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NORTHERN DISTRICT OF CALIFORNIA
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MEDTRONIC USA, INC.,
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MEDTRONIC SOFAMOR DANEK, INC., and
SDGI HOLDINGS, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MEDTRONIC, INC.,
MEDTRONIC VASCULAR, INC.,
MEDTRONIC USA, INC.,
MEDTRONIC VASCULAR GALWAY, LTD.,
MEDTRONIC SOFAMOR DANEK, INC., and
SDGI HOLDINGS, INC.

Plaintiffs,

v.

KYPHON INC.,

Defendant.

**CASE NO.**

**C06-02559 MEJ**

**COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT**

**DEMAND FOR JURY TRIAL**

Plaintiffs Medtronic, Inc., Medtronic Vascular, Inc., ("Medtronic Vascular"), Medtronic USA, Inc. ("Medtronic USA"), Medtronic Vascular Galway, Ltd. ("Medtronic Vascular Galway"), Medtronic Sofamor Danek, Inc. ("Medtronic Sofamor"), and SDGI Holdings, Inc. ("SDGI") (collectively "Medtronic"), for their Complaint against Defendant Kyphon Inc. ("Kyphon"), allege as follows:

## PARTIES

1. Plaintiff Medtronic, Inc. is a corporation organized and existing under the laws of Minnesota and has its principal place of business in Minneapolis, Minnesota.

2. Plaintiff Medtronic Vascular is a corporation organized and existing under the laws of Delaware and has its principal place of business in Santa Rosa, California. Medtronic Vascular was formerly named Medtronic AVE, Inc.

3. Plaintiff Medtronic USA is a corporation organized and existing under the laws of Minnesota and has its principal place of business in Minneapolis, Minnesota.

4. Plaintiff Medtronic Vascular Galway is a corporation organized and existing under the laws of the Republic of Ireland and has its principal place of business in Galway, Ireland.

5. Plaintiff Medtronic Sofamor is a corporation organized and existing under the laws of Indiana and has its principal place of business in Memphis, Tennessee.

6. Plaintiff SDGI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Wilmington, Delaware. Medtronic Sofamor is the sole shareholder of SDGI.

7. On information and belief, Defendant Kyphon is a corporation organized and existing under the laws of Delaware and has its principal place of business at 1221 Crossman Avenue, Sunnyvale, California, 94089.

## JURISDICTION

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

9. This action further arises under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, and is based on an actual and justiciable controversy between the parties under the patent laws of the United States, 35 U.S.C. §§ 1 et seq.

10. This Court has personal jurisdiction over Defendant because Defendant is a citizen and resident of California and because the claims asserted herein arise in substantial part from events that took place and are taking place in the State of California.

**VENUE**

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) because the Defendant resides in this District, Defendant has done and continues to do business in this District, and the claims asserted herein arise in substantial part from events that took place and are taking place in this District.

**INTRADISTRICT ASSIGNMENT**

12. This action should be assigned to the San Jose Division of this Court because Defendant resides in, and a substantial portion of the events giving rise to the claims herein occurred and are occurring in, Santa Clara County.

**BACKGROUND**

13. Medtronic is a world leader in medical technology providing lifelong solutions for people with chronic disease. Medtronic offers products, therapies and services used to treat conditions such as, for example, diabetes, heart disease, neurological disorders, urological and digestive disorders, vascular illnesses and spinal disorders.

14. In the area of the spine, Medtronic is a leader in providing the best and most advanced surgical tools for minimally invasive surgical procedures, allowing doctors to perform spinal surgery with much smaller incisions, more precision, less damage to the surrounding tissue, and faster recovery times. Technology developed and provided by Medtronic for minimally invasive spine surgery includes medical methods, instruments and devices, such as, for example, implants for treating spinal injuries.

15. As part of its business, Medtronic participates in intensive research, development, and innovation and, as a result, holds certain patents directed to its medical technologies, products, therapies, and services.

**A. Patent Infringement**

16. On April 11, 1989, U.S. Patent No. 4,820,349 (the "Saab '349 patent"), entitled "Dilation Catheter with Collapsible Outer Diameter," was duly and legally issued to Mark A. Saab. Medtronic Vascular is the owner by assignment of all right, title, and interest in and to the Saab '349 patent, a true and correct copy of which is attached hereto as Exhibit A.

17. On June 2, 1998, U.S. Patent No. 5,759,191 (the "Barbere '191 patent"), entitled "Coaxial PTCA Catheter with Anchor Joint," was duly and legally issued to Michael D. Barbere. Medtronic Vascular is the owner by assignment of all right, title, and interest in and to the Barbere '191 patent, a true and correct copy of which is attached hereto as Exhibit B.

18. On January 30, 2001, U.S. Patent No. 6,179,856 (the "Barbere '856 patent"), entitled "Coaxial PTCA Catheter with Anchor Joint," was duly and legally issued to Michael D. Barbere. Medtronic Vascular is the owner by assignment of all right, title, and interest in and to the Barbere '856 patent, a true and correct copy of which is attached hereto as Exhibit C.

19. On July 1, 2000, U.S. Patent No. 6,096,038 (the "Michelson '038 patent"), entitled "Apparatus for Inserting Spinal Implants," was duly and legally issued to Gary Karlin Michelson. SDGI is the owner by assignment of all right, title, and interest in and to the Michelson '038 patent, a true and correct copy of which is attached hereto as Exhibit D.

20. Defendant Kyphon's business is dependent on its sales of certain medical products, known in the industry as "balloon tamps," which are used to treat spinal conditions, such as "Vertebral Compression Fractures" ("VCFs"), through a procedure that has become known in the industry as "Kyphoplasty."

21. Defendant Kyphon has infringed the Saab '349 patent, the Barbere '191 patent, the Barbere '856 patent and at least claim 47 of the Michelson '038 patent by making, using, selling and/or offering to sell products for use in its Kyphoplasty procedures. This infringement has been willful.

**B. Declaratory Judgment**

22. Kyphon's balloon tamps require the inflation of a balloon inside a spinal bone, which has proven problematic over the years due to the lack of precise control over the direction and magnitude of the force resulting from the expansion of the balloon.

23. Medtronic has recently developed an innovative new osteotome that effectively treats spinal disorders and VCFs without the use of a balloon.

24. Medtronic believes that its osteotome has certain advantages over Kyphon's balloon tamps, and thus represents a threat to Kyphon's market share in the treatment of the spine using Kyphoplasty.

25. On information and belief, Kyphon owns certain patents related to its balloon tamp technology (hereinafter referred to as the "Kyphon Patents"). The Kyphon Patents are

a. U.S. Patent No. 4,969,888 ("'888 patent"), entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device," issued on November 13, 1990. On information and belief, Kyphon is the owner by assignment of all right, title, and interest in and to the '888 patent, a true and correct copy of the which is attached hereto as Exhibit E.

b. U.S. Patent No. 5,108,404 ("'404 patent"), entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device," issued on April 28, 1992. On information and belief, Kyphon is the owner by assignment of all right, title, and interest in and to the '404 patent, a true and correct copy of which is attached hereto as Exhibit F.

c. U.S. Patent No. 6,440,138 ("'138 patent"), entitled "Structures and Methods for Creating Cavities in Interior Body Regions," issued on August 27, 2002. On information and belief, Kyphon is the owner by assignment of all right, title, and interest in and to the '138 patent, a true and correct copy of which is attached hereto as Exhibit G.

d. U.S. Patent No. 6,863,672 ("'672 patent"), entitled "Structures and Methods for Creating Cavities in Interior Body Regions," issued on March 8, 2005. On

information and belief, Kyphon is the owner by assignment of all right, title, and interest in and to the '672 patent, a true and correct copy of which is attached hereto as Exhibit H.

e. U.S. Patent No. 6,235,043 ("'043 patent"), entitled "Inflatable Device For Use In Surgical Protocol Relating To Fixation Of Bone," issued on May 22, 2001. On information and belief, Kyphon is the owner by assignment of all right, title, and interest in and to the '043 patent, a true and correct copy of which is attached hereto as Exhibit I.

26. Kyphon initiated a patent infringement suit against Disc-O-Tech Medical Technologies Ltd. and Disc Orthopaedic Technologies Inc. in 2004 on several of its patents, including three of those involved in this action.

27. Earlier this year, Kyphon requested a sample of Medtronic's osteotome. Upon information and belief, this request was made in order to allege patent infringement.

28. On information and belief, Kyphon has also made statements to third parties expressing its intention to bring suit against Medtronic alleging that Medtronic's new competing product infringes Kyphon's patents.

29. Kyphon has sued Medtronic on another unrelated matter in Memphis, Tennessee.

30. Thus, there is an actual and justiciable controversy between the parties with respect to the non-infringement of Kyphon's Patents by Medtronic and the invalidity of Kyphon's Patents.

**FIRST COUNT**

**(Patent Infringement by Kyphon)**

31. Plaintiffs incorporate the allegations of the foregoing paragraphs by reference as if fully set forth herein.

32. Plaintiffs are informed and believe and based thereon allege that in violation of 35 U.S.C. § 271 Defendant Kyphon has been and is currently directly infringing, contributorily infringing, and/or inducing infringement of the Saab '349, Barbere '191, Barbere '856 and Michelson '038 patents by, among other things, making, using, offering to sell, selling, and/or importing without authority or

licenses from Medtronic infringing devices, including but not limited to balloon tamps. Such products include, but are not limited to, the KyphX Xpander® Inflatable Bone Tamp.

33. Plaintiffs are informed and believe and based thereon allege that Kyphon's infringement of the Saab '349, Barbere '191, Barbere '856 and Michelson '038 patents has been and continues to be willful.

34. Unless enjoined, Kyphon will continue to infringe the Saab '349, Barbere '191, Barbere '856 and Michelson '038 patents and Medtronic will suffer irreparable injury as a direct and proximate result of Kyphon's conduct.

35. Medtronic has been damaged by Kyphon's conduct and, until an injunction issues, will continue to be damaged in an amount yet to be determined.

**SECOND COUNT**

**(Non-Infringement and Invalidity of the Kyphon Patents)**

36. Plaintiffs incorporate the allegations of the foregoing paragraphs by reference as if fully set forth herein.

37. The manufacture, use, sale, offer to sell, and/or importation of Medtronic's osteotome does not infringe and has not infringed any valid claim of Kyphon's '888, '404, '138, '672 and '043 patents. Plaintiffs, their customers, and all others have the right to manufacture, have made, use, sell, offer to sell, and import Medtronic's osteotome, unhampered and unrestricted by Defendant.

38. The claims of Kyphon's '888, '404, '138, '672 and '043 patents are invalid for failure to comply with one or more provisions of the Patent Laws of the United States, Title 35, United States Code, §§ 101 et seq., including without limitation Sections 101, 102, 103 and/or 112.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment as follows:

1. A determination that Kyphon has infringed the Saab '349 patent, the Barbere '191 patent, the Barbere '856 patent and the Michelson '038 patent, directly, by inducement and/or contributorily;

2. A determination that such infringement by Kyphon has been willful and deliberate;

3. An award of damages adequate to compensate for such infringement;

4. An enhancement of the compensatory damages, up to three times;

5. A declaration that Medtronic's osteotome does not infringe and has not infringed any of the claims of the Kyphon Patents under any subsection of 35 U.S.C. § 271;

6. A declaration that the Kyphon Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112;

7. An order enjoining Defendant and its representatives, officers, partners, employees, agents, parents, subsidiaries, and affiliates from suing or threatening to sue for infringement of any of the Kyphon Patents on the basis of making, selling, offering for sale or importing of Medtronic's osteotome;

8. A determination that this case is "exceptional," in the sense of 35 U.S.C. § 285;

9. An award in favor of Plaintiffs, and against Defendant Kyphon, for the costs incurred in bringing and maintaining this action, including reasonable attorneys' fees;

10. Interest on all damages at the legal interest rate; and

11. Such other and further relief as this Court may deem just and proper.

Dated: April 13, 2006

AKIN GUMP STRAUSS HAUER & FELD LLP

By _____

Sean P. DeBruine
Steven M. Zager
Michael A. O'Shea
Michael Simons

Attorneys for Plaintiffs
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MEDTRONIC VASCULAR, INC.,
MEDTRONIC USA, INC.,
MEDTRONIC VASCULAR GALWAY, LTD.,
MEDTRONIC SOFAMOR DANEK, INC., and
SDGI HOLDINGS, INC.

**JURY DEMAND**

Plaintiffs MEDTRONIC, INC., MEDTRONIC VASCULAR, INC., MEDTRONIC USA, INC., MEDTRONIC VASCULAR GALWAY, LTD., MEDTRONIC SOFAMOR DANEK, INC., and SDGI HOLDINGS, INC. hereby demand a trial by jury.

Dated: April 13, 2006

AKIN GUMP STRAUSS HAUER & FELD LLP

By _____

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