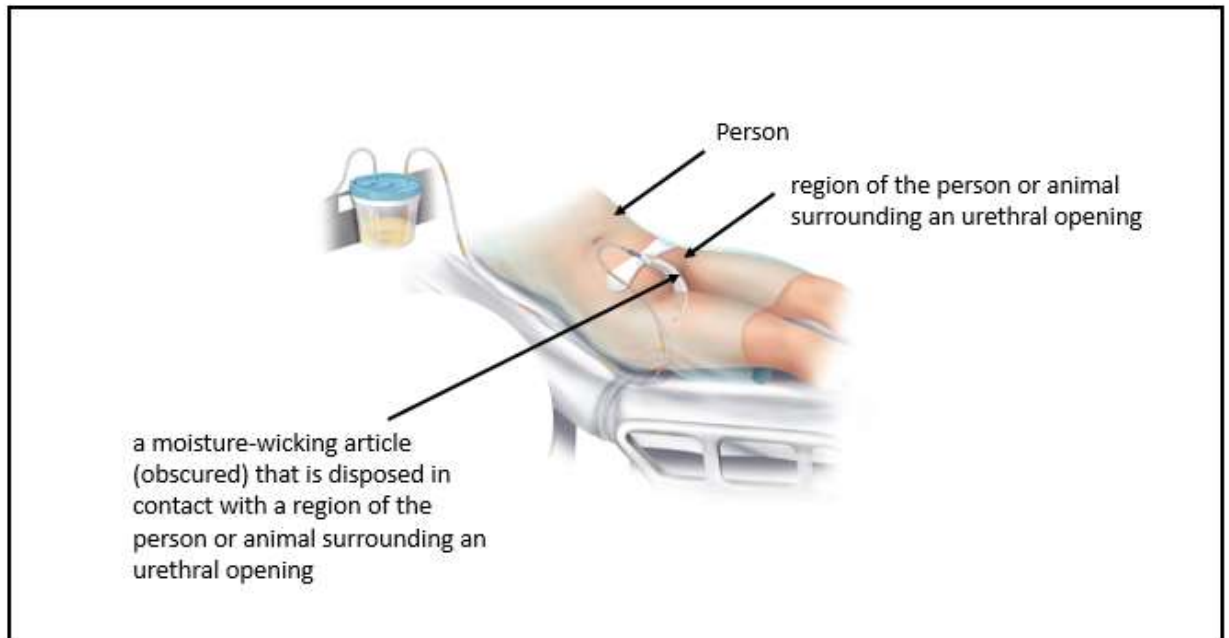


Exhibit 4.

48. The use of the PrimaFit™ product includes “drawing the urine from the moisture-wicking material, through the array of openings and into the chamber from the disposed moisture-wicking article.” Exhibit 1 at 8:1-3. Defendant’s product information states “[w]hen properly positioned, PrimaFit’s ultra-soft wicking fabric absorbs and diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister, helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” Exhibit 4.

49. Thus, the use of the PrimaFit™ product meets every limitation of at least independent claim 10 and Defendant directly infringes at least claim 10 when using the PrimaFit™ product in violation of 35 U.S.C. § 271(a).

50. Defendant also has indirectly infringed and continues to indirectly infringe the claims of the ’508 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

51. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant specifically intended to induce infringement of the '508 patent by its customers and users of the PrimaFit™ product and had knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

52. Defendant knew of the '508 patent since at least as early as June 2016, when it was identified by PureWick to Sage. On information and belief, Defendant's customers directly infringe the '508 patent. For example, when the PrimaFit™ product is sold to hospitals, medical professionals, and patients, those customers infringe at least independent claims 1 and 10 of the '508 patent through the use of the PrimaFit™ product.

53. On information and belief, Defendant specifically intends for customers to infringe the '508 patent. Defendant encourages infringement by customers at least by providing product support that instructs users on how to use the PrimaFit™ product. For example, Defendant provides a "Patient Education Card" and an "Instructions for Use" manual. Exhibits 4 and 5. The manual and education card give detailed instructions for use of the PrimaFit™ product for "non-invasive, non-sterile collection of urine for female patients." Exhibit 6.

54. On information and belief, despite Defendant's knowledge of the '508 patent and knowledge that customers will necessarily infringe the '508 patent when the PrimaFit™ product is used as instructed, Defendant continues to encourage infringement.

55. Defendant also contributes to infringement of the '508 patent by Defendant's customers in violation of 35 U.S.C. §271(c). Defendant knew of the '508 patent since at least as early as June 2016, when it was identified by PureWick to Sage. On information and belief, Defendant offers to sell and sells within the United States the PrimaFit™ product knowing that it constitutes a material part of the claimed inventions, knowing that the PrimaFit™ product is

especially made or especially adapted for use in infringing the '508 patent, and knowing that the PrimaFit™ product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

56. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

57. PureWick has complied with the requirements of 35 U.S.C. § 287 by, among other things, marking its products with the '508 patent, and giving actual notice to Sage by, *inter alia*, service of this Complaint.

58. As a result of Defendant's infringement of the '508 patent, Plaintiff has suffered damages and will continue to suffer damages.

59. On information and belief, the infringement of the '508 Patent by Defendant has been and continues to be willful. Defendant has had knowledge of the '508 patent and knowledge that the PureWick™ FEC Solution is covered by the '508 patent. On information and belief, Defendant copied the PureWick™ FEC Solution despite knowing that the PureWick™ FEC Solution is covered by the '508 patent. Defendant has thus sold the PrimaFit™ knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to Defendant. Despite this risk, Defendant has deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for PureWick's patent rights. Thus, Defendant's infringing actions have been and continue to be consciously wrongful, entitling PureWick to increased damages under 35 U.S.C. § 284.

60. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause

Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using selling, offering to sell, and/or importing Plaintiff's patented inventions. On information and belief, Defendant will continue to infringe the '508 patent unless permanently enjoined by the Court.

COUNT II

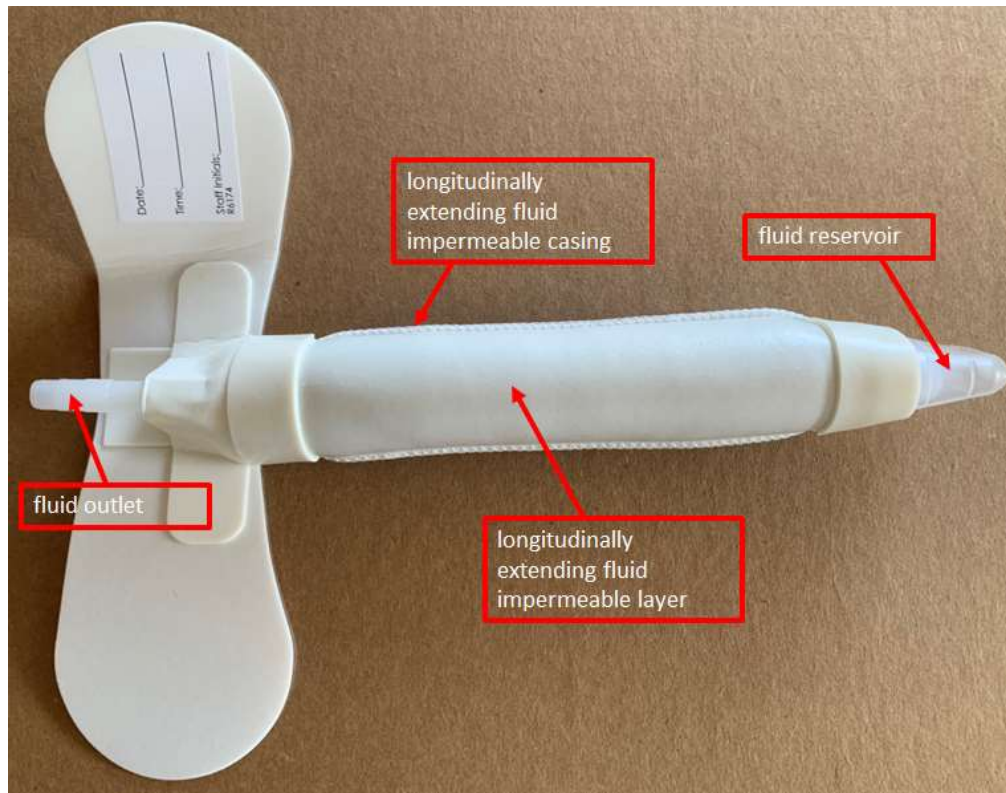
INFRINGEMENT OF THE '376 PATENT

61. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.

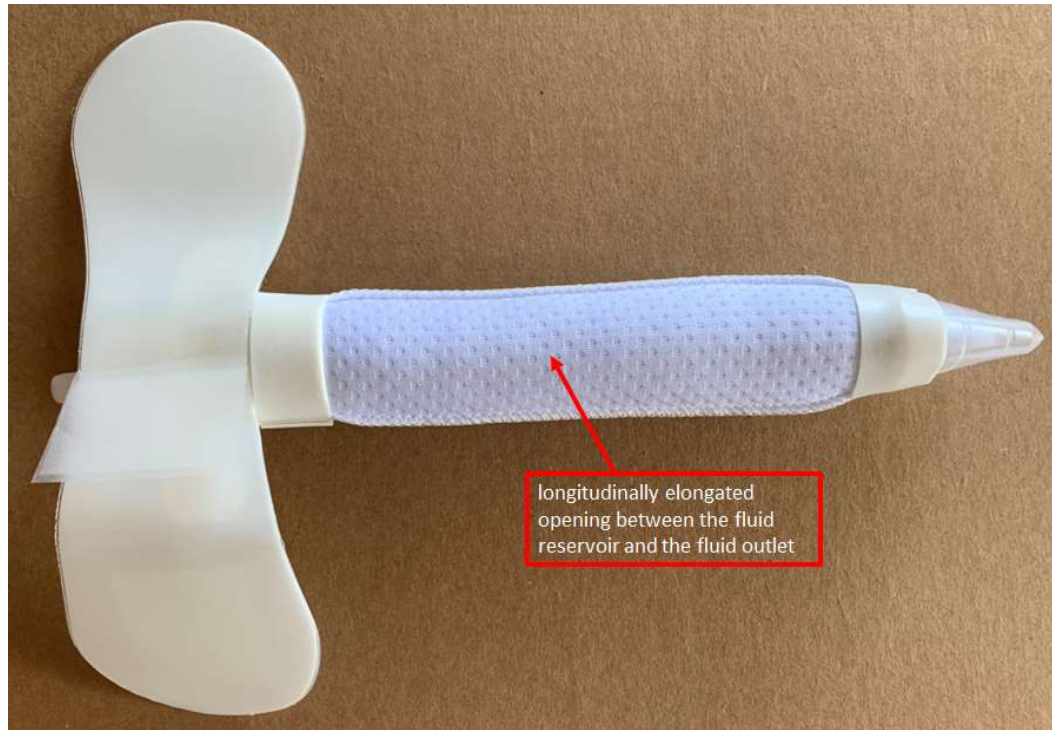
62. Defendant has directly infringed, and continues to directly infringe, claims 1-14 of the '376 patent by making, using, offering for sale, selling, and/or importing into the United States the PrimaFit™ product, and contributed to and/or induced infringement of the '376 patent by others, including hospitals, patients and other customers.

63. For example, and without limitation, on information and belief the PrimaFit™ product meets every limitation of at least independent claim 1 of the '376 patent, and Defendant's making, using, offering for sale, selling, and/or importing the PrimaFit™ product into the United States directly infringes at least claim 1 of the '376 patent under 35 U.S.C. § 271(a).

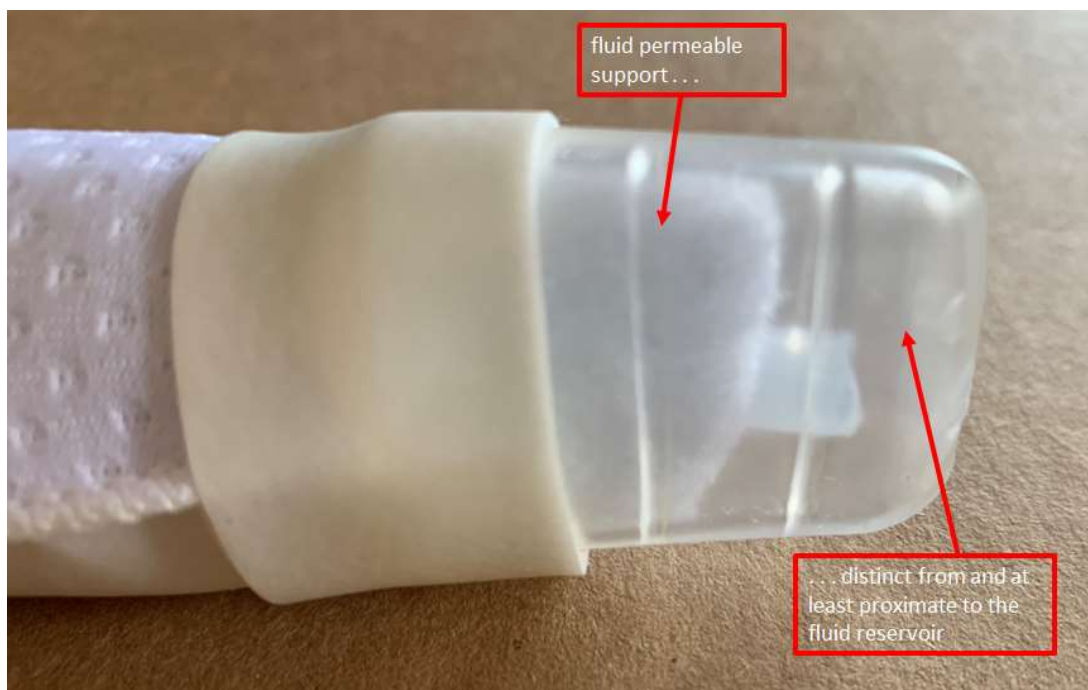
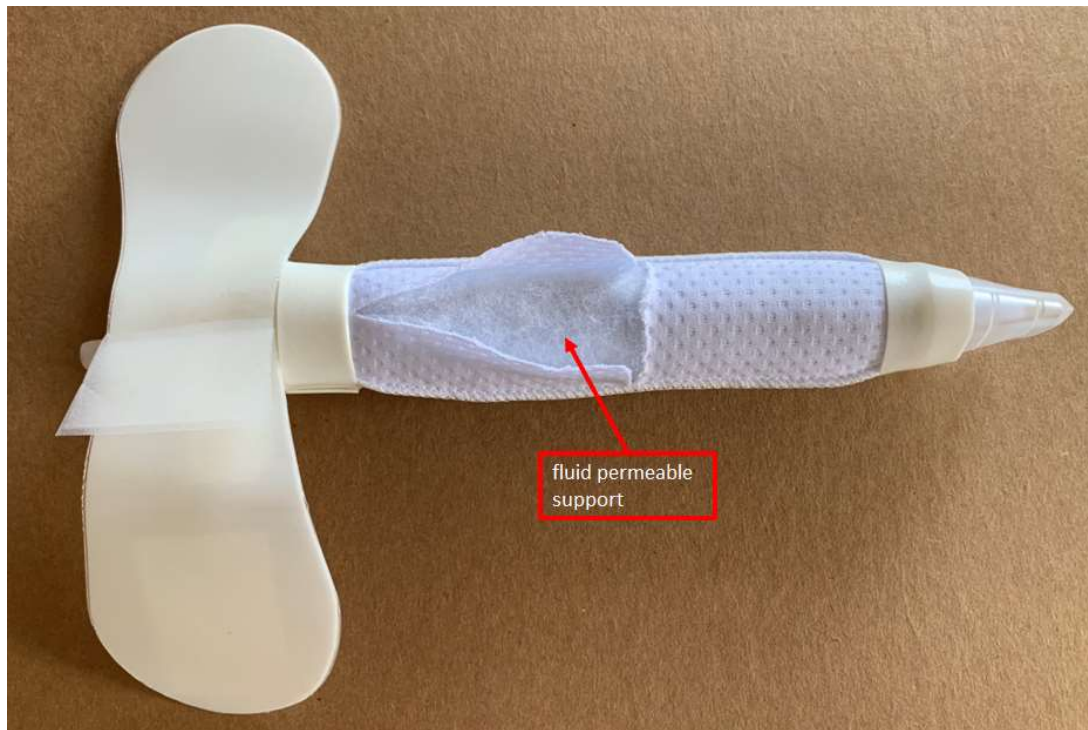
64. The PrimaFit™ product is “[a]n apparatus comprising: a fluid impermeable casing having a fluid reservoir at a first end, a fluid outlet at a second end, and a longitudinally extending fluid impermeable layer coupled to the fluid reservoir and the fluid outlet.” Exhibit 2 at 36:9-13. The annotated photograph below depicts these features of the PrimaFit™ product:



65. As shown in the annotated photograph below, the “longitudinally extending fluid impermeable layer” of the PrimaFit™ product “defin[es] a longitudinally elongated opening between the fluid reservoir and the fluid outlet.” Exhibit 2 at 36:13-15.

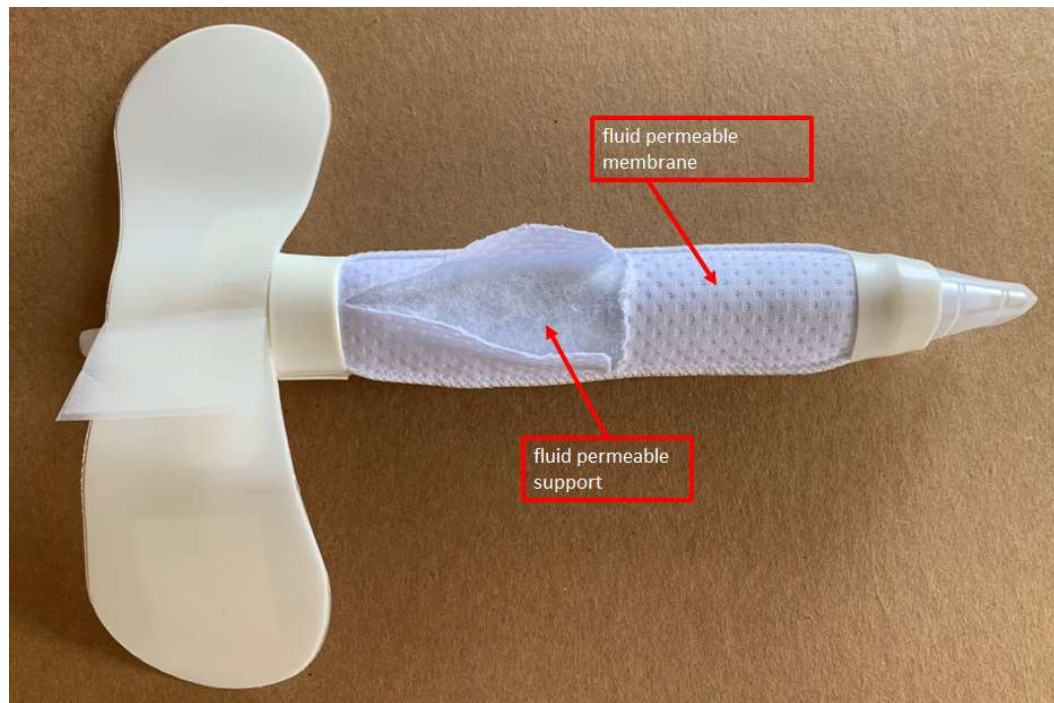


66. As shown in the annotated photographs below, the PrimaFit™ product includes “a fluid permeable support disposed within the casing with a portion extending across the elongated opening, wherein the fluid permeable support is distinct from and at least proximate to the fluid reservoir.” Exhibit 2 at 36:16-19.

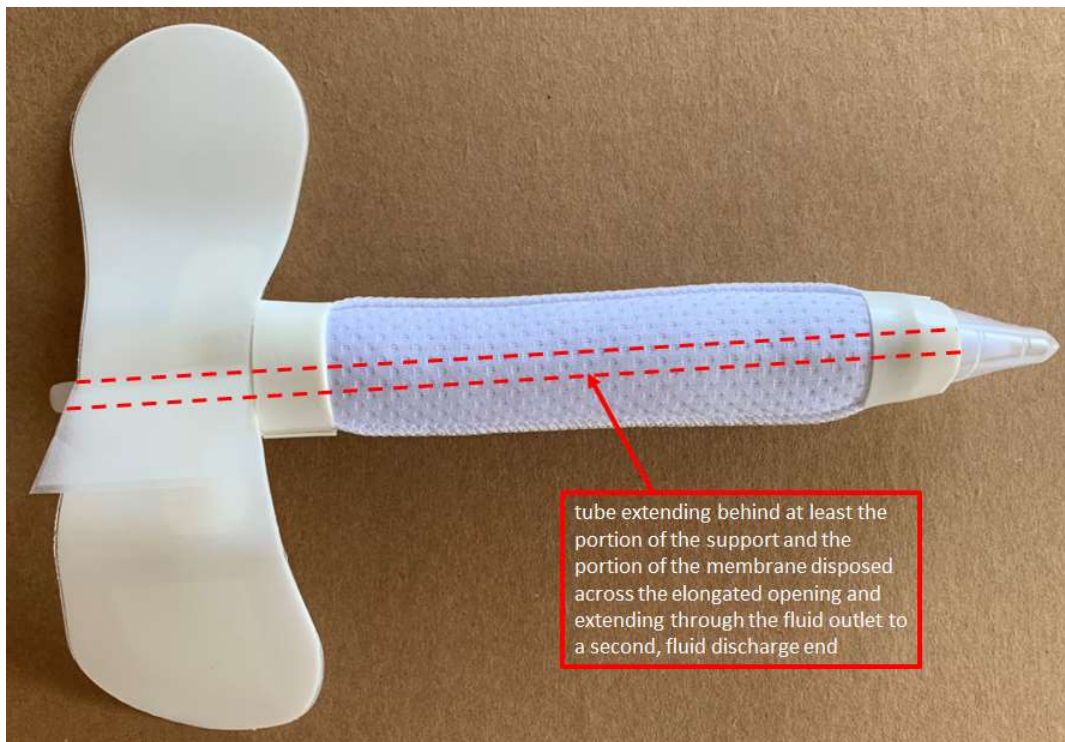
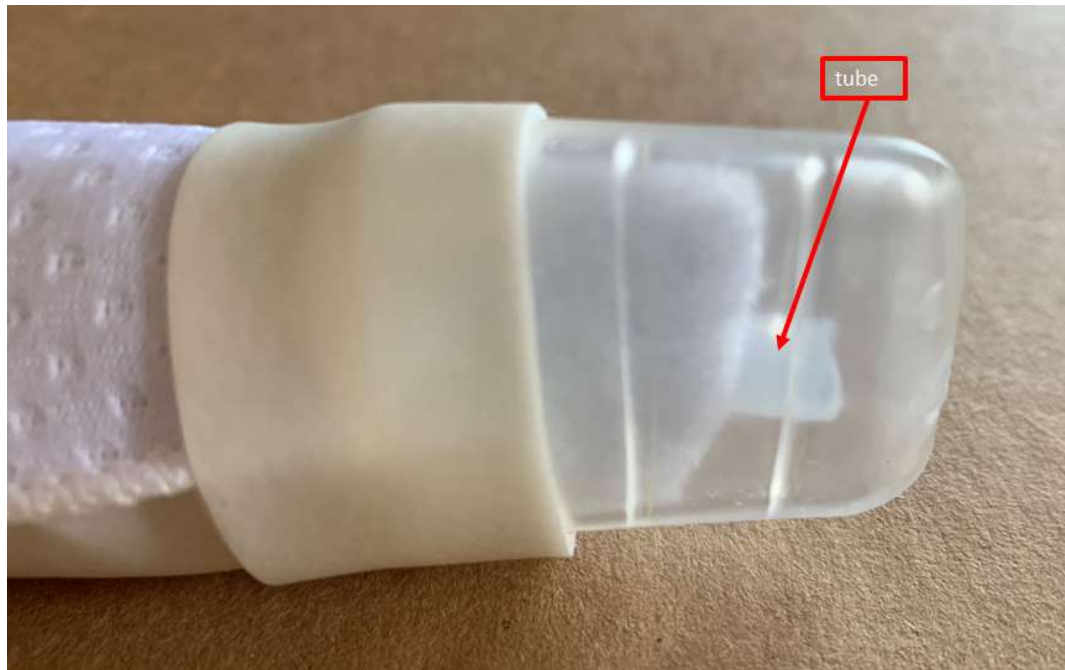


67. As shown in the annotated photograph below, the PrimaFit™ product includes “a fluid permeable membrane disposed on the support and covering at least the portion of the

support that extends across the elongated opening, so that the membrane is supported on the support and disposed across the elongated opening.” Exhibit 2 at 36:20-24.



68. As shown in the annotated photograph below, the PrimaFit™ product includes “a tube having a first end disposed in the reservoir and extending behind at least the portion of the support and the portion of the membrane disposed across the elongated opening and extending through the fluid outlet to a second, fluid discharge end.” Exhibit 2 at 36:25-29.



69. As shown in the annotated illustration below, the PrimaFit™ product is an apparatus “configured to be disposed with the opening adjacent to a urethral opening of a user.” Exhibit 2 at 36:30-31.

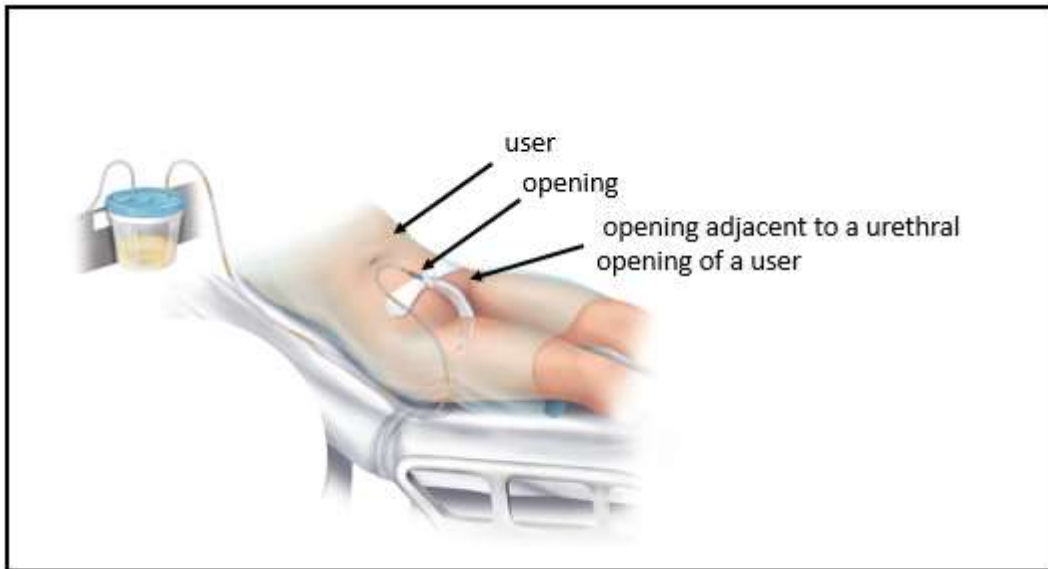
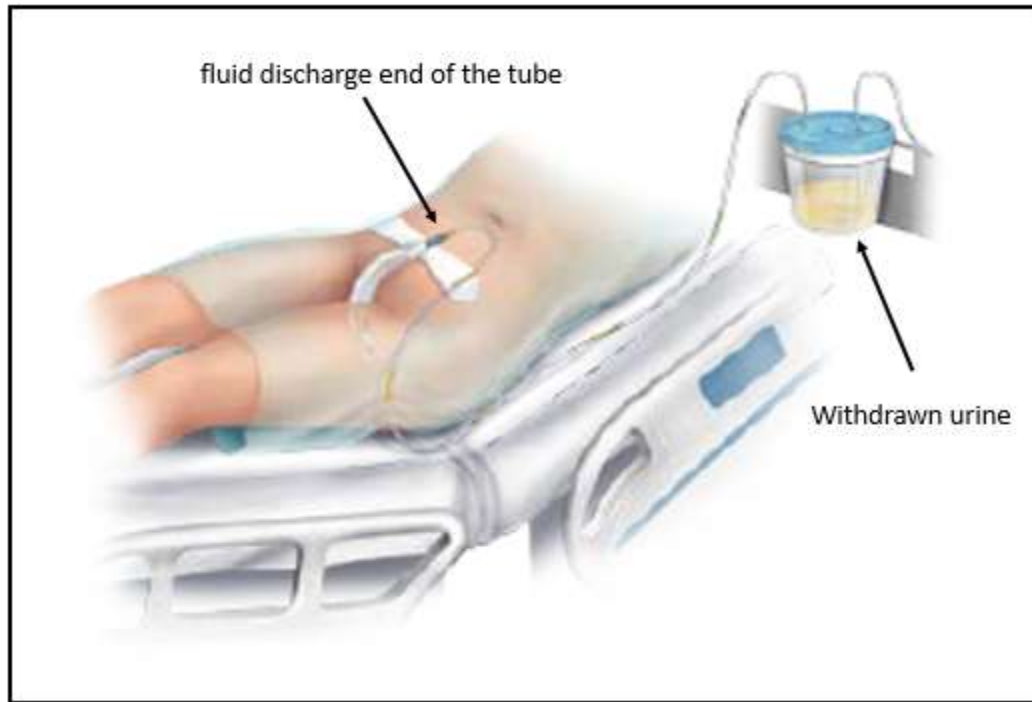


Exhibit 4.

70. The PrimaFit™ product is configured to “receive urine discharged from the urethral opening through the opening of the fluid impermeable layer, the membrane, the support, and into the reservoir.” Exhibit 2 at 36:31-34. The PrimaFit™ product brochure explains the PrimaFit™ product is configured to “divert[] urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister.” Exhibit 4.

71. The PrimaFit™ product is configured such that “the received urine withdrawn from the reservoir via the tube and out of the fluid discharge end of the tube.” Exhibit 2 at 36:34-36. The PrimaFit™ product brochure explains the PrimaFit™ product is configured to “divert[] urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister.” Exhibit 4.



72. Thus, the PrimaFit™ product meets every limitation of at least independent claim 1 of the '376 patent and Defendant directly infringe claim 1 in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling, and/or importing the PrimaFit™ product into the United States.

73. Defendant also has indirectly infringed and continues to indirectly infringe the claims of the '376 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

74. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant specifically intended to induce infringement of the '376 patent by its customers and users of the PrimaFit™ product and had knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

75. Defendant knew or should have known of the '376 patent on or around March 12, 2019 when the patent issued. The applications to which the '376 patent claims priority were identified to Sage by PureWick.

76. Additionally, Plaintiff and Defendant are direct and active competitors in the two-competitor field of female external urine management systems and thus it is highly likely that Defendant would have been aware when the '376 patent issued.

77. On information and belief, Defendant's customers directly infringe the '376 patent. For example, when the PrimaFit™ product is sold to hospitals, medical professionals, and patients, those customers infringe at least independent claim 1 of the '376 patent through the use of the PrimaFit™ product.

78. On information and belief, Defendant specifically intends for customers to infringe the '376 patent. Defendant encourages infringement by customers at least by providing product support that instructs users on how to use the PrimaFit™ product. For example, Defendant provides a "Patient Education Card" and an "Instructions for Use" manual. Exhibits 4 and 5. The manual and education card give detailed instructions for use of the PrimaFit™ for "non-invasive, non-sterile collection of urine for female patients." Exhibit 6.

79. On information and belief, despite Defendant's knowledge of the '376 patent and knowledge that customers will necessarily infringe the '376 patent when the PrimaFit™ product is used as instructed, Defendant continues to encourage infringement.

80. Defendant also contributes to infringement of the '376 patent by Defendant's customers in violation of 35 U.S.C. §271(c). On information and belief, Defendant was aware of the '376 patent at least as early as March 2019. On information and belief, Defendant offers to sell and sells within the United States the PrimaFit™ product knowing that it constitutes a

material part of the claimed inventions, knowing that the PrimaFit™ product is especially made or especially adapted for use in infringing the '376 patent, and knowing that the PrimaFit™ product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

81. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

82. PureWick has given actual notice to Sage of its infringement of the '376 patent by, *inter alia*, service of this Complaint.

83. As a result of Defendant's infringement of the '376 patent, Plaintiff has suffered damages and will continue to suffer damages.

84. On information and belief, the infringement of the '376 patent by Defendant has been and continues to be willful. Defendant has had knowledge of the '376 patent and knowledge that the PureWick™ FEC Solution is covered by the '376 patent. On information and belief, Defendant copied the PureWick™ FEC Solution and continued to sell the PrimaFit™ despite knowing that the PureWick™ FEC Solution is covered by the '376 patent. Defendant has thus sold the PrimaFit™ knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to Defendant. Despite this risk, Defendant has deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for PureWick's patent rights. Thus, Defendant's infringing actions have been and continue to be consciously wrongful, entitling PureWick to increased damages under 35 U.S.C. § 284.

85. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause

Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using selling, offering to sell, and/or importing Plaintiff's patented inventions. On information and belief, Defendant will continue to infringe the '376 patent unless permanently enjoined by the Court.

COUNT III

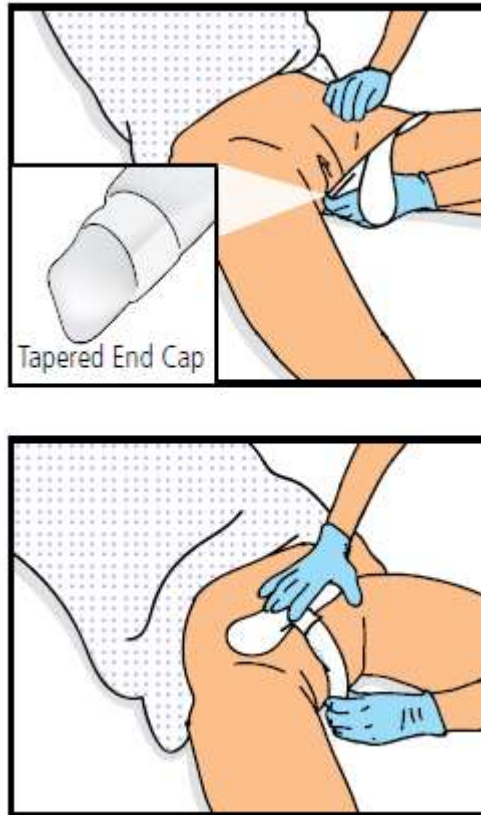
INFRINGEMENT OF THE '989 PATENT

86. The allegations in the preceding paragraphs are incorporated by reference as if fully set forth herein.

87. Defendant has directly infringed, and continues to directly infringe, claims 1-6 of the '989 patent by making, using, offering for sale, selling, and/or importing into the United States the PrimaFit™ product, and contributed to and/or induced infringement of the '989 patent by others, including hospitals, patients and other customers.

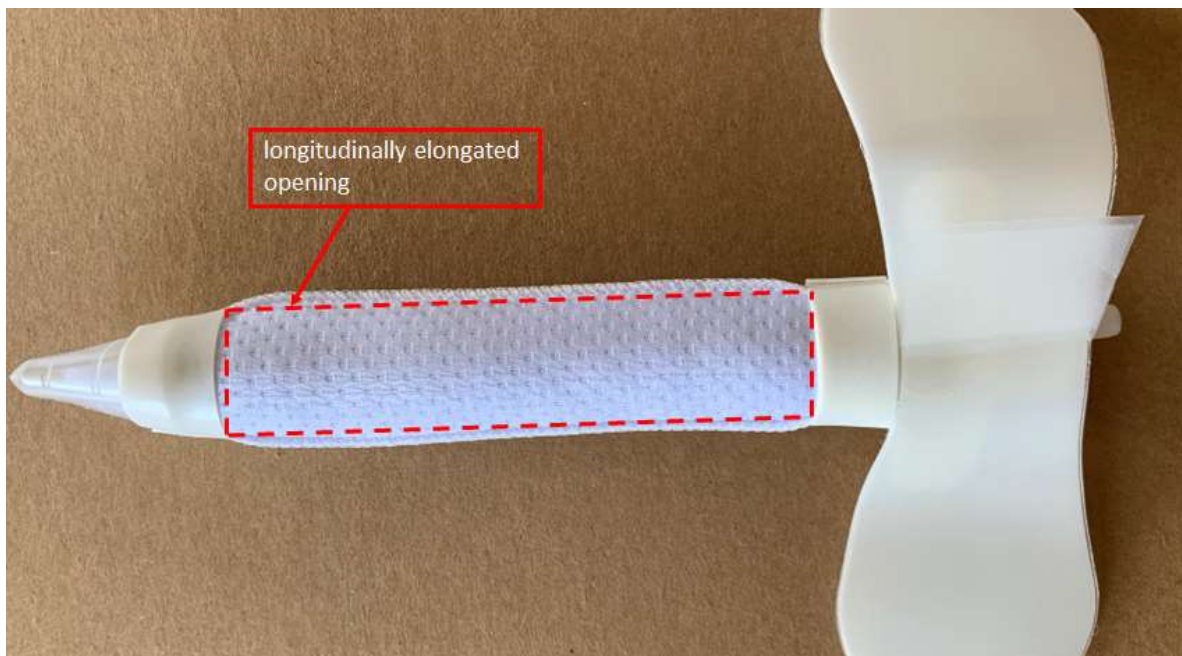
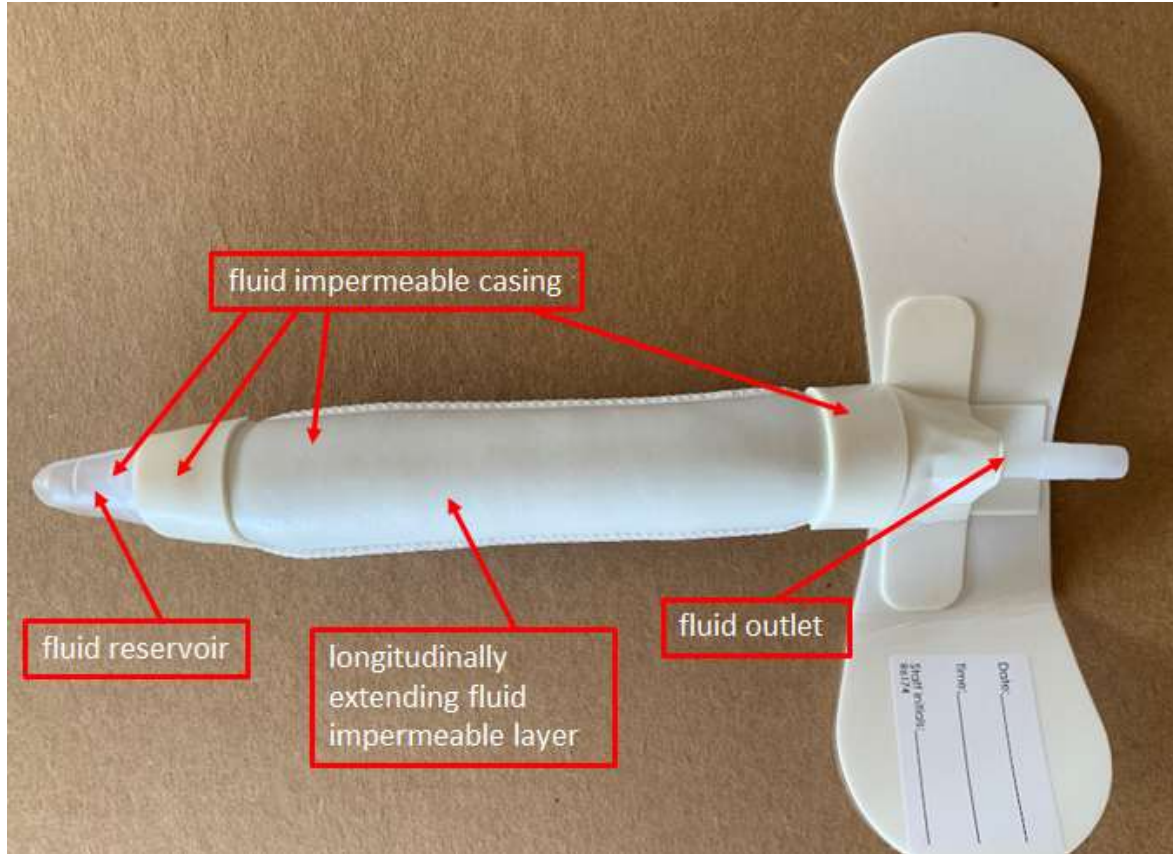
88. For example, and without limitation, on information and belief the PrimaFit™ product meets every limitation of at least independent method claim 1 of the '989 patent, and Defendant's making, using, offering for sale, selling, and/or importing the PrimaFit™ product into the United States directly infringes at least claim 1 of the '989 patent under 35 U.S.C. § 271(a).

89. The use of the PrimaFit™ product practices a "method comprising: disposing in operative relationship with the urethral opening of a female user a urine collecting apparatus." Exhibit 3 at 27:44-47. Defendant's Instructions for Use manual instructs the user to "[a]lign Tapered End Cap with perineum and place device between the labia and against the urethral opening. Ensure absorbent fabric is covering the urethral meatus" and illustrates such positioning on the user. Exhibit 5.

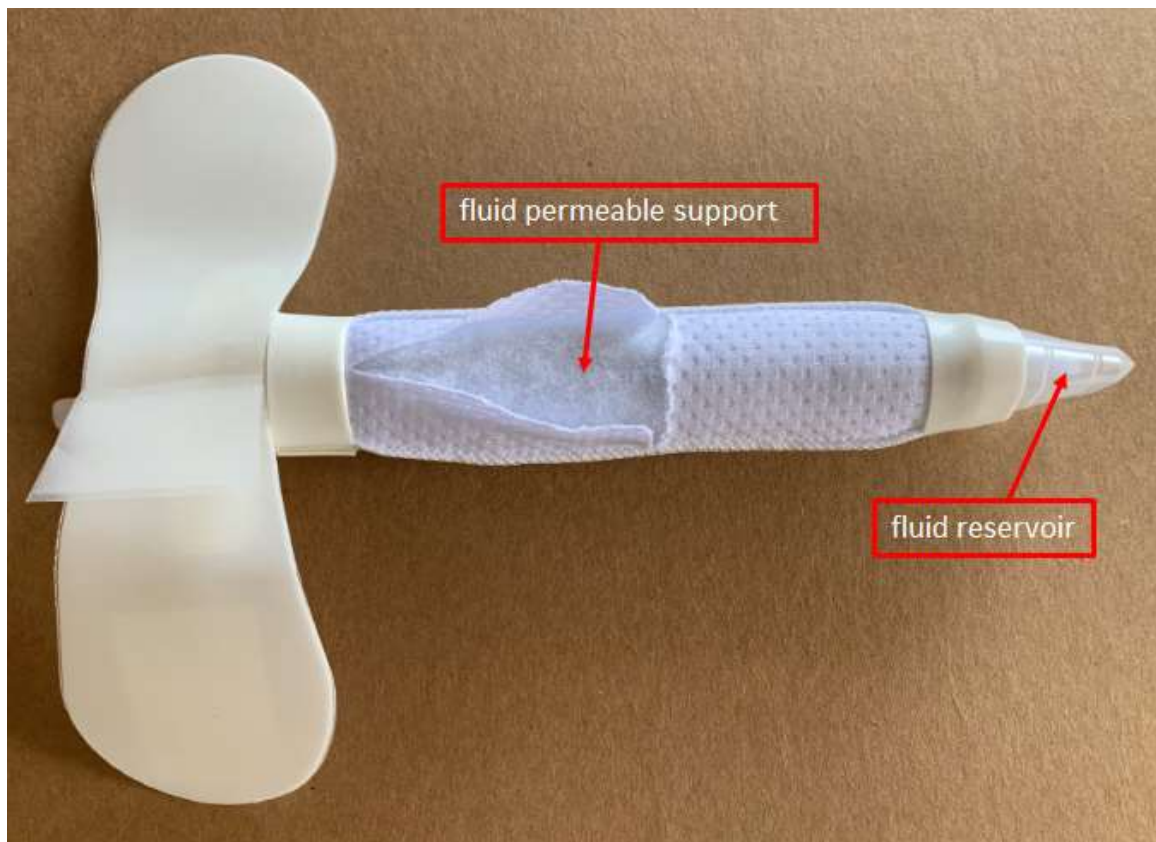


90. As shown in the photographs below, the PrimaFit™ product includes “a fluid impermeable casing having a fluid reservoir at a first end, a fluid outlet at a second end, and a longitudinally extending fluid impermeable layer coupled to the fluid reservoir and the fluid outlet and defining a longitudinally elongated opening between the fluid reservoir and the fluid

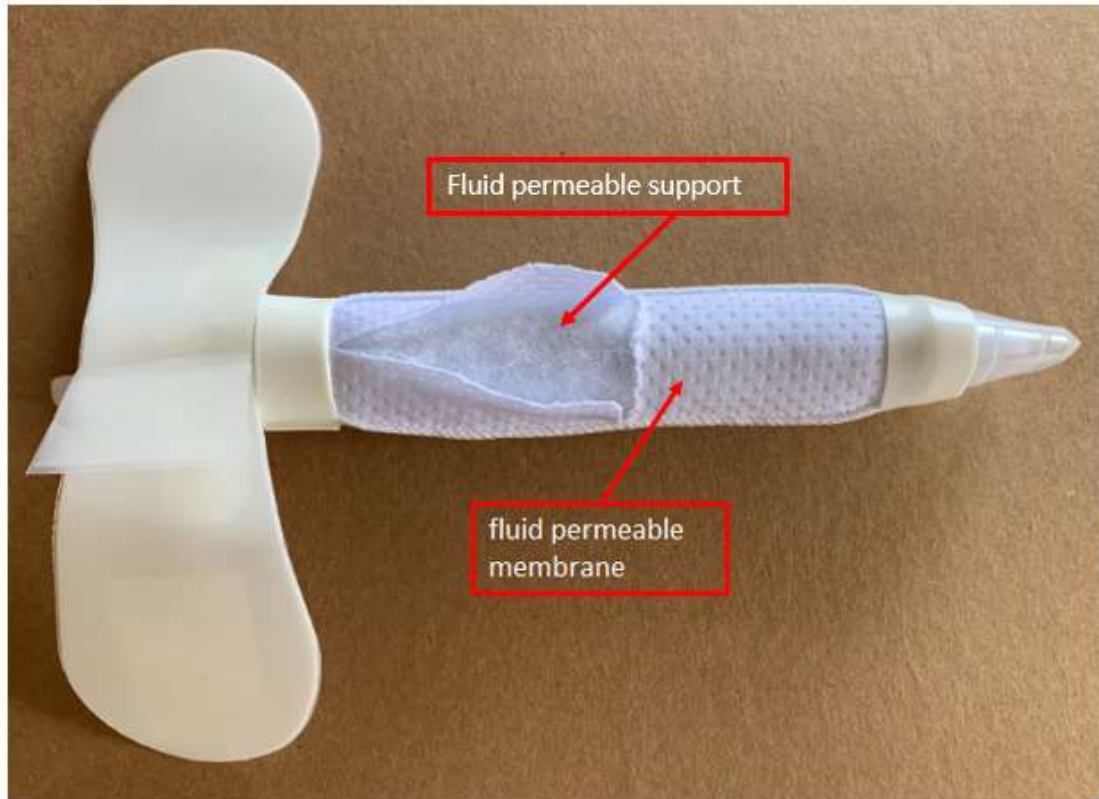
outlet” Exhibit 3 at 27:48-53.



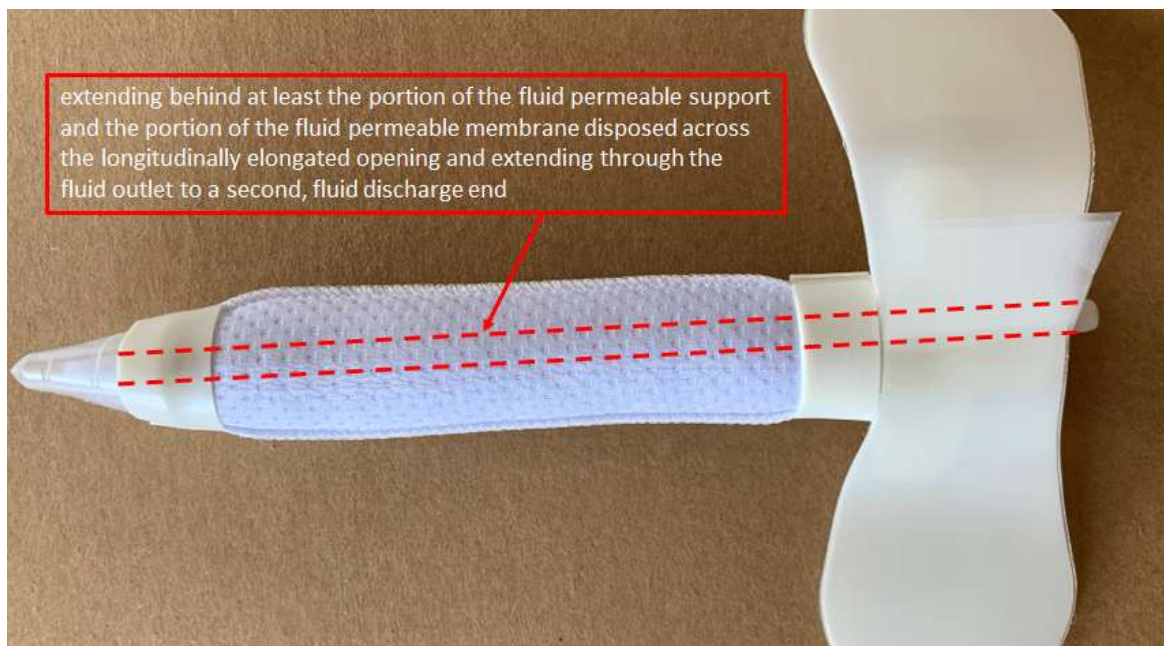
91. As shown in the photograph below, the PrimaFit™ product includes “a fluid permeable support disposed within the fluid impermeable casing with a portion extending across the longitudinally elongated opening, wherein the fluid permeable support is distinct from and at least proximate to the fluid reservoir.” Exhibit 3 at 54-58.



92. As shown in the photograph below, the PrimaFit™ product includes “a fluid permeable membrane disposed on the fluid permeable support and covering at least the portion of the fluid permeable support that extends across the longitudinally elongated opening, so that the fluid permeable membrane is supported on the fluid permeable support and disposed across the longitudinally elongated opening.” Exhibit 3 at 27:59-65



93. As shown in the photographs below, the PrimaFit™ product includes “a tube having a first end disposed in the fluid reservoir and extending behind at least the portion of the fluid permeable support and the portion of the fluid permeable membrane disposed across the longitudinally elongated opening and extending through the fluid outlet to a second, fluid discharge end, the operative relationship includes the longitudinally elongated opening being adjacent to the urethral opening.” Exhibit 3 at 27:66-28:4.

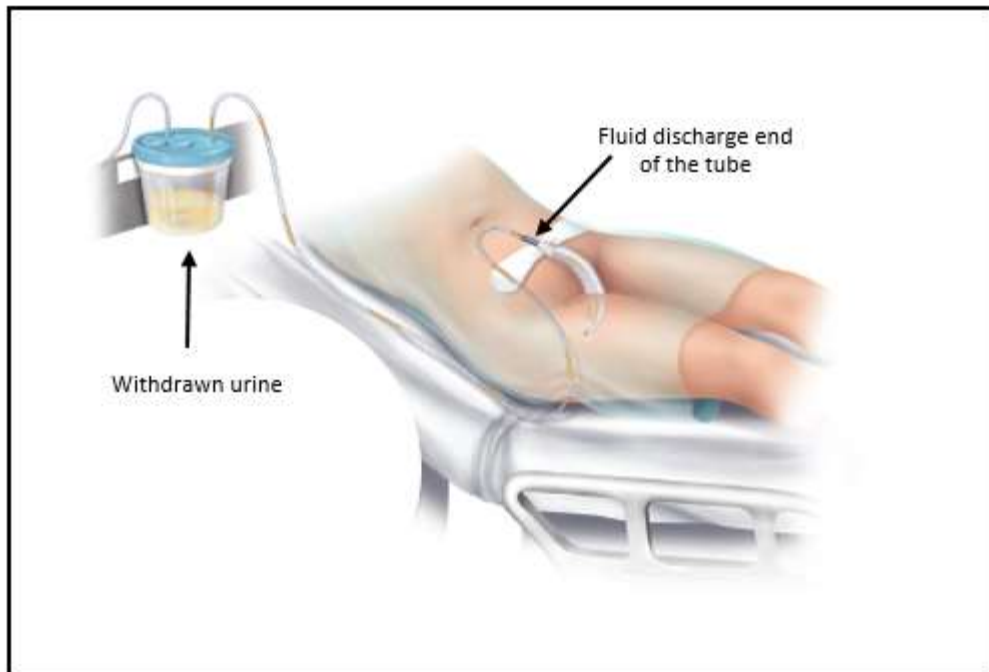


94. Use of the PrimaFit™ product “allow[s] urine discharged from the urethral opening to be received through the longitudinally elongated opening of the longitudinally extending fluid impermeable layer, the fluid permeable membrane, the fluid permeable support,

and into the fluid reservoir.” Exhibit 3 at 28:5-12. Defendant’s Product Brochure explains “[w]hen properly positioned, PrimaFit’s ultra-soft wicking fabric absorbs and diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister, helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” . Exhibit 4. This is further shown in the illustration provided in Defendant’s Product Brochure. *Id.*



95. Use of the PrimaFit™ product “allow[s] the received urine to be withdrawn from the fluid reservoir via the tube and out of the fluid discharge end of the tube.” Exhibit 3 at 28:13-15. Defendant’s Product Brochure explains “PrimaFit’s ultra-soft wicking fabric absorbs and diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister.” Exhibit 4. This is further shown in the illustration provided in Defendant’s Product Brochure. *Id.*



96. Thus, the use of the PrimaFit™ product meets every limitation of at least independent claim 1 of the '989 patent and Defendant directly infringes claim 1 in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling, and/or importing the PrimaFit™ product into the United States.

97. Defendant also has indirectly infringed and continues to indirectly infringe the claims of the '989 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

98. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant specifically intended to induce infringement of the '989 patent by its customers and users of the PrimaFit™ product and had knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

99. Defendant knew or should have known of the '989 patent on or around August 27, 2019 when the patent issued. The applications to which the '989 patent claims priority were identified to Sage by PureWick prior to the issuance of the '989 patent.

100. Additionally, Plaintiff and Defendant are direct and active competitors in the two-competitor field of female external urine management systems and thus it is highly likely that Defendant would have been aware when the '989 patent issued.

101. On information and belief, Defendant's customers directly infringe the '989 patent. For example, when the PrimaFit™ product is sold to hospitals, medical professionals, and patients, those customers infringe at least independent claim 1 of the '989 patent through the use of the PrimaFit™ product.

102. On information and belief, Defendant specifically intends for customers to infringe the '989 patent. Defendant encourages infringement by customers at least by providing product support that instructs users on how to use the PrimaFit™ product. For example, Defendant provides a "Patient Education Card" and an "Instructions for Use" manual. Exhibits 5 and 6. The manual and education card give detailed instructions for use of the PrimaFit™ for "non-invasive, non-sterile collection of urine for female patients." Exhibit 6.

103. On information and belief, despite Defendant's knowledge of the '989 patent and knowledge that customers will necessarily infringe the '989 patent when the PrimaFit™ product is used as instructed, Defendant continues to encourage infringement.

104. Defendant also contributes to infringement of the '989 patent by Defendant's customers in violation of 35 U.S.C. §271(c). On information and belief, Defendant was aware of the '989 patent at least as early as August 2019. On information and belief, Defendant offers to sell and sells within the United States the PrimaFit™ product knowing that it constitutes a

material part of the claimed inventions, knowing that the PrimaFit™ product is especially made or especially adapted for use in infringing the '989 patent, and knowing that the PrimaFit™ product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

105. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

106. PureWick has given actual notice to Sage of its infringement of the '989 patent by, *inter alia*, service of this Complaint.

107. As a result of Defendant's infringement of the '989 patent, Plaintiff has suffered damages and will continue to suffer damages.

108. On information and belief, the infringement of the '989 patent by Defendant has been and continues to be willful. Defendant has had knowledge of the '989 patent and knowledge that the PureWick™ FEC Solution is covered by the '989 patent. On information and belief, Defendant copied the PureWick™ FEC Solution and continued to sell the PrimaFit™ despite knowing that the PureWick™ FEC Solution is covered by the '989 patent. Defendant has thus sold the PrimaFit™ knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to Defendant. Despite this risk, Defendant has deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for PureWick's patent rights. Thus, Defendant's infringing actions have been and continue to be consciously wrongful, entitling PureWick to increased damages under 35 U.S.C. § 284.

109. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause

Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using selling, offering to sell, and/or importing Plaintiff's patented inventions. On information and belief, Defendant will continue to infringe the '989 patent unless permanently enjoined by the Court.

COUNT IV

INFRINGEMENT OF THE '407 PATENT

110. The allegations in the preceding paragraphs are incorporated by reference as if fully set forth herein.

111. Defendant has directly infringed, and continues to directly infringe, claims 1-16 of the '407 patent by making, using, offering for sale, selling, and/or importing into the United States the PrimoFit™ product.

112. For example, and without limitation, on information and belief the PrimoFit™ product meets every limitation of at least independent claim 1 of the '407 patent and Defendant's making, using, offering for sale, selling, and/or importing the PrimoFit™ product into the United States directly infringes claim 1 of the '407 patent under 35 U.S.C. § 271(a).

113. The PrimoFit™ product is “[a] device for use to collect urine flowing from a penis of a person or an animal in such a manner that the urine can be transported from the device as the urine is being collected.” Exhibit 7 at 3:20-23. Defendants' product information states that the PrimoFit™ is a “male urine management system [that] uses continuous suction to help promote early catheter removal.” <https://www.stryker.com/us/en/sage/products/sage-primofit.html>. Use of the device to collect urine is depicted in the diagram below:



114. As shown in the annotated photograph below, the PrimoFit™ product includes “a flexible layer of porous material having a first side and a second side.” Exhibit 7 at 3:24-35.



115. As shown in the photograph below, there is a “a flexible wicking material having a first side and a second side” and “the second side of the flexible wicking material [is] disposed on the first side of the flexible layer of porous material.” Exhibit 7 at 3:26-29.



116. The PrimoFit™ product includes “a flexible layer of impermeable material defining an interior portion of the device,” as shown in the photograph below. “[T]he flexible layer of porous material and the flexible wicking material [are] positioned within the interior portion defined by the flexible layer of impermeable material.” Exhibit 7 at 3:30-34.



117. The annotated photograph below further shows that “at least a portion of the second side of the flexible layer of porous material [is] secured to the flexible layer of impermeable material.” Exhibit 7 at 3:34-37.



118. As shown in the annotated photographs below, the PrimoFit™ product includes “a chamber of void space positioned within the interior portion of the device between the flexible layer of porous material and the flexible layer of impermeable material, the chamber being

defined at least partially by the second side of the porous material and the flexible layer of impermeable material.” Exhibit 7 at 3:38-43.



119. The diagram below shows that “the chamber is... configured to collect urine for transport.” Exhibit 7 at 3:38-44.



120. The chamber in the PrimoFit™ product includes “a port for receiving a tube to transport urine from the chamber by drawing urine from the chamber through the tube when a vacuum is applied within the chamber via the tube received by the port” (Exhibit 7 at 3:44-48), as shown below:



121. The diagram below further shows that the PrimoFit™ product includes “a receptacle within the interior portion of the device dimensioned and configured to receive a head of the penis within the receptacle, the receptacle being defined at least partially by at least a portion of the first side of the flexible wicking material, wherein the flexible wicking material and the layer of impermeable material are dimensioned and configured to shape the receptacle to receive the head of the penis therein.” Exhibit 7 at 3:49-57.



122. Defendant's product materials further show that "the receptacle is configured to draw urine flowing from said penis through the flexible wicking material and the porous material into the chamber when the head of the penis is disposed within the receptacle and the vacuum is applied within the chamber via the tube received by the port." Exhibit 7 at 3:57-62. For example, the product brochure states, consistent with the above diagram, that "PrimoFit's ultra-soft wicking fabric diverts urine away from the patient's skin. Urine is then diverted through the wicking chamber and suctioned into a canister."

123. Thus, the PrimoFit™ product meets every limitation of at least independent claim 1 of the '407 patent and Defendant directly infringes at least claim 1 in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling, and/or importing the PrimoFit™ product into the United States.

124. Defendant has committed and continues to commit the above acts of infringement without license or authorization.

125. As a result of Defendant's infringement of the '407 patent, Plaintiff has suffered damages and will continue to suffer damages.

126. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using selling, offering to sell, and/or importing Plaintiff's patented inventions. On information and belief, Defendant will continue to infringe the '407 patent unless permanently enjoined by the Court.

JURY DEMAND

127. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff respectfully demands a trial by jury of all issues so triable.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff requests that judgment be entered in favor of Plaintiff and against Defendant as follows:

- a. A judgment that the '508, '376 and '989 patents are directly and indirectly infringed by Defendant's manufacture, offers to sell, sales, or uses within the United States, or importation into the United States, of products, including without limitation PrimaFit™, that practice one more of the inventions claimed in the '508, '376 and '989 patents;
- b. A judgment that the '407 patent is directly infringed by Defendant's manufacture, offers to sell, sales, or uses within the United States, or importation into the United States, of products, including without limitation PrimoFit™, that practice one more of the inventions claimed in the '407 patent;

- c. An order permanently enjoining Defendant, its affiliates and subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing products claimed in any of the claims of the '508, '376, '989 and '407 patents, and from causing or encouraging others to use, sell, offer for sale, or import products that infringe any claim of the '508, '376, '989 and '407 patents, until after the expiration dates of the '508, '376, '989 and '407 patents, including any extensions and/or additional periods of exclusivity to which Plaintiff is or may become entitled;
- d. An order awarding damages under 35 U.S.C. § 284 in an amount sufficient to compensate Plaintiff for its damages arising from infringement by Defendant, including, but not limited to, lost profits and/or a reasonable royalty, together with pre-judgment and post-judgment interest, and costs;
- e. An order awarding treble damages for willful infringement by Defendant, pursuant to 35 U.S.C. § 284;
- f. An accounting and/or supplemental damages for all damages occurring after any discovery cutoff and through the Court's decision regarding the imposition of a permanent injunction;
- g. A judgment declaring that this case is exceptional and awarding Plaintiff its reasonable costs and attorneys' fees pursuant to 35 U.S.C. § 285; and
- h. Such other relief as this Court or a jury may deem proper and just under the circumstances.

Respectfully submitted,

/s/ *John W. Shaw*

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, Delaware 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

Steven C. Cherny
Brian P Biddinger
Matthew A. Traupman
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, New York 10010
(212) 849-7000

Amanda K. Antons
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
191 N. Wacker Drive, Suite 2700
Chicago, Illinois 60606
(312) 705-7400

Dated: May 18, 2020

Attorneys for Plaintiff