

Complaint

IN THE MATTER OF

**KYPHON INC.,
DISC-O-TECH MEDICAL TECHNOLOGIES LTD.
AND
DISCOTECH ORTHOPEDIC TECHNOLOGIES
INC.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT

Docket C-4201; File No. 071 0101

Complaint, October 5, 2007 – Decision, December 3, 2007

This consent order addresses the \$220 million acquisition by Kyphon Inc. (“Kyphon”) of certain assets from Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (collectively “Disc-O-Tech”). Respondents compete in the market for minimally invasive vertebral compression fracture (“MIVCF”) treatments, which doctors use to relieve pain when one or more vertebrae collapse. MIVCF treatments were developed to provide doctors and their patients with a safer and more effective treatment than pain management and open surgery. The complaint alleges that Disc-O-Tech developed an innovative MIVCF treatment system known as Confidence. The complaint further alleges that the acquisition of the assets related to Disc-O-Tech’s Confidence product lines would remove an actual, direct, and substantial competitor from the U.S. market for MIVCF treatment products. Under the consent order, both Kyphon and Disc-O-Tech must divest all Confidence assets (including intellectual property) to a third party and enable that third party to manufacture and sell the Confidence cement and delivery system. The order further requires Kyphon to provide a license for any other assets it acquired from Disc-O-Tech, which will ensure that the acquirer will be able to remain a viable competitor in the MIVCF treatment product market.

Participants

For the Commission: *Stephanie C. Bovee, Richard H. Cunningham, Sean G. Dillon, Daniel P. Ducore, Nwamaka Ejebe, Jonathan S. Klarfeld, Richard A. Levy, Randall A. Long, Michael R.*

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Moiseyev, Jana Pariser, Jeffrey H. Perry, Amy S. Posner, Ashley E. Reichenbach, and Matthew Riley.

For the Respondents: William Baer and Deborah L. Feinstein, Arnold & Porter LLP; Karen Silverman, Latham & Watkins, LLP; Rhett R. Krulla and John R. Ingrassia, Proskauer Rose LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission, having reason to believe that Kyphon Inc., a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets of Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc., corporations subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. DEFINITIONS

1. “Commission” means the Federal Trade Commission.
2. “Kyphon” means Kyphon Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Kyphon Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
3. “Disc-O-Tech” means Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation), its directors, officers, employees, agents, representatives, predecessors, successors, and

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assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation), including Discotech Orthopedic Technologies Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

4. “Vertebral Compression Fracture” or “VCF” means a fracture of the vertebral body such as that which may result from osteoporosis, cancer, or trauma.

5. “Kyphoplasty” means a minimally invasive vertebral compression fracture treatment during which bone cement is injected through a needle into the vertebral body after a void in the vertebral body has been created by the insertion and inflation of one or two balloon-tipped catheters.

6. “Vertebroplasty” means a minimally invasive vertebral compression fracture treatment during which cement is injected through a needle into the vertebral body.

7. “FDA” means the United States Food and Drug Administration.

II. RESPONDENTS

8. Respondent Kyphon is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 1221 Crossman Avenue, Sunnyvale, California 94089. Kyphon, among other things, is engaged in the design, manufacture, marketing, and sale of single-use and implantable medical device products used in minimally invasive therapies for the treatment and restoration of spinal anatomy, including the KyphX Kyphoplasty products.

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9. Respondent Disc-O-Tech is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Israel, with its office and principal place of business located at 11 Ha'hoshlim Street, Herzeliya, Israel 46724. Disc-O-Tech's United States subsidiary, doing business as Discotech Orthopedic Technologies Inc., is located at 7 Centre Dr., Suite 1, Monroe Township, New Jersey 08831. Disc-O-Tech, among other things, is engaged in the research, development, marketing, and sale of medical device products used in minimally invasive therapies for the treatment and restoration of spinal anatomy, including the Confidence Vertebroplasty system.

10. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. PROPOSED ACQUISITION

11. On December 20, 2006, Kyphon agreed to acquire the spinal assets of Disc-O-Tech (the "Acquisition"), including Disc-O-Tech's intellectual property, sales agreements, and other assets relating to its Confidence minimally invasive VCF treatment product business. The Acquisition was structured as two transactions - an Asset Purchase Agreement (Vertebroplasty Assets) and an Asset Purchase Agreement (Non-Vertebroplasty Assets) - that have a combined value of approximately \$220 million.

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IV. RELEVANT MARKET

12. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of minimally invasive VCF treatment products. Minimally invasive VCF treatment products include, among other things, Kyphoplasty products, Disc-O-Tech's Confidence system, and traditional Vertebroplasty products.

13. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant line of commerce. To compete in the United States minimally invasive VCF treatment product market, a firm must have FDA approval or clearance for its device, establish a local sales and service organization, and its product must not infringe any other firm's intellectual property.

V. STRUCTURE OF THE MARKET

14. Kyphon's Kyphoplasty products account for more than 90 percent of the market (by revenue) for research, development, manufacture, and sale of minimally invasive VCF treatment products. Disc-O-Tech's recently-launched Confidence system is a novel Vertebroplasty product that uses a highly viscous cement and proprietary delivery system. It is the only product currently on the market that is likely to provide significant and unique competition to Kyphon in the near term and is poised to take a significant share of Kyphon's sales. Disc-O-Tech's Confidence system would provide particularly vigorous competition to Kyphon if acquired by a major spine competitor, as would have occurred but for the Acquisition. Traditional Vertebroplasty products differ significantly from Kyphoplasty products and the Confidence system, and are low-cost products that are virtually commodities and provide only limited competition to Kyphon. There are other competitors in the minimally invasive VCF treatment product market, including

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Medtronic and Spineology, but none of those competitors provide the near-term competitive threat to Kyphon that Disc-O-Tech does. Although several additional firms are attempting to enter the minimally invasive VCF treatment product market, the time line for commercialization of those firms' products is significantly behind that of the Confidence system, and none appears to have the Confidence system's ultimate prospects for success.

VI. ENTRY CONDITIONS

15. Developing minimally invasive VCF treatment products, working around and/or acquiring the necessary licenses to critical intellectual property, obtaining FDA approval, and building a marketing infrastructure, takes significantly longer than two years. Therefore, entry into the relevant line of commerce described in Paragraph 12 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, would be substantially to lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. eliminating actual, direct, and substantial competition between Kyphon and Disc-O-Tech in the market for the research, development, marketing, and sale of minimally invasive VCF treatment products;
- b. increasing Kyphon's ability to raise prices unilaterally in the relevant market; and
- c. reducing research and development in the relevant market.

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VIII. VIOLATIONS CHARGED

17. The Asset Purchase Agreement (Vertebroplasty Assets) constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 11, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifth day of October, 2007, issues its Complaint against said Respondents.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition of certain vertebral compression fracture repair system assets of Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (hereafter collectively referred to as “Respondent DOT”) by Kyphon Inc. (hereafter referred to as “Respondent Kyphon”), and Respondents Kyphon and DOT having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the

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Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and issues the following Order to Hold Separate and Maintain Assets (“Hold Separate Order”):

1. Respondent Kyphon Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 1221 Crossman Avenue, Sunnyvale, CA 94089.
2. Respondent Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its office and principal place of business located at 11 Ha’hoshlim St., 46724 Herzeliya, Israel.

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3. Respondent Discotech Orthopedic Technologies Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 7 Centre Dr., Suite 1, Monroe Township, NJ 08831.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Hold Separate Order, the definitions in Paragraph I of the Decision and Order attached to the Agreement Containing Consent Orders in this matter shall apply to all capitalized terms in this Hold Separate Order, in addition to the following definitions:

- A. "Held Separate Business" means the Confidence Assets and the on-going manufacturing, distribution, marketing and sale of the Confidence Products.

II.

IT IS FURTHER ORDERED that:

- A. Until the Date Of Divestiture, Respondents shall:
1. take such actions as are necessary to maintain the viability and marketability of the Confidence Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of the Confidence Assets, except for ordinary wear and tear;

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2. not sell, transfer, encumber or otherwise impair the economic viability, marketability, or competitiveness of the Confidence Assets; and
3. not consummate the acquisition contemplated by the Kyphon-DOT APA (Vertebroplasty Assets).

B. Until the Date Of Divestiture:

1. Respondent DOT's personnel operating the Held Separate Business must retain and maintain all Material Confidential Information of the Held Separate Business on a confidential basis, separate and apart from Respondent Kyphon and, except as is requested by Kyphon for purposes of the divestiture of the Confidence Assets as required by the Decision and Order, in this matter, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to Respondent Kyphon or with Respondent Kyphon's personnel. Such DOT personnel shall also execute confidentiality agreements prohibiting the disclosure of any Material Confidential Information of the Held Separate Business; and
2. Respondent Kyphon and Respondent Kyphon's personnel shall not receive or use Material Confidential Information of the Held Separate Business except for purposes of divesting the Confidence Assets as required by the Decision and Order, in this matter.

C. Until the Date Of Divestiture and unless otherwise provided for in this Hold Separate Order, Respondent Kyphon shall not permit any of its employees, officers, or directors to be involved in the operations of the Held Separate Business.

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- D. Until the Date Of Divestiture, Respondent Kyphon shall not offer Respondent DOT employees Related To the Held Separate Business positions with Respondent Kyphon.
- E. Until the Date Of Divestiture, Respondents shall do nothing to prevent or discourage Suppliers that, prior to the Date Of Divestiture, supplied goods and services for the Confidence Assets from continuing to supply goods and services for the Confidence Assets.
- F. No later than five (5) days after the date this Hold Separate Order becomes final, Respondent DOT shall circulate to employees of the Held Separate Business and to Respondent DOT's employees who are responsible for the development, manufacture and sale of Confidence Products, a copy of this Hold Separate Order and the Consent Agreement.
- G. The purposes of this Hold Separate Order are to: (1) preserve the Held Separate Business as a viable, competitive, and ongoing business independent of Respondent Kyphon until the divestiture required by the Decision and Order is achieved; (2) assure that no Material Confidential Information is exchanged between Respondent Kyphon and the Held Separate Business, except in accordance with the provisions of this Hold Separate Order; (3) prevent interim harm to competition pending the relevant divestitures and other relief; and (4) help remedy any anticompetitive effects of the proposed Acquisition.

III.

IT IS FURTHER ORDERED that Respondent Kyphon shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent Kyphon,

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- B. Any proposed acquisition, merger, or consolidation of Respondent Kyphon, *provided, however*, if Medtronic acquires Respondent Kyphon, that acquisition shall be excluded from this notice requirement, or
- C. Any other change in Respondent Kyphon that may affect compliance obligations arising out of this Order, including but, not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondent Kyphon.

IV.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

V.

IT IS FURTHER ORDERED that this Hold Separate Order shall terminate at the earlier of:

- A. three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

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- B. the day after the Date Of Divestiture required by the Consent Agreement.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition of certain vertebral compression fracture repair system assets of Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (hereafter collectively referred to as “Respondent DOT”) by Kyphon Inc. (hereafter referred to as “Respondent Kyphon”), and Respondents Kyphon and DOT having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than

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jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Hold Separate and Maintain Assets ("Hold Separate Order"), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Kyphon Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 1221 Crossman Avenue, Sunnyvale, CA 94089.

2. Respondent Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its office and principal place of business located at 11 Ha'hoshlim St., 46724 Herzeliya, Israel.

3. Respondent Discotech Orthopedic Technologies Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 7 Centre Dr., Suite 1, Monroe Township, NJ 08831.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

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ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Kyphon” or “Respondent Kyphon” means Kyphon Inc., its directors, officers, employees, agents, representatives, successors (including Medtronic, if Kyphon is acquired by Medtronic), and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Kyphon, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “DOT” or “Respondent DOT” means Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc., their directors, officers, employees, agents, representatives, successors, and assigns; and their joint ventures, subsidiaries, divisions, groups and affiliates controlled by Disc-O-Tech Medical Technologies Ltd. and Discotech Orthopedic Technologies Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer” means each Person that receives the prior approval of the Commission to acquire the Confidence Assets pursuant to Paragraphs II or III of this Order. DOT is not excluded from being considered an Acquirer.
- E. “Affiliate” means any entity or acquired business that directly or indirectly is controlled by either Respondent or Acquirer, but only so long as such control exists, control being the direct or indirect ownership of at least fifty percent (50%) of the stock entitled to vote upon election of directors

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or persons performing similar functions, or direct or indirect ownership of the maximum percentage permitted under local laws or regulations in those countries where fifty percent (50%) ownership by a foreign entity is not permitted.

- F. “Assumed Contracts” means those contracts as defined and listed in the Kyphon-DOT APA (Vertebroplasty Assets).
- G. “Confidence Assets” means all assets and intellectual property of Respondent DOT Relating To the research, development, manufacture, marketing, distribution, and sale of products accessing, diagnosing, or treating spinal disease states or disorders that are proposed to be acquired or have been acquired by Respondent Kyphon pursuant to the Kyphon-DOT APA (Vertebroplasty Assets), which assets and intellectual property include, but are not limited to:
 - 1. the Confidence Products, together with the related cement system and cement injectors including, but not limited to:
 - a. documents Relating To quality control,
 - b. documents Relating To Suppliers,
 - c. copies of contracts with Suppliers, unless such contracts cannot, according to their terms, be disclosed to third parties even with the permission of Kyphon or DOT to make such disclosure;
 - 2. all Assumed Contracts;
 - 3. all Intangible Property exclusively Relating To the Confidence Products and the Next Generation Product;
 - 4. all technology rights licenses, franchises, know-how, inventions, designs, specifications, plans and drawings primarily used in the research, development,

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manufacture, marketing, distribution, and sale of products accessing, diagnosing, or treating spinal disease states or disorders;

5. all Books and Records, as that term is defined in the Kyphon-DOT APA (Vertebroplasty Assets);
6. brochures and marketing information;
7. all permits and licenses that are necessary to enable the Acquirer to manufacture, sell, and distribute the Confidence Products, including the related cement system and cement injectors;

Provided, however, that “Confidence Assets” does not include Excluded Assets.

- H. “Confidence Products” means the products or product line currently manufactured and sold by Respondent DOT and that the Acquirer develops, manufactures, distributes, or sells as a result of the acquisition of the Confidence Assets including, but not limited to, the cement and cement delivery system. Confidence Products refers solely to vertebroplasty products.
- I. “Date Of Divestiture” means the date upon which the Confidence Assets are divested to an Acquirer pursuant to this Order.
- J. “Excluded Assets” means:
 1. assets and Intangible Property that are proposed to be acquired or have been acquired from Respondent DOT by Respondent Kyphon pursuant to the Kyphon-DOT APA (Non-Vertebroplasty Assets) including, but not limited to, the B-Twin products and related Intangible

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Property, the SKy Bone Expander products and related Intangible Property, and other rights and assets proposed to be acquired or acquired pursuant to the Kyphon-DOT APA (Non-Vertebroplasty Assets);

2. all cash, cash equivalents, and short term investments of cash;
 3. accounts and notes receivable;
 4. rights to the names “Kyphon,” and “Disc-O-Tech” and any variation of those names;
 5. prepaid items or rebates;
 6. minute books, tax returns, and other corporate books and records;
 7. any inter-company balances due to or from DOT;
 8. all benefits plans;
 9. all writings and other items that are protected by the attorney-client privilege, the attorney work product doctrine or any other cognizable privilege or protection, except to the extent such information specifically Relates To the Confidence Assets;
 10. assets specifically excluded in the Kyphon-DOT APA (Vertebroplasty Assets).
- K. “Governmental Approvals” means any permissions or sanctions issued by any government or governmental organization, including, but not limited to, licenses, permits, accreditations, authorizations, registrations, certifications, certificates of occupancy, and certificates of need.

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- L. “Governmental Approvals For Divestiture” means any Governmental Approvals that an Acquirer must have to own, develop, manufacture, distribute, and sell the Confidence Assets.
- M. “Intangible Property” means intangible property including, but not limited to, intellectual property, software, computer programs, Patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property.
- N. “Kyphon-DOT APA (Non-Vertebroplasty Assets)” means the December 20, 2006, Asset Purchase Agreement (Non-Vertebroplasty Assets) by and among Disc-O-Tech Medical Technologies Ltd. (In Liquidation), Discotech Orthopedic Technologies Inc., and Kyphon Inc., including all amendments, exhibits, attachments, agreements, and schedules thereto.
- O. “Kyphon-DOT APA (Vertebroplasty Assets)” means the December 20, 2006, Asset Purchase Agreement (Vertebroplasty Assets) by and among Disc-O-Tech Medical Technologies Ltd. (In Liquidation), Discotech Orthopedic Technologies Inc., and Kyphon Inc., including all amendments, exhibits, attachments, agreements, and schedules thereto.
- P. “Material Confidential Information” means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person’s business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, Patents, technologies, processes, or other trade secrets.

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- Q. “Medtronic” means Medtronic, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Medtronic, Inc. (including Kyphon, after the date on which it acquires Kyphon) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- R. “Next Generation Product” means a vertebral compression fracture repair system, not yet fully developed or marketed by DOT, defined in Exhibit D (the “Non-Competition, Confidentiality and Development Agreement”) to the Kyphon-DOT APA (Vertebroplasty Assets).
- S. “Patents” means all patents, patent applications, and statutory invention registrations (which shall be deemed to include provisional applications, invention disclosures, certificates of invention and applications for certificates of invention), in each case existing as of the date this Order is accepted by the Commission for public comment, and includes all reissues, divisions, continuations, continuations-in-part, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the world.
- T. “Person” means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- U. “Relating To” or “Related To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- V. “Remedial Agreement” means any agreement between both or either of the Respondents and an Acquirer (or between a

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Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order.

- W. “Successor” means the Acquirer’s successor or Affiliate, or any Person or Persons to whom the Acquirer transfers, licenses, or authorizes to manufacture, develop or sell Confidence Products or Next Generation Products pursuant to Intangible Property transferred or licensed pursuant to Paragraphs II or III of this Order.
- X. “Supplier” means any Person that has sold to DOT any goods or services for use with the Confidence Assets.
- Y. “Third Party” means any private entity other than the following: (1) Respondents, (2) Medtronic, or (3) the Acquirer.
- Z. “Transferred Non-Vertebroplasty Intangible Property” means any Intangible Property that is proposed to be transferred or has transferred to Respondent Kyphon from Respondent DOT as part of the Kyphon-DOT APA (Non-Vertebroplasty Assets).
- AA. “Transferred Vertebroplasty Intangible Property” means any Intangible Property that has been transferred or licensed to the Acquirer from Respondents pursuant to the Remedial Agreement and this Decision and Order.

II.

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IT IS FURTHER ORDERED that:

- A. Respondent Kyphon shall, within sixty (60) days after the date on which the Agreement Containing Consent Orders, in this matter, is accepted by the Commission for placement on the public record for comment, divest, absolutely, and in good faith, at no minimum price, the Confidence Assets to an acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.
- B. Respondent DOT shall:
 - 1. take no actions to interfere with the divestiture of the Confidence Assets;
 - 2. enter into and execute all documents, agreements, and other instruments that may be required to consummate the divestiture of the Confidence Assets to an Acquirer; and
 - 3. transfer all assets and intellectual property required to be transferred to the Acquirer pursuant to the Remedial Agreement.
- C. Until the Date Of Divestiture, Respondents shall:
 - 1. take such actions as are necessary to maintain the viability and marketability of the Confidence Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of the Confidence Assets, except for ordinary wear and tear;
 - 2. not sell, transfer, encumber or otherwise impair the economic viability, marketability, or competitiveness of the Confidence Assets; and

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3. not consummate the acquisition contemplated by the Kyphon-DOT APA (Vertebroplasty Assets).

D. Respondent Kyphon shall:

1. not join, file, induce, prosecute or maintain any suit, in law or equity, against the Acquirer or Successor to the extent that such suit alleges that such Acquirer or Successor has infringed or is infringing any Transferred Non-Vertebroplasty Intangible Property with the Confidence Product or Next Generation Product developed, designed, manufactured, licensed, or otherwise sold by or on behalf of Acquirer or Successor pursuant to the Transferred Vertebroplasty Intangible Property, if such suit would have the potential to interfere with the Acquirer's freedom to practice in the research, development, manufacture, use, import, export, distribution or sale of such Confidence Products or Next Generation Products; and
2. in the event it assigns, transfers, or licenses Transferred Non-Vertebroplasty Intangible Property to a Third Party, include in such assignment, transfer, or license a covenant not to sue the Acquirer or Successor at least as protective as those extended pursuant to the preceding Paragraph II.D.1, as a condition of such assignment, transfer or license.

- E. Any Remedial Agreement related to the Confidence Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Confidence Assets shall constitute a failure to comply with this Order.
- F. The Remedial Agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order.

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Nothing in this Order shall reduce, or be construed to reduce, any rights or benefits of the Acquirer, or any obligations of Respondents, under the Remedial Agreement.

- G. Respondent Kyphon shall include in any Remedial Agreement related to the Confidence Assets the following provisions:
1. Respondent Kyphon shall covenant to the Acquirer that Respondent Kyphon shall not join, file, induce, prosecute or maintain any suit, in law or equity, against the Acquirer or Successor to the extent that such suit alleges that such Acquirer or Successor has infringed or is infringing any Transferred Non-Vertebroplasty Intangible Property with the Confidence Product or Next Generation Product developed, designed, manufactured, licensed, or otherwise sold by or on behalf of Acquirer or Successor pursuant to the Transferred Vertebroplasty Intangible Property, if such suit would have the potential to interfere with the Acquirer's freedom to practice in the research, development, manufacture, use, import, export, distribution or sale of such Confidence Products or Next Generation Product; and
 2. Respondent Kyphon shall covenant to the Acquirer that any Third Party assignee, transferee or licensee of Transferred Non-Vertebroplasty Intangible Property shall agree to provide a covenant not to sue the Acquirer or Successor at least as protective as those extended pursuant to the preceding Paragraph II.G.1, as a condition of such assignment, transfer or license.
- H. Respondents shall grant to the Acquirer royalty-free, perpetual, worldwide, non-exclusive licenses to the Transferred Non-Vertebroplasty Intangible Property for the field of use of vertebroplasty that, as of the time of the signing of the Agreement Containing Consent Orders in this

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matter, is used in the research, development, manufacture, use, export, distribution, or sale of Confidence Products or Next Generation Products (including the right to transfer or sublicense such license rights in such Intangible Property, exclusively or nonexclusively, to others by any means).

- I. Until the Date Of Divestiture, Respondents shall:
 1. cooperate with the Acquirer and assist the Acquirer, at no cost to the Acquirer, before the Date Of Divestiture in obtaining all Government Approvals For Divestiture;
 2. do nothing to prevent or discourage Suppliers that, prior to the Date Of Divestiture, supplied goods and services for the Confidence Assets from continuing to supply goods and services for the Confidence Assets.
- J. Respondent DOT shall, (i) at the option of the Acquirer, (ii) no later than the Date Of Divestiture, and (iii) as part of the Remedial Agreement, enter into:
 1. one or more transition agreements for the short-term provision of services to be provided by Respondent DOT to the Acquirer. *Provided, however,* Respondent DOT shall not be required to agree to transition services (i) other than those similar in form and substance to the transition services that are a part of the Kyphon-DOT APA (Vertebroplasty Assets), and (ii) for a term longer than nine (9) months, but in any case such transition agreements shall not terminate later than December 1, 2008; and
 2. one or more non-competition, confidentiality, and development agreements between Respondent DOT and the Acquirer similar in form and substance and length of time as similar agreements in Exhibit D to the Kyphon-DOT APA (Vertebroplasty Assets).

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- K. The purpose of Paragraph II of this Order is to ensure the continuation of the Confidence Assets as part of an ongoing viable enterprise engaged in the same business in which such assets were engaged at the time of the announcement of the acquisition by Kyphon of the Confidence Assets, to ensure that the Confidence Assets are operated independently of, and in competition with, Kyphon, and to remedy the lessening of competition alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

A. If Respondents:

1. have not divested, absolutely and in good faith and with the Commission's prior approval, the Confidence Assets pursuant to Paragraph II of this Order, the Commission may appoint a trustee to divest the Confidence Assets that have not been divested pursuant to Paragraph II of this Order in a manner that satisfies the requirements of Paragraph II of this Order. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other

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statute enforced by the Commission, for any failure by Respondents to comply with this Order; or

2. close the Kyphon-DOT APA (Vertebroplasty Assets) before the Date Of Divestiture as prohibited in Paragraph II.C of this Order, the Commission immediately may appoint a trustee to divest the Confidence Assets that have not been divested pursuant to Paragraph II of this Order, notwithstanding that the time allowed to divest pursuant to Paragraph II.A has not expired, in a manner that satisfies the requirements of Paragraph II of this Order. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after receipt of notice by the staff of the Commission to Respondents of the identity of any proposed

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trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee.

- C. Within ten (10) days after appointment of a trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestitures required by this Order.
- D. If a trustee is appointed by the Commission or a court pursuant to this Order, Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest the Confidence Assets that have not been divested pursuant to Paragraph II of this Order.
 - 2. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the trustee has submitted a divestiture plan or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be divested by this Order, and to any other relevant information, as the trustee may request. Respondents shall develop such financial or other information as the trustee may request

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and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph III in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.

4. The trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the trustee receives bona fide offers for particular assets from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity for such assets, the trustee shall divest the assets to the acquiring entity selected by Respondents from among those approved by the Commission; *provided, further, however*, that Respondents shall select such entity within five (5) days of receiving notification of the Commission's approval.
5. The trustee shall serve, without bond or other security, at the cost and expense of Respondent Kyphon, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by

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the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for the trustee's services, all remaining monies shall be paid at the direction of Respondents, and the trustee's power shall be terminated. The compensation of the trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.
7. The trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestiture.
9. Respondents may require the trustee and each of the trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the trustee from providing any information to the Commission.

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- E. If the Commission determines that a trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute trustee in the same manner as provided in this Paragraph III.
- F. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

IV.

IT IS FURTHER ORDERED that for a period of two (2) years from the date this Order becomes final, Respondent Kyphon shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly acquire or receive a license for any of the Confidence Assets transferred pursuant to the Remedial Agreement.

Said advance written notification shall contain (i) either a detailed term sheet for the proposed acquisition or license or the proposed agreement or license with all attachments, and (ii) documents that would be responsive to Item 4(c) of the Premerger Notification and Report Form under the Hart-Scott-Rodino Premerger Notification Act, Section 7A of the Clayton Act, 15 U.S.C. § 18a, and Rules, 16 C.F.R. §§ 801-803, relating to the proposed transaction (hereinafter referred to as “the Notification”), *provided, however*, (i) no filing fee will be required for the Notification, (ii) an original and one copy of the Notification shall be filed only with the Secretary of the Commission and need not be submitted to the United States Department of Justice, and (iii) the Notification is required from Kyphon and not from any other party to the transaction. Kyphon shall provide the Notification to the Commission at least thirty (30) days prior to consummating the transaction (hereinafter referred to as the “first waiting period”). If, within the first waiting period,

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representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Kyphon shall not consummate the transaction until thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

Provided, further, however, that prior notification shall not be required by this paragraph for a transaction for which Notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

V.**IT IS FURTHER ORDERED** that:

- A. Beginning thirty (30) days after the date this Order becomes final, and every thirty (30) days thereafter until Respondents have fully complied with Paragraphs II.A, II.B., II.C., II.G. II.H., II.I., and II.J. of this Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order and the Hold Separate Order.
- B. On the first and second anniversary of the date this Order becomes final, Respondent Kyphon shall submit to the Commission a verified written report setting forth in detail the manner and form in which it is complying and has complied with this Order, the Hold Separate Order, and the Remedial Agreement. Respondent Kyphon shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.

VI.

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IT IS FURTHER ORDERED that Respondent Kyphon shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent Kyphon,
- B. Any proposed acquisition, merger, or consolidation of Respondent Kyphon, *provided, however*, if Medtronic acquires Respondent Kyphon, that acquisition shall be excluded from this notice requirement, or
- C. Any other change in Respondent Kyphon that may affect compliance obligations arising out of this Order, including but, not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondent Kyphon.

VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

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VIII.

IT IS FURTHER ORDERED that this Order shall terminate on December 3, 2012.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

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**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT****I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Kyphon Inc. (“Kyphon”) and Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (collectively “Disc-O-Tech”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from Kyphon’s acquisition of Disc-O-Tech’s Confidence assets. Under the terms of the proposed Consent Agreement, Kyphon and Disc-O-Tech are required to divest all assets (including intellectual property) related to Disc-O-Tech’s Confidence business to a third party, enabling that third party to manufacture and sell the Confidence cement and delivery system for the treatment of vertebral compression fractures.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw the proposed Consent Agreement or make it final.

On December 20, 2006, Kyphon agreed to acquire certain spine-related assets from Disc-O-Tech, including the intellectual property, sales agreements, and other assets relating to Disc-O-Tech’s B-Twin, SKy Bone Expander, and Confidence product lines for approximately \$220 million (the “Acquisition”). The Commission’s complaint alleges that the proposed acquisition of the assets related to the Confidence system, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the

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Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an actual, direct, and substantial competitor from the U.S. market for minimally invasive vertebral compression fracture (“MIVCF”) treatment products. The proposed Consent Agreement would remedy the alleged violation by requiring a divestiture that will replace the competition that otherwise would be lost in this market as a result of the Acquisition.

II. The Parties

Kyphon develops and markets medical devices used to restore and preserve spinal function and diagnose the source of low back pain, including products used to treat vertebral compression fractures in a minimally invasive manner. In 2006, Kyphon reported worldwide sales of approximately \$408 million, and U.S. sales of \$324 million.

Disc-O-Tech, an Israeli corporation and its U.S. subsidiary that develops, manufactures, and sells products for minimally invasive orthopedic surgeries, introduced the Confidence system to the U.S. market in July 2006. Disc-O-Tech’s global revenues were approximately \$14 million in 2006.

III. Minimally Invasive Vertebral Compression Fracture Treatments

Vertebral compression fractures (“VCFs”) occur when one or more vertebral bodies collapse. Osteoporosis, a degenerative bone disease that largely affects elderly women, causes the vast majority of VCFs, but they can also be caused by cancerous tumors or traumatic injury. For some patients, VCFs cause extreme, persistent, and debilitating pain.

Doctors and their patients have few ways to effectively treat VCFs. In the past, physicians most commonly treated VCF patients with a variety of pain management techniques such as back braces, bed rest, and pain medication. For many patients, these techniques

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do not control the pain associated with VCFs and could lead to later health problems. Open surgery involving the placement of metal hardware is rarely performed to repair a VCF because the patients are typically elderly and not good candidates for successful procedures. MIVCF treatments were developed to provide doctors and their patients with a VCF treatment that is more effective than pain management and safer and more effective than open surgery.

Vertebroplasty, the first MIVCF treatment to be introduced, involves the injection of a fairly liquid polymethylmethacrylate bone cement into the fractured vertebral body under fluoroscopy image guidance. The bone cement sets quickly, stabilizing the fracture and eliminating painful movement of loose bone in the vertebra. Vertebroplasty effectively relieves pain, but many doctors have safety concerns regarding the risk of the liquid bone cement leaking out of the vertebral body.

Kyphoplasty, introduced by Kyphon in 1999, is similar to vertebroplasty, except that the physician performs the additional step of inflating one or two balloons inside the vertebral body before injecting the bone cement. The principal advantage of kyphoplasty is that the inflation of the balloons creates a cavity into which the bone cement can flow, reducing the likelihood that cement will leak outside of the vertebral body. Kyphoplasty may have the additional benefit of helping to restore the vertebral body towards its pre-fracture shape and height. Because of its safety advantage and other perceived advantages, kyphoplasty is the most widely used MIVCF treatment product in the United States.

Because of the superiority of MIVCF treatment products over alternatives, the relevant product market in which to analyze the competitive effects of the Acquisition is no larger than MIVCF treatment products. The relevant geographic market is the United States. MIVCF treatment products are medical devices that are regulated by the United States Food and Drug Administration ("FDA"). MIVCF treatment products sold outside the United States,

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but not approved for sale in the United States, are not viable alternatives for U.S. consumers and hence are not in the relevant market.

Kyphon's premium-priced kyphoplasty product dominates the MIVCF treatment product market with more than a ninety percent share based on revenues. Disc-O-Tech's Confidence system is the first MIVCF treatment product that uses a highly viscous cement. Both Kyphon's product, which uses balloons, and Disc-O-Tech's product, which uses a highly viscous cement, have substantially lower risks of leakage from the vertebral body following injection than do the "traditional" vertebroplasty products offered by numerous other firms. All of the latter inject a low viscosity cement. As a result, Disc-O-Tech's Confidence system is poised to become a closer substitute for Kyphon's product than are the traditional vertebroplasty products. For this reason, traditional vertebroplasty products will not constrain the prices for Kyphon's product to the same extent that Disc-O-Tech's Confidence system would, absent its acquisition by Kyphon.

There are other competitors in the MIVCF treatment product market, including Medtronic and Spineology, but none provides the near-term competitive threat to Kyphon posed by Disc-O-Tech's offering. Medtronic has had limited success selling its Arcuate XP product to date, and its product appears to hold limited growth prospects. Spineology's MIVCF offering has been and appears likely to remain a niche product that competes primarily for younger VCF patients. Although several additional firms are attempting to enter the MIVCF treatment product market, the time line for commercialization of these products is significantly behind that of the Confidence system, and none appears to have the Confidence system's immediate prospects for success.

IV. Competitive Effects and Entry Conditions

The Acquisition would cause significant competitive harm in the market for MIVCF treatment products. Confidence is Kyphon's principal competitive threat, and, but for the Acquisition, would

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make significant inroads into Kyphon's near-monopoly position. Because both products offer a safe method for treating VCFs, many physicians consider the Confidence system to be the best alternative to kyphoplasty, particularly for elderly osteoporotic patients who receive the vast majority of kyphoplasty treatments. By eliminating such a close competitor, the Acquisition would likely allow Kyphon to unilaterally raise prices in the MIVCF treatment market. The anticompetitive effects of the Acquisition are exacerbated by the fact that it appears to have been undertaken with the specific goal of precluding other major spine companies from acquiring Confidence and marketing it against kyphoplasty, which would have happened had Kyphon not acquired Confidence itself. By enabling Kyphon, rather than a major spine company, to control the further development and positioning of Confidence, Kyphon would be able to avoid the competition that it otherwise would have faced in the MIVCF treatment product market. As such, the Acquisition, if consummated, would have a significant, adverse effect on competition.

New entry is not likely to avert the anticompetitive effects of the proposed transaction. It likely would take more than two years for a would-be entrant to develop a product, conduct clinical trials, and submit the product for FDA approval. After submitting an application for FDA clearance or approval, a firm must wait for the FDA to review the material and respond to any questions the FDA may have. In addition to the development and regulatory time requirements for firms seeking to enter the MIVCF treatment product market, there are substantial intellectual property barriers an entrant must overcome. Patent litigation among competitors in this market is ongoing, and key patents act as a major obstacle to any prospective entrant. As such, any new MIVCF treatment device of any competitive significance would have to be designed around existing patents. Finally, even after a non-infringing design is developed and the product is manufactured, a firm would still need to establish a U.S. sales and marketing force. Considering all these factors, entry into the manufacture and sale of MIVCF treatment

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products is likely to take longer than two years. Thus, timely and sufficient entry in response to a small but significant price increase is extremely unlikely.

V. The Proposed Consent Agreement

The parties have agreed, pursuant to the proposed Consent Agreement, to divest Disc-O-Tech's Confidence assets to a Commission-approved acquirer no later than 60 days after the Commission accepts the Consent Agreement for public comment, effectively remedying the Acquisition's anticompetitive effects in the MIVCF treatment product market. The Consent Agreement requires that the parties divest all assets relating to the Confidence system, including tangible property, intellectual property, and any permits and licenses that are necessary to manufacture, distribute, and sell the Confidence system. In addition, the parties must divest the rights to certain Disc-O-Tech development efforts related to the Confidence system. To the extent that an acquirer of the Confidence assets requires additional assets not included in the asset package, the Consent Agreement requires Kyphon to provide a license to any other assets it acquired from Disc-O-Tech, which will ensure that the acquirer will be able to immediately enter the MIVCF treatment product market and remain a viable competitor.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. First, the Commission will evaluate possible purchasers of the divested assets to ensure that the competitive environment that would have existed but for the transaction is restored. If the parties do not divest the Confidence assets within the 60-day time period to a Commission-approved buyer, or if Kyphon closes on the acquisition of the Confidence assets, the Consent Agreement provides for the Commission to appoint a trustee to divest the assets. Second, Disc-O-Tech is required to provide transitional services to the Commission-approved buyer. These transitional services, which are similar in form to what Disc-O-Tech would have provided to Kyphon, may be necessary for a smooth transition of the Confidence assets to the

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acquirer and to ensure continued and uninterrupted service to customers during the transition. The Consent Agreement also requires that Kyphon covenant not to sue the acquirer of the Confidence assets for infringing any intellectual property Kyphon acquired from Disc-O-Tech that is not being divested. This covenant covers not only the Confidence assets, but also extends to any developments an acquirer might make to the Confidence assets. This provision is designed as a safety net to ensure that Kyphon does not interfere with the acquirer's freedom to compete in the U.S. MIVCF treatment product market with a patent infringement lawsuit based on former Disc-O-Tech intellectual property. Finally, to ensure that the Commission will have an opportunity to review any attempt by Kyphon to acquire or license any of the Confidence assets at any time within the next two years, the proposed Consent Agreement contains a prior notice provision committing Kyphon to an H-S-R framework, even if such a transaction otherwise would be non-reportable.

The Order to Hold Separate and Maintain Assets that is included in the Consent Agreement requires that Disc-O-Tech maintain the viability of the Confidence business as a competitive operation until the business is transferred to a Commission-approved buyer. Specifically, Disc-O-Tech must maintain the confidentiality of sensitive business information, and take all actions required to prevent the destruction or wasting of the Confidence assets. Kyphon may not interfere with the Confidence business during the pendency of the divestiture by having any involvement in the Confidence business, making offers of employment to Disc-O-Tech employees involved in the Confidence business before the Confidence assets are divested, or interfering with Disc-O-Tech's suppliers of materials for the Confidence product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

KYPHON INC.

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Complaint

IN THE MATTER OF

OWENS CORNINGCONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket C-4210; File No. 061 0281**Complaint, December 4, 2007 – Decision, December 4, 2007*

This consent order addresses the acquisition by Owens Corning (“Respondent”) of certain assets of Compagnie de Saint Gobain (“Saint Gobain”). The complaint alleges that Respondent and Saint Gobain account for more than 90 percent of the Continuous Filament Mat (“CFM”) sold in North America. CFM is an input in the production of non-electrical laminate, marine parts and accessories, and other products where its strength and other desirable characteristics make it the most cost effective material to use. The complaint alleges that the acquisition would reduce competition by eliminating direct competition between these two companies. Under the consent order, Respondent must divest its CFM business to AGY Holding Corp., which develops, manufactures, and markets a wide range of glass fiber yarns and reinforcement materials, within 10 days of the acquisition. Respondent is also required to divest its Huntingdon Facility that produces CFM and its Marbles Furnace, which supplies the Huntingdon Facility with essential glass fiber marbles used in production.

Participants

For the *Commission*: Daniel P. Ducore, Wallace W. Easterling, Mark Frankena, David Glasner, Sebastian Lorigo, David Morris, Catherine M. Moscatelli, Louis Silvia, Jacqueline Tapp, and Leonor Valazquez.

For the *Respondent*: Deborah L. Feinstein and Mark R. Merley, Arnold and Porter LLP.