UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GENZYME CORPORATION Plaintiff, v. ANIKA THERAPEUTICS, INC. Defendant.	**C.A. NO.: _____** **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff Genzyme Corporation ("Genzyme"), by and through undersigned counsel, files this Complaint against Anika Therapeutics, Inc. ("Anika") and alleges as follows:

The Parties

1. Plaintiff Genzyme Corporation is a corporation organized under the laws of the Commonwealth of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts.

2. Upon information and belief, Defendant Anika Therapeutics, Inc. is a corporation organized under the laws of the Commonwealth of Massachusetts, having its principal place of business at 32 Wiggins Avenue, Bedford, Massachusetts.

Jurisdiction And Venue

3. This is an action arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has personal jurisdiction over Anika. Upon information and belief, Anika is incorporated and maintains its principal place of business in the Commonwealth of Massachusetts. Furthermore, upon information and belief, Anika has engaged and currently engages in continuous and systematic contacts with the Commonwealth of Massachusetts.

6. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

The Patents-In-Suit

7. Genzyme is a global biotechnology company with products and services focused on rare inherited disorders, kidney disease, orthopedics (including the treatment of osteoarthritis), cancer, transplant and immune disease, and diagnostic testing. Genzyme protects these products and services through, *inter alia*, its intellectual property portfolio, including patents. Genzyme has expended significant resources to develop and acquire this intellectual property.

8. Genzyme is the record assignee of U.S. Patent 5,143,724 (the "'724 patent"), entitled "Biocompatible Viscoelastic Gel Slurries, Their Preparation And Use". The inventors of the '724 patent are Edward Leshchiner, Endre A. Balazs, Nancy E. Larsen and Adelya Leshchiner.

9. The '724 patent claims, among other things, a biocompatible viscoelastic gel slurry comprising a two-phase mixture, the first phase being a particulate biocompatible gel phase and the second phase being a polymer solution of a water-soluble biocompatible polymer. The United States Patent and Trademark Office duly and legally issued the '724 patent on September 1, 1992. A true and correct copy of the '724 patent is attached to this Complaint as Exhibit A.

10. Genzyme is the record assignee of U.S. Patent 5,399,351 (the "'351 patent"), entitled "Biocompatible Viscoelastic Gel Slurries, Their Preparation and Use". The inventors of the '351 patent are Edward Leshchiner, Endre A. Balazs, Nancy E. Larsen and Adelya Leshchiner.

11. The '351 patent claims, among other things, a method of viscosupplementation for medical purposes which comprises implanting a biocompatible viscoelastic gel slurry comprising a two-phase mixture, the first phase being a particulate biocompatible gel phase and the second phase being a polymer solution of a water-soluble biocompatible polymer, into a space of a living body where rheological control is desired. The United States Patent and Trademark Office duly and legally issued the '351 patent on March 21, 1995. A true and correct copy of the '351 patent is attached to this Complaint as Exhibit B.

Factual Background

12. Upon information and belief, Anika manufactures and sells Monovisc®, an injectable product that is used for the treatment of osteoarthritis. Upon further information and belief, Anika manufactures Monovisc® at facilities located within the Commonwealth of Massachusetts.

13. Upon information and belief, Anika received European CE Mark approval for Monovisc® in October 2007, and began sales of Monovisc® in Europe during the second quarter of 2008. Upon further information and belief, Anika also began sales of Monovisc® in Turkey during the second quarter of 2008.

14. Upon information and belief, Anika received approval to market Monovisc® in Canada in August 2009, and began sales of Monovisc® in Canada during 2009.

COUNT I
(INFRINGEMENT OF U.S. PATENT 5,143,724 UNDER 35 U.S.C. § 271 BY ANIKA)

15. Genzyme realleges and incorporates by reference paragraphs 1 through 14, inclusive, as if fully set forth in this paragraph.

16. Upon information and belief, Anika has infringed, and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '724 patent by making, using and/or offering to sell Monovisc® in the United States for use and sale in, at least, Europe, Turkey and Canada.

17. Anika's activities have been without express or implied license from Genzyme.

18. Upon information and belief, Anika knew or should have known of the '724 patent as of at least the date of Anika's first manufacture of Monovisc® in the United States. The filing of this Complaint also constitutes actual notice of the '724 patent to Anika under 35 U.S.C. § 287.

19. As a result of Anika's infringement of the '724 patent, Genzyme has suffered and will continue to suffer irreparable harm, for which Genyzme has no adequate remedy at law, unless the Court enjoins such infringing activities pursuant to 35 U.S.C. § 283.

20. As a result of Anika's infringement of the '724 patent, Genzyme has been damaged and will be further damaged, and is entitled to be compensated for such damages, pursuant to 35 U.S.C. § 284, in an amount to be determined at trial.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT 5,399,351 BY ANIKA)

21. Genzyme realleges and incorporates by reference paragraphs 1 through 20, inclusive, as if fully set forth in this paragraph.

22. Upon information and belief, Anika has applied to the United States Food and Drug Administration (the "FDA") for approval to sell Monovisc® in the United States for the treatment of osteoarthritis.

23. Specifically, upon information and belief, Anika:

a. filed an investigational device exemption application with the FDA;

b. completed the clinical segment of the U.S. Monovisc® pivotal trial in June 2009;

c. completed a follow-on retreatment study in September 2009; and

d. submitted the final module of a Pre-Market Approval ("PMA") filing for Monovisc® with the FDA in December 2009, which filing is currently under FDA review.

24. Upon information and belief, Anika has publicly stated that it expects to receive PMA approval for Monovisc® for the treatment of osteoarthritis in the United States, and to launch Monovisc® in the United States in the second half of 2010.

25. Upon information and belief, Anika has publicly stated that it will commercialize Monovisc® for the treatment of osteoarthritis in the United States, and that it will add resources and materials to implement this plan in 2010.

26. Upon information and belief, Anika has already begun advertising for field sales representatives for Monovisc® in the United States.

27. Upon information and belief, in view of Anika's public statements and actions concerning its intent to enter the U.S. market upon FDA approval of the PMA for Monovisc®, it is unlikely that Anika will make any material alterations to Monovisc® as described in its pending PMA.

28. Upon information and belief, after receipt of regulatory approval from the FDA, Anika will make, use, sell and/or offer to sell FDA-approved Monovisc® in the United States for the treatment of osteoarthritis.

29. Upon information and belief, Anika will directly infringe, contributorily infringe and/or actively induce the infringement by others under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, one or more claims of the '351 patent, by activities including but not limited to making, using, selling and/or offering to sell FDA-approved Monovisc® in the United States for the treatment of osteoarthritis, together with instructing, directing, and/or advising others how to carry out such infringement using such Monovisc®.

30. Upon information and belief, Anika will sell FDA-approved Monovisc® with a package insert that will include instructions for a method of treating osteoarthritis using such Monovisc®.

31. Upon information and belief, Anika will actively induce the infringement of one or more claims of the '351 patent, either literally or under the doctrine of equivalents, by making, offering for sale and/or selling FDA-approved Monovisc® in the United States, together with a package insert setting forth instructions for a method of treating osteoarthritis using such Monovisc®.

32. Upon information and belief, when physicians or others use FDA-approved Monovisc® according to the method of treating osteoarthritis set forth on the package insert

provided by Anika, those acts will constitute direct infringement of one or more claims of the '351 patent, either literally or under the doctrine of equivalents.

33. Upon information and belief, Anika will contributorily infringe, either literally or under the doctrine of equivalents, one or more claims of the '351 patent by offering for sale and/or selling FDA-approved Monovisc® in the United States, while knowing that such Monovisc® is especially made or especially adapted for use in the infringement of the '351 patent, and is not a staple article suitable for substantial non-infringing use.

34. Upon information and belief, Anika knew or should have known of the '351 patent as of at least the date of Anika's first FDA filing in connection with its application for approval of Monovisc® in the United States. The filing of this Complaint also constitutes actual notice of the '351 patent to Anika under 35 U.S.C. § 287.

35. By virtue of, *inter alia*, the facts alleged in paragraphs 21-35, inclusive, of this Complaint, there exists an actual and justiciable case or controversy between the parties that is ripe for adjudication under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) as to whether Anika will infringe one or more claims of the '351 patent.

COUNT III
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT 5,143,724 BY ANIKA)

36. Genzyme realleges and incorporates by reference paragraphs 1 through 35, inclusive, as if fully set forth in this paragraph.

37. Upon information and belief, after FDA regulatory approval of Monovisc®, Anika will make, use, sell and/or offer to sell FDA-approved Monovisc® in the United States for the treatment of osteoarthritis.

38. Upon information and belief, Anika will infringe, either literally or under the doctrine of equivalents, one or more claims of the '724 patent by making, using, selling and/or offering to sell FDA-approved Monovisc® in the United States.

39. By virtue of, *inter alia*, the facts alleged in paragraphs 36-39, inclusive, of this Complaint, there exists an actual and justiciable case or controversy between the parties that is ripe for adjudication under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) as to whether Anika will infringe one or more claims of the '724 patent.

Prayer For Relief

WHEREFORE, Genzyme requests the Court to enter judgment in its favor and grant the following relief:

(a) A judgment that Anika has infringed the '724 patent by making, using and/or offering to sell Monovisc® in the United States;

(b) A judgment that Anika will directly infringe, contribute to and/or actively induce the infringement of the '351 patent by making, using, selling and/or offering to sell FDA-approved Monovisc® in the United States;

(c) A judgment that Anika will directly infringe the '724 patent by making, using, selling and/or offering to sell FDA-approved Monovisc® in the United States;

(d) A judgment and order permanently restraining and enjoining Anika and its directors, officers, agents, servants, employees, attorneys, others controlled by them, and all persons in active concert or privity with them, from infringing the '724 and '351 patents by making, using, selling or offering to sell Monovisc® or FDA-approved Monovisc® in the United States;

(e) A judgment and order requiring Anika to pay all available and legally permissible damages to compensate Genzyme for Anika's infringing acts, but in no event less than a reasonable royalty in accordance with 28 U.S.C. § 284;

(f) A finding that the complained-of conduct by Anika has been willful, warranting an award of treble damages under 35 U.S.C. § 284;

(g) A finding that this case is exceptional under 35 U.S.C. § 285, warranting an award to Genzyme of its costs, including attorney fees and other expenses incurred in connection with this action;

(h) A judgment and order requiring Anika to pay Genzyme pre-judgment interest and post-judgment interest on all damages awarded; and

(i) Such further relief as this Court deems just and appropriate.

Demand For Jury Trial

Pursuant to Fed. R. Civ. P. 38, Genzyme demands a trial by jury of all issues so triable.

Respectfully submitted,

Dated: July 7, 2010

By: /s/ Alison E.H. McLaughlin

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