UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

GLYCOBIOSCIENCES, INC.)
Plaintiff,))
v. INNOCUTIS HOLDING, LLC, et al.) Civil Case No. 1:12-CV-01901-RDM)
Defendants.)))

FIRST AMENDED COMPLAINT AGAINST FIDIA FARMACEUTICI S.p.A.

Plaintiff GLYCOBIOSCIENCES, INC. ("GLYCO"), by and through its undersigned counsel, files this First Amended Complaint against Fidia Farmaceutici S.p.A. ("Fidia") and alleges as follows. This First Amended Complaint is filed within 21 days after service of Fidia's Rule 12(b) Motion [DE 73, filed August 11, 2015] and is therefore filed as a matter of course and timely pursuant to Federal Rules of Civil Procedure 15(a)(1)(B).

FACTS COMMON TO AND APPLICABLE TO ALL COUNTS

1. Plaintiff Glycobiosciences, Inc. is a corporation duly organized and existing under the laws of the Province of Ontario, Canada, and having a principal place of business at 7 Timber Court, Georgetown, Ontario L7G 4S4 Canada.

- 2. Glyco is the developer of numerous pain relief products used in the treatment of damaged skin, wounds, ulcers, sores and pain management, as well as several other diseases and conditions utilizing the Glyco's proprietary and patented Ionic Polymer Matrix ("IPM") delivery system.
- 3. Glyco is the owner of various United States patents including U.S. Patent No. 6,387,407 which was duly and legally issued on May 14, 2002. A True and Correct Copy of U.S. Patent No. 6,387,407 is attached as Exhibit A. A True and Correct Copy of the documents evidencing title in the name of Glyco is attached as Exhibit B.
 - 4. U.S. Patent No. 6,387,407 lapsed on May 14, 2006.
 - 5. U.S. Patent No. 6,387,407 was reinstated on June 20, 2014.
- 6. U.S. Patent No. 6,387,407 was reinstated on June 20, 2014 with retroactive effect as though it had not lapsed.
 - 7. U.S. Patent No. 6,387,407 was lawfully reinstated on June 20, 2014.
- 8. U.S. Patent No. 6,387,407 was lawfully reinstated on June 20, 2014 with retroactive effect as though it had not lapsed.
- 9. Defendant Innocutis Holdings, LLC ("Innocutis") is, on information and belief, a corporation duly organized and existing under the laws of the State of South Carolina and has a principal place of business at 171 Church Street, Charleston, South Carolina.

10. Defendant DARA Biosciences, Inc. ("Dara"), upon information and belief, is a corporation organized and existing under the laws of the State of North Carolina and has a principal place of business at 8601 Six Forks Road, Raleigh, North Carolina.

11. Defendant Fidia Farmaceutici S.p.A. ("Fidia") is, on information and belief, an Italian Company having a principal place of business at Via Ponte della Fabbrica 3/A, 35031 Abano Terme (PD), Italy, and having United States subsidiary known as Fidia Pharma USA, located in Parsippany, New Jersey.

- 12. Innocutis does business in the United States.
- 13. On information and belief, Innocutis does business within the District of Columbia.
 - 14. Dara does business in the United States.
- 15. On information and belief, Dara does business within the District of Columbia.
 - 16. Fidia does business in the United States.
- 17. On information and belief, Fidia does business within the District of Columbia.

Jurisdiction and Venue

- 18. This is a suit for infringement of United States Patent No. 6,387,407 (the "407 Patent"), as well as for misappropriation and misuse of trade secrets, and unlawful trade practices.
- 19. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §1400(b) because this suit is brought under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and pursuant to 28 U.S.C. §§1331 and 1367.
 - 20. Fidia advertises that it manufactures a product known as Bionect Gel.
- 21. Fidia advertises that it manufactures a product known as Bionect Gel under U.S. Patent No. 5,925,626.
- 22. Fidia and Innocutis advertise that Fidia manufactures BIONECT Gel for Innocutis.
- 23. Fidia and Innocutis advertise that Fidia manufactures BIONECT Gel for Innocutis under U.S. Patent No. 5,925,626.
- 24. Dara advertises that it obtained a license from Innocutis for the exclusive rights to market Bionect products in both radiation and oncology.
 - 25. Dara advertises that Bionect Gel products are patent protected.
- 26. Dara maintains a website (<u>www.darabio.com</u>) which contains a link to http://bionect.com.

- 27. The website http://bionect.com contains, through various links, the advertisement that Bionect Gel is manufactured under U.S. Patent No. 5,925,626 (the "'626 Patent").
- 28. Venue is proper in this District at least pursuant to 28 U.S.C. § 1391 (b,d).
- 29. Bionect Gel is identified as a clear colorless gel for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), wounds including cuts, abrasions, donor sites, and post-operative incisions, irritations of the skin, and first and second degree burns.
 - 30. At least as early as 2003, Fidia had actual knowledge of the '407 patent.
- 31. At least as early as 2003, Fidia had actual knowledge of European patent EP 0859597 which is based on the same application that became the '407 patent.
- 32. At least as early as 2003, Fidia, using in part the same attorneys that are representing all Defendants in this suit, began its program of tortious activities as will be described in greater detail.
- 33. On or about May 30, 2003, Leonard Svensson Esq, on behalf of Fidia, asserted the Fidia '626 Patent against L.A.M. Pharmaceutical ("L.A.M."), Glyco's predecessor and threatened to challenge the European and U.S. Patents if Glyco's predecessor did not capitulate to Fidia's demands. A copy of the letter is attached as Exhibit C.

- 34. Incensed that Glyco's predecessor did not capitulate to its demands, threats and intimidation tactics, Fidia proceeded to challenge the European patent but Fidia's challenge was ultimately unsuccessful.
 - 35. Fidia's '626 Patent expired on December 23, 2003.
- 36. Continuing its program of bullying, threats and intimidation, but recognizing that it could not obtain injunctive relief against alleged infringement of the expired '626 patent, and only nominal damages for any pre-expiration alleged infringement, Fidia threatened to appeal the adverse decision regarding the European Patent EP 0859597 unless Glyco's predecessor entered into negotiations to sell its IPM Wound Gel intellectual property to Fidia.
- 37. Among the intellectual property that Fidia sought to purchase were the '407 patent, the European Patent EP 0859597, all of the rights under L.A.M.'s FDA 510(k) No. K020325 relating to IPM Wound Gel, and all technical information relating to the IPM Wound Gel.
- 38. In furtherance of its scheme, Fidia entered into a first agreement with L.A.M. in May 2006 and did not pursue any other challenge to L.A.M.'s patents.
 - 39. L.A.M. furnished all requested information to Fidia in confidence.
- 40. Part of the information furnished by L.A.M. in confidence included the molecular weight of the hyaluronic acid sodium salt in the IPM Wound Gel product.

- 41. Fidia's '626 Patent describes, *inter alia*, that two different "fractions" of hyaluronic acid ("HA") should be utilized, a first "fraction" or portion of HA having an average molecular weight from about 50,000 to about 100,000 and a second "fraction" or portion having an average molecular weight of about 500,000 to about 730,000.
- 42. Fidia's '626 patent further explains that the HA in the first fraction is to be used for wound healing and the second fraction is to be used for joint therapy and ocular surgery.
- 43. Fidia knew, or in the exercise of reasonable diligence should have known, that the L.A.M. IPM Wound Gel did not include multiple 'fractions' as described in the Fidia '626 patent, nor the "first" fraction for wound healing, and was not for joint therapy and ocular surgery and therefore could not possible infringe the '626 Patent and, therefore, that its patent infringement assertions were not made in good faith.
- 44. In a good faith effort to resolve disputes, even though Fidia's patent was not infringed and had expired, L.A.M. entered into an agreement with Fidia in May 2006 and thereafter provided all its confidential information to Fidia in the mistaken belief that Fidia was proceeding in good faith.

- 45. Fidia had obtained from the F.D.A. its own 510(k) Registrations (K984262, K984264, K984266, K 984267 and K984413) for its Bionect products. Fidia owns and/or controls these five 510(k) registrations.
- 46. Fidia had previously identified its Bionect product as being within the scope of the '626 patent (i.e., "patent marking").
- 47. After obtaining L.A.M.'s confidential information and learning about the HA molecular weight in the IPM Wound Gel product, Fidia embarked on a program to surreptitiously change the molecular weight of the HA in its own products to correspond to the information provided in confidence by L.A.M.
- 48. After making the change referred to in the preceding paragraph, Fidia did not advise the FDA nor, on information and belief, did Fidia run comparative tests to determine if the Bionect product could still be marketed under the existing FDA 510(k), nor did Fidia submit a new 510(k) application indicating the changes to the Bionect product.
- 49. With full knowledge that its products no longer contained "fractions" of HA as described in its patent and with full knowledge that its products contained a higher molecular weight HA than Fidia had not tested for wound healing but rather included the higher molecular weight that Fidia had represented was for ocular surgery and joint therapy, Fidia continued to market its Bionect product as covered by its patent and advertised that its Bionect product was to be used for wound healing.

50. Fidia, having obtained all the technology knowledge in confidence from

L.A.M. regarding the IPM Wound gel, thereafter communicated to L.A.M. its decision

not to purchase the assets.

51. The "decision" referred to in the preceding paragraph was, on

information and belief, reached prior to Fidia receiving any information in confidence

from L.A.M.

52. In late 2009 or early 2010, Fidia and Glyco entered into negotiations for

an agreement under which Fidia would manufacture the IPM Wound Gel for Glyco.

53. Glyco entered into an agreement referred to in the preceding paragraph

in good faith on or about February 24, 2010.

54. Fidia, on information and belief, did not enter into the February 24,

2010 agreement in good faith but rather to surreptitiously and deceitfully obtain

updated technical information from Glyco.

55. Glyco provided, in good faith and confidence, the technical information

requested by Fidia.

56. Fidia decided not to manufacture IPM Wound Gel for Glyco.

57. On information and belief, Fidia had decided not to manufacture IPM

Wound Gel for Glyco before signing the agreement on or about February 24, 2010,

and had entered into that agreement only to obtain updated technical information

about the IPM Wound Gel product.

- 58. Fidia's Bionect Gel product is advertised as having 0.2% HA when, in fact, Fidia's Bionect Gel product contains more than 2½ times that quantity, specifically, 0.522% HA.
- 59. Fidia did not disclose to the FDA the change in the amount of HA in its product, and, on information and belief, did not run any comparative studies regarding the increased amount of HA in its product to determine if its product was still eligible to be marketed under the existing FDA 510(k), nor did Fidia submit a new 510(k) application indicating the changes to the Bionect product.
- 60. When Fidia obtained FDA 510(k) registration for Bionect, one of the ingredients was Carbomer 940.
- 61. At some point in time, Fidia changed from using Carbomer 940 to Carbomer 980.
- 62. Fidia did not disclose to the FDA the change in the Carbomer ingredient in its product, and, on information and belief, did not run any comparative studies regarding the different Carbomer ingredient to determine if its product was still eligible to be marketed under the existing FDA 510(k), nor did Fidia submit a new 510(k) application indicating the changes to the Bionect product.
- 63. Without limiting any other allegation in this Amended Complaint, the ingredients of Bionect Gel include the sodium salt of hyaluronic acid, Carbomer 980, sodium hydroxide and purified water.

- 64. Hyaluronic acid falls within the definition of a mucopolysaccharide.
- 65. Hyaluronic acid (at least in solution) falls within the definition of a negatively charged polymer.
- 66. The HA in the Bionect Gel product has a molecular weight of between about 650,000 to about 800,000 as that phrase is properly construed.
- 67. Pleading in the alternative, the HA in the Bionect Gel product has a molecular weight that is equivalent under the doctrine of equivalents to a molecular weight of between about 650,000 to about 800,000.
- 68. In the Bionect Gel product manufactured and sold by one or more

 Defendants, the hyaluronic acid (and/or its sodium salt) and the Carbomer 980 form

 a blended gelled composition
 - 69. Carbomer 980 is a non-ionic polymer as that term is properly construed.
- 70. Pleading in the alternative, Carbomer 980 in the Bionect Gel is equivalent to a non-ionic polymer.
- 71. The sodium salt of hyaluronic acid in one sample of the Bionect Gel as manufactured by Fidia has a weight average molecular weight of 565,419.
- 72. The Bionect Gel as manufactured offered for sale and sold by Fidia has a sulphated ash content below about 15%.
- 73. The Bionect Gel as manufactured offered for sale and sold by Fidia has a protein content below about 5%.

- 74. The Bionect Gel as manufactured offered for sale and sold by Fidia has a purity of at least 98%.
- 75. The sodium salt of hyaluronic acid in one sample of the Bionect Gel as manufactured and sold by Fidia has a peak molecular weight of 818,472.
- 76. Fidia has registered its Bionect product with the FDA as a medical device.
- 77. Fidia has not registered its Bionect product with the FDA for any purpose other than as a medical device
- 78. Fidia has registered its Bionect product with the FDA as a product that may be topically applied to a human.
- 79. Fidia has not registered its Bionect product with the FDA as a product that may be applied to a human other than by topical application.
 - 80. Carbomer 980 is a cross-linked polyacrylic acid.
 - 81. U.S. Patent No. 5,925,626 does not refer to a gel.
 - 82. U.S. Patent No. 5,925,626 does not refer to a non-ionic polymer.
 - 83. U.S. Patent No. 5,925,626 does not refer to Carbomer 980.
 - 84. U.S. Patent No. 5,925,626 does not refer to cross-linking.
 - 85. U.S. Patent No. 5,925,626 does not refer to polyacrylic acid.
 - 86. U.S. Patent No. 5,925,626 does not refer to sodium hydroxide.

- 87. The claims of U.S. Patent No. 5,925,626 exclude hyaluronic acid having a molecular weight over 800,000.
- 88. Bionect Gel as manufactured by Fidia is not made in accordance with U.S. Patent No. 5,925,626.
- 89. The claims of U.S. Patent No. 5,925,626 do not cover or read on the Bionect Gel as manufactured by Fidia.

COUNT I INDIRECT PATENT INFRINGEMENT AGAINST FIDIA ACTIVE INDUCEMENT OF INFRINGEMENT

- 90. Glyco realleges paragraphs 1 89 as fully and completely as if set forth herein verbatim.
 - 91. Claim 1 of the '407 Patent reads as follows:
 - 1. A process for the use of a composition as a medical device, for drug delivery, the application of a diagnostic agent, or the prevention of post operative adhesions, said process comprises topically administering to a mammal an aqueous based gelled composition containing a polymer matrix composed of a negatively charged polymer material blended with a nonionic polymer;
 - wherein the negatively charged polymer material is hyaluronate sodium salt; and
 - wherein the hyaluronate sodium salt has a weight average molecular weight from about 650,000 to about 800,000, a sulphated ash content below about 15%, a protein content below about 5% and purity of at least 98%.
- 92. Within the six years immediately preceding the filing of this Complaint, Fidia has indirectly infringed claim 1 of U.S. Patent No. 6,387,407 by actively inducing

others, including physicians and patients, to topically administer, within the United

States, the Bionect Gel product described above without authority, license or

permission from Glyco.

93. Fidia does not know of any use for the Bionect Gel other than as a

medical device for topical administration.

94. Fidia does not advertise any use for the Bionect Gel other than as a

medical device for topical administration.

95. Fidia does not have FDA approval for any use for the Bionect Gel other

than as a medical device for topical administration.

96. A human is a mammal.

97. Fidia expects physicians to prescribe Bionect Gel for topical

administration to humans.

98. Fidia has no market in the United States for Bionect Gel other than as a

medical device for topical administration to humans.

99. Fidia does not encourage physicians to prescribe any use for Bionect Gel

other than for topical administration to humans.

100. Fidia does not know of any FDA approved use for Bionect Gel other

than for topical administration to humans.

101. Fidia never sought U.S. FDA approval for Bionect Gel other than for

topical administration to humans.

- 102. On information and belief, Fidia engaged in tortious activities by bullying, threating, intimidating, and challenging the '407 patent and its corresponding European patent, because Fidia had specific knowledge that Fidia would be infringing if the '407 patent and its corresponding European remained enforceable.
- 103. On information and belief, Fidia engaged in tortious activities because the '407 patent would prevent Fidia from encouraging others to administer, prescribe or use Fidia's Bionect Gel.
- 104. Fidia had actual and specific knowledge that encouraging others to administer, prescribe or use Bionect Gel constituted infringement of the '407 patent.
- 105. The activities of Fidia as set forth in this Count I constitute inducement of infringement in violation of 35 U.S.C. § 271(b).
- 106. The infringement referred to in this Count I has been to the injury and detriment to Glyco in an amount to be determined at trial.
- 107. On information and belief and based at least on the submissions to the Court in this case, the infringement referred to in this Count I has been willful and deliberate.

COUNT II INDIRECT PATENT INFRINGEMENT AGAINST FIDIA CONTRIBUTORY INFRINGEMENT

- 108. Glyco realleges paragraphs 1 107 as fully and completely as if set forth herein verbatim.
 - 109. At least as early as 2003, Fidia had actual knowledge of the '407 patent.
- 110. Bionect Gel is especially made and/or especially adapted for use as a medical device for topical administration to humans.
- 111. Bionect Gel is not a staple article of commerce suitable for substantial non-infringing use.
- 112. Fidia manufactures Bionect Gel which is sold, distributed, topically administered, prescribed and/or used by others, including physicians and patients within the United States.
- 113. At least physicians and patients topically administer, prescribe and/or use Fidia's Bionect Gel within the United States.
- 114. The activities of Fidia as set forth in this Count II constitute contributory infringement of claim 1 of the '407 patent in violation of 35 U.S.C. § 271(c).
- 115. The infringement referred to in this Count II has been to the injury and detriment to Glyco in an amount to be determined at trial.

116. On information and belief and based at least on the submissions to the Court the infringement referred to in this Count II has been willful and deliberate.

COUNT III FALSE PATENT MARKING AGAINST FIDIA

- 117. Glyco realleges paragraphs 1 116 as fully and completely as if set forth herein verbatim.
- 118. This Count III is based on false patent marking in violation of Title 35 U.S.C. § 292.
- 119. Within the six years immediately preceding the filing of this Second Amended Complaint, Fidia has advertised in connection with the Bionect Gel the legend "U.S. Pat. No. 5,925,626."
- 120. Bionect Gel as tested by an independent laboratory is not covered by any claims of U.S. Pat. No. 5,925,626.
- 121. Bionect Gel does not contain at least two hyaluronic acid fractions, one of which has an average molecular weight of between 30,000 and 730,000 and which is free of low molecular weight hyaluronic acid having a molecular weight of less than 30,000.
 - 122. Bionect Gel is not covered by claim 1 of the '626 patent.
- 123. A method of using Bionect Gel for enhancing the healing of tissue wounds does not include the Bionect Gel with a hyaluronic fraction having an average

molecular weight of between about 250,000 and about 300,000 and which is free of

hyaluronic acid having a molecular weight of less than 30,000.

124. Fidia did not test the use of Bionect Gel that has a hyaluronic fraction

with an average molecular weight of between about 250,000 and about 300,000 and

which is free of hyaluronic acid having a molecular weight of less than 30,000 for

enhancing the healing of tissue wounds.

125. Fidia did not test the use of Bionect Gel for enhancing the healing of

tissue wounds where the gel included a hyaluronic fraction with an average molecular

weight of between about 30,000 and about 100,000 and which is free of hyaluronic

acid having a molecular weight of less than 30,000.

126. Fidia did not rely on any predicate device in its 510(k) where the

predicate device had a hyaluronic fraction with an average molecular weight of

between about 30,000 and about 100,000 and which was free of hyaluronic acid

having a molecular weight of less than 30,000 for enhancing the healing of tissue

wounds.

127. Fidia did not test the use of Bionect Gel that has a hyaluronic fraction

with an average molecular weight of between about 50,000 and about 100,000 and

which is free of hyaluronic acid having a molecular weight of less than 30,000 for

enhancing the healing of tissue wounds.

- 128. Fidia did not rely on any predicate device in its 510(k) where the predicate device included a hyaluronic fraction with an average molecular weight of between about 50,000 and about 100,000 and which was free of hyaluronic acid having a molecular weight of less than 30,000 for enhancing the healing of tissue wounds.
- 129. Fidia does not have a 510(k) covering the use of Bionect Gel for injection into a joint and/or for injecting into an ocular area.
- 130. Fidia changed at least the molecular weight of the HA in its own products, which corresponds to the information provided by Glyco and Glyco's predecessor. This change as well as other factors, has precludes the Bionect Gel from being covered by the claims of the '626 patent.
- 131. After making the change referred to in the preceding paragraph, Fidia intentionally refrained from advising the FDA and from running comparative tests to determine if Fidia's Bionect product could still be marketed under the existing FDA 510(k), nor did Fidia submit a new 501(k) application indicating the changes to the Bionect product.
- 132. Fidia did not update Bionect's label/marking, including correction of the improper patent marking, because if Fidia had done so, Glyco was likely to note that Fidia was utilizing Glyco's technical data and other intellectual property.

- 133. Fidia has at least one other patent relating to hyaluronic acid, namely, U.S. Patent No. 4,736,024.
- 134. Fidia's U.S. Patent No. 4,736, 024 does not cover the Bionect Gel product.
 - 135. Fidia knew the difference as to when a patent did not cover its product.
- 136. Fidia engaged in false patent marking for its Bionect product by using the number of the '626 patent.
- 137. The activities complained of in this Count III were made for the purpose of having the public rely thereon.
- 138. The activities complained of in this Count III were made for the purpose of deceiving the public.
- 139. The value of patent marking is demonstrated by the fact that Innocutis and/or Dara employ patent marking in connection with the Bionect product.
- 140. The intent of Fidia to use patent marking includes, at least, to benefit in its dealings with Innocutis and/or Dara and so that Innocutis and/or Dara could thereafter obtain the benefit of patent marking in their dealings with the persons who purchase and/or prescribe the Bionect product.
- 141. The activities complained of in this Count III were made for the purpose of deceiving the public.

- 142. In the instant civil action, Fidia has, on information and belief, paid for and participated in the defenses asserted by Defendants Dara and Innocutis, and have represented to the Court that the Fidia-manufactured Bionect Gel is covered by one or more claims of U.S. Pat. No. 5,925,626.
- 143. The activities complained of in the preceding paragraph were made for the purpose of having the Court rely thereon.
- 144. Glyco is a competitor of Defendants and has been damaged by the activities complained of in this Count III including but not limited to a loss of market opportunity in an amount to be determined at trial.

COUNT IV MISAPPROPRIATION OF TRADE SECRETS AGAINST FIDIA

- 145. Glyco realleges paragraphs 1 144 as fully and completely as if set forth herein verbatim.
- 146. This Count IV is based on misappropriation of trade secrets in violation of D.C. Code §§36-401, 36-410.
- 147. Within the three years immediately preceding the filing of this Amended Complaint, Glyco learned that Fidia has used and disclosed technical data originating from Glyco and identified as a trade secret during a joint venture, including information regarding a cost effective method and formulation for manufacturing HA and an IPM Wound Gel.

148. On information and belief, Fidia's Bionect Gel incorporates at least the

trade secrets identified in the paragraph above.

149. The use and disclosure mentioned in the paragraph above was not

authorized, licensed or permitted by Glyco.

150. On information and belief, there are circumstances that can only have

arisen through misappropriation of Glyco's trade secrets, as follows.

151. On information and belief, Fidia's Bionect Gel existed and was

previously marketed without use of the technical data and/or the updated technical

data acquired from Glyco.

152. On information and belief, the presence of Glyco's technical data and

updated technical data in Fidia's Bionect Gel is striking and surprising, and would be

extremely unlikely to have happened based on chance selection.

153. Fidia intentionally did not update is packaging nor its FDA disclosure to

indicate the changes to its product so as to actively and intentionally conceal the use

of Glyco's trade secret information.

154. On information and belief, the identified trade secrets are commercially

valuable but are not technologically necessary elements of Fidia's Bionect Gel.

155. On information and belief, Fidia entered into a first agreement with

L.A.M. in May 2006.

- 156. By virtue of the first agreement referenced above, Glyco's predecessor disclosed technical data to Fidia related to IPM Wound Gel product.
- 157. On information and belief, Fidia signed another agreement with Glyco on or about February 24, 2010, and entered into that agreement by misrepresenting that Fidia intended to manufacture the IPM Wound Gel product for Glyco.
- 158. By virtue of the agreement referenced in the paragraphs above, Glyco and/or its predecessor disclosed updated technical data to Fidia related to IPM Wound Gel product.
- 159. Glyco has at all times maintained and continues to maintain the technical data and updated technical data as a trade secret.
- 160. Glyco only disclosed the technical data and the updated technical data after entering into non-disclosure agreements.
 - 161. Glyco has a process in place for protecting its technical data.
- 162. The value of the technical data and the updated technical data derive from its secrecy.
- 163. Bionect Gel, as tested by an independent laboratory, uses Glyco's technical data in the Bionect Gel.
- 164. Fidia used stealth, deception and trickery to gain access to Glyco's trade secrets after: (1) threatening to challenge European and U.S. Patents of Glyco's predecessor; (2) challenging the European Patent of Glyco's predecessor; (3)

threatening to appeal the adverse decision regarding the European Patent unless

Glyco's predecessor entered into negotiations to sell its IPM Wound Gel intellectual

property to Fidia; (4)seeking to purchase the European and U.S. Patents, rights under

Glyco's FDA 510(k) No. K020325 and technical information relating to IPM Wound

Gel; and (5) obtaining further information from Glyco under false confidence and

false pretenses.

165. After Fidia's acts as indicated in the paragraphs above, Fidia, having

obtained the desired confidential and trade secret information, unilaterally terminated

its business relationship with Glyco, and changed its Bionect Gel using Glyco's

technical data.

166. Fidia, abusing Glyco's good faith, entered into negotiations for an

agreement under which Fidia would manufacture the IPM Wound Gel for Glyco,

only to surreptitiously and deceitfully obtain updated technical information.

167. Fidia used misrepresentations and bad faith to obtain access to the

technical data and updated technical data from Glyco.

168. On information and belief, Fidia acquired the technical data by improper

means.

169. On information and belief, Fidia disclosed the technical information

about IPM Wound Gel for obtaining contracts with a third party.

170. The activities complained of in this Count IV resulted in: (a) a loss in at

least the value of the technical information; (b) loss of sales of the IPM Wound Gel

product; and (c) and loss of exclusivity in the method, all to the harm and damage of

Glyco, a reduction in profits, and in Glyco's share of the market.

171. Glyco is a competitor of Defendants and has been damaged by the

activities complained of in this Count IV in an amount to be determined at trial.

172. On information and belief, Fidia intends to continue its unlawful

infringing activity, and Glyco continues to and will continue to suffer irreparable harm

– for which there is no adequate remedy at law.

COUNT V UNLAWFUL TRADE PRACTICES AGAINST FIDIA

173. Glyco realleges paragraphs 1 –172 as fully and completely as if set forth

herein verbatim.

174. Fidia has engaged in unfair trade practices by representing to consumers

that Fidia's Bionect Gel has characteristics or formulas that they do not have.

175. Fidia misrepresented that Bionect Gel products are patent protected, are

registered with the FDA, and that Fidia's Bionect Gel has characteristics that it does

not have.

176. Fidia has engaged in false and misleading representations and omissions

of material fact to consumers and has engaged in deceptive conduct.

177. Fidia has misrepresented material facts which have tendency to mislead

prospective licensees and consumers of IPM Wound Gel products.

178. Fidia has led prospective licensees to believe that Glyco's technical

information is irrelevant because Fidia's Bionect Gel product, use, or method of

manufacturing would lead to results similar to the results of Glyco's IPM Wound Gel

product, use, or method of manufacturing without requiring Glyco's technical

information.

179. Fidia has disparaged the goods and services and business of Glyco and

falsely promoted its own products, through false and misleading representations of

material facts.

180. By reasons of Fidia's knowingly false and misleading representations of

fact and conduct, Fidia has violated the District of Columbia's Consumer Protection

Procedures Act § 28-3904.

181. As a direct result of said misleading and deceptive conduct, Glyco has

sustained and is likely to continue to sustain damages, including lost profits, license

fees and lost sales.

182. Glyco has no adequate remedy at law.

183. Pursuant to the District of Columbia's Consumer Protection Procedures

Act \(28-3905 \) (k)(1), Glyco is entitled to enjoin Defendants' unlawful conduct as well

as obtain treble damages, punitive damages, and attorney's fees.

COUNT VI

COMMON LAW UNFAIR COMPETITION AGAINST FIDIA

184. Glyco realleges paragraphs 1 - 183 as fully and completely as if set forth

herein verbatim.

185. Fidia has engaged in false and misleading representations and omissions

of material fact and has engaged in deceptive conduct by representing to consumers

that Fidia's Bionect Gel has characteristics or formulas that it does not have, and

further by misrepresenting its intentions to Glyco in its business dealings and

contractual negotiations.

186. Fidia has engaged in false and misleading representations and omissions

of material fact and has engaged in deceptive conduct.

187. Fidia's false and misleading representations and deceptive conduct are

material in that the same were and are likely to affect prospective licensees and/or

consumers of Glyco's IPM Wound Gel products and the like.

88. Fidia has engaged in unfair competition under the common law of the

District of Columbia.

- 189. As a direct result of said deceptive conduct, Glyco has sustained and is likely to continue to sustain damages.
 - 190. Glyco has no adequate remedy at law.
- 191. Glyco is entitled to exemplary and punitive damages by reason of Defendants' willful, reckless, deliberate and intentional conduct.

COUNT VII UNJUST ENRICHMENT

- 192. Glyco realleges paragraphs 1 191 as fully and completely as if set forth herein verbatim.
- 193. As a consequence of Fidia's actions, Glyco has been denied financial compensation, partnership opportunities, joint ventures, license revenue and businesses opportunities in connection with the misappropriation, use and disclosure by Fidia of Glyco's technical data, Fidia's fraudulent business practices, intentionally misleading conduct and misrepresentations.
- 194. As a consequence of Fidia's actions, Fidia has been unjustly enriched by the manner and use of Glyco's technical data in connection with Bionect Gel.
- 195. The circumstances are such that equity and good conscience requires
 Fidia to disgorge its profits and make restitution in an amount to be proven at trial.

WHEREFORE, GLYCO PRAYS AS FOLLOWS:

- 1. For judgment that claim 1 of U.S. Patent No. 6,387,407 remain valid;
- 2. For judgment that Fidia is liable for active inducement of infringement of claim 1 of U.S. Patent No. 6,387,407;
- 3. For judgment that Fidia is liable for contributory infringement of claim 1 of U.S. Patent No. 6,387,407;
- 4. For judgment that Fidia has engaged in false patent marking in violation of 35 U.S.C. § 292 (a);
- 5. For an accounting and an award of damages to Glyco against Fidia in an amount to be determined at trial but in no event less than a reasonable royalty for patent infringement;
- 6. For an increase in damages for willful infringement;
- 7. For an accounting and an award of damages to Glyco against

 Defendants, jointly and severally, in an amount to be determined at trial for false patent marking;
- 8. That Fidia be declared to have misappropriated, and/or induced others to misappropriate, and/or benefited from misappropriation by others, with respect to the trade secrets of Glyco;
- 9. That Fidia be declared to have committed acts of unlawful trade practice with respect to Fidia's Bionect Gel misrepresentations;

- 10. That Fidia be declared to have been unjustly enriched with respect to Fidia's Bionect Gel misappropriation, use and disclosure by Fidia of Glyco's technical data, and misrepresentations;
- 11. That Fidia be found to have committed acts of unfair competition in its deceitful and deliberate misrepresentations to Glyco during business dealings and contract negotiations;
- 12. That Fidia be ordered to account for and pay to Glyco all damages caused to Glyco by reason of Fidia's misappropriation of Glyco's trade secrets, unlawful trade practice and unjust enrichment;
- 13. For an increase in damages for willful misappropriation;
- 14. That Glyco be granted pre-judgment and post-judgment interest on the damages caused to it by reason of Fidia's misappropriation of Glyco's trade secrets;
- 15. For a finding that this is an exceptional case based, at least in part, on the submissions heretofore filed in this Court;
- 16. For an award of taxable costs in favor of Glyco and against Fidia; and
- 17. For such other and further relief as to the Court appears just and proper.

Dated: September 2, 2015 Respectfully submitted,

/s/Joseph J. Zito JOSEPH J. ZITO DC Bar No. 410913 **DNL ZITO**

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Counsel for Plaintiff Glycobiosciences, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 2, 2015, the foregoing document was served this day on all counsel of record electronically via CM/ECF as set forth below.

/s/ Jerold I. Schneider
JEROLD I. SCHNEIDER

SERVICE LIST

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