141 0187

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
MEDTRONIC, INC., **a corporation;**	)	
and	)	**Docket C-**
COVIDIEN PLC, **a public limited company.**	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the acquisition by Respondent Medtronic, Inc. ("Medtronic") of the voting securities of Respondent Covidien plc ("Covidien"), collectively ("Respondents"), and Respondents having been furnished thereafter with a copy of a draft of the 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 Order ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of the 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 said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint, 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 Medtronic, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its headquarters address located at 710 Medtronic Parkway, Minneapolis, MN 55432-5604.

2. Respondent Covidien plc is a public limited company, organized, existing, and doing business under and by virtue of the laws of Ireland, with its headquarters address located at 20 on Hatch, Lower Hatch Street, Dublin 2, Ireland.

3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER
I.

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

A. "Medtronic" means Medtronic, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Medtronic, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Medtronic shall include Covidien and Medtronic plc.

B. "Covidien" means Covidien plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Covidien, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Covidien shall not include Medtronic.

C. "New Medtronic" means Medtronic Holdings Limited (f/k/a Kalani I Limited), which will become Medtronic plc, the new Irish holding company that will exist after the acquisition of Covidien by Medtronic.

D. "Respondent(s)" means Medtronic and Covidien, individually and collectively.

E. "Commission" means the Federal Trade Commission.

F. "Actual Cost" means the actual cost incurred to provide the relevant goods or services, including the cost of direct labor and direct material used and allocation of overhead that is consistent with past custom and practice.

G. "Acquisition" means the acquisition of Covidien by Medtronic under New Medtronic pursuant to the Transaction Agreement between Medtronic, Covidien, New Medtronic, Makani II Limited, Aviation Acquisition Co., Inc., and Aviation Merger Sub, LLC dated as of June 15, 2014.

H. "Acquisition Date" means the date on which the Acquisition is consummated.

I. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of the Drug-Coated Balloons. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").

J. "Assets To Be Divested" means the Drug-Coated Balloon Business, the PTA License, the PTA Materials, and the Background IP License.

K. "Background IP" means all patents, copyrights, trade secrets or other intellectual property rights owned by Covidien as of the Closing Date (other than trademarks or trade dress), that are used in or would otherwise be infringed by the Drug-Coated Balloon Business or the research, Development, and manufacture of PTA Products for the incorporation of such PTA Products into Drug-Coated Balloons as of the Closing Date but that are not included in the Drug-Coated Balloon Business, the PTA License, and the PTA Materials.

L. "Background IP License" means a royalty-free, fully paid-up, perpetual, irrevocable, worldwide, non-exclusive license to the Commission-Approved Acquirer under any Background IP to operate the Drug-Coated Balloon Business, including the research, Development, manufacture, distribution, marketing or sale of Drug-Coated Balloons anywhere in the world and the research, Development, and manufacture of PTA Products for the incorporation of such PTA Products into Drug-Coated Balloons anywhere in the world.

M. "Clinical Trial(s)" means a controlled study in humans of the safety or efficacy of a product, and includes, without limitation, such clinical trials as are designed to satisfy the requirements of an Agency in connection with any product and any other human study used in research and Development of a product.

N. "Closing Date" means the date on which Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Assets To Be Divested to a Commission-Approved Acquirer pursuant to this Order.

O. "Commission-Approved Acquirer" means the following:

1. Spectranetics; or

2. An entity that receives the prior approval of the Commission to acquire the Assets To Be Divested.

P. "Confidential Business Information" means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Drug-Coated Balloon Business. The term "Confidential Business Information" excludes the following:

1. Information relating to any Respondent's general business strategies or practices that does not discuss with particularity the Drug-Coated Balloon Business;

2. Information that is contained in documents, records or books of any Respondent that are provided to the Commission-Approved Acquirer by a Respondent that is unrelated to the Drug-Coated Balloon Business acquired by the Commission-Approved Acquirer or that is exclusively related to the Retained Business;

3. Information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws;

4. Information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality and non-disclosure agreement with respect to such information by Respondents;

5. Information related to the Drug-Coated Balloon Business that Medtronic can demonstrate it obtained without the assistance of Covidien prior to the Acquisition;

6. Information that is required by Law to be disclosed;

7. Information that does not directly relate to the Drug-Coated Balloon Business; and

8. Information that Respondents demonstrate to the satisfaction of the Commission, in the Commission's sole discretion:

    a. Is necessary to be included in Respondents' mandatory regulatory filings, *provided, however,* that Respondents shall make all reasonable efforts to maintain the confidentiality of such information in the regulatory filings;

    b. Is information the disclosure of which is consented to by the Commission-Approved Acquirer;

    c. Is necessary to be exchanged in the course of consummating the Acquisition or the transaction under the Remedial Agreement; or

    d. Is disclosed in complying with this Order.

Q. "Development" means all preclinical and clinical drug and medical device development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a product (including any government price or reimbursement

approvals), product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

R. "Divestiture Agreement" means the "Asset Purchase Agreement" by and between Covidien LP and Spectranetics dated as of October 31, 2014, and all amendments, exhibits, attachments, agreements and schedules, in each case thereto or contemplated thereby, related to the Assets To Be Divested, that have been approved by the Commission to accomplish the requirements of this Order. The Divestiture Agreement is attached to this Order as Non-Public Appendix A.

S. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

T. "Drug-Coated Balloons" means Covidien's over the wire percutaneous transluminal angioplasty balloon catheters with paclitaxel coated balloons for peripheral vascular use; provided, however, that Drug-Coated Balloons shall not include PTA Products that do not contain a paclitaxel coated balloon.

U. "Drug-Coated Balloon Business" means all of Covidien's right, title and interest in and to the assets, tangible and intangible, businesses and goodwill as of the Closing Date, that are related primarily to the research, Development, manufacture, marketing, sale or distribution of Drug-Coated Balloons, including, without limitation, all of Covidien's right, title and interest as of the Closing Date, in and to the following:

1. All Drug-Coated Balloon Intellectual Property;

2. The Drug-Coated Balloon Plant Lease;

3. All Drug-Coated Balloon Manufacturing Technology;

4. All Drug-Coated Balloon Scientific and Regulatory Material;

5. All of Covidien's books, records and files to the extent primarily related to the research, Development, manufacture, marketing, distribution, or sale of Drug-Coated Balloons;

6. All Drug-Coated Balloon Manufacturing Equipment and the Plymouth Facility Manufacturing Equipment;

7. All contracts entered into with any Third Party in the ordinary course of business with suppliers, personal property lessors, personal property lessees, licensors, licensees, consignors, and consignees, to the extent primarily related to the research, Development, manufacture, marketing, distribution, or sale of Drug-Coated Balloons;

8. All inventory, including raw materials, packaging materials, work-in-process, and finished goods, in each case to the extent consisting of, or intended for use in the manufacture or packaging of, Drug-Coated Balloons; and

9. All commitments and orders for the purchase of goods that have not been shipped, to the extent consisting of, or intended for use in the manufacture of, Drug-Coated Balloons;

provided, however, that "Drug-Coated Balloon Business" does not include the Retained Business or any assets, tangible or intangible, businesses or goodwill that relate to PTA Products (other than as used in the incorporation of such PTA Products into Drug-Coated Balloons); and

provided further, however, that with respect to documents or other materials included in the Drug-Coated Balloon Business that contain information (a) that relates both to Drug-Coated Balloons and to other products of Respondents or (b) for which Respondents have a legal obligation to retain the original copies, Respondents shall be required to provide only copies or, at their option, relevant excerpts of such documents and materials, but Respondents shall provide the Commission-Approved Acquirer access to the originals of such documents as necessary, it being a purpose of this proviso to ensure that Respondents not be required to divest themselves completely of records or information that relate to products other than Drug-Coated Balloons.

V. "Drug-Coated Balloon Employees" means all employees of Covidien whose job responsibilities are primarily related to the research, Development, manufacture, distribution, marketing or sale of Drug-Coated Balloons, in each case as listed in Non-Public Appendix B.

W. "Drug-Coated Balloon Intellectual Property" means all of the following to the extent primarily related to the research, Development, manufacture, marketing, distribution, or sale of Drug-Coated Balloons:

1. United States and foreign patents and patent applications in each case filed, or in existence, on or before the Closing Date and covered under the patent families listed in Non-Public Appendix C, and any renewal, derivation, divisions, reissues, continuation, continuations in-part, modifications, or extensions thereof; and

2. Trademarks, trade dress, copyrights, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; in each case, other than patents or patent applications (which are addressed in Item 1, above).

X. "Drug-Coated Balloon Manufacturing Equipment" means all machinery and equipment, molds, dies and other tools primarily used or held for use in the manufacture of Drug-Coated Balloons, wherever located, other than with respect to packaging or labeling.

Y. "Drug-Coated Balloon Manufacturing Technology" means all tangible technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise), in each case to the extent primarily related to the manufacture of Drug-Coated Balloons, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating

procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Approval(s) conformance, and labeling and all other information related to the manufacturing process, and supplier lists.

Z. "Drug-Coated Balloon Plant Lease" means the lease of the facility currently used by Covidien in Fremont, California, dated February 8, 2012, as amended from time to time, by and among Covidien LP (as successor-in-interest to CV Ingenuity Corp.), John Arrillaga, or his Successor Trustee, UTA dated 7/20/77, as amended, and Richard T. Perry, or his Successor Trustee, UTA dated 7/20/77, as amended.

AA. "Drug-Coated Balloon Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information, to the extent each of the foregoing are primarily related to the research, Development, manufacture, marketing, distribution, or sale of Drug-Coated Balloons.

BB. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, Agency, or government commission, or any judicial or regulatory authority of any government.

CC. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order.

DD. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

EE. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

FF. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

GG. "Plymouth Facility Manufacturing Equipment" means all assets purchased by Covidien for exclusive use in the manufacture, research, and Development of Drug-Coated Balloons at its Plymouth, Minnesota plant.

HH. "PTA Intellectual Property" means all of the following owned by Covidien as of the Closing Date to the extent primarily related to the research, Development, and manufacture of PTA Products (except to the extent related to any Retained Product):

1. United States and foreign patents and patent applications in each case filed, or in existence, on or before the Closing Date and covered under the patent families listed in Non-Public Appendix D, and any renewal, derivation, divisions, reissues, continuation, continuations in-part, modifications, or extensions thereof; and

2. Copyrights, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; in each case, other than patents or patent applications (which are addressed in Item 1, above).

II. "PTA License" means a royalty-free, fully paid-up, perpetual, irrevocable, worldwide, non-exclusive license to the Commission-Approved Acquirer under any PTA Intellectual Property and PTA Product Manufacturing Technology to operate the Drug-Coated Balloon Business, including (i) to make, have made, use, offer to sell, sell, import, and export any Drug-Coated Balloons, and (ii) the research, Development, and manufacture of PTA Products for the incorporation of such PTA Products into Drug-Coated Balloons.

JJ. "PTA Materials" means copies of the following items (or relevant excerpts thereof) owned by and in possession of Covidien as of the Closing Date (except to the extent related to any Retained Product):

1. All PTA Product Scientific and Regulatory Material;

2. All books, records and files with respect to PTA Intellectual Property; and

3. All books, records and files with respect to PTA Product Manufacturing Technology or otherwise to the extent primarily related to the research, Development, and manufacture of PTA Products.

KK. "PTA Product(s)" means the following:

1. Covidien's EverCross™ .035 percutaneous transluminal angioplasty balloon catheter;

2. Covidien's NanoCross Elite™ .014 percutaneous transluminal angioplasty balloon catheter;

3. Covidien's PowerCross™ .018 percutaneous transluminal angioplasty balloon catheter; and

4. Covidien's RapidCross™ .014 percutaneous transluminal angioplasty balloon catheter.

provided, *however*, that PTA Products shall not include any Retained Product.

LL. "PTA Product Manufacturing Technology" means all tangible technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise), in each case to the extent primarily related to the manufacture of PTA Products, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Approval(s)

conformance, and labeling and all other information related to the manufacturing process, and supplier lists.

MM. "PTA Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information, to the extent each of the foregoing are primarily related to the research, Development, or manufacture of PTA Products.

NN. "Remedial Agreement(s)" means the following:

1. The Divestiture Agreement; and

2. Any agreement between a Respondent and a Commission-Approved Acquirer (or between a Divestiture Trustee and a Commission-Approved Acquirer that has received the prior approval of the Commission) to accomplish the requirements of this Order, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Assets To Be Divested, that have been approved by the Commission to accomplish the requirements of this Order.

OO. "Retained Business" means:

1. All right, title and interest in and to the name "Covidien," together with all variations thereof and all trademarks and trade dress containing, incorporating or associated with any of the foregoing, and any trademark and trade dress other than Stellarex™;

2. Any of the assets, tangible or intangible, businesses or goodwill that relate to the Retained Products;

3. Cash and cash equivalents; tax assets; stock in any entity; corporate and tax records of any entity; insurance policies; benefit plans; and accounts receivable arising prior to the Closing Date; and

4. Any assets, tangible or intangible, businesses or goodwill owned by Medtronic.

PP. "Retained Product" means any product researched, Developed, manufactured, marketed, sold or distributed by Covidien other than Drug-Coated Balloons or PTA Products, and includes but is not limited to (i) any balloon-expandable stent, including the Visi-Pro® Peripheral Stent System and (ii) any high-pressure balloon product.

QQ. "Spectranetics" means The Spectranetics Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns, its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by The Spectranetics Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

RR. "Transition Services Agreement" means an agreement by Respondents to provide all advice, consultation, and assistance reasonably necessary for any Commission-Approved Acquirer to receive and use, in any manner related to achieving the purposes of this Order, any assets, right, or interest relating to the Assets To Be Divested.

SS. "Third Party(ies)" means any non-governmental Person other than the Respondents, or the Commission-Approved Acquirer.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Covidien shall divest the Assets To Be Divested, absolutely and in good faith, to Spectranetice pursuant to, and in accordance with, the Divestiture Agreement(s) (which agreement(s) shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of the Commission-Approved Acquirer or to reduce any obligations of Covidien under such agreement(s)), and each such agreement, if it becomes a Remedial Agreement, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Assets To Be Divested to Spectranetic prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Spectranetics is not an acceptable purchaser of the Assets To Be Divested, then Respondents shall immediately rescind the transaction with Spectranetics, in whole or in part, as directed by the Commission, and shall divest the Assets To Be Divested within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Assets To Be Divested to Spectranetics prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Assets To Be Divested to Spectranetics (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

B. Respondents shall secure all consents and waivers with respect to any rights expressly granted to Covidien by Third Parties or Government Entities, or to Third Parties or Government Entities by Covidien, from all Third Parties or Government Entities necessary for the divestiture of the Assets To Be Divested to the Commission-Approved Acquirer, or for the continued research, Development, manufacture, distribution, marketing or sale of Drug-Coated Balloons or the continued research, Development, or manufacture of PTA Products for the incorporation of such PTA Products into Drug-

Coated Balloons by the Commission-Approved Acquirer. Respondents' obligations shall be satisfied as follows:

1. Prior to the Closing Date, Respondents shall provide all required notices to Third Parties and Government Entities in connection with agreements where no consent from such Third Parties and Government Entities is required to assign the rights granted to Covidien, including complying with any required notice requirements as to time prior to the transfer;

2. Prior to the Closing Date, Respondents shall secure all consents or waivers to assign to the Commission-Approved Acquirer all the agreements listed on Non-Public Appendix E; and

3. Within fifteen (15) days after the Closing Date, Respondents shall secure all the consents or waivers to assign to the Commission-Approved Acquirer at least 90 percent of the agreements listed in Non-Public Appendix F.

C. Respondents shall:

1. submit to the Commission-Approved Acquirer, at Respondents' expense, all Confidential Business Information related to the Assets To Be Divested;

2. deliver all Confidential Business Information related to the Assets To Be Divested to the Commission-Approved Acquirer:

    a. in good faith;

    b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

    c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such Confidential Business Information to the Commission-Approved Acquirer, provide the Commission-Approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Assets To Be Divested that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order.

D. Respondents shall not use, directly or indirectly, any Confidential Business Information (other than as necessary to comply with the requirements of this Order, any Remedial Agreement, or any Law) related to the Drug-Coated Balloon Business, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any Person except in connection with the divestiture of the Assets To Be Divested, to the Interim Monitor, if any, and to the Divestiture Trustee, if any, *provided however*, that:

1. This Paragraph II.D. shall not apply to any Confidential Business Information related to the Drug-Coated Balloon Business that Respondents can demonstrate to the Commission that Medtronic obtained other than in connection with the Acquisition;

2. This Paragraph II.D. shall not apply to any Confidential Business Information to the extent related to Retained Products, the Retained Business or PTA Products;

3. This Paragraph II.D. shall not apply to the use of Confidential Business Information by Respondents in complying with the requirements or obligations of the Laws of the United States or other countries;

4. This Paragraph II.D. shall not apply to the use of Confidential Business Information by Respondents to defend against legal claims brought by any Third Party, or investigations or enforcement actions by Government Entities; and

5. This Paragraph II.D. shall not apply to the use of Confidential Business Information by Respondents to the extent consented to by the Commission-Approved Acquirer;

provided, however, that Respondents shall require any Covidien employees or agents who as of the Closing Date have access to Confidential Business Information related to the Drug-Coated Balloon Business to enter into, no later than thirty (30) days after the Closing Date, confidentiality agreements with Respondents and the Commission-Approved Acquirer not to disclose such Confidential Business Information except as set forth in this Paragraph II.D.

E. Respondents shall:

1. Enter into an agreement to supply PTA Products to the Commission-Approved Acquirer at no more than Respondents' Actual Cost for a period of one (1) year following the Closing Date; and

2. At the Commission-Approved Acquirer's option, renew the supply agreement for PTA Products for up to two (2) additional one-year terms under such terms and conditions as approved by the Commission.

F. Respondents shall:

1. Not later than fifteen (15) days before the Closing Date (a) provide to the Commission-Approved Acquirer a list of all Drug-Coated Balloon Employees; and (b) in compliance with all Laws, allow the Commission-Approved Acquirer to inspect the personnel files and other documentation relating to such Drug-Coated Balloon Employees;

2. Not later than fifteen (15) days before the Closing Date provide an opportunity for the Commission-Approved Acquirer: (a) to meet personally, and outside the presence or hearing of any employee or agent of Respondents, with any one or more of the Drug-Coated Balloon Employees; and (b) to make offers of employment to any one or more of the Drug-Coated Balloon Employees;

3. Not interfere, directly or indirectly, with the hiring or employing by the Commission-Approved Acquirer of Drug-Coated Balloon Employees, and shall remove any impediments or incentives within the control of Respondents that may deter these employees from accepting employment with the Commission-Approved Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-Approved Acquirer. In addition, Respondents shall not make any counteroffer to a Drug-Coated Balloon Employee who receives a written offer of employment from the Commission-Approved Acquirer; and

4. Not, for a period of one (1) year following the Closing Date without the Commission-Approved Acquirer's prior written consent, directly or indirectly, solicit or otherwise attempt to induce any of the Drug-Coated Balloon Employees to terminate their employment with the Commission-Approved Acquirer; *provided, however,* that Respondents may:

    a. Advertise for employees in newspapers, trade publications or other media not targeted specifically at Drug-Coated Balloon Employees, or

    b. Hire Drug-Coated Balloon Employees who apply for employment with Respondents, as long as such employees were not solicited by Respondents in violation of this Paragraph.

Provided, however, that this Paragraph shall not prohibit Respondents from making offers of employment to or employing any Drug-Coated Balloon Employee after the Closing Date where the Commission-Approved Acquirer has notified Respondents in writing that the Commission-Approved Acquirer does not intend to make an offer of employment to that Drug-Coated Balloon Employee.

G. Respondents shall include in any Remedial Agreement at the option of the Commission-Approved Acquirer a Transition Services Agreement, subject to the approval of the Commission, *provided however,* the term of any Transition Services Agreement shall be at the option of the Commission-Approved Acquirer, but not longer than two (2) years from the Closing Date unless extended due to breach by Respondents.

H. The purpose of the divestiture of the Assets To Be Divested to a Commission-Approved Acquirer is to create an independent, viable and effective competitor in the Drug-Coated Balloon market and to remedy the lessening of competition from the Acquisition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Remedial Agreement(s).

B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of this Order in a manner consistent with the purposes of this Order.

D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and related requirements of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve at least until the latter of (i) the end of the supply agreement entered into pursuant to Paragraph II.E. of this Order, and (ii) the end of the Transition Services Agreement entered into pursuant to Paragraph II.G. of this Order.

E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with its obligations under this Order, including, but not limited to, its obligations related to the Assets To Be Divested. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or

impede the Interim Monitor's ability to monitor Respondents' compliance with this Order.

F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations 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 Interim Monitor.

H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-Approved Acquirer, with respect to the performance of Respondents' obligations under this Order or the Remedial Agreement. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under this Order.

I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

M. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the obligations to divest the Assets To Be Divested as required by this Order, if required, the Commission may appoint a trustee ("Divestiture Trustee") to divest the Assets To Be Divested. In the event that the Commission or the Attorney General brings an action pursuant to § 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 Divestiture Trustee in such action to divest the Assets To Be Divested. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture 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 Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the Assets To Be Divested.

2. The Divestiture Trustee shall have one (1) year after 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 one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court appointed

Divestiture Trustee, by the court; provided, however, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the Assets To Be Divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' 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 Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; provided further, however, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture 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 reasonably necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of the Assets To Be Divested.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Assets To Be Divested; provided, however, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order.

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; provided, however, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the Divestiture required by this Order.

G. The Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order.

V.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated into this Order.

B. Any failure by Respondents to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondents shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.

D. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to the Assets To Be Divested, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

E. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VI.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every thirty (30) days thereafter until Respondents have fully complied with Paragraphs II.A. and II.C. of this Order, and every sixty (60) days thereafter until Respondents have fully complied with the Paragraphs II.E. and II.F. of this Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time:

1. A full description of the efforts being made to comply with the relevant Paragraphs of this Order;

2. A detailed plan to deliver all Confidential Business Information required to be delivered to the Commission-Approved Acquirer pursuant to Paragraph II.C. and agreed upon by the Commission-Approved Acquirer and the Interim Monitor (if applicable) and any updates or changes to such plan;

3. A description of all Confidential Business Information delivered to the Commission-Approved Acquirer, including the type of information delivered, method of delivery, and date(s) of delivery;

4. A description of the Confidential Business Information currently remaining to be delivered and a projected date(s) of delivery; and

5. A description of all technical assistance provided to the Commission-Approved Acquired during the reporting period.

VII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of a Respondent; (2) acquisition, merger or consolidation of Respondents; or (3) other change in the Respondents 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 Respondents.

VIII.

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 and with reasonable notice to Respondents made to their principal United States offices, 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 the Respondents, who may have counsel present, regarding such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate ten years from the Order Date.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED:

Nonpublic Appendices A-F

[Redacted From the Public Record Version, But Incorporated By Reference]