

**UNITED STATES DISTRICT COURT  
DISTRICT OF COLUMBIA**

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GLYCOBIOSCIENCES, INC.  
7 TIMBER COURT  
GEORGETOWN, ONTARIO  
L7G 4S4 ONTARIO, CANADA

Plaintiff

v.

ANIKA THERAPEUTICS, INC.  
32 WIGGINS AVENUE  
BEDFORD MASSACHUSETTS 01730

Defendant

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Civil Action No.

12-1963

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, GlycoBioSciences, Inc., by counsel, for its complaint against Defendant, Anika Therapeutics, Inc., states as follows:

**JURISDICTION AND VENUE**

1. This is an action for patent infringement under 35 U.S.C. § 271.
2. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331, 1338(a).
3. Plaintiff, GlycoBioSciences, is a corporation existing under the laws of Canada located at 7 Timber Court, Georgetown, Ontario, L7G 4S4, Ontario Canada, is the developer of a product for relief of pain, referred to as IPM Diclofenac Pain Gel and as Hylase and is the owner of United States Letters Patent 6,120,804 (the '804 patent) and 6,723,345 (the '345 patent) both entitled Topical Drug Preparations.
4. Defendant Anika Therapeutics, Inc. (Anika), upon information and belief, is a corporation organized and existing under the laws of the State of Massachusetts and has a

principle place of business at: 32 Wiggins Avenue, Bedford Massachusetts, and is the seller of the FDA approved drug product called HYALOFILL®. Anika is engaged in making, importing, using, offering for sale and/or selling the HYALOFILL® pharmaceutical product which includes the formulation as taught and claimed in the '804 and '345 patents in suit and is covered by claims of the '804 and '345 patents. The products, which are covered under the claims of the '804 and '345 patents in suit, are being sold throughout the United States, including substantial sales in Washington, DC in this Judicial District. Jurisdiction and Venue are proper in this District as to Defendant Anika, under 28 U.S.C. §1391(b), and §1400(b).

### **GENERAL ALLEGATIONS**

5. Plaintiff is a research pharmaceutical company which has developed IPM Diclofenac Pain Gel for Pain and a wound healing gel as well as other formulations for the treatment of dermatological conditions and other indications.

6. Plaintiff has invested significant resources in the development of IPM Diclofenac Pain Gel, has obtained FDA approval for use as a topical treatment introduced as Hylase.

7. Defendant manufactures, offers for sale and sells HYALOFILL® which is advertised and approved for the topical treatment of dermatological conditions.

8. The HYALOFILL® product literature HYALOFILL® as:

#### **Description**

Hyalofill® wound dressings are absorbent, soft and conformable fibrous fleece (F) or rope (R) composed of HYAFF®, an ester of hyaluronic acid. Upon absorption with wound exudate, the Hyalofill forms a soft, cohesive gel providing a moist hyaluronic acid enriched wound environment which is supportive of the healing process by aiding autolytic debridement and allowing non-traumatic removal of the dressing without damaging newly formed tissue. Hyalofill wound dressings absorb and wick away wound fluid. Hyalofill wound dressings can be cut to suit various wound shapes without linting.

#### **Indications**

Hyalofill wound dressing-F may be used for wounds such as abrasions, lacerations, minor cuts and first degree burns. Under the supervision of a

healthcare professional, Hyalofill might be used for wounds such as: diabetic ulcers, venous ulcers, pressure ulcers (I-IV), surgical wounds, second degree burns, management of wounds that are prone to bleeding, such as wounds that were mechanically and surgically debrided. HA Absorbent Wound Dressing-R is indicated for management of deep exuding wounds and fistulae.

#### Features

When Hyalofill is in contact with wound exudate or serum, a hydrophilic gel is produced. The Hyalofill gel overlays the wound and provides a protective microenvironment. The gel absorbs the wound exudate efficiently, and creates a thick hyaluronan-rich tissue interface which is conducive to healing.

a water-insoluble biocompatible gels, films . . . reacting hyaluronic acid, or a salt thereof, with a carbodiimide in the absence of a nucleophile or a polyanionic polysaccharide. . . wherein the modified hyaluronic acid is crosslinked with a biscarbodiimide.

### **THE PATENTS IN SUIT**

#### **U.S. 6,120,804:**

9. United States Patent 6,120,804, entitled Topical Drug Preparations, issued on September 19, 2000 from a patent application with a filing priority date of September 29, 1995.

10. The '804 patent was issued after careful examination by the United States Patent and Trademark Office, which determined the invention as claimed to be new, useful and unobvious.

11. The '804 patent grants protection to Plaintiff's claimed formulation for Topical Drug Preparations and includes claim 1, which describes the protected invention:

Claim 1. A method for treating pain in an animal for a sustained period of time, which comprises:  
topically applying to said animal a gelled composition comprising a therapeutically effective dose of a drug for treating pain; said drug being uniformly distributed in a polymer matrix which is suspended in a liquid medium;  
wherein the polymer matrix contains sodium hyaluronate combined with a nonionic polymer.

#### **6,723,345:**

12. United States Patent 6,723,345, entitled Topical Drug Preparations, issued on

April 20, 2004 from a patent application with a filing priority date of September 29, 1995.

13. The '345 patent was issued after careful examination by the United States Patent and Trademark Office, which determined the invention as claimed to be new, useful and unobvious.

14. The '345 patent grants protection to Plaintiff's claimed formulation for a Topical Drug Preparation and includes claims 1, 3, 5 and 8, which describe the protected invention:

Claim 1. A method for treating a dermatologic condition in an animal, which comprises:  
topically applying to said animal a therapeutically effective dose of a gelled composition for treating said dermatologic condition comprising a polymer matrix which is suspended in a liquid medium;  
wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer.

Claim 3. The method of claims 1, wherein said condition is dermatitis.

Claim 5. A method for treating a dermatologic condition in an animal, which comprises:  
topically applying to said animal a gelled composition comprising a therapeutically effective dose of a drug for treating the dermatologic condition uniformly distributed in a polymer matrix which is suspended in a liquid medium;  
wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer.

Claim 8. The method of claim 5, wherein said dermatologic condition is dermatitis.

15. HYALOFILL<sup>®</sup> is a polymer cross linked matrix which forms a gelled composition when used to treat dermatological conditions and pain associated therewith, which comprises: a matrix containing a negative charged polymer consisting of sodium hyaluronate blended with a nonionic polymer (polyethyleneglycol / carbodiimide (e.g. dimethylaminopropyl (EDC4/CMC/ETC) and/or (EDC/EDAC/EDCI)).

16. HYALOFILL<sup>®</sup> is used as a method for treating a dermatologic condition in an animal, by topically applying to said animal a therapeutically effective dose of a gelled

composition for treating said dermatologic condition comprising a polymer matrix which is suspended in a liquid medium when applied; wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer.

**COUNT I**  
**PATENT INFRINGEMENT OF 6,120,804**

17. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

18. Plaintiff owns and has at all relevant times owned, has acquired from Lam Pharmaceuticals by assignment and acquisition and has and has had standing to sue for infringement of United States Letters Patent 6,120,804.

19. The '804 patent properly names as inventors Alen Drizen, Peter Rothbart and Gary Nath and was properly assigned to Lam Pharmaceuticals.

20. Upon information and belief, Defendant Anika has infringed and continues to infringe claim 1 of the '804 patent.

21. Upon information and belief, Defendant Anika has infringed and continues to infringe the '804 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, the FDA approved drug product called HYALOFILL<sup>®</sup> within the United States.

22. HYALOFILL<sup>®</sup> pharmaceutical products include the formulation as taught and claimed in the '804 patent in suit and its use is covered by Claim 1 of the '804 patent as described above.

23. Anika's infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

24. Plaintiff is entitled to recover from the Defendant Anika the damages sustained,

reasonable royalty, lost profits of Plaintiff and/or profits of Defendant as a result of Defendant's infringing acts.

25. Defendant Anika has had knowledge of Plaintiff's rights in the '804 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

**COUNT II**  
**PATENT INFRINGEMENT OF US 6,723,345**

26. Plaintiff realleges each and every allegation set forth above and incorporates them herein by reference.

27. Plaintiff owns and has at all relevant times owned, has acquired from Lam Pharmaceuticals by assignment and acquisition and has and has had standing to sue for infringement of United States Letters Patent 6,723,345.

28. The '345 patent properly names as inventors Alen Drizen, Peter Rothbart and Gary Nath and was properly assigned to Lam Pharmaceuticals.

29. Upon information and belief, Defendant Anika has infringed and continues to infringe claims 1, 3, 5 and 8 of the '345 patent.

30. Upon information and belief, Defendant Anika has infringed and continues to infringe the claims of the '345 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, through its wholly owned subsidiary PharmaDerm, the FDA approved drug product called HYALOFILL<sup>®</sup> within the United States.

31. HYALOFILL<sup>®</sup> pharmaceutical products include the formulation as taught and claimed in the '345 patent in suit and its use is covered by Claims 1, 3, 5 and 8 of the '345 patent as described above.

32. Anika's infringement is a literal infringement and/or an equivalent infringement

of the claims and is direct, contributory and inducing.

33. Plaintiff is entitled to recover from the Defendant Anika the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendant as a result of Defendant's infringing acts.

34. Defendant Anika has had knowledge of Plaintiff's rights in the '345 patent and has continued infringement with full knowledge of and in disregard for those rights, such actions constituting willful infringement.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgement against Defendant as follows:

35. That Defendant be held to have infringed the claims of the '804 and '345 patents in suit.

36. That the Defendant be held to have willfully infringed the patents in suit.

37. That Defendant, its customers, licensees, directors, officers, agents, servants, employees and all other persons in active concert or privity or in participation with them be enjoined from directly or indirectly infringing Plaintiff's patents.

38. That judgement be awarded to Plaintiff under 35 U.S.C. §§271, 281, 284 and/or 285.

39. That judgement be entered for Plaintiff against Defendant, for Plaintiff's actual damages according to proof, for reasonable royalties and for any profits attributable to infringements of Plaintiff's patents.

40. That judgement be entered for Plaintiff against Defendant, for statutory damages based upon Defendant's acts of patent infringement and for its other violations of law.

41. That Defendant be required to account for all gains, profits, and advantages derived from its acts of infringement and for its other violations of law.

42. That judgement be entered for Plaintiff and against Defendant, for trebling of the damages awarded for patent infringement due to willful infringement.

43. That Plaintiff have judgement against the Defendant for Plaintiff's costs and attorney's fees.

44. That the Court grant such other, further, and different relief as the Court deems proper under the circumstances.

### **DEMAND FOR JURY TRIAL**

Plaintiff hereby requests and demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Joseph J. Zito

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