

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC. and)	
ALLERGAN INDUSTRIE SAS,)	
)	
Plaintiffs,)	
)	C.A. No. 19-126 (CFC)
v.)	
)	JURY TRIAL DEMANDED
PROLLENIUM US INC. and PROLLENIUM)	
MEDICAL TECHNOLOGIES INC.,)	
)	
Defendants.)	

AMENDED COMPLAINT

Plaintiffs Allergan USA, Inc. and Allergan Industrie SAS (collectively, “Allergan” or “Plaintiffs”), for their amended complaint against Defendants Prollenium US Inc. (“PUS”) and Prollenium Medical Technologies, Inc. (“PMT”) (PUS and PMT collectively “Prollenium”), hereby allege as follows and demand a jury trial on all issues so triable.

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 8,450,475 (“the ’475 patent”), 8,357,795 (“the ’795 patent”), 8,822,676 (“the ’676 patent”), 9,089,519 (“the ’519 patent”), 9,238,013 (“the ’013 patent”), and 9,358,322 (“the ’322 patent”), which arises under the Patent Laws of the United States, Title 35, United States Code, §§ 100 *et seq.*, including 35 U.S.C. §§ 271 and 281.

PARTIES

2. Allergan USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

3. Allergan Industrie SAS is a company incorporated in France, with a principal place of business at Route de Promery, 254 ZA Pre Mairy, 74370 Pringy, France.

4. On information and belief, Prollenium US Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 9121 Anson Way, Suite 200, Raleigh, North Carolina 27615.

5. On information and belief, Prollenium Medical Technologies Inc. is a corporation organized and existing under the laws of Canada, with a principal place of business at 138 Industrial Parkway N, Aurora, Ontario Canada.

6. On information and belief, Prollenium US Inc. is a subsidiary of Prollenium Medical Technologies Inc.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because the action concerns a federal question arising under patent laws of the United States including 35 U.S.C. §§ 271 and 281.

8. On information and belief, this Court has jurisdiction over Prollenium. On information and belief, PUS is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Raleigh, North Carolina. On information and belief, PMT is a foreign corporation organized and existing under the laws of Canada.

9. On information and belief, Prollenium has placed infringing products into the stream of commerce by manufacturing, shipping, importing, offering for sale and/or selling those products in this judicial district and/or knowing that such products would be manufactured, imported and/or shipped into this judicial district to be offered for sale and/or sold in this judicial district.

10. On information and belief, Prollenium has made, used, sold, offered to sell, and/or imported into this judicial district products that infringe the '475, '795, '676, '519, '013, and '322 Patents in this district.

11. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

The Patents-In-Suit

12. The '475 Patent, titled "Hyaluronic Acid-Based Gels Including Lidocaine," duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on May 28, 2013. A true and correct copy of the '475 Patent is attached to this complaint as Exhibit A.

13. The '475 Patent is assigned to Allergan Industrie SAS.

14. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the '475 Patent.

15. Allergan USA, Inc. is the exclusive licensee of the '475 Patent.

16. The '795 Patent, titled "Hyaluronic Acid-Based Gels Including Lidocaine," duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on January 22, 2013. A true and correct copy of the '795 Patent is attached to this complaint as Exhibit B.

17. The '795 Patent is assigned to Allergan Industrie SAS.

18. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the '795 Patent.

19. Allergan USA, Inc. is the exclusive licensee of the '795 Patent.

20. The '676 Patent, titled "Hyaluronic Acid-Based Gels Including Lidocaine," duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on September 2, 2014. A true and correct copy of the '676 Patent is attached to this complaint as Exhibit C.

21. The '676 Patent is assigned to Allergan Industrie SAS.

22. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the '676 Patent.

23. Allergan USA, Inc. is the exclusive licensee of the '676 Patent.

24. The '519 Patent, titled "Hyaluronic Acid-Based Gels Including Lidocaine," duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on July 28, 2015. A true and correct copy of the '519 Patent is attached to this complaint as Exhibit D.

25. The '519 Patent is assigned to Allergan Industrie SAS.

26. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the '519 Patent.

27. Allergan USA, Inc. is the exclusive licensee of the '519 Patent.

28. The '013 Patent, titled "Hyaluronic Acid-Based Gels Including Lidocaine," duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton on January 19, 2016. A true and correct copy of the '013 Patent is attached to this complaint as Exhibit E.

29. The '013 Patent is assigned to Allergan Industrie SAS.

30. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the '013 Patent.

31. Allergan USA, Inc. is the exclusive licensee of the '013 Patent.

32. The '322 Patent titled "Hyaluronic Acid-Based Gels Including Lidocaine," duly and legally issued by the United States Patent & Trademark Office to inventor Pierre F. Lebreton

on June 7, 2016. A true and correct copy of the '322 Patent is attached to this complaint as Exhibit F.

33. The '322 Patent is assigned to Allergan Industrie SAS.

34. Allergan Industrie SAS, as assignee, owns the entire right, title, and interest in the '322 Patent.

35. Allergan USA, Inc. is the exclusive licensee of the '322 Patent.

36. The '475, '795, '676, '519, '013, and '322 Patents are directed to dermal and subdermal fillers based on hyaluronic acid and pharmaceutically acceptable salts thereof. Dermal fillers are compositions that are injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth.

37. Hyaluronic acid-based compositions are injected into patients. These injections can cause discomfort. The use of therapeutic agents, such as anesthetic agents like lidocaine, to mitigate the pain experience upon injection was desirable. However, prior hyaluronic acid-based compositions that attempted to include lidocaine during the manufacturing process were unsuccessful because they were prone to partial or almost complete degradation prior to injection. The '475, '795, '676, '519, '013, and '322 Patents represent, among other things, inventions of formulations for and methods of manufacturing hyaluronic acid-based compositions that include lidocaine.

38. After the '475 and '795 Patent issued, a third-party named Teoxane S.A. ("Teoxane") asked the United States Patent & Trademark Office's Patent Trial and Appeal Board ("PTAB") to review the patentability of the '475 and '795 Patents. Teoxane filed petitions for inter partes review, in which it sought the cancellation of claims 1-9 and 18-37 of the '475 and claims 1-11, 22, 26-38, 40 and 41 of the '795 Patents on grounds that the claims

were allegedly unpatentable as anticipated or obvious. The PTAB denied the petitions, finding that Teoxane had failed to show that there was a reasonable likelihood that it would prevail with respect any of the challenged claims of the '475 and '795 Patents.

Allergan's Hyaluronic Acid + Lidocaine Products

39. Allergan is a leading developer, manufacturer, and distributor of dermal filler products in the United States. Among those products are JUVEDÉRM® Ultra XC, JUVEDÉRM® Ultra Plus XC, and JUVEDÉRM® VOLUMA® XC (together, "Allergan's JUVEDÉRM® Products").

40. Allergan's JUVEDÉRM® Products are injectable hyaluronic acid gels that contain a small quantity of local anesthetic, lidocaine. Allergan's JUVEDÉRM® Products temporarily add volume to facial tissue and restore a smoother appearance to the face. The lidocaine included in the gel improves the comfort of the injection. The effects of Allergan's JUVEDÉRM® Products last about 9 months to 1 year. Allergan's JUVEDÉRM® Products were approved by the U.S Food and Drug Administration to last up to one year from initial treatment. Allergan's JUVEDÉRM® Products account for more than \$500 million of sales per year in the United States.

41. Allergan has published a webpage located at <https://www.allergan.com/products/patents> on which it gives notice to the public that its JUVEDÉRM® Products are patented, and more particularly by patents that include the '475, '795, '676, and '519 Patents.

PROLLENIUM' S ACCUSED PRODUCTS

42. On information and belief, Prollenium makes, uses, sells, offers to sell, and/or imports into the United States Revanesse® Versa+™, a dermal filler. (See Exhibit G, Prollenium Press Release, dated Dec. 17, 2018, available at <https://www.prnewswire.com/news->

releases/prollenium-us-announces-the-release-of-revanesse-versa--with-lidocaine-

300767213.html). On information and belief, Revanesse® Versa+™ is an injectable hyaluronic acid gel that includes lidocaine, and is indicated for the correction of moderate to severe facial wrinkles and folds. (*See id.*)

43. As used hereinafter, the phrase “Accused Products” shall mean Revanesse® Versa+™ dermal filler products.

44. The Accused Products, and the method of making the Accused Products, satisfy all of the elements of one or more of the claims of each of the ’475, ’795, ’676, ’519, ’013, and ’322 Patents. For example, the Accused Products infringe at least claims 1 and 34 of the ’475 Patent, claims 1 and 29 of the ’795 Patent, claims 1 and 2 of the ’676 Patent, claims 1 and 2 of the ’519 Patent, claim 1 of the ’013 Patent, and claims 1 and 4 of the ’322 Patent.

45. The Accused Products infringe claim 1 of the ’475 Patent because, literally or under the doctrine of equivalents, they include a stable, sterile soft tissue filler comprising a hyaluronic acid (HA) component comprising HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and uncrosslinked HA, wherein the HA component comprises greater than about 10% uncrosslinked HA by volume; and lidocaine combined with said crosslinked HA component.

46. The Accused Products infringe claim 34 of the ’475 Patent because, literally or under the doctrine of equivalents, they include a stable, sterile soft tissue filler comprising: a hyaluronic acid (HA) component comprising HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and uncrosslinked HA; and lidocaine at a concentration of about 0.3% by weight of the soft tissue filler combined with said crosslinked HA component; wherein the soft tissue

filler is stable after heat sterilization at between about 120 degrees C. and about 130 degrees C.; and wherein the soft tissue filler has a pH of about 7.

47. The Accused Products infringe claim 1 of the '795 Patent because, literally or under the doctrine of equivalents, they include a soft tissue filler composition comprising: a hyaluronic acid (HA) component crosslinked with a crosslinking agent selected from the group consisting of 1,4-butanediol diglycidyl ether (BDDE), 1,4-bis(2,3-epoxypropoxy)butane, 1,4-bisglycidylloxybutane, 1,2-bis(2,3-epoxypropoxy)ethylene and 1-(2,3-epoxypropyl)-2,3-epoxycyclohexane, and 1,4-butanediol diglycidyl ether; wherein the HA is not crosslinked to a non-HA biopolymer; and lidocaine combined with said crosslinked HA component; wherein the lidocaine is freely released in vivo; and wherein the composition is sterile.

48. The Accused Products infringe claim 29 of the '795 Patent because, literally or under the doctrine of equivalents, they include a sterile composition comprising a crosslinked hyaluronic acid (HA) at a concentration of about 22 mg/mL and lidocaine at a concentration of about 0.2% to about 1% by weight, wherein the composition is stable during storage under ambient conditions for at least 3 months.

49. The Accused Products infringe claim 1 of the '676 Patent because, literally or under the doctrine of equivalents, they include a dermal filler composition comprising hyaluronic acid (HA) crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and about 0.3% lidocaine by weight, wherein the lidocaine is freely released in vivo, and wherein the composition is sterile.

50. The Accused Products infringe claim 2 of the '676 Patent because, literally or under the doctrine of equivalents, they include a dermal filler composition comprising hyaluronic acid (HA) crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and about 0.3% lidocaine

by weight, wherein the lidocaine is freely released in vivo, wherein the composition is sterile, wherein the composition further comprises free HA.

51. The Accused Products infringe claim 1 of the '519 Patent because, literally or under the doctrine of equivalents, they include a first sterile dermal filler composition comprising hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and about 0.3% lidocaine by weight, wherein the first composition fills in facial lines and depressions substantially the same as a second sterile dermal filler comprising hyaluronic acid crosslinked with BDDE wherein the second composition does not include lidocaine but otherwise has the same composition as the first composition.

52. The Accused Products infringe claim 2 of the '519 Patent because, literally or under the doctrine of equivalents, they include a first sterile dermal filler composition comprising hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and about 0.3% lidocaine by weight, wherein the first composition fills in facial lines and depressions substantially the same as a second sterile dermal filler comprising hyaluronic acid crosslinked with BDDE wherein the second composition does not include lidocaine but otherwise has the same composition as the first composition, wherein the lidocaine in the first composition is freely released in vivo.

53. The Accused Products infringe claim 1 of the '013 Patent because, literally or under the doctrine of equivalents, they include dermal filler comprising: (a) a mixture comprising particles of hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether, and free hyaluronic acid; (b) about 0.3% by weight lidocaine combined with the mixture; wherein the dermal filler is heat sterile and has a pH of about 7.

54. The Accused Products infringe claim 1 of the '322 Patent because, literally or under the doctrine of equivalents, they include a soft tissue filler composition comprising a sterile, stable injectable gel comprising a mixture of soluble form hyaluronic acid (HA), particles of HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and lidocaine in an amount effective to mitigate pain upon injection of the gel.

55. The Accused Products infringe claim 4 of the '322 Patent because, literally or under the doctrine of equivalents, they include a soft tissue filler composition comprising a sterile, stable injectable gel comprising a mixture of soluble form hyaluronic acid (HA), particles of HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and lidocaine in an amount effective to mitigate pain upon injection of the gel, wherein lidocaine is at a concentration of between about 0.1% and about 5% by weight of said composition.

56. In addition to the foregoing examples, the Accused Products infringe other claims of the '475, '795, '676, '519, '013, and '322 Patents.

57. On information and belief, PUS makes, uses, offers for sale, sells, and/or imports the Accused Products in the United States, including within this district, and/or imports the Accused Products into the United States.

58. On information and belief, PMT manufactures the Accused Products in Canada and acts in concert with and/or directs PUS regarding the manufacture, use, offer for sale, sale, and/or import of the Accused Products into the United States.

59. On information and belief, Prollenium was aware of Allergan's JUVEDÉRM® Products that practice the '475, '795, '676, '519, '013, and '322 Patents at least as early as August 2016. On information and belief, because Prollenium was aware of Allergan's JUVEDÉRM® Products at least as early as August 2016, Prollenium was also aware of the '475,

'795, '676, and '519 Patents as a result of, at least, patent marking, including marking on the webpage located at <https://www.allergan.com/products/patents>.

COUNT I
(Infringement of the '475 Patent Under 35 U.S.C. § 271)

60. Allergan incorporates fully herein paragraphs 1 to 59 as set forth above.

61. Prolenium has been and is directly infringing the claims of the '475 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

62. On information and belief, Prolenium has induced, and continues to induce, infringement of the '475 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the '475 Patent. On information and belief, those customers or healthcare providers in fact infringe the '475 Patent by using the Accused Products in the United States. Prolenium has engaged in those activities with knowledge of the '475 Patent and specific intent to infringe that patent.

63. Prolenium does not have a license to practice the subject matter claimed by the '475 Patent. Prolenium does not have any other authority to practice the subject matter claimed by the '475 Patent.

64. Upon information and belief, Prolenium has been aware of the '475 Patent at all relevant times. Upon information and belief, Prolenium has been aware of the '475 Patent since at least December 17, 2018.

65. Upon information and belief, Prolenium has willfully infringed the '475 Patent. Prolenium's willful infringement of the '475 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

66. As a result of Prolenium's infringement of the '475 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prolenium the damages adequate to compensate for such infringement, which have yet to be determined.

67. Prolenium's acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prolenium's infringement of the '475 Patent. Considering the balance of hardships between Allergan and Prolenium, an injunction is warranted because the hardships that would be imposed upon Prolenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served by issuance of an injunction. Prolenium's infringement of the '475 Patent has also caused damages in an amount to be determined at trial.

COUNT II

(Infringement of the '795 Patent Under 35 U.S.C. § 271)

68. Allergan incorporates fully herein paragraphs 1 to 67 as set forth above.

69. Prolenium has been and is directly infringing the claims of the '795 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

70. On information and belief, Prolenium has induced, and continues to induce, infringement of the '795 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the '795 Patent. On information and belief, those customers or healthcare providers in fact infringe the

'795 Patent by using the Accused Products in the United States. Prolenium has engaged in those activities with knowledge of the '795 Patent and specific intent to infringe that patent.

71. Prolenium does not have a license to practice the subject matter claimed by the '795 Patent. Prolenium does not have any other authority to practice the subject matter claimed by the '795 Patent.

72. Upon information and belief, Prolenium has been aware of the '795 Patent at all relevant times. Upon information and belief, Prolenium has been aware of the '795 Patent since at least December 17, 2018.

73. Upon information and belief, Prolenium has willfully infringed the '795 Patent. Prolenium's willful infringement of the '795 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

74. As a result of Prolenium's infringement of the '795 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prolenium the damages adequate to compensate for such infringement, which have yet to be determined.

75. Prolenium's acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prolenium's infringement of the '795 Patent. Considering the balance of hardships between Allergan and Prolenium, an injunction is warranted because the hardships that would be imposed upon Prolenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served

by issuance of an injunction. Prolenium's infringement of the '795 Patent has also caused damages in an amount to be determined at trial.

COUNT III
(Infringement of the '676 Patent Under 35 U.S.C. § 271)

76. Allergan incorporates fully herein paragraphs 1 to 75 as set forth above.

77. Prolenium has been and is directly infringing the claims of the '676 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

78. On information and belief, Prolenium has induced, and continues to induce, infringement of the '676 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the '676 Patent. On information and belief, those customers or healthcare providers in fact infringe the '676 Patent by using the Accused Products in the United States. Prolenium has engaged in those activities with knowledge of the '676 Patent and specific intent to infringe that patent.

79. Prolenium does not have a license to practice the subject matter claimed by the '676 Patent. Prolenium does not have any other authority to practice the subject matter claimed by the '676 Patent.

80. Upon information and belief, Prolenium has been aware of the '676 Patent at all relevant times. Upon information and belief, Prolenium has been aware of the '676 Patent since at least December 17, 2018.

81. Upon information and belief, Prolenium has willfully infringed the '676 Patent. Prolenium's willful infringement of the '676 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

82. As a result of Prolenium's infringement of the '676 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prolenium the damages adequate to compensate for such infringement, which have yet to be determined.

83. Prolenium's acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prolenium's infringement of the '676 Patent. Considering the balance of hardships between Allergan and Prolenium, an injunction is warranted because the hardships that would be imposed upon Prolenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served by issuance of an injunction. Prolenium's infringement of the '676 Patent has also caused damages in an amount to be determined at trial.

COUNT IV
(Infringement of the '519 Patent Under 35 U.S.C. § 271)

84. Allergan incorporates fully herein paragraphs 1 to 83 as set forth above.

85. Prolenium has been and is directly infringing the claims of the '519 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

86. On information and belief, Prolenium has induced, and continues to induce, infringement of the '519 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the '519 Patent. On information and belief, those customers or healthcare providers in fact infringe the

'519 Patent by using the Accused Products in the United States. Prolkenium has engaged in those activities with knowledge of the '519 Patent and specific intent to infringe that patent.

87. Prolkenium does not have a license to practice the subject matter claimed by the '519 Patent. Prolkenium does not have any other authority to practice the subject matter claimed by the '519 Patent.

88. Upon information and belief, Prolkenium has been aware of the '519 Patent at all relevant times. Upon information and belief, Prolkenium has been aware of the '519 Patent since at least December 17, 2018.

89. Upon information and belief, Prolkenium has willfully infringed the '519 Patent. Prolkenium's willful infringement of the '519 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

90. As a result of Prolkenium's infringement of the '519 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prolkenium the damages adequate to compensate for such infringement, which have yet to be determined.

91. Prolkenium's acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prolkenium's infringement of the '519 Patent. Considering the balance of hardships between Allergan and Prolkenium, an injunction is warranted because the hardships that would be imposed upon Prolkenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served

by issuance of an injunction. Prolenium's infringement of the '519 Patent has also caused damages in an amount to be determined at trial.

COUNT V
(Infringement of the '013 Patent Under 35 U.S.C. § 271)

92. Allergan incorporates fully herein paragraphs 1 to 91 as set forth above.

93. Prolenium has been and is directly infringing the claims of the '013 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

94. On information and belief, Prolenium has induced, and continues to induce, infringement of the '013 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the '013 Patent. On information and belief, those customers or healthcare providers in fact infringe the '013 Patent by using the Accused Products in the United States. Prolenium has engaged in those activities with knowledge of the '013 Patent and specific intent to infringe that patent.

95. Prolenium does not have a license to practice the subject matter claimed by the '013 Patent. Prolenium does not have any other authority to practice the subject matter claimed by the '013 Patent.

96. Upon information and belief, Prolenium has been aware of the '013 Patent at all relevant times. Upon information and belief, Prolenium has been aware of the '013 Patent since at least December 17, 2018.

97. Upon information and belief, Prolenium has willfully infringed the '013 Patent. Prolenium's willful infringement of the '013 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

98. As a result of Prolenium's infringement of the '013 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prolenium the damages adequate to compensate for such infringement, which have yet to be determined.

99. Prolenium's acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prolenium's infringement of the '013 Patent. Considering the balance of hardships between Allergan and Prolenium, an injunction is warranted because the hardships that would be imposed upon Prolenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served by issuance of an injunction. Prolenium's infringement of the '013 Patent has also caused damages in an amount to be determined at trial.

COUNT VI
(Infringement of the '322 Patent Under 35 U.S.C. § 271)

100. Allergan incorporates fully herein paragraphs 1 to 99 as set forth above.

101. Prolenium has been and is directly infringing the claims of the '322 Patent, literally and/or under the doctrine of equivalents, by making, using, offering to sell and/or selling within the United States, and/or importing into the United States, the Accused Products.

102. On information and belief, Prolenium has induced, and continues to induce, infringement of the '322 Patent by actively encouraging customers or healthcare providers to use the Accused Products in the United States with knowledge that such use would infringe the '322 Patent. On information and belief, those customers or healthcare providers in fact infringe the

'322 Patent by using the Accused Products in the United States. Prolenium has engaged in those activities with knowledge of the '322 Patent and specific intent to infringe that patent.

103. Prolenium does not have a license to practice the subject matter claimed by the '322 Patent. Prolenium does not have any other authority to practice the subject matter claimed by the '322 Patent.

104. Upon information and belief, Prolenium has been aware of the '322 Patent at all relevant times. Upon information and belief, Prolenium has been aware of the '322 Patent since at least December 17, 2018.

105. Upon information and belief, Prolenium has willfully infringed the '322 Patent. Prolenium's willful infringement of the '322 Patent renders this an exceptional case pursuant to 35 U.S.C. § 285.

106. As a result of Prolenium's infringement of the '322 Patent, Allergan has suffered and will continue to suffer damage including but not limited to monetary damages. Allergan is entitled to recover from Prolenium the damages adequate to compensate for such infringement, which have yet to be determined.

107. Prolenium's acts of infringement have caused and will continue to cause irreparable harm to Allergan unless and until enjoined by this Court. The remedies available at law to Allergan are inadequate to address the injuries that Allergan has suffered and will continue to suffer as a result of Prolenium's infringement of the '322 Patent. Considering the balance of hardships between Allergan and Prolenium, an injunction is warranted because the hardships that would be imposed upon Prolenium by issuance of an injunction are less than those faced by Allergan should an injunction not issue. The public interest would also be served

by issuance of an injunction. Prolenium's infringement of the '322 Patent has also caused damages in an amount to be determined at trial.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Allergan hereby demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

Allergan respectfully requests that this Court enter judgment and provide relief as follows:

a. Adjudging that Prolenium has directly infringed the '475, '795, '676, '519, '013, and '322 Patents;

b. Adjudging that Prolenium has induced infringement of the '475, '795, '676, '519, '013, and '322 Patents;

c. Permanently enjoining Prolenium, and its respective officers, agents, servants, employees, attorneys, and all persons in active concert or participation with any of them directly or indirectly, from making, using, offering for sale and/or selling within the United States, and/or importing into the United States, the Accused Products and any products that infringe or induce the infringement of the '475, '795, '676, '519, '013, and '322 Patents prior to the expiration of those patents, including any extensions;

d. Awarding Allergan damages from Prolenium in amounts sufficient to compensate it for Prolenium's infringement of the '475, '795, '676, '519, '013, and '322 Patents, together with prejudgment and post judgment interest and costs, pursuant to 35 U.S.C. § 284;

e. Ordering that Prolenium to account for additional damages for any and all periods of infringement not included in the damages awarded by the Court or jury, including

specifically any time periods between any order or verdict awarding damages and entry of final judgment;

f. Adjudging that Prolenium has willfully infringed the '475, '795, '676, '519, '013, and '322 Patents and trebling the damages awarded for Prolenium's infringement pursuant to 35 U.S.C. § 284;

g. Declaring that this is an exceptional case under 35 U.S.C. § 285, and Allergan be awarded reasonable attorneys' fees and costs incurred in this action;

h. Awarding Allergan such other equitable or legal relief as the Court may deem just and proper.

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