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### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

CURLIN MEDICAL INC., ZEVEX, INC., and MOOG INC.,

Attorneys for Plaintiffs

Plaintiffs Hon. Stanley R. Chesler

v. Civil No. 2:16-cv-02464-SRC-CLW

ACTA MEDICAL, LLC, JOHN HARRY BREWER, and EVAN BREWER,

Defendants.

### FIRST AMENDED COMPLAINT

Curlin Medical Inc. ("Curlin"), ZEVEX, Inc. ("Zevex"), and Moog Inc. ("Moog") (collectively "plaintiffs") for their First Amended Complaint against ACTA Medical, LLC ("ACTA"), John Harry Brewer, and Evan Brewer allege as follows:

### **The Parties and Relevant Individuals**

Moog is a New York corporation with a principal place of business at 400
 Jamison Road, East Aurora, New York 14052. Moog is a worldwide designer, manufacturer,
 and integrator of precision motion control products and systems.

- 2. Curlin is a Delaware corporation with a principal place of business at Seneca and Jamison Road, East Aurora, New York 14052. Curlin is a wholly-owned subsidiary of Moog. It is a leading developer and supplier of infusion therapy products around the world.
- 3. Zevex is a Delaware corporation with a principal place of business at 4314 Zevex Park Lane, Salt Lake City, Utah 84123. Zevex is a wholly-owned subsidiary of Curlin. Zevex is one of the world's leading suppliers of enteral products, including portable and stationary pumps, disposable sets, and related accessories.
- 4. ACTA is a New Jersey limited liability company with a principal place of business at 4 Nevius Drive, Flemington, New Jersey 08822. ACTA distributes and sells certain medical products throughout the United States, including New Jersey.
- John Brewer is an individual who resides in the State of New Jersey. John
   Harry Brewer is the founder and sole owner of ACTA.
- 6. Evan Brewer is an individual who resides in the State of New Jersey. Evan Brewer is and was at all relevant times an officer, director, and employee of ACTA.
- 7. ACTA, John Brewer, and Evan Brewer are referred to collectively as "defendants."
- 8. James Bruno is an individual who resides in the State of New Jersey.

  Bruno is and was at all relevant times a distributor of certain medical products and an agent or representative of ACTA. Following commencement of this lawsuit, plaintiffs and Bruno resolved all claims asserted against Bruno, and Bruno has been dismissed as a defendant in this lawsuit.

#### Jurisdiction and Venue

- 9. This is a patent and trademark infringement action brought under the patent laws of the United States, 35 U.S.C. Section 101, *et seq.*, including 35 U.S.C. Section 271, and the trademark laws of the United States, including 15 U.S.C. Sections 1114, 1121(a), and 1125(a).
- 10. Plaintiffs seek damages for patent infringement and an injunction precluding defendants from making, using, importing, selling or offering to sell, and/or from inducing or contributing to the infringement by others of, plaintiffs' patented technology. Curlin also seeks damages for unfair competition and violations of the Lanham Act, and seeks an injunction precluding defendants from using and infringing Curlin's trademark, trade dress, and product images, and from make false statements regarding the nature, characteristics, and qualities of defendants' products.
- 11. This Court has subject matter jurisdiction under 28 U.S.C. Sections 1331 and 1338(a) and 15 U.S.C. Section 1121(a).
- 12. This Court has personal jurisdiction over ACTA because ACTA has a principal place of business in New Jersey, because a substantial part of the events or omissions giving rise to the claims occurred within this district and state, and ACTA is subject to service in this district.
- 13. This Court has personal jurisdiction over John Brewer and Evan Brewer because they are domiciled in the State of New Jersey, because a substantial part of the events or omissions giving rise to the claims occurred within this district and state, and they are subject to service in this district.

14. Venue is proper under 28 U.S.C. Sections 1400 and 1391 because defendants are subject to personal jurisdiction in this district. Defendants have also committed acts of patent infringement and trademark infringement in this district.

#### **Background and Facts**

### **Plaintiffs' Infusion Therapy Products**

- 15. Plaintiffs' expertise in the medical market includes the application of advanced technologies to the precision control of motion and fluids. Plaintiffs are regarded as leading developers of infusion therapy products, which are products used by caregivers to intravenously administer medication to a patient.
- 16. Plaintiffs have invested substantial time and resources in research and development in order to design and develop advanced infusion systems that improve medication safety, optimize application performance, and reduce medication expenses. Plaintiffs offer a range of medical pump technologies and fluid delivery systems with the goal of simplifying processes, increasing safety, and enhancing patient and caregiver outcomes.
- 17. By investing substantial time and resources in research and development, plaintiffs have achieved unmatched dependability, ease-of-use, and flexibility in application of its patented products. These three characteristics define the plaintiffs' line of infusion pumps, and is why they are so highly regarded by the caregivers who use them.
- 18. Plaintiffs have a highly positive and well-known reputation and have developed positive and valuable goodwill in their trade name and products.

- 19. Plaintiffs' infusion pumps require the use of an infusion administration set. An "administration set" is a specially-designed and engineered tubing assembly, and associated customized components, used to transport liquids from a pump to a patient. Plaintiffs' administration sets are designed specifically and exclusively for use with plaintiffs' line of infusion pumps and are not intended for use, or properly used, with any other manufacturer's pumps.
- 20. The administration sets designed for use with plaintiffs' line of infusion pumps include an anti-free flow feature/device that prevents inadvertent free flow of the infusion liquid. The anti-free flow device also allows the intentional priming of the set by gravity, thereby reducing the set-up time.
- 21. Plaintiffs' administration sets are uniquely designed to be easy for caregivers to use while still providing exceptional patient care and safety.
- 22. Plaintiffs' administration sets are specifically designed to be used exclusively with plaintiffs' line of infusion pumps as a complete system. At great expense, plaintiffs have subjected and continuously subject the complete system to rigorous testing to ensure the accuracy and safety of its functions.
- 23. Use of administration sets not specifically designed and tested for use with plaintiffs' line of infusion pumps poses a material risk of inaccuracy in the flow rate leading to underinfusion and overinfusion, which is dangerous and may be fatal. In addition, the use of contaminated or incorrect materials to construct the administration sets poses a risk of leaching and contamination of fluids, placing patients at risk.

#### **Plaintiffs' Patents**

- 24. Plaintiffs have obtained patent protection for their important invention.
- 25. On December 26, 2000, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 6,164,921 (the "'921 Patent'), entitled "Curvilinear Peristaltic Pump Having Insertable Tubing Assembly." A copy of the '921 Patent is attached as **Exhibit 1**.
  - 26. Curlin is the owner of all rights, title, and interest in the '921 Patent.
- 27. On April 16, 2002, the USPTO issued U.S. Patent No. 6,371,732 (the "'732 Patent"), entitled "Curvilinear Peristaltic Pump." A copy of the '732 Patent is attached as **Exhibit 2**.
  - 28. The '732 Patent is a continuation of the '921 Patent.
  - 29. Curlin is the owner of all rights, title, and interest in the '732 Patent.
- 30. The '732 Patent and the '921 Patent will be referred to collectively as the "patents."

### **Curlin's Trademarks**

31. Curlin owns U.S. Trademark Registration No. 3,855,036 for the word "CURLIN" for use on medical infusion pumps and administration sets (the "CURLIN Mark"). The registration was issued on September 28, 2010. A copy of the Curlin registration is attached as **Exhibit 3**.

- 32. Curlin has used the CURLIN Mark in U.S. commerce since at least as early as April 2009, and it has the exclusive right to use the CURLIN Mark, nationwide, on its medical infusion pumps and administration sets.
- 33. Curlin has invested substantial resources to develop, grow, and promote its CURLIN Mark. As a direct result of Curlin's continuous and exclusive use of the CURLIN Mark, it has become widely known and recognized in the industry as Curlin's trademark and as a strong indicator of the source and quality of Curlin's goods.
- 34. By virtue of Curlin's methods, the duration and scope of its use of the CURLIN Mark, the expenditure of considerable sums for promotional activities, and by virtue of the excellence of its goods, Curlin has obtained for the CURLIN Mark a most valuable reputation. The CURLIN Mark, and the associated goods, have gained substantial recognition and goodwill in the marketplace.
- 35. The CURLIN Mark is strong and distinctive and designates Curlin as the source of all goods advertised, marketed, sold, or used in connection with its mark in the United States. In addition, by virtue of Curlin's use of the mark in connection with its products, and its extensive marketing, advertising, promotion, and sale of its products under that mark, the CURLIN Mark has acquired secondary meaning whereby the consuming public of this district, the State of New Jersey, and the United States associate the CURLIN Mark with a single source of high quality products and services.

### **Defendants' Patent Infringement**

- 36. Defendants have been and are infringing, actively inducing others to infringe, and/or contributing to the infringement of one or more claims of each of plaintiffs' patents by, directly or through intermediaries, making, using, importing, selling, and/or offering for sale, in this district and elsewhere, certain medical products, including but not limited to, ACTA's "IV Administration Infusion Pump Set" which defendants represent as being "compatible with the Curlin infusion pump" (the "ACTA sets" or "infringing products").
- 37. Specifically, immediately prior to the commencement of this lawsuit, defendants offered for sale the infringing products at the 2016 National Home Infusion Association Annual Conference and Exhibition held March 21-24, 2016 in New Orleans, Louisiana. At that conference, defendants displayed the infringing products and indicated that they were being introduced into the market to compete with plaintiffs' products. In addition, defendants performed demonstrations of the infringing products loaded into a Curlin infusion pump.
- 38. At the New Orleans conference, defendants also falsely represented that they had obtained the appropriate FDA clearance (*i.e.*, "510(k)") required to market and sell the infringing products. A "510(k)" is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device. A company is not permitted to market or sell a Class II medical device, like an infusion pump and administration set system, until the FDA issues a "510(k)" or a premarket approval.

- 39. Since the commencement of this lawsuit, defendants continue to offer for sale the infringing products, representing them to be intended for use with the Curlin infusion pump, and have sold thousands of infringing products to their customers.
- 40. Defendants also continue to market and sell the infringing products as having the appropriate FDA clearance. At the time this action was commenced, however, defendants had not obtained such clearance and, upon information and belief, still have not obtained the appropriate FDA clearance required to legally market and sell the infringing products.
- 41. By making, using, importing, offering for sale and selling their infringing products to their customers, defendants have been and are knowingly directly and indirectly infringing and inducing infringement of one or more claims of each of plaintiffs' patents. In addition, infringement of one or more claims of plaintiffs' patents occurs when defendants and/or their customers load the infringing products into a Curlin infusion pump. Moreover, defendants have been and are inducing infringement by instructing their customers that the ACTA sets are compatible with the Curlin infusion pump and directing their customers to use the ACTA sets with the Curlin infusion pump.
- 42. Further, defendants contribute to the infringement of one or more claims of plaintiffs' patents because defendants know that the ACTA sets are made for unlawful infringing uses and are not staple articles of commerce suitable for substantial non-infringing uses.
- 43. John Brewer directed and controlled the decision to copy, make, import, use, offer for sale, and sell the infringing products to ACTA's customers. Specifically, John

Brewer's goal was to copy plaintiffs' patented administration sets to create a generic alternative that would be offered at a reduced cost to plaintiffs' customers. In addition, John Brewer personally sold and/or offered for sale the infringing ACTA sets.

- 44. As ACTA's director of business development, Evan Brewer offers for sale and sells the infringing products to plaintiffs' customers, and instructs the customers that the infringing products are intended only for use with the Curlin infusion pumps. As part of his sales efforts, Evan Brewer infringes and has infringed plaintiffs' patents by performing sales demonstrations of the infringing products loaded into a Curlin infusion pump.
- 45. Defendants' marketing strategy related to the infringing products is to undercut the price of plaintiffs' administration sets.

### **Defendants' Trademark Infringement**

- 46. The infringing products do not simply infringe. In appearance, they are nearly exact copies of plaintiffs' patented products.
- 47. Defendants have copied Curlin's color schemes for the administration sets. Those color schemes are non-functional in nature. Defendants have also copied Curlin's product codes for the infringing products, as the last three numbers of the infringing products' product codes are identical to the last three numbers of Curlin's product codes. These similarities were intended to, and do, invoke a false association with Curlin which, due to the inferior nature of the infringing products, causes damage to Curlin's reputation.
- 48. John Brewer directed that the ACTA product codes match the comparable Curlin product codes.

- 49. In addition, ACTA's marketing and promotional materials use the CURLIN Mark and product images, without Curlin's consent, for the infringing products, which are nearly exact (but inferior) copies of plaintiffs' patented products. A copy of an ACTA promotional brochure for the infringing products is attached as **Exhibit 4**.
- 50. Evan Brewer designs the ACTA promotional materials with the specific intent to market the infringing products as intended only for use with the Curlin infusion pumps.
- 51. Defendants' unauthorized use of the CURLIN Mark for the infringing products is likely to cause confusion or mistake or to deceive others as to the affiliation, connection, or association between Curlin and ACTA, as well as confusion concerning the source, sponsorship or approval of the infringing products.
- 52. Defendants' conduct, including its false representations as to status of obtaining FDA approval, leads customers for the products to believe that the only difference between defendants' infringing products and those sold by plaintiffs is price.
- 53. Moreover, the inferior quality and nature of the infringing products together with their false association with Curlin, damages Curlin's reputation and goodwill.
- 54. Defendants are well aware of the reputation of Curlin and the CURLIN Mark, and their infringing conduct was intentionally calculated to misappropriate and trade off the goodwill developed by Curlin.
- 55. Defendants' statutory violations and other wrongful acts have injured and threaten to injure plaintiffs, including loss of customers, dilution of goodwill, confusion of existing and potential customers, and injury to plaintiffs' reputation.

### First Claim for Relief (Direct Infringement of the '921 Patent)

- 56. Plaintiffs repeat the allegations set forth in paragraphs 1 through 55.
- 57. On December 26, 2000, the USPTO issued the '921 Patent.
- 58. Curlin is the owner of all rights, title, and interest in the '921 Patent.
- 59. Defendants have infringed and continue to infringe, literally or under the doctrine of equivalents, at least claims 15-34 of the '921 Patent by making, using, importing, selling, and/or offering for sale, in this district and elsewhere, certain infusion therapy products, including but not limited to, ACTA's "IV Administration Infusion Pump Set" without plaintiffs' consent or permission.
- 60. Defendants' infringing acts include importing, selling and offering for sale the ACTA sets, as well as demonstrating the ACTA sets on Curlin infusion pumps for potential customers, including without limitation, at a trade show in New Orleans in March 2016.
- 61. Defendants' actions in infringing the '921 patent have been, and continue to be, willful, deliberate, and/or in conscious disregard of plaintiffs' rights, making this an exceptional case within the meaning of 35 U.S.C. Section 285. Among other things, defendants have continued to commit acts of infringement after the commencement of this action and after they had actual notice of the unlawful nature of their conduct.
- 62. As a result of defendants' infringing activities, plaintiffs have sustained damages in an amount to be proven at trial.
  - 63. Defendants are continuing and will continue their infringing activities

unless and until they are restrained and enjoined by this Court.

64. Defendants' infringing activities have caused, and will continue to cause, plaintiffs irreparable harm for which there is no adequate remedy at law, including without limitation damage to plaintiffs' reputation as suppliers of high quality unique infusion therapy products and loss of customers.

### Second Claim for Relief (Direct Infringement of the '732 Patent)

- 65. Plaintiffs repeat the allegations set forth in paragraphs 1 through 64.
- 66. On April 16, 2002, the USPTO issued the '732 Patent.
- 67. The '732 Patent issued from a continuation of the application of the '921 Patent.
  - 68. Curlin is the owner of all rights, title, and interest in the '732 Patent.
- 69. Defendants have infringed and continue to infringe, literally or under the doctrine of equivalents, one or more claims of the '732 Patent by making, using, importing, selling, and/or offering for sale, in this district and elsewhere, certain infusion therapy products, including but not limited to, ACTA's "IV Administration Infusion Pump Set."
- 70. Among other things, defendants have directly infringed all three of the claims of the '732 Patent by demonstrating the ACTA sets on Curlin infusion pumps for potential customers, including without limitation, at a trade show in New Orleans in March 2016.

- 71. Defendants' actions in infringing the '732 Patent have been, and continue to be, willful, deliberate, and/or in conscious disregard of plaintiffs' rights, making this an exceptional case within the meaning of 35 U.S.C. Section 285.
- 72. As a result of defendants' infringing activities, plaintiffs have sustained damages in an amount to be proven at trial.
- 73. Defendants will continue their infringing activities unless and until they are restrained and enjoined by this Court.
- 74. Defendants' infringing activities have caused, and will continue to cause, plaintiffs irreparable harm for which there is no adequate remedy at law, including without limitation damage to plaintiffs' reputation as suppliers of high quality unique infusion therapy products and loss of customers.

# Third Claim for Relief (Indirect Patent Infringement of the '921 Patent )

- 75. Plaintiffs repeat the allegations set forth in paragraphs 1 through 74.
- 76. Defendants have actively induced others to infringe, and contributed to the infringement of, the '921 Patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. Sections 271(b) and (c).
- 77. Defendants have been and are knowingly inducing infringement of at least claims 1-14 of the '921 Patent with specific intent to do so by, without limitation, making, using, importing, selling and/or offering for sale the infringing products for or to its customers.

- 78. Infringement of at least claims 1-14 of the '921 Patent occurs when defendants' customers load the infringing products into a Curlin infusion pump. Defendants have been and are further inducing infringement by instructing their customers that the infringing products are compatible with Curlin infusion pumps and directing their customers to use the infringing products with Curlin infusion pumps.
- 79. Defendants have knowledge of, and intend, these infringing uses by their customers.
- 80. Further, defendants have contributed to, and are continuing to contribute to, the infringement of at least claims 1-14 of the '921 Patent because defendants know and intend that their infringing products are material components of a patented combination, are made for use in infringement, and are not staple articles of commerce suitable for non-infringing use.
- 81. The infringement by defendants is and was intentional and willful, making this an exceptional case within the meaning of 35 U.S.C. Section 285.
- 82. With knowledge of the '921 Patent, and after plaintiffs commenced this lawsuit in May 2016, defendants continue to directly and indirectly infringe the '921 Patent, and continue to induce others to infringe the '921 Patent.
- 83. As a result of defendants' infringing activities, plaintiffs have sustained damages in an amount to be proven at trial.
- 84. Defendants will continue their infringing activities unless and until they are restrained and enjoined by this Court.

85. The infringement by defendants has caused, and will continue to cause, plaintiffs irreparable harm for which there is no adequate remedy at law, including without limitation damage to plaintiffs' reputation as suppliers of high quality unique infusion therapy products and loss of customers.

## Fourth Claim for Relief (Indirect Patent Infringement of the '732 Patent )

- 86. Plaintiffs repeat the allegations set forth in paragraphs 1 through 85.
- 87. Defendants have actively induced others to infringe, and contributed to the infringement of, the '732 Patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. Sections 271(b) and (c).
- 88. Defendants have been and are knowingly inducing infringement of claims 1-3 of the '732 Patent with specific intent to do so by, without limitation, making, using, importing, selling and/or offering for sale the infringing products for or to its customers.
- 89. Infringement of claims 1-3 of the '732 Patent occurs when defendants' customers load the infringing products into a Curlin infusion pump. Defendants have been and are further inducing infringement by instructing their customers that the infringing products are compatible with Curlin infusion pumps and directing their customers to use the infringing products with Curlin infusion pumps.
- 90. Defendants have knowledge of, and intend, these infringing uses by their customers.

- 91. Further, defendants have contributed to, and are continuing to contribute to, the infringement of claims 1-3 of the '732 Patent because defendants know that their infringing products are material components of a patented combination, are made for use in infringement, and are not staple articles of commerce suitable for non-infringing use.
- 92. The infringement by defendants is and was intentional and willful, making this an exceptional case within the meaning of 35 U.S.C. Section 285.
- 93. With knowledge of the '732 Patent, and after plaintiffs commenced this lawsuit in May 2016, defendants continue to directly and indirectly infringe the '732 Patent, and continue to induce others to infringe the '732 Patent.
- 94. As a result of defendants' infringing activities, plaintiffs have sustained damages in an amount to be proven at trial.
- 95. Defendants will continue their infringing activities unless and until they are restrained and enjoined by this Court.
- 96. The infringement by defendants has caused, and will continue to cause, plaintiffs irreparable harm for which there is no adequate remedy at law, including without limitation damage to plaintiffs' reputation as suppliers of high quality unique infusion therapy products and loss of customers.

## Fifth Claim for Relief (Trademark Infringement (15 U.S.C. Section 1114))

- 97. Plaintiffs repeat the allegations set forth in paragraphs 1 through 96.
- 98. Curlin owns the CURLIN Mark.

- 99. Defendants have used the CURLIN Mark, without Curlin's permission, for the infringing products, which are nearly exact copies of plaintiffs' patented products, including non-functional attributes of the physical design and color schemes of the CURLIN Mark.
- 100. Defendants' use of the CURLIN Mark in connection with the marketing of infusion therapy products is likely to cause confusion or mistake or to deceive others as to the source of the infringing products.
- 101. Defendants' actions constitute trademark infringement under 15 U.S.C. Section 1114 and have caused Curlin to sustain damages in an amount to be determined at trial.
- 102. Upon information and belief, defendants had actual knowledge of the CURLIN Mark. Defendants were on constructive notice of the CURLIN Mark based on the federal registration for this mark and Curlin's use of the mark in interstate commerce. As a result, defendants' unauthorized use of the CURLIN Mark on, and in connection with advertising and marketing for their infringing products, has been knowing, intentional, and willful.
- 103. Pursuant to 15 U.S.C. Section 1117, Curlin is entitled to treble damages, as well as the recovery of defendants' profits, the cost of this action, reasonable attorneys' fees, and a preliminary and permanent injunction restraining defendants from any further use of the CURLIN Mark and product images, including but not limited to use on their website and promotional materials.

# Sixth Claim for Relief (Trademark Infringement (15 U.S.C. Section 1125(a))

104. Plaintiffs repeat the allegations set forth in paragraphs 1 through 103.

- 105. Curlin has used the CURLIN Mark in commerce for infusion therapy products since at least 2009.
- 106. Defendants have used, and are continuing to use, the CURLIN Mark and Curlin product images, without Curlin's consent, in connection with the infringing products.
- 107. Defendants' use of the CURLIN Mark and product images is likely to cause confusion, to cause mistake, or to deceive as to the affiliation, connection, or association between ACTA and Curlin, or as to the origin, sponsorship, or approval of the infringing products in violation of 15 U.S.C. Section 1125.
- 108. By reason of the foregoing, Curlin has been damaged in an amount to be determined at trial.
- 109. Pursuant to 15 U.S.C. Section 1117, Curlin is entitled to treble damages, as well as the recovery of defendants' profits, the costs of this action, reasonable attorneys' fees, and a preliminary and permanent injunction restraining defendants from any further use of the CURLIN Mark and product images, including but not limited to use on their website and promotional materials.

### Seventh Claim for Relief (Unfair Competition (N.J.S.A. Section 56:4-1))

- 110. Plaintiffs repeat the allegations set forth in paragraphs 1 through 109.
- 111. This cause of action arises under N.J.S.A. Section 56:4-1 et seq.

- 112. Defendants' unauthorized use in commerce of the CURLIN Mark and product images is likely to cause confusion, mistake or deception of purchasers and potential purchasers as to the origin, sponsorship, or approval of the infringing products by Curlin.
- 113. Defendants' unauthorized use in commerce of the CURLIN Mark and product images falsely designates the origin of the infringing products and is likely to cause confusion, mistake or deception about the origin of the infringing goods.
- 114. By using copies of the CURLIN Mark and product images, defendants have falsely and misleadingly described and suggested that the infringing products they are selling and offering for sale emanate from and are sponsored or approved by Curlin.
- 115. Defendants' statutory violations and other wrongful acts have injured and threaten to injure Curlin, including by the loss of customers, dilution of goodwill, confusion of existing and potential customers, and injury to its reputation.
- 116. Defendants' acts are and have been willful and have damaged Curlin and, unless restrained, will continue to cause irreparable damage to Curlin, including damage to reputation and goodwill and confusion among customers and potential customers, in an amount that cannot now be determined. Curlin has no adequate remedy at law.

# Eighth Claim for Relief (Violations of the Lanham Act)

- 117. Plaintiffs repeat the allegations set forth in paragraphs 1 through 116.
- 118. Defendants have falsely represented and misled their customers as to the nature, characteristics, and qualities of their infringing products by stating that they have

obtained appropriate FDA clearance (*i.e.* a "510(k)") in order to market and sell their medical devices.

- 119. A "510(k)" is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, "substantially equivalent," to a legally marketed device. A company is not permitted to market or sell a medical device until the FDA issues a "510(k)."
- 120. Defendants have admitted that, as of June 30, 2016, they have not obtained the required FDA clearance to market and sell their infringing products.
- 121. Upon information and belief, defendants continue to market and sell the infringing products in interstate commerce without having obtained the appropriate FDA clearance.
- 122. Upon information and belief, defendants have made the aforesaid misrepresentations when marketing and selling their infringing products in such interstate markets as Louisiana, Texas, New York, Illinois, and Kansas.
- 123. Defendants' misrepresentations were and are likely to cause deception as to the quality, safety characteristics, origin, sponsorship, and FDA approval of the infringing products. Defendants' misrepresentations were and are further likely to lead purchasers of the products to believe, falsely, that the only difference between defendants' infringing products and those sold by plaintiffs is price.

- 124. The purpose of the misrepresentations by defendants was and is to influence customers to purchase the defendants' infringing products rather than plaintiffs' products, and that deception is likely to influence purchasing decisions.
- 125. The misrepresentations by defendants were and are knowing, intentional, and willful and violate 15 U.S.C. Section 1125(a)(1)(A) and 15 U.S.C. Section 1125(a)(1)(B).
- 126. As a result of this conduct by defendants, plaintiffs have sustained damages in an amount to be proven at trial.
- 127. The misrepresentations by defendants have caused and will continue to cause plaintiffs irreparable harm for which there is no adequate remedy at law.

# Ninth Claim for Relief (Common Law Trademark Infringement and Unfair Competition)

- 128. Plaintiffs repeat the allegations set forth in paragraphs 1 through 127.
- 129. Defendants' sale of the infringing products constitutes unfair competition in violation of the laws of New Jersey. Defendants, by copying plaintiffs' product and by copying the CURLIN Mark and product images, have misappropriated plaintiffs' significant investment and expenditures in the marketing of plaintiffs' products and the acquisition of the CURLIN Mark, and are seeking to take advantage of the market plaintiffs have created for their products.
- 130. Upon information and belief, defendants' conduct is specially designed to capitalize on the goodwill of plaintiffs and has injured and threatens to injure plaintiffs, including loss of customers, dilution of goodwill and injury to their reputation.

- 131. Defendants have unfairly competed with plaintiffs in violation of plaintiffs' common law rights.
- 132. Upon information and belief, defendants' conduct was and is willful and intentional.
- 133. Defendants' acts have damaged plaintiffs, and unless restrained, will continue to cause irreparable damage to plaintiffs, including damage to reputation and goodwill, in an amount that cannot now be determined. Plaintiffs have no adequate remedy at law.

### **Jury Demand**

134. Plaintiffs demand trial by jury on all matters triable by jury.

WHEREFORE, plaintiffs are entitled to judgment for the following relief:

- (1) declaring that defendants have infringed one or more claims of the '921 and '732 Patents;
  - (2) declaring that defendants have infringed the CURLIN Mark;
- (3) granting an injunction precluding defendants, their officers, directors, agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with them, from making, using, importing, selling, and/or offering for sale any products that infringe one or more claims of the '921 or '732 Patents, or otherwise directly or indirectly committing further acts of infringement of those patents;
- (4) granting an injunction precluding defendants, their officers, directors, agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with

them, from infringing the CURLIN Mark;

(5) granting an injunction precluding defendants, their officers, directors,

agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with

them, from marketing and/or selling the infringing products as having obtained the appropriate

FDA clearance;

(6) ordering an accounting for damages arising from defendants' acts of

patent and trademark infringement and unfair competition;

(7) awarding compensatory, exemplary, and punitive damages, with interest;

(8) finding that defendants' patent and trademark infringements are willful,

that this is an exceptional case, and awarding enhanced damages and reasonable attorneys' fees

and costs to plaintiffs; and

(9) awarding such further relief as this Court deems proper.

Dated: January 5, 2017

HODGSON RUSS LLP

Attorneys for Plaintiffs

By: s/Neil B. Friedman

Neil B. Friedman

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**RULE 11.2 CERTIFICATION** 

I certify that, to the best of my knowledge, the matter in controversy is not the

subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor

are there any non-parties known to plaintiffs that should be joined to this action. In addition, I

recognize a continuing obligation during the course of this litigation to file and to serve on all

other parties and with the Court an amended certification if there is a change in the facts stated in

this original certification.

Dated: January 5, 2017

s/Neil B. Friedman

Neil B. Friedman

**RULE 201.1 CERTIFICATION** 

I hereby certify that the above-captioned matter is not subject to compulsory

arbitration in that the plaintiffs seek, inter alia, injunctive relief.

Dated: January 5, 2017

s/Neil B. Friedman

Neil B. Friedman

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