

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

_____)	
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 Respondent), 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

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.
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 Respondent, 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, 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’s 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. “Responder(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 DrugCoated Balloons. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- J. "Assets To Be Divested" means the DrugCoated 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 DrugCoated Balloon Business or the research, Development, and manufacture of PTA Products for the incorporation of such PTA Products into DrugCoated Balloons (the "D2G" / EMC /

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 each case there to 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 attached to this Order as ~~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;

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, ~~Coated~~ 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
 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 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

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 royaltyfree, fully paidup, perpetual, irrevocable, worldwide, non-exclusive license to the Commission Approved Acquirer under any PATIntellectual PropertyandPTA Product LA29 -1.en;tc4(l)-2(e)4(t)-2n-2(s)4(n)-2T02 0 T2.5 free-2(c)4)mri2 0 3

- 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 Respondent 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 Spectranetic pursuant to and in accordance with, the Divestiture Agreement(s) (which agreements 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 Commission Approved Acquirer or to reduce any obligations of Covidien under such agreement(s)), and each such agreement, if it becomes a Remedial Agreement 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, Respondents shall immediately rescind the transaction with Spectranetics in whole or in part, as directed by the Commission, and shall divest Assets To Be Divested within one hundred eighty (180) days from the Order Date, absolutely and in good faith at a 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 Respondent in the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent to 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 or 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 notice 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 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 Public Appendix F

C. Respondents shall:

1. submit to the Commission Approved Acquirer, at Respondents' expense, all

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.
- 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, 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

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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,

M. The Interim Monitor appointed pursuant to this Order may be the same Person 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 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 Monitor pursuant to the relevant provisions of this Order.
8. The Divestiture Trustee shall report in writing to Respondent to the Commission every sixty (60) days concerning th

- E. Respondent 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, Respondent 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 Respondent has fully complied with this Order.

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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, 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 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

Nonpublic Appendices AF

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