

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

GENZYME CORPORATION)

Plaintiff,)

v.)

SEIKAGAKU CORPORATION,)
ASSOCIATES OF CAPE COD, INC.,)
ZIMMER HOLDINGS INC., ZIMMER,)
INC., ZIMMER U.S., INC., and ZIMMER)
NEW ENGLAND, INC.,)

Defendants.)

C.A. NO.: _____

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff Genzyme Corporation (“Genzyme”), by and through its undersigned counsel, files this Complaint against Seikagaku Corporation, Associates of Cape Cod, Inc., Zimmer Holdings Inc., Zimmer, Inc., Zimmer U.S., Inc., and Zimmer New England, Inc. (collectively, “Defendants”) 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 Seikagaku Corporation is a corporation organized under the laws of Japan with a principal place of business at Marunouchi Center Building, 6-1 Marunouchi 1-chome, Chiyoda-ku, Tokyo 100-0005, Japan.

3. Upon information and belief, defendant Associates of Cape Cod, Inc. is a subsidiary of Seikagaku Corporation and is organized under the laws of the Commonwealth of Massachusetts, having its principal place of business at 124 Bernard East St. Jean Drive, East Falmouth, Massachusetts 02536.

4. Upon information and belief, the acts of Associates of Cape Cod, Inc. are performed at the direction and/or authorization of, and/or with the cooperation and/or assistance of Seikagaku Corporation, and are performed at least in part for the benefit of Seikagaku Corporation.

5. Upon information and belief, defendants Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. are corporations organized under the laws of the State of Delaware, having their principal place of business at 345 East Main Street, Warsaw, Indiana 46580.

6. Upon information and belief, Zimmer New England, Inc. is a corporation organized under the laws of the state of New York, having its principal place of business at 20 Computer Drive West, Albany, New York. Upon information and belief, Zimmer New England, Inc. has a satellite office at 10 Tech Circle, Natick, Massachusetts 01760.

7. Upon information and belief, Zimmer U.S., Inc. and Zimmer New England, Inc. are corporations registered to conduct business in the Commonwealth of Massachusetts.

8. Upon information and belief, the acts of Zimmer, Inc., Zimmer U.S., Inc. and Zimmer New England, Inc. are performed at the direction and/or authorization of, and/or with the cooperation and/or assistance of Zimmer Holdings Inc., and are performed at least in part for the benefit of Zimmer Holdings Inc.

Jurisdiction And Venue

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

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

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

12. The Court has personal jurisdiction over Seikagaku Corporation. Upon information and belief, Seikagaku Corporation engages in continuous and systematic contacts with the Commonwealth of Massachusetts through its subsidiary, Associates of Cape Cod, Inc.

13. The Court has personal jurisdiction over Zimmer Holdings Inc., Zimmer, Inc., and Zimmer U.S., Inc. Upon information and belief, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. have engaged and currently engage in continuous and systematic contacts with the Commonwealth of Massachusetts. Specifically, and upon information and belief, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. have marketed, placed, and continue to place medical products into the stream of commerce via established distribution channels, with the knowledge and/or understanding that such products are marketed and/or sold within this District. Upon further information and belief, Zimmer U.S., Inc. is incorporated in the state of Delaware and is registered to conduct business in the Commonwealth of Massachusetts.

14. This Court has personal jurisdiction over Zimmer New England, Inc. Upon information and belief, Zimmer New England, Inc. is incorporated in the state of New York and registered to conduct business in the Commonwealth of Massachusetts. Furthermore, upon information and belief, Zimmer New England, Inc. has engaged and currently engages in

continuous and systematic contacts with the Commonwealth of Massachusetts. Furthermore, upon information and belief, Zimmer New England, Inc. has a satellite office in the Commonwealth of Massachusetts at 10 Tech Circle, Natick, Massachusetts 01760.

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

The Patent-In-Suit

16. 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. 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.

17. Genzyme is an innovator and leader in the field of cross-linked hyaluronic acid technology, and in particular for its use in the treatment of knee pain in osteoarthritis of the knee.

18. Genzyme first obtained United States Food and Drug Administration (“FDA”) approval of Synvisc[®] for the treatment of pain in osteoarthritis of the knee in the U.S. in August 1997. It was one of only two hyaluronic acid (“HA”)-based treatments for the pain of osteoarthritis approved in the United States prior to 2001.

19. Synvisc[®] is characterized by an elastic and viscous cross-linked HA gel. The Synvisc[®] treatment regimen uses three injections, 7 days apart, and provides pain relief for up to 6 months.

20. Genzyme obtained FDA approval to market Synvisc-One[®] for the treatment of pain in osteoarthritis of the knee in February 2009. It was the first single injection HA-based treatment regimen for pain in osteoarthritis of the knee approved for sale in the U.S. Like Synvisc[®], Synvisc-One[®] is characterized by an elastic and viscous cross-linked HA gel.

Moreover, like the Synvisc[®] three injection regimen, Synvisc-One[®]'s single injection regimen provides pain relief for up to six months.

21. Upon information and belief, no other single injection HA-based regimen for pain in osteoarthritis of the knee was approved in the U.S. after the Synvisc-One[®] approval until Gel-One[®] was approved by the FDA on March 22, 2011.

22. Genzyme is the lawful owner of all right, title and interest in U.S. Patent 7,931,030 (the "'030 patent"), entitled "Regimens for Intra-Articular Viscosupplementation". The inventor of the '030 patent is Francois Bailleul.

23. The '030 patent claims, among other things, methods for treating a knee joint of a human subject suffering from a joint pathology, including osteoarthritis, or osteoarthritic pain in the knee joint, the method comprising a treatment regimen, the regimen being characterized by the step of administering a single administration dose, within a 24 hour period, of a viscosupplement intra-articularly into the knee joint of the human subject, wherein the viscosupplement comprises a cross-linked HA and does not contain additional active components, and wherein the treatment regimen does not comprise administering the viscosupplement in weekly intervals.

24. The United States Patent and Trademark Office ("PTO") duly and legally issued the '030 patent on April 26, 2011. A true and correct copy of the claims as allowed in the 11/313,706 application that issued as the '030 patent is attached to this Complaint as Exhibit A.¹

¹ Note that Exhibit A shows the claims as allowed at the close of prosecution. The PTO will renumber the claims and correspond the appropriate dependent claims in the issued '030 patent.

Factual Background

25. Upon information and belief, Seikagaku Corporation manufactures Gel-One[®], an intra-articular injectable product that will be used for the treatment of pain in osteoarthritis of the knee.

26. Upon information and belief, Gel-One[®] is also known by its development code, “Gel-200”.

27. Upon information and belief, Gel-One[®] is a viscosupplement solution composed of a cross-linked hyaluronate hydrogel that does not contain other active components and that is administered in a single intra-articular injection regimen characterized by the step of administering a single administration dose within a 24 hour period, which regimen does not comprise administration in weekly intervals.

28. Upon information and belief, Seikagaku received FDA approval to market Gel-One[®] on March 22, 2011 and plans to launch Gel-One[®] in 2011 through a distribution agreement with Zimmer, Inc. See March 24, 2011 Seikagaku Corporation Press Release attached to this Complaint as Exhibit B. A May 29, 2009 Press Release announcing that Seikagaku Corporation had entered into a sole distribution agreement for Gel-200 in the United States with Zimmer, Inc., is attached to this Complaint as Exhibit C.

COUNT I
(DECLARATORY JUDGMENT OF INFRINGEMENT
OF U.S. PATENT 7,931,030 BY DEFENDANTS)

29. Genzyme realleges and incorporates by reference paragraphs 1 through 28, inclusive, as if fully set forth in this paragraph.

30. Upon information and belief, Gel-One[®] is a single injection viscosupplement composed of a cross-linked hyaluronate hydrogel that is produced by photo cross-linking, that

does not include other active components, and that will be administered in a single dose within a 24 hour period and not administered in weekly intervals.

31. Upon information and belief, Gel-One[®] has a high viscoelasticity, which results in residual presence in the knee joint cavity which is said to enable long-term pain relief from a single intra-articular injection.

32. Upon information and belief, Seikagaku Corporation has represented that a single injection of Gel-One[®] is expected to have efficacy similar to current multiple injection formulations over the same time span.

33. Upon information and belief, Seikagaku Corporation has represented that Gel-One[®] will expand treatment options for osteoarthritis patients in the United States.

34. Upon information and belief, Seikagaku Corporation has indicated its intent to market Gel-One[®] in the United States in 2011.

35. Upon information and belief, one or more of the following entities will be involved with the distribution of Gel-One[®] in the United States: Zimmer Holdings Inc., Zimmer, Inc., Zimmer U.S., Inc. and Zimmer New England, Inc.

36. Upon information and belief, Defendants 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 '030 patent, by activities including but not limited to using, selling, importing and/or offering to sell FDA-approved Gel-One[®] in the United States for the treatment of pain in osteoarthritis of the knee, together with instructing, directing, and/or advising others how to carry out such infringement using such Gel-One[®].

37. Upon information and belief, Defendants will sell FDA-approved Gel-One[®] with a package insert that will include instructions for a method of treating pain in osteoarthritis of the knee using such Gel-One[®].

38. Upon information and belief, Defendants will actively induce the infringement of one or more claims of the '030 patent, either literally or under the doctrine of equivalents, by offering for sale and/or selling FDA-approved Gel-One[®] in the United States, together with a package insert setting forth instructions for a method of treating pain in osteoarthritis of the knee using such Gel-One[®].

39. Upon information and belief, when physicians or others use FDA-approved Gel-One[®] according to the method of treating pain in osteoarthritis of the knee set forth on the package insert provided by Defendants, those acts will constitute direct infringement of one or more claims of the '030 patent, either literally or under the doctrine of equivalents.

40. Upon information and belief, Defendants will contributorily infringe, either literally or under the doctrine of equivalents, one or more claims of the '030 patent by offering for sale and/or selling FDA-approved Gel-One[®] in the United States, while knowing that such Gel-One[®] is especially made or especially adapted for use in the infringement of the '030 patent, and is not a staple article suitable for substantial non-infringing use.

41. Upon information and belief, Defendants knew or should have known of the '030 patent as of at least July 2008, the date of filing the original application for premarket approval ("PMA"). Defendants knew or should have known of the '030 patent at this time because, among other reasons, corporate entities that conduct diligence to protect their intellectual property would have been aware of the application for the '030 patent, the prosecution status of which was publicly available via Patent Application Information Retrieval at the PTO website

(<http://portal.uspto.gov/external/portal/pair>) since the application published in July 2006. The filing of this Complaint also constitutes actual notice of the '030 patent to Defendants under 35 U.S.C. § 287.

42. By virtue of, *inter alia*, the facts alleged in paragraphs 29-41, 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 Defendants will infringe one or more claims of the '030 patent.

Prayer For Relief

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

(a) A judgment that Defendants will directly infringe, contribute to and/or actively induce the infringement of the '030 patent by using, selling, importing and/or offering to sell FDA-approved Gel-One® in the United States;

(b) A judgment and order permanently restraining and enjoining Defendants and their directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all persons in active concert or privity with them, and their successors and assigns, from infringing the '030 patent by using, selling, importing or offering for sale FDA-approved Gel-One® in the United States;

(c) A judgment and order requiring the Defendants to pay all available and legally permissible damages to compensate Genzyme for Defendants' infringing acts, but in no event less than a reasonable royalty in accordance with 35 U.S.C. § 284;

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

(e) 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;

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

(g) 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: April 26, 2011

By: /s/ Lara Oravec

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