UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

GLYCOBIOSCIENCES, Inc. 7 Timber Court Georgetown, Ontario L7G 4S4 Ontario, Canada Plaintiff v. Innocutis Holdings, LLC 171 Church Street Suite 140 Charleston, South Carolina 29401 DARA BioSciences, Inc. 8601 Six Forks Road Suite 160 Raleigh, North Carolina 27615 Defendants	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, GlycoBioSciences, Inc., by counsel, for its complaint against Defendants, Innocutis Holdings, LLC and DARA BioSciences, 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 Innocutis Holdings, LLC (Innocutis), upon information and belief, is a corporation organized and existing under the laws of the State of South Carolina and has a principle place of business at: 171 Church Street in Charleston, South Carolina is the seller of the FDA approved drug product called BIONECT® . Innocutis is engaged in making, importing, using, offering for sale and/or selling the BIONECT® pharmaceutical product which include 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 Innocutis, under 28 U.S.C. §1391(b), and §1400(b).

5. Defendant DARA BioSciences, Inc., (DARA), upon in formation and belief, is a corporation organized under the laws of the State of North Carolina and has a principle place of business at 8601 Six Forks Road in Raleigh, North Carolina. DARA markets and sells BIONECT® as the exclusive licensee of Innocutis for certain indications of BIONECT® , 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 PharmaDerm, under 28 U.S.C. §1391(b), and §1400(b).

GENERAL ALLEGATIONS

6. 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.

7. 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.

8. Defendants manufacture, offer for sale and sell BIONECT® which is advertised and approved for the topical treatment of dermatological conditions.

9. The BIONECT® product literature and FDA product information sheet describes BIONECT® as:

> Product Description: BIONECT® Cream is a white, viscous cream. BIONECT® Gel is a clear, colorless gel. . . .The principal component is the sodium salt of hyaluronic acid (0.2%).
>
> "Ideal for Managing Redness, Inflammation & Discomfort Associated with Irritations of the Skin"
>
> Indications: BIONECT® is indicated 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. The dressing is intended to cover a wound or burn on a patient's skin, and protect against abrasion, friction, and desiccation.
>
> Ingredients: BIONECT® Cream - Hyaluronic acid sodium salt (Hyalastine®), polyethyleneglycol 400 monostearate, decyl ester of oleic acid, emulsifying wax, glycerol, sorbitol solution 70%, sodium dehydroacetate, methylparaben, propylparaben, fragrance, purified water. BIONECT® Gel - Hyaluronic acid sodium salt, sorbitol solution 70%, sodium dehydroacetate, methylparaben, propylparaben, carbomer 980, sodium hydroxide, purified water.

THE PATENTS IN SUIT

U.S. 6,120,804:

10. 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.

11. 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.

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

> 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:

13. 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.

14. 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.

15. 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:

> 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.
>
> 3. The method of claims 1, wherein said condition is dermatitis.
>
> 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.
>
> 8. The method of claim 5, wherein said dermatologic condition is dermatitis.

16. BIONECT® is a gelled composition 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).

17. BIONECT® 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; wherein the polymer matrix contains sodium hyaluronate in combination with a nonionic polymer (polyethyleneglycol).

PATENT INFRINGEMENT OF US 6,120,804

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

19. 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.

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

COUNT I
PATENT INFRINGEMENT OF '804 BY INNOCUTIS

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

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

23. Upon information and belief, Defendant Innocutis 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 BIONECT® within the United States.

24. BIONECT® 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.

25. Innocutis' infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

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

27. Defendant Innocutis 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 '804 BY DARA

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

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

30. Upon information and belief, Defendant DARA 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 BIONECT® within the United States.

31. BIONECT® 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.

32. DARA'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 DARA the damages sustained, reasonable royalty, lost profits of Plaintiff and/or profits of Defendants as a result of Defendant's infringing acts.

34. Defendant DARA 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.

PATENT INFRINGEMENT OF US 6,723,345

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

36. 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.

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

COUNT III
PATENT INFRINGEMENT OF '345 BY INNOCUTIS

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

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

40. Upon information and belief, Defendant Innocutis 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 BIONECT® within the United States.

41. BIONECT® pharmaceutical products include the formulation as taught and claimed in the '345 patent in suit and it use is covered by Claims 1, 3, 5 and 8 of the '345 patent as described above.

42. Innocutis' infringement is a literal infringement and/or an equivalent infringement of the claims and is direct, contributory and inducing.

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

44. Defendant Innocutis 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.

COUNT IV
PATENT INFRINGEMENT BY DARA

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

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

47. Upon information and belief, Defendant DARA 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 the FDA approved drug product called

BIONECT® within the United States.

48. BIONECT® pharmaceutical products include the formulation as taught and claimed in the '345 patent in suit and it use is covered by Claims 1, 3, 5 and 8 of the '345 patent as described above.

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

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

51. Defendant DARA 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 Defendants as follows:

52. That Defendants be each individually held to have infringed the claims of the '804 and '345 patents in suit.

53. That the Defendants be held to have willfully infringed the patents in suit.

54. That Defendants, their 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.

55. That Defendants each individually be enjoined to deliver upon oath, to be impounded during the pendency of this action, and delivered to Plaintiff pursuant to judgement herein, all originals, copies, facsimiles, or duplicates of any device shown by the evidence to infringe Plaintiff's patents.

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

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

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

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

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

61. That Plaintiff have judgement against the Defendants for Plaintiff's costs and attorney's fees.

62. 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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