

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF COLUMBIA

GYLCOBIOSCIENCES INC.)	
)	
Plaintiff)	
)	
v.)	Civil Action No.
)	
FIDIA FARMACEUTICI S.p.A.)	
)	
Defendant)	

COMPLAINT

Plaintiff, by and through counsel, files this Complaint and alleges as follows:

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. Plaintiff 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 Plaintiff's proprietary and patented Ionic Polymer Matrix (IPM) delivery system.

3. Plaintiff 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 Plaintiff is attached as Exhibit B.

4. U.S. Patent No. 6,387,407 expired on May 14, 2006.

5. U.S. Patent No. 6,387,407 was reinstated on June 20, 2104.

6. U.S. Patent No. 6,387,407 was reinstated on June 20, 2104 with retroactive effect as though it had not lapsed.

7. U.S. Patent No. 6,387,407 was lawfully reinstated on June 20, 2104.

8. U.S. Patent No. 6,387,407 was lawfully reinstated on June 20, 2104 with retroactive effect as though it had not lapsed.

9. 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.

10. FIDA does business in the United States at least through licensees, distributors, and/or through its United States subsidiary known as Fidia Pharma USA, located in Parsippany, New Jersey.

11. On information and belief FIDIA does business within the District of Columbia at least through licensees, distributors, and/or through its United States subsidiary known as Fidia Pharma USA.

Jurisdiction and Venue

12. This is a suit for infringement of United States Patent No. 6,387,407 (the '407 Patent) and for false patent marking.

13. 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.*

14. FIDIA advertises that it manufactures a product known as Bionect Gel.

15. FIDIA advertises that it manufactures a product known as Bionect Gel under U.S. Patent No. 5,925,626.

16. FIDIA advertises that it manufactures BIONECT Gel.

17. FIDIA advertises that it manufactures BIONECT Gel under U.S. Patent No. 5,925,626.

18. Venue is proper in this District at least pursuant to 28 U.S.C. § 1391 (b,d) and because, on information and belief, FIDIA has participated directly or indirectly in the defense of Civil Action 1:12-cv-01901-RDM presently pending in this Court.

19. 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.

20. Without limiting any other allegation in this Complaint, the ingredients of Bionect Gel include the sodium salt of hyaluronic acid, Carbomer 980, sodium hydroxide and purified water.

21. Hyaluronic acid falls within the definition of a mucopolysaccharide.

22. Hyaluronic acid (at least in solution) falls within the definition of a negatively charged polymer.

23. In the Bionect Gel product manufactured and sold by FIDIA, the hyaluronic acid (and/or its sodium salt) and the Carbomer 980 form a blended gelled composition

24. Carbomer 980 is initially an ionic polymer having a charge which is neutralized by sodium hydroxide in the manufacture of Bionect Gel so that in the Bionect Gel as manufactured and sold by FIDIA, the Carbomer 980 has no charge and/or a neutralized charge.

25. Alternatively, Carbomer 980 is initially an ionic polymer that reacts with sodium hydroxide during the manufacture of Bionect Gel and functions as though it has no charge on it in the blended gelled

composition with hyaluronic acid (and/or its sodium salt) as manufactured and sold by FIDIA.

COUNT ONE – PATENT INFRINGEMENT

26. Plaintiff reasserts paragraphs 1 – 25 as fully and completely as if set forth verbatim.

27. During the six years immediately preceding the filing of this Complaint, Defendant FIDIA has infringed at least claims 1 – 3 of the ‘407 Patent in violation of 35 U.S.C. § 271.

28. The specific subsections of 35 U.S.C. § 271, including but not limited to whether there has been direct or indirect infringement by FIDIA, will be identified more fully after discovery regarding at least (a) the location of manufacture of Bionect Gel by FIDIA, (b) the location of transfer of title of Bionect Gel from FIDIA to any third persons, (c) advertisements from FIDIA regarding use of Bionect Gel, (d) known uses of Bionect Gel, (e) purchasers of Bionect Gel in the United States including but not limited to hospitals and pharmacies, (f) importers of

Bionect Gel, (g) the entity that places orders for Bionect Gel; and(h) distributors of Bionect Gel.

29. Upon information and belief the infringement by FIDIA has been willful and deliberate.

30. The infringement referred to in this Count I has been to the injury and detriment to Plaintiff in an amount to be determined at trial.

COUNT TWO

31. Plaintiff realleges paragraphs 1 – 25 as fully and completely as if set forth herein verbatim.

32. This Count Two is based on false patent marking in violation of Title 35 U.S.C. § 292.

33. Carbomer 980 is a cross-linked polyacrylic acid.

34. U.S. Patent No. 5,925,626 does not refer to a gel.

35. U.S. Patent No. 5,925,626 does not refer to a non-ionic polymer.

36. U.S. Patent No. 5,925,626 does not refer to Carbomer 980.

37. U.S. Patent No. 5,925,626 does not refer to cross-linking.

38. U.S. Patent No. 5,925,626 does not refer to polyacrylic acid.

39. U.S. Patent No. 5,925,626 does not refer to sodium hydroxide.

40. The claims of U.S. Patent No. 5,925,626 exclude hyaluronic acid having a molecular weight over 800,000.

41. Bionect Gel as manufactured by FIDIA is not made in accordance with U.S. Patent No. 5,925,626.

42. The claims of U.S. Patent No. 5,925,626 do not cover or read on the Bionect Gel as manufactured by FIDIA.

43. Within the six years immediately preceding the filing of this Complaint, FIDIA has used and/or authorized the use in advertising in connection with the FIDIA-manufactured Bionect Gel the legend “U.S. Pat. No. 5,925,626.”

44. The FIDIA-manufactured Bionect Gel as tested by an independent laboratory is not covered by any claims of U.S. Pat. No. 5,925,626.

45. The activities complained of in Count Two were made for the purpose of having the public rely thereon.

46. The activities complained of in Count Two were made for the purpose of deceiving the public.

47. FIDIA has participated, directly or indirectly, in the defense of the civil action in this Court identified as Glycobiosciences, Inc. v. Innocutis Holdings, LLC et al, Civil Action 1:12-cv-01901-RDM.

48. In the civil action referred to in paragraph 46, Defendants DARA and INNOCUTIS 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.

49. On information and belief, the activities complained of in paragraph 47 have been with the full knowledge, assistance and cooperation of FIDIA.

50. The activities complained of in paragraph 47 were made for the purpose of having the Court rely thereon.

51. Plaintiff is a competitor of FIDIA and has been damaged by the activities complained of in this Count Two in an amount to be determined at trial.

WHEREFORE, PLAINTIFF PRAYS AS FOLLOWS:

1. For judgment that claims 1 – 3 of U.S. Patent No. 6,387,407 remain valid;
2. For judgment that at least one of claims 1-3 of U.S. Patent No. 6,387,407 have been directly infringed by users of the FIDIA-manufactured Bionect Gel product;
3. For judgment that FIDIA is liable for infringement of at least one of claims 1-3 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 Plaintiff 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 Plaintiff against FIDIA, jointly and severally, in an amount to be determined at trial for false patent marking;
8. For an injunction against further false patent marking;
9. For an award of taxable costs Plaintiff against FIDIA; and

10. For such other and further relief as to the Court appears just and proper.

April 20, 2015

Respectfully submitted,

/s/ Jerold I. Schneider

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