EN

Case No COMP/M.7326 - MEDTRONIC/ COVIDIEN

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 28/11/2014

In electronic form on the EUR-Lex website under document number 32014M7326

Office for Publications of the European Union
L-2985 Luxembourg

EUROPEAN COMMISSION

Brussels, 28.11.2014
C(2014) 9215 final

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

To the notifying party:

Dear Madam(s) and/or Sir(s),

Subject: **Case M.7326 – Medtronic/ Covidien**
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the EEA Agreement

(1) On 10 October 2014**,** the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which the undertaking Medtronic, Inc. ("Medtronic", US) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of Covidien plc ("Covidien", Ireland) by way of public bid ("the Transaction"). Medtronic and Covidien are collectively referred to as "the Parties".[2]

I. THE PARTIES

(2) **Medtronic** develops medical technology and provides products, therapies and services treating a variety of medical conditions, including cardiac and vascular diseases, diabetes, and neurological and musculoskeletal conditions. It is headquartered in Minneapolis, Minnesota and employs over 46 000 people in more than 140 countries.

---

1 OJ L 24, 29.1.2004, p. 1 ('the Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 Publication in the Official Journal of the European Union No C371, *18.10.2014*, p. 21.

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.

(3) **Covidien** is active in the development, manufacturing and sale of a diverse range of medical devices and supply products, including for laparoscopic surgery, electrosurgery, biosurgery and vascular therapies. Covidien employs more than 38 000 people in more than 70 countries and sells its products in more than 150 countries worldwide.

II. THE OPERATION AND THE CONCENTRATION

(4) On 15 June 2014, Medtronic announced its intention to acquire sole control over Covidien. The Transaction is structured as a public bid under the Irish Takeover Code and is expected to close at the end of 2014.

(5) Post-Transaction, the businesses of Medtronic and Covidien will be combined under a new entity to be called Medtronic plc. The combined entity will maintain Medtronic's operational headquarters in Minneapolis and have its principle executive offices in Covidien's current headquarters in Ireland. Medtronic will continue to be a public company listed on the New York Stock Exchange and will not be controlled by any shareholder.

(6) Therefore, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the EU Merger Regulation.

III. EU DIMENSION

(7) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million.[3] Each of them has an EU-wide turnover in excess of EUR 250 million, but each does not achieve more than two-thirds of its aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension pursuant to Article 1(2) of the EU Merger regulation.

IV. ASSESSMENT

IV.1. Introduction

(8) The transaction is essentially complementary in nature with Medtronic being primarily active in the treatment of heart diseases (in the various markets of cardiac rhythm disease management, coronary segment and structural heart), spine implants, neurology and diabetes treatment, where Covidien is not active. Nevertheless, the Parties' activities overlap in the area of peripheral vascular devices and in (advanced) electrosurgical devices.

(9) Medtronic used to overlap with Covidien also in relation to laparoscopic devices and non-advanced electrosurgical devices (open surgery electrosurgical forceps and laparoscopic active electrodes). However, on 17 September 2014, Medtronic announced that it had reached an agreement with Integra Life Sciences to sell its MicroFrance business, consisting of its laparoscopic and electrosurgical devices. The sale was closed on 27 October 2014. The divestment of MicroFrance eliminates the

---

3 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p. 1).

overlaps between Medtronic and Covidien in relation to laparoscopic devices and non-advanced electrosurgical devices. The only devices which Medtronic kept in its portfolio in this space are its advanced energy devices PlasmaBlade, Aquamantys and its monopolar sealers, large surface coagulation devices that are not marketed under the Aquamantys brand.

IV.2. Peripheral vascular devices

(10) Peripheral vascular ("PV") or endovascular devices are used for the minimally invasive treatment of peripheral vascular (or endovascular) diseases.

(11) PV surgeries are carried out by interventional radiologists (around 50% of the time), vascular surgeons (around 40% of the time), and by interventional cardiologists (around 10% of the time). A typical PV procedure involves the following steps (which have been somewhat simplified)[4]:

a) An X-ray is used to locate the relevant vessel and the blockage or "lesion",

b) An introducer **needle** is then applied to gain entry through the skin and into the artery or vein. A **sheath** is inserted over the needle. Some interventions may be performed using only a sheath.

c) Depending on how severe the lesion is, different devices are introduced to reach and potentially open the blockage:

- Where required, a **guidewire** is inserted through the needle and into the artery or vein to maintain entry to the lesion and to serve as a "guide" to enable the entry of other devices. Guidewires may be used in conjunction with a **guide catheter**, which facilitates entry but also allows a "contrast medium"[5] to be used to enable the interventionist to monitor the position of the devices with an X-ray or a fluoroscopy. Once the guidewire is inserted, the introducer needle is removed.

- If the lesion is particularly severe and cannot be reached with only a guidewire, a **support catheter** (a stronger, more rigid device) is introduced to "push" through the blockage of the lesion.

- If the vessel is entirely blocked and cannot be "pushed" through, a **chronic total occlusion** ("CTO") crossing device is introduced to either go around the lesion by cutting into the sub-intimal part of the vessel or by using micro-dissection (i.e. scissor-like cutting).[6]

---

4 Form CO, paragraph 32.

5 A substance used to enhance the contrast of structures or fluids within the body in medical imaging.

6 It is possible to address entirely blocked lesions through a new, second incision from "below" the lesion. This is an alternative to the use of CTO crossing devices. This option is frequently used in Europe, which leads to low levels of usage for CTO crossing devices.

d) Using the guidewire or a support catheter as a guide, a **Percutaneous Transluminal Angioplasty** ("PTA") balloon catheter is inserted and fed to the lesion. Once at the point of the lesion, the PTA balloon catheter is expanded and pushes the plaque against the wall of the vessel, allowing blood to flow.

e) Where lesions are more prone to restenosis,[7] or where there is a tear in the vessel, the interventionist may insert and deploy a **stent**, a **drug coated balloon (DCB)**, or a **drug-eluting stent (DES)**.

– **Balloon expanding stents** ("BX stents") are stents mounted on a PTA balloon catheter. As the balloon is expanded, the stent, which is made of rigid material, expands, and then stays in place once the balloon is removed.

– Other stents are **self-expanding stents** ("SX stents") and have their own plastic delivery mechanism, which is inserted separately from, and subsequent to, the PTA balloon catheter.

(12) PV diseases may impede blood supply in the vessels of various parts of the body according to which PV procedures are distinguished:

- Brain (carotid arteries),
- Kidneys (renal arteries),
- Liver, gall bladder and bile ducts (bilary arteries),
- Lower abdomen and upper legs (iliac or ilio-femoral arteries),
- Thighs (femoral or "SFA" arteries),
- Arteries around and above the knee (popliteal arteries), and
- Below the knee (infra-popliteal arteries).

IV.2.1. Product market definition

(13) The Commission has already been called upon assessing transactions in the field of endovascular devices, namely in the cases *Johnson & Johnson / Guidant*[8] and *Abbott / Guidant*.[9] Specifically, the Commission analysed the following markets in the area of endovascular devices, namely the markets for (i) stents, (ii) guiding catheters, (iii) steerable guidewires, (iv) PTA balloon catheters, (v) embolic protection devices.[10] A

---

7 A re-narrowing of the blood vessel.

8 Case M.3687 Johnson & Johnson / Guidant, L173 Of 27.06.2006.

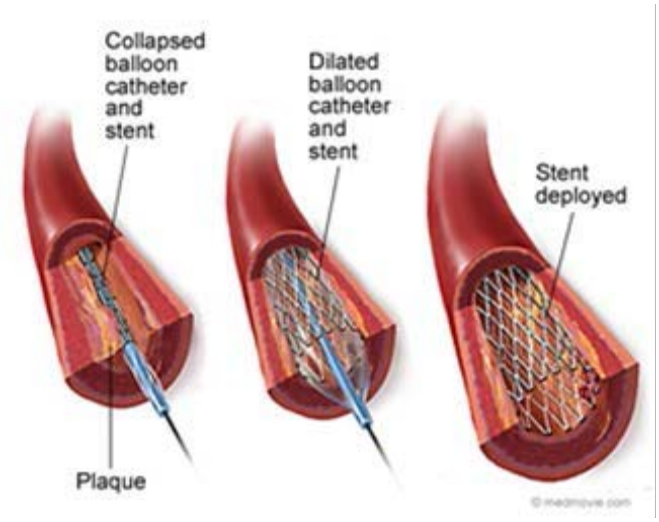
9 Case M.4150 Abbott / Guidant, C256 Of 24.10.2006.

10 Case M.3687 Johnson & Johnson / Guidant, recitals 34-54; Case M.4150 Abbott / Guidant, paragraphs 25-35.

number of these markets are affected by the proposed Transaction and will be analysed in this decision.

IV.2.1.1. Stents

(14) PV stents are small expandable metallic tubes designed to treat a narrowing or blockage in a peripheral artery.



IV.2.1.1.a. Commission's previous practice

(15) In previous decisions, the Commission divided endovascular stents into three different product markets, namely in balloon expendable stents ("BX stents"), in self-expandable non-carotid stents ("non-carotid SX stents") and in self-expandable carotid stents ("carotid SX stents").[11]

(16) Several factors led to distinguishing between BX and SX stents. First, the degree of demand side substitutability between the two kinds of stents is very limited: the use of one or the other is determined by the type of procedure (e.g. BX for renal, SX for carotid) and the type of lesion. Secondly, SX stents are considerably more expensive than BX stents. From the supply side BX and SX stents have different design, they are made of different materials, they use different deployment techniques and they require different manufacturing processes. In addition, the Commission defined a separate market for SX stents for carotid procedures mainly due to the fact that they undergo different regulatory approval process than other stents and the fact that dedicated stents are used for carotid procedures.[12]

(17) The Commission also considered that stents within the BX and non-carotid SX categories could potentially be further segmented by size and use, as well as by

11 Case M.3687 Johnson & Johnson / Guidant, recital 47; Case M.4150 Abbott / Guidant, paragraph 31.

12 Case M.3687 Johnson & Johnson / Guidant, recitals 40-45.

procedure, because of the high degree of heterogeneity, and the low degree of substitutability.[13]

IV.2.1.1.b. Notifying Party's views

(18) The Notifying Party considers that BX stents and SX stents, and potentially SX stents for carotid indications, are the narrowest relevant markets in this case and that no further sub-segmentation by procedure or by size (length and diameter) is warranted. The Notifying Party explains that stents are typically indicated for more than one type of procedures. Regarding segmentation by size, all manufacturers have a range of various lengths and diameters; can therefore easily switch from one size to another. It also argues that physicians can deploy two stents instead of one for long lesions without any therapeutic downside, and rarely use stents of unusual diameters.

IV.2.1.1.c. Assessment of the Commission

BX stents vs SX stents

(19) The results of the market investigation supported the conclusion in the Commission's precedents, namely that BX stents and SX stents are not interchangeable in particular due to differences in terms of flexibility, precision and pressure they can tolerate. BX stents are more precise and more suitable for very calcified lesions while SX stents are more flexible, more resistant to deformation and are therefore used in more tortuous regions. BX stents and SX stents are used for different types of lesions and usually also in different locations. In the parts of the body where physicians can use both types of stents, the length and calcification of the lesion determines the choice of using either BX stents or SX stents.[14]

Segmentation of BX stents by procedure

(20) The results of the market investigation indicated that BX stents are overall not to be further segmented by procedure, except for renal procedures which can require specific stent profile and length. Iliac and infra-popliteal procedures are the two other procedures which often require BX stents; nevertheless, the differences of the BX stents used in these cases mainly differ in terms of length and diameter.[15]

Segmentation of SX stents by procedure

(21) SX stents are usually used for iliac, SFA, popliteal and carotid procedures. Most respondents indicated that SX stents for carotid procedures are specifically designed and thus different from other SX stents, in particular in terms of design and to some extent delivery system and that other stents cannot be used for these procedures.[16] As concerns SX stents for non-carotid procedures, the market investigation provided

---

13 Case M.3687 Johnson & Johnson / Guidant, recital 46.

14 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 8 and 8.1.

15 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 11 and 11.1.

16 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 16.1; replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Questions 12 and 13.1.

indications that within the non-carotid procedures there are so-called multipurpose SX stents that can be used for multiple procedures. Different parameters such as the flexibility of the stent can however influence the choice of a stent for a given procedure.

Segmentation of stents by size

(22) Generally, physicians choose the length of a stent depending on the vessel and lesion to be treated. They therefore avoid using two shorter stents instead of one longer one, as this would increase the risk of the procedure and post-operation complications.[17] Physicians however rarely use these very long stents and often order them separately.[18]

IV.2.1.1.d. Conclusion

(23) The Commission therefore considers that in line with the past practice the stents market should be first subdivided into BX stents and SX stents. In addition, the SX stents should be broadly subdivided by procedure into SX stents for carotid procedures and SX stents for non-carotid procedures. Any further segmentation by procedure or size is not necessary for the purposes of the present decision as the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to stents markets irrespective of the exact product market definition.

IV.2.1.2. Endovascular accessories: guidewires, support catheters, PTA balloons

(24) **Guidewires** are thin, flexible wires made out of stainless steel springs surrounding a stiff metal rod, or nitinol. They are often coated to reduce friction as they are passed through vessels (the coatings can be of Teflon, silicon or hydrophilic). Guidewires are used to reach and maintain access to the lesion.

(25) **A support catheter** is introduced if a lesion is particularly calcified or stiff and cannot be reached only with a guidewire. A support catheter is a stronger, more rigid device, which allows the interventionalist to "push" through the blockage of the calcified lesion. As with guidewires, support catheters are typically coated in a substance that prevents sticking.

(26) **PTA balloon catheters** are inserted to the lesion and are expanded to push the plaque against the wall of the vessel, allowing blood to flow.

(27) Medtronic is not active in the supply of guiding catheters for peripheral vascular procedures. There is thus no overlap in guiding catheters. Therefore, guiding catheters will not be discussed further in this decision.

IV.2.1.2.a. Commission's previous practice

(28) The Commission has previously defined separate markets for endovascular accessories and in particular for the following three categories: guiding catheters, steering

---

17 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 13.

18 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 86.

guidewires and PTA balloon catheters for endovascular procedures due to the absence of demand-side and supply-side substitutability between these products. These markets were however not further segmented by dimension or shape due to a high supply-side substitutability, all major manufacturers offering a broad range of products.[19]

(29) The Commission has not previously defined a market for support catheters.

IV.2.1.2.b. Notifying Party's views

(30) The Notifying Party submits that endovascular guidewires, support catheters and PTA balloon catheters constitute separate markets. Guidewires come in multiple thicknesses and lengths, support catheters in different diameters and lengths, PTA balloon catheters in a range of lengths, diameters and guidewire compatibility (thickness). The Notifying Party considers, however, that each category forms a single relevant market, regardless of length, diameter and thickness, as there is a high supply-side substitutability.

IV.2.1.2.c. Assessment of the Commission

Support catheters

(31) The results of the market investigation indicated that support catheters are overall not substitutable with other peripheral vascular accessories.[20] Only a few physicians indicate using PTA balloon catheters and to a lower extent other types of catheters (guiding catheters, diagnostic catheters) as substitutes to support catheters.[21] Most physicians overall indicated that guiding catheters, diagnostic catheters and support catheters present significant differences in terms of tip design and stiffness.[22]

(32) From a supply-side perspective the market investigation was inconclusive, as some competitors indicated that they use the same technologies for all of these products, while others consider that the manufacturing processes and associated IP rights are different and therefore do not allow for swift switching between the various types of catheters.[23] Within support catheters, there are no specific difficulties for manufacturers to produce support catheters of different diameters and lengths.[24]

Guidewires

(33) Regarding the absence of substitutable products to guidewires, no element was brought to the Commission's attention that would lead to different conclusions from those formulated in the Commission's past decisions.

---

19 Case M.3687 Johnson & Johnson / Guidant, recitals 49 and 52.

20 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 48.

21 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 48.

22 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 48.1 and 48.2.

23 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Questions 33 and 33.1.

24 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Questions 31 and 31.1.

(34) From a supply-side perspective, competitors indicated that the main supply-side challenge for switching from one guidewire to another concerns the coating formulation, but they did not mention specific hurdles regarding the production of different thicknesses.[25]

PTA balloon catheters

(35) The results of the market investigation indicate that no other device is considered as substitutable to PTA balloon catheters in terms of the therapeutic indication.[26] Physicians consider that the main features of PTA balloon catheters are the length, diameter, thickness of compatible guidewire, profile (in French units) and withstand pressure.[27] Prices can vary depending on these features, and rise in particular in case of high pressure.[28]

(36) Overall, PTA balloon catheters compatible with 0.035" guidewires are the most commonly used by physicians.[29] PTA balloon catheters with 0.014" and 0.018" compatibility are used for below the knee procedures and distal lesions.

(37) From a supply-side perspective, some competitors indicated that all PTA balloon catheters are produced based on the same technology, while others consider that the manufacturing processes vary, for example depending on the shaft configuration, and that differences in terms of marketing approval depending on the indication can impact the supply-side substitutability (class III for carotid indication, class IIa for other procedures). No manufacturer pointed out specific difficulties to produce PTA balloon catheters of different sizes.[30]

IV.2.1.2.d. Conclusion

(38) Therefore, the Commission concludes, in line with its past practice, that guidewires, support catheters and PTA balloons constitute separate relevant markets. Any further segmentation by size is not necessary for the purposes of the present decision, as the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to endovascular accessories markets, irrespective of the exact product market definition.

IV.2.1.3. Embolic protection devices (EPDs)

(39) EPDs are small umbrella-type devices that are placed beyond the lesion with the aim of trapping any material or debris dislodged during procedures and carried by circulation

---

25 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Questions 28 and 28.1.

26 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 22.

27 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 23 and 24.

28 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 25 and 25.1.

29 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 45; Minutes of a conference call with a competitor, on 31 October 2014, paragraph 13.

30 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Questions 15.1, 16 and 16.1.

(emboli). If an embolus travels to the brain, it can cause stroke. Embolic protection devices thus have a high utilisation rate in carotid interventions.

(40) **Filter baskets** are net-like structures that are placed beyond the lesion to allow for the trapping of plaque without blocking blood flow. Filters can come pre-mounted on a PTA balloon catheter or can go "over the guidewire."

(41) **A proximal occlusion balloon** is a balloon deployed upstream of the lesion. Once inflated, it stops the blood flow to the brain and/or kidneys. Any emboli knocked loose from the procedure are prevented from traveling in the bloodstream.

(42) **A distal occlusion balloon** is a balloon deployed downstream of the lesion. Once inflated, it stops the flow of blood from entering the treatment area and thus stops any emboli travelling to the brain or kidneys.[31]

IV.2.1.3.a. Commission's previous practice

(43) The Commission has found in its previous decisional practice that all EPDs are part of the same market.[32]

IV.2.1.3.b. Notifying Party's views

(44) The Notifying Party submits that there are three types of EPDs: filter baskets, proximal occlusion balloons and distal occlusion balloons. Medtronic predominantly sells proximal occlusion balloons while Covidien exclusively sells filter baskets. The Notifying Party submits that filter baskets and proximal occlusion balloons do not belong to the same product markets.

IV.2.1.3.c. Assessment of the Commission

(45) During the market investigation surgeons indicated that they use EPDs to a very large extent for carotid procedures only, although some of them also use EPDs in other situations for example when there is a complete occlusion and the risk of emboli to get released into the bloodstream.[33] They usually use filter baskets only, or sometimes filter baskets and occlusion balloons, therefore confirming the Notifying Party's submission regarding the predominance of filter baskets.[34] This seems to be due to the fact that filter baskets are easier to use and present the advantage of preserving the blood flow.[35]

---

31 Distal occlusion balloons were the first type of EPD to be marketed. They are no longer sold in Europe primarily because of the introduction of filter baskets, which are considered to be a higher quality product. Proximal occlusion balloons are more recent still, but today account for only around 10% of European demand (filter baskets account for the remaining 90%).

32 Case M.3687 Johnson & Johnson / Guidant, recital 54.

33 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 27.

34 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 26.

35 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 31.1.

(46) On the supply-side it seems that filter baskets and occlusion balloons are based on different technology, filter baskets being the leading technology on the market.[36]

IV.2.1.3.d. Conclusion

(47) In any event, for the purpose of the present decision, it is not necessary to conclude whether the EPD market should be further subdivided into filter baskets, proximal occlusion balloons and distal occlusion balloons, as the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to embolic protection devices markets, irrespective of the exact product market definition.

IV.2.1.4. Drug coated balloons (DCBs) and drug eluting stents (DES)

(48) The Commission has not previously analysed drug coated balloons for peripheral vascular use.[37] Drug coated balloon catheters[38] function in broadly the same manner as PTA balloon catheters, but unlike PTA balloon catheters, DCBs also contain a drug - usually paclitaxel[39] - and a drug-releasing mechanism. Therefore, besides having a mechanical effect of pushing the plaque against the wall of the vessel, paclitaxel acts as an agent preventing the re-narrowing of the vessel by limiting the cells growth thus interrupting the vessel's tendency to (re)narrow.

IV.2.1.4.a. Notifying Party's views

(49) The Notifying Party submits that DCBs constitute a separate relevant market from other endovascular devices and PTA balloon catheters in particular given that on the demand side DCBs have potentially significant clinical advantages as compared to PTA balloon catheters, and DCBs are sold at a much higher (more than double) price than PTA balloon catheters. In addition, the Notifying Party argues that there are important manufacturing differences and associated IP linked to the application of drug coating on the balloons, which impede any supply-side substitution.

(50) However, the Notifying Party considers that there is substitution between DCBs and drug eluting stents (DESs) given that interventionalists would be unlikely to use both in a procedure and an interventionalist minded to use drug-eluting technology for a given procedure could decide to use a DCB or a DES to achieve clinically equivalent results.

---

36 Minutes of a conference call with a competitor, on 31 October 2014, paragraph 23.

37 For an analysis of drug eluting stents for coronary use, Commission's decision of 25 August 2005, M.3687 Johnson&Johnson/Guidant, recitals 11-20.

38 Drug coated balloon catheters are sometimes called drug-eluting balloons, and those terms are interchangeable. In practice, Covidien considers that there may be a technical difference, because paclitaxel on a DCB is not implanted along with an elution matrix (as would be the case in a drug-eluting stent). Covidien considers the term "drug-coated balloon" to be scientifically the more accurate term.

39 A cell proliferation inhibitor often used in cancer treatment.

IV.2.1.4.b. Assessment of the Commission

(51) The Commission tested the scope of the relevant market for DCBs and in particular whether DCBs compete with non-coated PTA balloons and/or DESs. Surgeons having responded to the Commission's market investigation indicated that they would typically use a DCB either as a first line of treatment of different types of above the knee lesions, in particular SFA and popliteal lesions, or in situations of a restenosis after previous angioplasty or stenting done before[40].

(52) As concerns the substitutability with other PV devices and PTA balloons in particular, the market investigation indicated that DCBs are not substitutable or even comparable to any other peripheral vascular devices in terms of their characteristics, performance, medical efficacy, etc.[41]

(53) Similarly, as concerns the substitutability with DESs, the majority of customers explained that DCBs and DESs cannot in principle be used in an interchangeable manner for a given patient.[42] DESs would be used only for certain more severe indications or for indications in which a DCB cannot be used[43] and in all cases cannot be used in arteries which are subject to bending (for example when walking).[44] Generally, the market investigation did not confirm the clinical substitution between DCBs and DESs also because DCBs present the main advantage of not leaving a foreign element behind contrary to DESs.[45] Therefore, from a clinical point of view, DESs are considered as much more invasive therapy than DCBs and would typically be used in different situations and never as a first line of treatment. In addition, customers explained that DCBs and DESs are not comparable in terms of price, DESs being more expensive than DCBs, making economic substitution unlikely.[46]

(54) Similarly, from a supply-side perspective, competitors indicated that DCBs and DESs are not produced based on the same technology, IP, and manufacturing process[47] and that developing a new device is a costly process which would last approximately 2-3 years.[48]

---

40 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 32.1. In addition, at this stage there seems to be no sufficient evidence that DCBs would be efficient in below the knee procedures.

41 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 38.

42 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Questions 32.3, 33 and 34

43 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Questions 32.3 and 33.1.

44 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 33.1.

45 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Questions 33.1

46 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Questions 36 and 37.

47 Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 20.

48 Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 22.

IV.2.1.4.c. Conclusion

(55) Therefore, considering the characteristics, clinical use and manufacturing processes for DCBs, the Commission concludes for the purpose of the present decision that DCBs constitute a separate relevant market from other endovascular devices, and from DESs in particular.

IV.2.1.5. CTO crossing devices

(56) Chronic total occlusion ("CTO") refers to a situation where a vessel is completely blocked. Vessels suffering from highly calcified CTO cannot usually be crossed using a guidewire or support catheter and are therefore treated with CTO crossing devices.

IV.2.1.5.a. Commission's previous practice

(57) The Commission has not analysed the market for CTO crossing devices in the past.

IV.2.1.5.b. Notifying Party's views

(58) The Notifying Party submits that there are two types of CTO crossing devices:

a) recanalization devices, which use high frequency vibrations and micro-dissection (i.e. scissor-like cutting), and

b) re-entry devices, which cut into the sub-intimal part of the vessel itself (outside the lumen) and thereby go around the lesion and then "re-enter" the vessel.

(59) The Notifying Party considers that the relevant market should include all CTO crossing devices based on the fact that they are used to achieve the same result and the prices are similar.

IV.2.1.5.c. Assessment of the Commission

(60) Physicians indicated during the market investigation that CTO crossing devices overall serve the same purpose as guidewires and support catheters but are usually used when the first line of treatment fail (i.e. for difficult lesions, total occlusions).[49] The market investigation revealed that physicians are relatively rarely familiar with both products. One physician explained that re-entry devices are only used where entry through the true vessel lumen is not possible.[50]

(61) Medtronic's internal documents indicate that the market contains three segments depending on the severity of lesions namely catheters used for low severity lesions, recanalisation devices which are better suited for lesion of medium severity, and re-entry devices used for high-severity lesions.[51]

---

49 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 41.

50 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 42.1 and 42.2.

51 Medtronic's internal document, Annex I.17 - Total CTO phase 0 PRC final 12192013 (19 December 2013, p. 5).

(62) From a supply-side perspective, competitors indicated that there is no substitutability between re-entry devices and recanalization devices, because of different IPs, different technology and manufacturing processes.[52] Competitors also indicated that there is a significant price difference between re-entry devices and recanalization devices, although different estimations of this price difference were given.[53] The existence of a price difference is also supported by Medtronic's internal documents which show that re-entry devices are typically more expensive than recanalization devices.[54] In addition, competitors indicated that there are significant differences between the development and production of CTO crossing devices for larger vessels and smaller vessels that limit the supply-side substitutability. A competitor explained for example that the profile and size of the artery is impacting the profile of the device and sheath compatibility, leading to differences in the design of the device and in the production.[55]

IV.2.1.5.d. Conclusion

(63) In any event, for the purpose of the present decision, it is not necessary to conclude whether the market for CTO crossing devices should be further subdivided by type of CTO or by vessel indication, as the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to CTO crossing devices, irrespective of the exact product market definition.

IV.2.2. Geographic market definition

(64) The Commission previously considered that the scope of the relevant geographic market for medical devices including peripheral vascular devices, irrespective of the type of device, are national,[56] despite the fact that the applicable regulatory scheme (the CE mark) is EU-wide in scope. This is in particular due to:

a) National reimbursement schemes influencing which products are reimbursed and under which conditions (e.g. based on costs incurred, on type of condition treated, etc.);

b) Procurement processes and patterns (e.g. purchasing groups, tenders at hospital level, etc.);

c) Significant price differences between countries;

d) Necessity for suppliers to have local sales offices; and

e) Significant variations of competitors' market shares across the countries.

---

52 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Question 24.

53 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Question 26.

54 However, Boston Scientific prices both products at a similar price and Medtronic intends to sell its re-entry device at a lower price than existing CTO devices of both types.

55 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Questions 25 and 25.1.

56 Case M.3687 Johnson & Johnson / Guidant, recitals 67-69.

(65) Without contesting the appropriateness of the national market definition, the Notifying Party considers that EEA-wide data may, in certain circumstances, be more reflective of the supply capabilities of certain competitors.

(66) The market investigation did not surface any element which would lead to a different conclusion from the previous Commission's cases in medical devices and peripheral vascular devices in particular.

(67) Therefore, the Commission concludes for the purpose of the present decision that the geographic markets in relation to the various PV devices concerned by this decision are national in scope.

IV.2.3. Competitive assessment

IV.2.3.1. General features of peripheral vascular devices markets

(68) Before analysing the overlaps *per se* the Commission sets out a number of general medical devices market features which have an influence on the market structure.

(69) Peripheral vascular devices markets are characterised by a number of features related to the access to the market, including development and approval issues, distribution patterns, as well as reimbursement and pricing. These features impact companies' strategy decisions and more particularly their ability to enter a given product market and their incentive to enter a given geographic market.

IV.2.3.1.a. Research and development

(70) Most peripheral vascular devices that are currently on the market are technologically mature and do not attract significant R&D spend. R&D spend is typically used to maintain competitiveness by process innovation (e.g. range expansion) or lowering the cost of the goods.

(71) The research in the peripheral vascular devices area focuses on products which can appreciably reduce restenosis rates beyond existing levels (e.g. DCBs) and those which reduce invasiveness (e.g. bio-absorbable stents).[57] R&D spend mainly comprises investment in technological developments and clinical studies.

(72) Product development follows a number of phases, beginning with a concept phase, and a design development phase which often involves Key Opinion Leaders for completing and freezing the product design. Afterwards manufacturers typically complete design verification, regulatory submissions, and prepare for clinical trials and process validation. Animal and human tests would typically take place during this phase if required. Products under development are then typically two years away from launch. With the first clinical trials ongoing and data available, pipeline products begin to be competitively significant. Manufacturers usually then validate the manufacturing process, evaluate the clinical evidence and prepare the commercial release.

---

57 Neither Party is active in the supply of bio-absorbable stents.

(73) The recent development of DCBs typically took 6-7 years and required several hundreds of million euros. By way of example, Medtronic decided to develop a DCB in […], started the development in […], and sold its first DCB in the EU in […]. It spent overall USD […], million on the research, development, manufacture, license, and sale of its DCB product, including for the development of the PTA balloon. Likewise, CV Ingenuity Corp. ("CVI") (a company ultimately acquired by Covidien) and Covidien filed its first DCB patent in […], began the first in-human-trial in […], and is expected to sell its first DCB early […]. Covidien expects to have spent around USD […] million on R&D and clinical trial costs from CVI's first investments until […]. Bard has spent around USD 325 million on its DCB, Lutonix.[58]

(74) The quality and amount of clinical data obtained via trials are key supporting elements for the promotion of new products, as physicians strongly base their decision-making on these data. Clinical trials need to be run with a sufficient number of patients to be reliable and therefore constitute a significant financial investment in the development cost of a new product. By way of example, Covidien expects to spend more than half of its total development costs for clinical trials.

IV.2.3.1.b. Approval process

(75) Peripheral vascular devices, like all other medical devices, must be approved under Union-wide legislation before they may be marketed for sale in Europe (i.e. obtaining of the CE mark). For the purpose of the conformity assessment procedures, the EU groups the devices into four product classes (class I, class IIa, class IIb, class III) depending on their impact on the human body. This classification takes into account the potential risks associated with the technical design and manufacture of the devices. Most peripheral vascular devices analysed in this decision are class IIa or IIb, except SX stents for carotid procedures (class III) which therefore require prior authorisation in addition to the notification requirements and risk of inspection common with the class II conformity procedures.

IV.2.3.1.c. Reimbursement and pricing

(76) In addition to obtaining the CE mark, a medical device supplier must secure the reimbursement of the device in all countries where it intends to market the product. To obtain the reimbursement, the market investigation indicated that robust clinical data needs to be presented, in particular in some countries such as France.[59]

IV.2.3.1.d. Distribution

(77) Manufacturers can either sell directly, via distributors (exclusive or not), via agents or via a hybrid model combining different types of distribution channels. The distribution in these markets depends on the size and expected potential of the geographic markets, availability of external expertise, as well as on the product characteristics, in particular the product maturity and need to train physicians.

---

58 Response to request for information of the Commission to the Notifying Party ("RFI") 7, question 14.

59 Replies to Questionnaire Q2 – Competitors Peripheral vascular devices, Question 35.

IV.2.3.1.e. Contract allocation process

(78) PV devices are mainly hospital products for which hospitals in the EEA typically organize tenders. There is an increasing trend towards combining purchases of different hospitals through buying groups, practice largely exercised in certain countries such as Germany or Austria. These buying groups may either bilaterally negotiate or organise tenders on behalf of a number of hospitals, which consequently are bound by the arrangement of the buyer group with the manufacturer. Tenders are in principle organised for a specific product or type of products. Even in the case of multiproduct tenders, these are usually structured on the basis of lots, in order to ensure that competition takes place in relation to all individual products sold.

(79) Both medical staff and personnel in charge of purchasing are usually involved in the selection of the medical devices.[60] The physicians using specific devices are usually consulted and can express strong preference in particular for new devices, where clinical data is a key selection criterion, or for devices, which require some training/habit of use. Mirroring this, manufacturers' and distributors' sales forces are also specialised on certain types of products (e.g. on peripheral vascular or electrosurgical devices), which enable easier contact, marketing and training.

IV.2.3.2. Competitive landscape of various peripheral vascular devices markets

(80) The competitive landscape in the various peripheral vascular devices markets depends to a certain degree on their maturity, going from mature (stents) to early stage (drug-coated balloons). Generally, the main players in the peripheral vascular devices area are Abbott, Boston Scientific, J&J/Cordis, Bard, Cook Medical, Medtronic, Covidien, and Gore. They are generally active in several product areas while some of them cover a whole range of devices used in the treatment of peripheral vascular diseases, as can be seen from Table 1 below. Smaller, more specialised, competitors can have a sizeable presence, in particular in the less commoditised markets.

60 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 56.

Table 1 - Product range by supplier[61]

Competitor	BX stents	SX stents carotid	SX stents non-carotid	PTA Balloon Catheters	EPDs	CTO Crossing Device	Drug Coated Balloons
Abbott	✓	✓	✓	✓	✓	✓	
Boston Scientific	✓	✓	✓	✓	✓	✓	✓
J&J/Cordis	✓	✓	✓	✓	✓	✓	
Bard	✓	✓	✓	✓	✓	✓	✓
Cook Medical	✓	✓	✓	✓			✓
Medtronic	✓	✓	✓	✓	✓		✓
Covidien	✓	✓	✓	✓	✓	✓	
Gore	✓	✓	✓	✓	✓		
Biotronik	✓		✓	✓			✓
Terumo	✓		✓	✓			
Eurocor				✓			✓
Aachen Resonance				✓			✓
Atrium Medical	✓			✓			✓
Cardionovum							✓

Source: Form CO (Desktop Research)

IV.2.3.3. Stents

IV.2.3.3.a. Common features

(81) The stent markets are mature markets (decades old), with a number of established players that are present throughout the EEA. The main players in Europe are Bard, Abbott and Johnson&Johnson ("J&J"), as well as Medtronic, Boston Scientific, Covidien, Cook Medical and Biotronik. Most of these companies offer various types of

61 The Commission will provide the market shares for these competitors per product and in each of the EEA countries assessed below, as submitted by the Notifying Party. The Commission's market investigation revealed that, for some of these products in some countries, there was a different ranking of the other competitors than that indicated by the Notifying Party. However, the Commission's conclusions remain the same.

stents (BX stents, SX stents for carotid and non-carotid procedures) as shown in the Table 1 above.

(82) These markets are also relatively commoditised, with little differentiation between stents produced by different suppliers. In this context the market investigation indicated that stents (excluding DES) of different manufacturers are broadly comparable.[62] Customers can easily switch between stents of different suppliers, which translates also into multisourcing.[63] Competition therefore takes place at the level of portfolio breadth, rather than on technical differentiation.[64]

(83) Prices of stents vary from around EUR 200 to more than EUR 1000 primarily depending on the country, but also the stent type and characteristics (e.g. size).

IV.2.3.3.b. BX stents

IV.2.3.3.b.i. Overview

(84) Table 2 below sets out the Parties' position in BX stents in the countries where their activities overlap and give rise to affected markets:[65]

Table 2 - BX stents

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Austria	1.048	[10-20]%	[0-5]%	**[20-30]%**	[10-20]%	[10-20]%
Bulgaria	0.141	[20-30]%	[5-10]%	**[30-40]%**	[10-20]%	N/A
Finland	0.335	[20-30]%	[0-5]%	**[20-30]%**	[20-30]%	[10-20]%
Germany	13.934	[10-20]%	[0-5]%	**[20-30]%**	[10-20]%	[10-20]%
Lithuania	0.132	[60-70]%	[0-5]%	**[60-70]%**	[30-40]%	[40-50]%
Portugal	0.146	[30-40]%	[0-5]%	**[30-40]%**	[30-40]%	[10-20]%
Slovenia	0.200	[0-5]%	[10-20]%	**[20-30]%**	[40-50]%	N/A

62 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 79.

63 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Questions 59 and 70.

64 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 85.1.

65 Should the market for BX stents be further divided by indication, the only additional affected markets would be the market for iliac BX stents and the market for renal BX stents in Estonia with a combined market share of [20-30]%, representing respectively sales of EUR […] and EUR […], and the market for renal BX stents in Italy with a combined market share of [20-30]%. In any event, according to the information collected by the Commission during its market investigation, other existing competitors have sizeable presence in the market for BX stents in Italy and are able to offer BX stents for both iliac and renal indications. Competition concerns can therefore be excluded in these markets.

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Sweden	0.655	[20-30]%	[10-20]%	**[30-40]%**	[40-50]%	N/A
United Kingdom	2.325	[10-20]%	[10-20]%	**[30-40]%**	[20-30%	[20-30]%
Norway	0.348	[50-60]%	[10-20]%	**[60-70]%**	[60-70]%	[40-50]%
EU Total	62.364	[10-20]%	[5-10]%	**[10-20]%**	N/A	N/A

Source: Form CO

IV.2.3.3.b.ii. Austria, Finland, Germany, Lithuania, Slovenia and the United Kingdom

(85) As can be seen in Table 2 above, in Austria, Finland, Germany, Slovenia and the United Kingdom, the Parties' combined market shares are below 35%. Even if the combined market shares are above 35% in Lithuania, the increment brought about by the Transaction will be minimal at <1%. According to the information collected by the Commission during its market investigation, the Parties' combined market shares might exceed 35% in some more of these countries, in all of which however, other existing competitors such as Abbott, Biotronik or Boston Scientific have a sizeable presence and are expected to continue exerting competitive pressure on the merged entity.

(86) The market for BX stents is mature and commoditised and customers of BX stents often multisource. Customers (hospitals) having responded to the Commission's market investigation generally indicated that they use two or more suppliers for BX stents and rarely buy from both Parties. Several companies were mentioned as credible suppliers in this area, in particular Abbott, Cordis (J&J) and Boston Scientific, but also Cook, Bard and Biotronik.[66]

(87) The merged entity is expected to continue facing competition from other significant players on this market such as Abbott, J&J, Boston Scientific or Cook Medical in these countries. Indeed, Abbott holds more than 30% market share in Austria, Finland, Germany and Slovenia and other competitors such as J&J, (in Austria, Germany and Slovenia), or Boston Scientific (Finland) have a similar or more significant presence than the merged entity would have post-Transaction. In the UK, several players have a sizeable presence such as Bard ([20-30]%), Boston Scientific ([10-20]%) or Abbott ([10-20]%). In Lithuania, Covidien has a minimal market share ([0-5]%), while Abbott and Boston Scientific have a sizeable presence ([10-20]% each).[67]

(88) Therefore the Transaction does not raise any serious doubts in Austria, Finland, Germany, Lithuania, Slovenia and the United Kingdom as to its compatibility with the internal market in relation to BX stents.

66 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 59.

67 Annex III.8.a to the Form CO.

IV.2.3.3.b.iii. Bulgaria, Portugal, Sweden and Norway

(89) The situation in Bulgaria, Portugal, Sweden and Norway will be assessed separately below.

Bulgaria

(90) The Parties' combined market share in Bulgaria amounts to [30-40]% with an increment of [5-10]% representing only EUR […].

(91) At least one other competitor (Boston Scientific: [30-40]%) holds a market share of comparable size to the Parties, while other competitors, such as Abbott and Cook also have established presence in Bulgaria, with market shares above 10% each.

(92) Moreover, the current size of the market for BX stents in Bulgaria might limit the incentives of manufacturers to enter at this point in time. There are however more sizeable competitors producing BX stents in the EEA, which would face few objective regulatory barriers, if they decided to enter in Bulgaria, since they already have the CE mark and successfully market the product in other countries. Therefore, if the merged entity were to raise prices significantly or if the size of the market were to increase, other manufacturers could expand their activities in Bulgaria and start competing with the merged entity.

(93) In addition, the Notifying Party explains that approximately 70-85% of the hospital procurements in Bulgaria are conducted via tenders which typically involve the entire portfolio of peripheral vascular products and are often based on a "winner takes all" model. Companies, which do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(94) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to BX stents in Bulgaria.

Portugal

(95) The Parties' combined market share in Portugal amounts to [30-40]% with an increment of [0-5]% representing only EUR […].

(96) In any event, there are already several other competitors, such as Abbott, Biotronik, Cook or J&J, which have market shares above 10% each. These competitors are therefore expected to continue to exert competitive pressure on the merged entity.

(97) In addition, the Notifying Party explains that 80% of procurements by hospitals in Portugal are organised by tender, 10% are off-tender procurement and the remaining 10% are structured as bilateral negotiations. Companies that do not have an established relationship with a particular hospital could therefore win a contract, if they provide competitive pricing.

(98) Moreover, the current size of the market for BX stents in Portugal might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing BX stents in the EEA, which would face few objective regulatory barriers if they decided to enter in Portugal since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other

manufacturers could expand their activities in Portugal and start competing with the merged entity.

(99) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to BX stents in Portugal.

Sweden

(100) The Parties' combined market share in Sweden amounts to [30-40]%, with an increment of [10-20]% representing sales of EUR […].

(101) Abbott is currently the market leader in Sweden with [30-40]% market share, while J&J has a market share of [10-20]%. Other large companies such as Bard ([5-10]%), Cook ([5-10]%) and Boston Scientific ([0-5]%) are also present in the market.

(102) In addition, the Notifying Party explains that all procurements by hospital purchasing groups or individual hospitals are conducted via tenders, although 30% of demand in such tenders are generally "off tender allowed" (i.e. the hospital is permitted to purchase from a supplier other than the tender winner in certain circumstances). The award of the tender does not guarantee a volume commitment, therefore leaving room for price competition. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(103) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to BX stents in Sweden.

Norway

(104) The Parties' combined market share in Norway amounts to [60-70]%, with an increment of [10-20]% representing sales of EUR […].

(105) Abbott has a significant presence in Norway with a market share of [30-40]% and is expected to continue to exert competitive pressure on the merged entity.

(106) In addition, the Notifying Party explains that in Norway, 50% of the market is accounted for by one hospital purchasing group customer (Sykehuspartner). Given the concentration of demand, Sykehuspartner exercises countervailing buyer power. In addition, all procurements in Norway are conducted by tenders which. typically are for single products and have one phase. Market shares could vary over time, as companies that do not have an established relationship with a particular hospital could win contracts if they provide competitive pricing.

(107) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to BX stents in Norway.

IV.2.3.3.c. Non-carotid SX stents

IV.2.3.3.c.i. Overview

(108) Table 3 below sets out the Parties' position in Non-carotid SX stents on the affected markets:[68]

Table 3 - Non-carotid SX stents

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Bulgaria	0.357	[20-30]%	[20-30]%	[50-60]%	N/A	N/A
Denmark	1.476	[0-5]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Estonia	0.161	[10-20]%	[40-50]%	[50-60]%	[40-50]%	N/A
Germany	24.818	[5-10-]%	[10-20]%	[20-30]%	[20-30]%	[20-30]%
Italy	10.074	[0-5]%	[10-20]%	[20-30]%	[20-30]%	[20-30]%
Latvia	0.246	[0-5]%	[20-30]%	[30-40]%	N/A	N/A
Lithuania	0.362	[10-20]%	[5-10]%	[20-30]%	[20-30]%	[20-30]%
Poland	3.847	[10-20]%	[10-20]%	[20-30]%	[30-40]%	[20-30]%
Slovenia	0.260	[20-30]%	[5-10]%	[30-40]%	[40-50]%	N/A
Spain	6.273	[5-10]%	[10-20]%	[20-30]%	[20-30]%	[20-30]%
Sweden	2.212	[5-10]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
United Kingdom	6.530	[0-5]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
EU Total	116.618	[5-10]%	[10-20]%	[10-20]%	N/A	N/A

Source: Form CO

IV.2.3.3.c.ii. Denmark, Germany, Italy, Latvia, Lithuania, Poland, Slovenia, Spain and the United Kingdom

(109) As can be seen from Table 3, the Parties' combined market shares remain below 35% in Denmark, Germany, Italy, Latvia, Lithuania, Poland, Slovenia, Spain and the United

68 Should the market for non-carotid SX stents be further divided by indication, the only additional affected markets would be the market for iliac SX stents and the market for SFA SX stents in Portugal with a combined market share of [20-30]%, but an increment of [0-5]%. Competition concerns can therefore be excluded in these markets.

Kingdom. In some of these countries, according to the information collected by the Commission during its market investigation, the Parties' combined market shares might exceed 35%, however, in all these countries other existing competitors are present and have a sizeable presence and are expected to continue to exert competitive pressure on merged entity.

(110) The market for non-carotid SX stents is mature and commoditised, and customers of non-carotid SX stents often multisource. A majority of the customers having responded to the Commission's market investigation indicated that they use two or more suppliers for non-carotid SX stents; almost half of them buy from more than three suppliers. When they buy from both Parties, they also buy from other manufacturers. Several companies were mentioned as suppliers, in particular Abbott, Boston Scientific and Bard, but also Cordis (J&J), Cook, Biotronik and Terumo.[69]

(111) The Commission notes that the merged entity […]* expected to continue to face competition from other significant players on this market such as Abbott, J&J, Boston Scientific, Bard or Cook Medical in these countries. Indeed these other competitors and in particular Bard in Denmark, Abbott in Germany and Slovenia, Abbott and J&J in Italy, Boston Scientific in Latvia, Lithuania and Poland, Abbott and Boston Scientific in Spain, Boston Scientific and J&J in the UK have a similar or more significant presence than the merged entity would have post-Transaction.[70]

(112) Therefore the Transaction does not raise any serious doubts in Denmark, Germany, Italy, Latvia, Lithuania, Poland, Slovenia, Spain and the United Kingdom as to its compatibility with the internal market in relation to non-carotid SX stents.

IV.2.3.3.c.iii. Bulgaria, Estonia and Sweden

(113) The situation in Bulgaria, Estonia and Sweden will be assessed separately below.

Bulgaria

(114) The Parties' combined market share in Bulgaria […]* to [50-60]% with an increment of [20-30]% representing sales of EUR […].

(115) There are currently three other competitors of similar size to Medtronic, namely Boston Scientific ([10-20]%), Cook ([10-20]%) and Abbott ([10-20]%), which are expected to continue to be active in non-carotid SX stents and exert significant competitive pressure on the merged entity post-Transaction.

(116) In addition, the Notifying Party explains that approximately 70-85% of the hospital procurements in Bulgaria are conducted via tenders which typically involve the entire portfolio of peripheral vascular products and are often based on a "winner takes all" model, which intensifies price competition. Companies that do not have an established

---

69 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 59.

* Should read: is.

70 Annex III.8.a to the Form CO.

* Should read: amounts.

relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(117) Moreover, the current size of the market for non-carotid SX stents in Bulgaria might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing non-carotid SX stents in the EEA, which would face few objective regulatory barriers if they decided to enter in Bulgaria since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other manufacturers could expand their activities in Bulgaria and start competing with the merged entity.

(118) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to non-carotid SX stents in Bulgaria.

Estonia

(119) The Parties' combined market share in Estonia amounts to [50-60]% with an increment of [10-20]% representing sales of EUR […].

(120) Two other competitors of significant size are expected to continue to be active in non-carotid SX stents and exert significant competitive pressure on the merged entity post-Transaction, namely J&J, which has a market share of [30-40]%, and Abbott with a market share of [10-20]%.

(121) The Notifying Party submits that all hospital procurements in the Baltic States are conducted by tender of which 80% are annual tenders involving the entire portfolio of peripheral vascular products and 20% are tenders for single products. The tenders may be single or multi-phase and hospitals usually multi-source. The winning bidder is typically awarded the right to supply a minimum quantity of the product awarded. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(122) Moreover, the current size of the market for non-carotid SX stents in Estonia might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing non-carotid SX stents in the EEA, which would face few objective regulatory barriers if they decided to enter in Estonia since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other manufacturers could expand their activities in Estonia and start competing with the merged entity.

(123) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to non-carotid SX stents in Estonia.

Sweden

(124) The Parties' combined share in Sweden amounts to [30-40]%, with an increment of [5-10]% representing sales of EUR […].

(125) Other competitors such as Bard ([10-20]%), Boston Scientific ([5-10]%), Abbott ([10-20]%), Cook ([5-10]%), J&J ([10-20]%) are active on the market and are expected to continue to exert competitive pressure on the merged entity.

(126) In addition, the Notifying Party explains that all procurements by hospital purchasing groups or individual hospitals are conducted via tenders, although 30% of demand in such tenders are generally "off tender allowed" (i.e. the hospital is permitted to purchase from a supplier other than the tender winner in certain circumstances). The award of the tender does not guarantee a volume commitment, therefore leaving room for price competition. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(127) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to non-carotid SX stents in Sweden.

IV.2.3.3.d. Carotid SX stents

IV.2.3.3.d.i. Overview

(128) Table 4 below sets out the Parties' position in carotid SX stents on the affected markets:

Table 4 - Carotid SX stents

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Bulgaria	0.127	[50-60]%	[10-20]%	[60-70]%	[70-80]%	N/A
Greece	0.281	[0-5]%	[20-30]%	[20-30]%	[40-50]%	[70-80]%
Italy	2.519	[10-20]%	[10-20]%	[30-40]%	[30-40]%	[30-40]%
Latvia	0.027	[10-20]%	[10-20]%	[20-30]%	N/A	N/A
Poland	0.427	[40-50]%	[10-20]%	[50-60]%	[50-60]%	[40-50]%
Romania	0.125	[10-20]%	[10-20]%	[30-40]%	[30-40]%	[20-30]%
Slovenia	0.180	[10-20]%	[10-20]%	[20-30]%	[20-30]%	N/A
Spain	0.697	[0-5]%	[10-20]%	[20-30]%	[30-40]%	[40-50]%
EU Total	16.447	[5-10]%	[5-10]%	[10-20]%	N/A	N/A

Source: Form CO

IV.2.3.3.d.ii. Greece, Italy, Latvia, Romania, Slovenia and Spain

(129) As can be seen from Table 4 above, the Parties' combined market shares will remain below 35% in Greece, Italy, Latvia, Romania, Slovenia and Spain.

(130) Half of the customers having responded to the Commission's market investigation indicated that they use two or more suppliers for carotid SX stents and rarely buy from both Parties. Several companies were mentioned as suppliers, in particular Abbott, Cordis (J&J) and Boston Scientific, but also Bard and Optimed.[71]

71 Replies to Questionnaire Q1 – Customers Peripheral vascular devices, Question 59.

(131) The Commission notes that the merged entity is expected to continue to face competitive pressure from other significant players on this market such as Boston Scientific, Abbott, J&J in these countries. Indeed, these other competitors and, in particular, Boston Scientific in Italy ([40-50]%) and Greece ([40-50]%), Abbott in Slovenia ([50-60]%), Romania ([40-50]%) and Latvia ([30-40]%) have a similar or more significant presence than the merged entity would have post-Transaction. In Spain, three competitors have a sizeable presence (10-20%), namely Abbott, Boston Scientific and J&J.[72]

(132) Therefore the Transaction does not raise any serious doubts in Greece, Italy, Latvia, Romania, Slovenia and Spain as to its compatibility with the internal market in relation to carotid SX stents.

IV.2.3.3.d.iii. Bulgaria and Poland

(133) The situation in Bulgaria and Poland will be assessed separately below.

Bulgaria

(134) The Parties' combined market share in Bulgaria amounts to [60-70]% with an increment of [10-20]% representing sales of EUR […].

(135) Two other competitors have a sizeable presence in Bulgaria, namely Boston Scientific ([10-20]%) and Abbott ([10-20]%). These are expected to continue being active in non-carotid SX stents and to exert significant competitive pressure on the merged entity post-Transaction.

(136) In addition, the Notifying Party explains that approximately 70-85% of the hospital procurements in Bulgaria are conducted via tenders which typically involve the entire portfolio of peripheral vascular products and are often based on a "winner takes all" model, which intensifies price competition. Companies who do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(137) Moreover, the current size of the market for carotid SX stents in Bulgaria might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing carotid SX stents in the EEA, which would face few objective regulatory barriers if they decided to enter in Bulgaria since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other manufacturers could expand their activities in Bulgaria and start competing with the merged entity.

(138) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to carotid BX stents in Bulgaria.

72 Annex III.8.a to the Form CO.

Poland

(139) The Parties' combined market share in Poland amounts to [50-60]% with an increment of [10-20]% representing sales of EUR […].

(140) Other competitors with an established position in Poland, such as Abbott ([20-30]%), Boston Scientific ([20-30]%) and J&J ([5-10]%) are expected to continue their activity in carotid SX stents and to exert significant competitive pressure on the merged entity post-Transaction.

(141) In addition, the Notifying Party explains that 80% of hospital procurement in Poland are organised by tender, which are usually single-phase processes with no subsequent negotiation phase. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(142) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to carotid BX stents in Poland.

IV.2.3.4. PTA balloon catheters

IV.2.3.4.a. Overview

(143) Table 5 below sets out the Parties' position in PTA balloon catheters in the European countries where the Transaction gives rise to affected markets:

Table 5 - PTA balloon catheters

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Austria	2.876	[10-20]%	[0-5]%	[20-30]%	[10-20]%	[20-30]%
Bulgaria	0.182	[20-30]%	[20-30]%	[40-50]%	[20-30]%	N/A
Estonia	0.089	[5-10]%	[30-40]%	[30-40]%	[40-50]%	[20-30]%
Germany	26.996	[20-30]%	[0-5]%	[20-30]%	[20-30]%	[40-50]%
Italy	12.227	[10-20]%	[5-10]%	[20-30]%	[20-30]%	[20-30]%
Latvia	0.137	[10-20]%	[10-20]%	[20-30]%	[10-20]%	[20-30]%
Malta	0.096	[20-30]%	[0-5]%	[30-40]%	N/A	N/A
Poland	2.210	[10-20]%	[5-10]%	[20-30]%	[10-20]%	[20-30]%
Slovenia	0.485	[20-30]%	[0-5]%	[20-30]%	[20-30]%	N/A
Sweden	1.772	[10-20]%	[10-20]%	[30-40]%	[20-30]%	[10-20]%
Norway	0.680	[40-50]%	[10-20]%	[50-60]%	[50-60]%	[20-30]%

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
EU Total	91.339	[10-20]%	[5-10]%	[10-20]%	N/A	N/A

Source: Form CO

IV.2.3.4.b. Austria, Germany, Italy, Latvia, Malta, Poland, Slovenia and Sweden

(144) As can be seen from Table 5 above, the Parties' combined market shares will remain below 35% in Austria, Germany, Italy, Latvia, Malta, Poland, Slovenia and Sweden. In some of these countries, according to the information collected by the Commission during its market investigation, the Parties' combined market shares might exceed 35%, however, in all these countries other existing competitors such as Abbott, Biotronik or Boston Scientific have a sizeable presence and are expected to continue to exert competitive pressure on the merged entity.

(145) The market for PTA balloon catheters is mature and commoditized and customers of PTA balloon catheters multisource. The majority of customers having responded to the Commission's market investigation indicated that they use two or more suppliers for PTA balloon catheters and most often, other than the Parties, companies such as Cordis (J&J), Boston Scientific, Cook, Bard, Abbott, Biotronik or Terumo were mentioned.[73]

(146) The Commission notes that the merged entity is expected to continue facing competition from other significant players on this market such as Boston Scientific, Abbott, J&J, Bard or Cook Medical which all have a presence in these countries. Indeed these other competitors and in particular Boston Scientific in Austria ([30-40]%), Germany ([20-30]%), Italy ([20-30]%), Latvia ([30-40]%) and Malta ([20-30]%), Abbott in Poland ([20-30]%) and Slovenia ([50-60]%) and Bard in Sweden ([20-30]%) have a similar or more significant presence then the merged entity would have post-Transaction.[74]

(147) Therefore, the Transaction does not raise any serious doubts in Austria, Germany, Italy, Latvia, Malta, Poland, Slovenia and Sweden as to its compatibility with the internal market in relation to PTA balloon catheters.

IV.2.3.4.c. Bulgaria, Estonia and Norway

(148) The situation in Bulgaria, Estonia and Norway will be assessed separately below.

Bulgaria

(149) The Parties' combined share in Bulgaria amounts to [40-50]%, with an increment of [20-30]% representing sales of only EUR […].

73 Replies to Questionnaire Q1- Customers peripheral vascular devices, Question 59.

74 Annex III.8.a to the Form CO.

(150) The other competitors active in Bulgaria, Abbott, Boston Scientific and Biotronik each achieved market shares of [10-20]% each[75].

(151) In addition, the Parties sell mainly via tenders to hospital customers in Bulgaria, as approximately 70-85% of procurements are conducted in this way which typically involves the entire portfolio of peripheral vascular products and are often based on a "winner takes all" model, which intensifies price competition. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(152) Moreover, the current size of the market for PTA balloon catheters in Bulgaria might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing PTA balloon catheters in the EEA, which would face few objective regulatory barriers if they decided to enter in Bulgaria since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other manufacturers could expand their activities in Bulgaria and start competing with the merged entity.

(153) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to PTA balloon catheters in Bulgaria.

Estonia

(154) The Parties' combined market share in Estonia amounts to [30-40]%, with an increment of [5-10]%, representing sales of only EUR […].

(155) Other significant competitors active in Estonia have a sizeable presence in Estonia, namely Abbott ([20-30]%) or J&J ([20-30]%) and Boston Scientific.[76] It is therefore expected that the other existing competitors will likely continue to exert competitive pressure on the merged entity.

(156) In addition, the Notifying Party submits that all hospital procurements in the Baltic States are conducted by tender of which 80% are annual tenders involving the entire portfolio of peripheral vascular products and 20% are tenders for single products. The tenders may be single or multi-phase and hospitals usually multi-source. The winning bidder is typically awarded the right to supply a minimum quantity of the product awarded. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(157) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to PTA balloon catheters in Estonia.

---

75 Annex III.8.a to the Form CO.

76 Annex III.8.a to the Form CO.

Norway

(158) The Parties' combined market share in Norway amounts to [50-60]%, with an increment of [10-20]% representing sales of only EUR […].

(159) Other significant competitors active in Norway have a sizeable presence in Norway, namely J&J ([5-10]%), Boston Scientific ([5-10]%), Abbott ([5-10]%) or Bard ([10-20]%). It is therefore expected that the other existing competitors will likely continue to exert a competitive pressure on the merged entity.

(160) In addition, the Notifying Party explains that in Norway, 50% of the market is accounted for by one hospital purchasing group customer (Sykehuspartner). Given the concentration of demand, Sykehuspartner exercises countervailing buyer power. In addition, all procurements in Norway are conducted by tenders which typically are for single products and typically have one phase. Market shares could vary over time, as companies that do not have an established relationship with a particular hospital could win contracts if they provide competitive pricing.

(161) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to PTA balloon catheters in Norway.

IV.2.3.5. EPDs

IV.2.3.5.a. Overview

(162) Table 6 below sets out the Parties' position in all EPDs (without a further distinction between filter baskets and proximal occlusion balloons) on the affected markets[77]:

Table 6 - All EPDs

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Bulgaria	0.086	[0-5]%	[20-30]%	[20-30]%	N/A	N/A
France	0.466	[0-5]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%
Italy	6.199	[10-20]%	[10-20]%	[30-40]%	[20-30]%	[20-30]%
Latvia	0.052	[5-10]%	[50-60]%	[60-70]%	[60-70]%	[70-80]%
Poland	1.342	[10-20]%	[10-20]%	[20-30]%	[10-20]%	[20-30]%
Slovenia	0.168	[10-20]%	[20-30]%	[40-50]%	[30-40]%	N/A

77 The Transaction would not lead to any affected market on a potential segment for filter baskets, the only EPDs on which the Parties' sales overlap.

Country	Market Size (€m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Sweden	0.129	[5-10]%	[20-30]%	[30-40]%	[30-40]%	[20-30]%
United Kingdom	0.400	[5-10]%	[20-30]%	[30-40]%	[30-40]%	[30-40]%
EU Total	21.882	[5-10]%	[10-20]%	[20-30]%	N/A	N/A

Source: Form CO

IV.2.3.5.b. Bulgaria, France, Italy, Poland, Sweden and the United Kingdom

(163) As can be seen from Table 6 above, the Parties' combined market shares will remain below 35% in Bulgaria, France, Italy, Poland, Sweden and the United Kingdom. In some of these countries, according to the information collected by the Commission during its market investigation, the Parties' combined market shares might exceed 35%, however, in all these countries other existing competitors such as Abbott or Boston Scientific have a sizeable presence and are expected to continue to exert competitive pressure on the merged entity.

(164) In addition, customers of EPDs multisource, the majority of customers having responded to the Commission's market investigation indicated that they use two or more suppliers for EPDs and most often, other than the Parties, companies such as Abbott, Boston Scientific or J&J are mentioned.[78]

(165) The Commission notes that the merged entity is expected to continue facing competition from other significant players on this market such as Abbott, Boston Scientific or J&J which all have a presence in these countries. Indeed these other competitors and in particular Boston Scientific in Bulgaria, France, Italy, Sweden, United Kingdom and Abbott in Poland have a similar or more significant presence then the merged entity would have post-Transaction[79].

(166) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise any serious doubts in Bulgaria, France, Italy, Poland, Sweden and the United Kingdom as to its compatibility with the internal market in relation to EPDs.

IV.2.3.5.c. Latvia and Slovenia

(167) The situation in Latvia and Slovenia will be assessed separately below.

Latvia

(168) The Parties' combined market share in Latvia amounts to [60-70]% with an increment of [5-10]%, representing sales of only EUR […].

78 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 59.

79 Annex III.8.a to the Form CO.

(169) Other significant competitors are active in Latvia, namely Boston Scientific and J&J which achieved market shares of [10-20]% each[80]. Boston Scientific and J&J sell filter baskets (like Covidien) and are therefore much closer competitors to Covidien than Medtronic which almost exclusively produces proximal occlusion balloons. Boston Scientific and J&J therefore exert a stronger competitive pressure on Covidien than Medtronic, and are expected to continue doing so post-Transaction.

(170) Moreover, the current size of the market for EPDs in Latvia might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing EPDs in the EEA, which would face few objective regulatory barriers if they decided to enter in Latvia since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other manufacturers could expand their activities in Latvia and start competing with the merged entity.

(171) In addition, the Notifying Party submits that all hospital procurements in the Baltic States are conducted by tender of which 80% are annual tenders involving the entire portfolio of peripheral vascular products and 20% are tenders for single products. The tenders may be single or multi-phase and hospitals usually multi-source. The winning bidder is typically awarded the right to supply a minimum quantity of the product awarded. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

(172) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to EPDs in Latvia.

Slovenia

(173) The Parties' combined market share in Slovenia amounts to [40-50]%, with an increment of [10-20]% representing sales of only EUR […].

(174) In Slovenia, Abbott has a significant presence, having achieved a market share of [40-50]% while J&J also has a sizeable presence with [10-20]%.[81] Abbott and J&J produce filter baskets (like Covidien) and are therefore much closer competitors to Covidien than Medtronic which almost exclusively produces proximal occlusion balloons. Abbott and J&J therefore exert a stronger competitive pressure on Covidien than Medtronic, and are expected to continue doing so post-Transaction.

(175) In addition, the Notifying Party submits that approximately 90% of procurements in Slovenia are conducted through tenders. The only procurement which are not conducted by tender are those with a total value of less than EUR 10 000. The scope of the tender typically involves the entire peripheral vascular portfolio. Hospitals do not tend to multi-source, Slovenia being more a "winner takes it all" market, which intensifies price competition. Companies that do not have an established relationship with a particular hospital could therefore win a contract if they provide competitive pricing.

---

80 Annex III.8.a to the Form CO.

81 Annex III.8.a to the Form CO.

(176) Moreover, the current size of the market for EPDs in Slovenia might limit the incentives of manufacturers to enter. There are however more sizeable competitors producing EPDs in the EEA, which would face few objective regulatory barriers if they decided to enter in Slovenia since they already have the CE mark. Therefore, if the merged entity raises prices significantly or if the size of the market increases, other manufacturers could expand their activities in Slovenia and start competing with the merged entity.

(177) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to EPDs in Slovenia.

IV.2.3.6. Drug coated balloons

IV.2.3.6.a. Framework for the assessment of overlaps between an existing product and a pipeline product

(178) According to the Horizontal merger guidelines[82] horizontal mergers may significantly impede effective competition by eliminating actual competitive constraints between the firms leading to increased market power[83]. Mergers between an actual competitor and a potential competitor may have a similar anti-competitive effect provided that the potential competitor already exerts a significant constraining influence and there is no sufficient number of other actual or potential competitors which could maintain sufficient competitive pressure post-merger.[84]

(179) The situation in this medical devices merger giving rise to an overlap between an actual product and a product in the pipeline is slightly different from the two scenarios described in the Horizontal merger guidelines. This is because the Parties are neither actual competitors nor potential competitors in the sense of the Horizontal merger guidelines. However, in this case, whilst one of the Parties is not yet present on the market for DCBs and therefore not currently exerting competitive pressure on the market, there is reasonable certainty that its product will be reaching the market upon completion of the regulatory approval process in the near future. Given the fact that the regulatory approval process has a clear timeline and the milestones are known to everybody, the constraining effect of a product in the pipeline is non-existent until the moment the product actually comes on the market. This is different from the typical potential competition scenario envisaged in the Horizontal merger guidelines in which a competitor which is not yet on the market could easily decide to enter should prices rise. This mere threat of imminent entry has a disciplining effect on the companies present on the market even in the absence of actual entry.

---

82 Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, Official Journal C 31, 05.02.2004, p. 5-18.

83 Horizontal merger guidelines, paragraphs 22 and seq.

84 Horizontal merger guidelines, paragraphs 58-60.

(180) Therefore, the Commission analysed the impact of the Transaction on the DCB market against the test for elimination of future competition, taking account of the elements set out in the Horizontal merger guidelines pertaining to the elimination of competition between actual competitors, except for the assessment of the market shares of the merging entities.

IV.2.3.6.b. Background on DCB market

(181) The market for DCBs is a relatively new market and both Covidien and Medtronic expect significant growth in this market in the next five years. This is amongst others linked to healthcare economics; DCBs appear to provide a strong opportunity considering that the total cost of care for a patient is smaller when using a DCB compared to using a PTA balloon.[85]

(182) The current penetration of DCBs, i.e. the rate at which DCBs are used in treatments, is quite limited; in 2013 it was 7% for the various indications while in 2021 it is expected that DCBs will have a penetration rate of 31%.[86] Covidien expects the market to grow between 24% and up to 61% year on year until 2018 with further growth above 5% until 2021.[87] By way of comparison the market for stents and PTA are expected to grow at a significantly smaller rate or even decrease.[88] Similarly, Medtronic sees in DCBs the highest growth potential in the peripheral vascular devices area in the next 5 years.[89] For Medtronic, the DCB adoption will drive the greatest growth for itself (in addition to the increasing footprint) and Medtronic states that they "*win with DEB [DCB]*" and that DCB "*represents huge clinical opportunity*" with a value proposition residing in stent like efficacy with no stent.[90]

85 Form CO, Annex 16, 1.2.1.2 Stellarex AVF, p. 8.

86 Form CO, Annex 16, EU DCB, Covidien document, p. 11.

87 For instance in 2018 the market for DCBs is expected to grow 34% vs 2017 and in 2019 it is expected to increase 14% vs 2018, see Form CO, Annex 16, EU DCB, Covidien document, p. 13.

88 For PV stents growth of between 1-3% in most years and up to maximum 6% in 2023; for PTAs decrease of around 0.5%-1%, see Form CO, Annex 16, EU DCB, Covidien document, p. 13.

89 Form CO, Annex III.37, Peripheral vascular leadership, Medtronic document.

90 Form CO, Annex III.37, Peripheral vascular leadership, Medtronic document.

Table 7 - Market size of DCB market by country (2013)

Country	Market Size (EUR m)
Austria	1.100
Belgium	0.800
Bulgaria	0.050
Croatia	0.003
Cyprus	0.009
Czech Republic	0.240
Denmark	0.240
Estonia	0.052
Finland	0.240
France	0.720
Germany	16.500
Greece	0.070
Hungary	0.070
Ireland	0.150
Italy	1.200
Latvia	0.080
Lithuania	0.118
Luxembourg	0.305
Malta	0.004
Netherlands	0.320
Poland	0.120
Portugal	0.050
Romania	0.003
Slovakia	0.350
Slovenia	0.034
Spain	0.500
Sweden	0.500
United Kingdom	1.000
EU Total	24.826
Norway	0.197

Source: Form CO

(183) In this context, the market investigation confirmed that DCBs are a very promising and growing therapy. It is indeed becoming the first line of treatment for the peripheral vascular diseases where it is proven to be particularly effective, such as SFA and popliteal procedures.

(184) The Commission will first describe the existing and pipeline DCBs in the EEA in Section IV.2.3.5.c before assessing the effects of the Transaction on the market for DCBs in Section IV.2.3.5.d.

IV.2.3.6.c. Description of existing and pipeline DCBs

(185) Given the promising nature of the therapy and the ensuing market growth many start-up and major medical device companies have invested in the development of DCBs.

(186) Currently, in Europe, 10 companies have a DCB with CE mark, namely Medtronic (described in Section IV.2.3.6.c.i), Aachen Resonance, Atrium Medical, Bard, Biotronik, Boston Scientific, Cardionovum, Cook Medical, Eurocor and iVascular (described in Section IV.2.3.6.c.ii).

(187) Covidien, on the other hand, only has a pipeline DCB called Stellarex which is described in Section IV.2.3.6.c.iii.

IV.2.3.6.c.i. Medtronic's existing DCBs

(188) Medtronic was the first medical device supplier to launch a drug coated balloon catheter in Europe in early 2009. Medtronic currently markets two types of DCBs (i) a product called IN.PACT Admiral and (ii) a product called IN.PACT Pacific. Both DCB products use the drug paclitaxel and are offered in a range of diameters (4.0 – 7.0mm) and four lengths (40, 60, 80 and 120mm). Medtronic's DCBs are indicated for above the knee indications (SFA and popliteal procedures).

(189) The only difference between the two Medtronic's DCBs is that one is compatible with 0.035" guidewires while the other one is compatible with 0.018" guidewires.

IV.2.3.6.c.ii. Other existing DCBs on the market

(190) Table 8 below lists all manufacturers which currently market a DCB in the EEA and highlights the main characteristics of their device:

Table 8 - Other existing DCBs in the EEA markets

Supplier	Product	Launch Date (historic or expected)	Drug Used	Excipient / Polymer
Aachen Resonance	*Elutax*	(At least 2012)	Paclitaxel	None
Atrium Medical	*Clearway*	2007	Various therapeutic and diagnostic agents	Unknown – it is an infusion balloon
Bard	*Lutonix*	2011 or later	Paclitaxel	Polysorbate + Sorbitol
Biotronik	*Passeo-18*	2014	Paclitaxel	BTHC-Butyryl-tri-hexyl Citrate
Boston Scientific	*Ranger*	2014 (historic)	Paclitaxel	Citrate Ester
Cardionovum	*Legflow*	2012	Paclitaxel	Shellolic Acid
Cook Medical	*Advance 18 PTX*	2012	Paclitaxel	None

Supplier	Product	Launch Date (historic or expected)	Drug Used	Excipient / Polymer
Eurocor	*Biosensors Range* *Freeway*	2013 2010	Paclitaxel	Unknown Shellac
iVascular	*Luminor*	2014 (historic)	Paclitaxel	Unknown

Source: Form CO

(191) As can be seen from Table 8 above, most if not all DCBs available on the market in the EEA use the drug paclitaxel and different excipients / polymers.

(192) According to the Notifying Party, at least eight players offer DCBs for above the knee indications (Bard, Aachen Resonance, Cardionovum, Cook Medical, Eurocor, Biotronik, iVascular and Boston Scientific), six of which also offer DCBs for below the knee indications (Bard, Aachen Resonance, Cardionovum, Eurocor, iVascular and Boston Scientific).

(193) The success rate on the market of these various DCBs will be assessed in Section IV.2.3.6.d.iii below.

IV.2.3.6.c.iii. Covidien's pipeline DCB - Stellarex

(194) Covidien does not currently market a DCB in the EEA or elsewhere but it has a product in development, called Stellarex. Covidien acquired the drug eluting balloon technology through the acquisition of CV Ingenuity at the beginning of 2013.[91] CV Ingenuity filed its first DCB patent in June 2008 and commenced the first-in-human trial in 2011.[92]

(195) Covidien began the regulatory process to obtain CE Mark for above-the-knee indications in the EU in early March 2013 and completion is anticipated in late 2014 or early 2015. Covidien aims to launch the above-the-knee Stellarex with an indication for use in SFA and popliteal arteries in late 2014 or early 2015 in Europe.

(196) Covidien is also developing Stellarex for use in below the knee procedures, but this project is not yet as developed as the one for above-the-knee indication. In Europe, Covidien has not submitted an application for CE Mark for below the knee indications, and it does not expect to submit it before […]. It is therefore unlikely that the product could be launched before […].

91 Covidien initiated the acquisition process in November 2012 and completed the acquisition in January 2013, see also http://www.covidien.com/investor/phoenix.zhtml?c=207592&p=irol-newsArticle&ID=1773433

92 Response to RFI 7, question 14.

IV.2.3.6.d. Assessment of the Commission

IV.2.3.6.d.i. Relevant metrics for comparing the various DCBs

(197) To assess the competitive constraint of various devices on the market as well as the future constraint of those in the pipeline the Commission endeavoured to compare the various DCBs. In this context, the Notifying Party put forward various metrics while the Commission also considered other relevant indicators.

IV.2.3.6.d.i.1. TLR rate, patency rate, clinical data and other metrics

(198) The Notifying Party compares its product to the ones of its competitors' and to Stellarex by referring to the target lesion revascularisation rate ("TLR rate"), i.e. a measure of how often, after 12 or 24 months, a new surgery/intervention is required as a result of restenosis or re-narrowing of the vessel.

(199) Based on the results of the market investigation, it seems that the relevance of the TLR rate as a comparison parameter is limited for a number of reasons. First, the comparative value of the TLR rate may be limited as the available rates do not derive from head-to-head clinical trials but rather from independent trials based on different samples of patients. The Commission understands that head-to-head trials for DCBs do not exist yet.

(200) Second, the market investigation provided indications that the TLR rate is not the one single factor distinguishing the DCBs from each other and allowing concluding on the clinical efficacy of the various devices. Indeed, customers take into account various data, such as the technical characteristics of the product (e.g. DCB's pressure, flexibility and stiffness), availability and robustness of clinical data, etc.

(201) The "Primary Patency Rate" (PPR) is a measure of how often a vessel remains "open", which itself is determined by an ultrasound machine. For example, if the ultrasound reading is that a vessel is still 50% "open" 12 or 24 month after the surgery/intervention, then it will include that result as a positive metric when measuring effectiveness of the DCB.

(202) As concerns the clinical data, the market investigation provided indications that this is one of the most important criteria (both in terms of the results and the amount of the data) taken into account by surgeons when selecting which device to implant.[93] Similarly, competitors confirmed that the strength of clinical data is an important parameter of competition in this space allowing manufacturers to differentiate themselves in the field of drug coated balloons.[94]

(203) Finally, the market investigation highlighted that other factors such as the overall track record of a company, ease of use and the availability of the reimbursement are also relevant for surgeons to select a DCB. While the market is still relatively new and the clinical efficacy of the various devices has not yet been fully tested and proven, the surgeons during the market investigation indicated that there are two elements which

93 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 87.

94 Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 48.

may play a role in the efficacy of a DCB, namely the excipient which has an influence on the coating durability during the implantation and the concentration or dosage of the drug needed.[95]

IV.2.3.6.d.i.2. Market shares, Commission's market investigation and Covidien's internal documents

(204) The Commission also considered the rate of success of the existing DCB suppliers as reflected by their sales in the various EEA countries. The Commission further took into account the views of the respondents to the Commission's market investigation including key opinion leaders about the other existing and pipeline DCBs as well as Parties' internal documents comparing their devices.

(205) The Notifying Party argues that there are 9 other suppliers of DCBs active in Europe with CE mark and which took market share from Medtronic, such as Aachen Resonance, Atrium Medical, Bard, Biotronik, Boston Scientific, Cardionovum, Cook Medical, Eurocor or iVascular.

IV.2.3.6.d.ii. Medtronic's DCB: current leader in the EEA

(206) Based on the information provided by the Notifying Party, and the results of the market investigation Medtronic is a clear market leader in most EEA countries in terms of market share.[96] Indeed, in 17 EEA countries it estimates that it has more than 50% market share, while in further 7 countries its market shares are above 30%. Medtronic's presence is significant in the eight EEA countries which represent close to 90% of the total sales of DCBs in the EEA,[97] with market shares ranging between 46% and 68%. In the largest EEA country for DCBs, Germany, Medtronic is by far the biggest and most significant player.

(207) Table 9 below sets out the market shares of Medtronic in 2013 with its DCB in the EU and the various EEA countries:

95 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 88 and Replies to Questionnaire Q2-Competitors peripheral vascular devices, Question 49.

96 Form CO, Annex III.37, Bard Lutonix Attack Pack Final, slide 4, Annex III.37, Q1 FY15 DCB Overview Deck, slides 6-7.

97 These are Austria, Belgium, France, Germany, Italy, Spain, Sweden and the United Kingdom. See Annex III.6 to the Form CO.

Table 9 - Market shares Medtronic DCB

EU / EEA country	Medtronic's DCB Market share
EU total	***[60-70]%***
Croatia	[90-100]%
Cyprus	[90-100]%
Malta	[90-100]%
Ireland	[90-100]%
Romania	[70-80]%
Luxembourg	[70-80]%
Finland	[70-80]%
Germany	[60-70]%
The Netherlands	[60-70]%
Sweden	[60-70]%
Austria	[60-70]%
Denmark	[50-60]%
Czech Republic	[50-60]%
Poland	[50-60]%
Spain	[50-60]%
Slovenia	[50-60]%
Norway	[50-60]%
Italy	[40-50]%
France	[40-50]%
Belgium	[40-50]%
United Kingdom	[40-50]%
Greece	[40-50]%
Portugal	[40-50]%
Hungary	[30-40]%
Bulgaria	[20-30]%
Slovakia	[20-30]%
Lithuania	[10-20]%
Latvia	[0-5]%

Source: Annex III.6 to the Form CO

(208) Medtronic's high market share can partially be explained by historical reasons and namely the fact that Medtronic was the first mover in the market and currently has the strongest clinical data.

(209) Respondents to the Commission's market investigation pointed to the strong position of Medtronic on the market for DCBs.[98] Indeed, the majority of respondents either use only Medtronic's DCB product or sometimes also another device, most often Bard's DCB Lutonix. DCBs of other competitors are mentioned only rarely.[99] The majority of customers also indicated that they would use Medtronic as a first choice, only a few respondents mentioned Bard as the first choice, while the rest of the suppliers such as iVascular, Boston Scientific, Biotronik and Eurocor are barely mentioned.[100]

(210) Based on their experience and available clinical information, when assessing advantages and disadvantages, overall appreciation on the market positioning, clinical efficacy, strength of clinical data, etc., of various existing DCBs, respondents to the Commission's market investigation indicated that Medtronic's DCB is always comparable or better than the other DCBs.[101]

98 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 89; replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 50.

99 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 59.

100 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 91.

101 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 90.

(211) When comparing Medtronic's DCBs with those of its competitors, respondents to the Commission's market investigation noted that Bard's DCB would currently be the most similar alternative/closest competitor of Medtronic in terms of product characteristics and price.[102] When looking at clinical data, such as TLR rate and PPR, it appears that Medtronic's clinical data are better than those of Bard.[103] Medtronic indicates that its DCB have a TLR of 2.4% and a PPR of 89.8% respectively, while Bard's DCB have TLR of 13.3% and a PPR of 73.5%[104]. A further analysis of Bard's DCB is conducted in Section IV.2.3.6.d.iii.1 below.

(212) In the light of the above, it can be concluded that Medtronic currently appears to have a strong position on the market for DCBs in most EEA countries.

IV.2.3.6.d.iii. Other existing DCBs

(213) As indicated above, a number of medical device companies market DCBs in the EEA. However, most of these only have a minimal presence and do not seem to be gaining traction, although a number of them entered the market several years ago (e.g. Atrium Medical in 2007, Eurocor in 2010, Bard in 2011).

(214) Based on the results of the market investigation, except for Medtronic, only the devices of Bard, Biotronik and Eurocor have currently a sizeable presence in the market. Therefore, the devices of other competitors having a market share at European level below 1% are not analysed in detail in this decision.

IV.2.3.6.d.iii.1. Bard's Lutonix

(215) According to the Notifying Party, Bard's estimated market shares in the EU and the various EEA countries are as follows[105]:

---

102 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 72; replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 42.

103 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 90.

104 Response to RFI 8, question 20.

105 The Notifying Party explains that the market shares for competitors are *pro forma* estimates of the current position of the competitors, based on the adoption rates in a given country, Medtronic's own sales and estimates of its position, which hospitals/clinics used DCBs, and customer feedback.

Table 10 - Bard's market shares EEA

EU/ EEA country	Bard's DCB Market share
EU	***[10-20]%***
Hungary	[60-70]%
France	[40-50]%
Norway	[30-40]%
Estonia	[20-30]%
Latvia	[20-30]%
Greece	[20-30]%
Lithuania	[20-30]%
Belgium	[20-30]%
UK	[20-30]%
Portugal	[20-30]%
Denmark	[20-30]%
Spain	[10-20]%
Italy	[10-20]%
Germany	[10-20]%
Poland	[10-20]%
Sweden	[10-20]%
The Netherlands	[10-20]%
Austria	[10-20]%
Czech Republic, Finland, Ireland, Luxembourg, Slovakia	<10%

Source: Annex III.6 to the Form CO

(216) Medtronic argues that Bard is the closest competitor to its existing DCBs, primarily considering that it is the only other competitor with comparable clinical data to Medtronic, having realised the IDE testing on 476 patients in randomised control trials for safety and efficacy.

(217) This was confirmed during the market investigation pursuant to which Bard appears to be the closest competitor of Medtronic on the DCB market so far.[106] Respondents to the Commission's market investigation consider that, while Bard's clinical data is not as good as Medtronic's data, its data is overall sufficiently good.[107] Bard itself considers that it has a good product with strong clinical evidence. In its view, its advantages are that it has a good brand image, good relationships with surgeons and strong clinical data that led to FDA clearance. However, Bard considers as a disadvantage that it has higher prices compared to its competitors.[108]

(218) In its internal documents, Covidien treats Bard as a competitor with a sizeable presence on the DCB market. According to Covidien, Bard's competitive strength on the DCB market is the […] compared to Medtronic's DCB. However, according to Covidien, Bard's product seems to have a […]. In addition it has some issues linked to the implantation, namely the fact that its balloon platform is prone to twist.[109] This was also voiced during the market investigation with one surgeon pointing to the bad navigability and crossing of Bard's DCB.[110] The Commission notes that in terms of clinical data, Bard and Medtronic have undergone similar types of clinical trials and of

106 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 72; replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 42.

107 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 90.

108 Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 51.

109 Submission of 22 October 2014, Covidien document, p. 26.

110 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 90. See also Form CO, Annex III.37, Bard Lutonix Attack Pack Final, slide 19.

all competitors active on the market, have the most results available. In addition, Bard's DCB currently appears as the second best alternative to Medtronic's DCB.[111] However, compared to Medtronic, Bard only managed to achieve a bigger presence in France, Hungary, Norway, Estonia, Latvia and Greece which represent a small part of the EEA market for DCBs.[112] Its market share in the other EEA countries, including in the countries where DCBs are more widely used such as in Germany, Bard does not appear to have any supremacy.

IV.2.3.6.d.iii.2. Eurocor's Biosensors Range and Freeway

(219) According to the Notifying Party, Eurocor's estimated market shares in the EU and the various EEA countries are as follows[113]:

Table 11 - Eurocor's market shares EEA

EU / EEA country	Eurocor's DCB Market share
EU total	***[5-10]%***
Estonia	[40-50]%
Latvia	[40-50]%
Lithuania	[30-40]%
Poland	[20-30]%
The U.K	[20-30]%
The Czech Republic	[20-30]%
Portugal	[20-30]%
Greece	[10-20]%
Slovakia	[10-20]%
Italy	[10-20]%
Spain	[10-20]%
Belgium	[10-20]%
Netherlands	[10-20]%
Austria	[10-20]%
Germany, Denmark, Finland, Ireland, Sweden	<10%

Source: Annex III.6 to the Form CO

(220) Medtronic argues that Eurocor is its closest competitor based on TLR rate (2.4% for Medtronic vs 3.5% for Eurocor's Freeway, launched in 2010). In addition, Medtronic argues that Eurocor is particularly price competitive exerting strong pressure on Medtronic which translated in Eurocor taking share away from Medtronic in a number of EEA countries.

(221) Respondents to the Commission's market investigation have not named Eurocor as a close competitor to Medtronic in the DCB area.[114] Contrary to Medtronic, Eurocor is never mentioned as market leader by customers[115] and it is only rarely mentioned as a

111 Form CO, Annex I.16, DCB Strategic Bet Review, EU Developed, January 14, p. 6.

112 According to the Notifying Party, the market value in these five latter countries together is of below EUR 300 000, which is merely 1% of the total EEA market for DCBs. If sales in France are included, the total market value would increase to EUR 1 million, representing only 4% of the total EEA market for DCBs. See Annex III.6 to the Form CO.

113 The Notifying Party explains that the market shares for competitors are *pro forma* estimates of the current position of the competitors, based on the adoption rates in a given country, Medtronic's own sales and estimates of its position, which hospitals/clinics used DCBs, and customer feedback.

114 Eurocor was only mentioned as second closest after Bard by 1 respondent, see replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 72 and replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 42.

115 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 89.

first choice for DCBs.[116] Respondents mentioned that while Eurocor's product has a good drug transfer and is cheaper, it uses an old technology, it has little or no clinical data proving safety and efficacy and may have issues with reimbursement in some countries.[117] Eurocor is also given as a typical example of a company which may not have the financial strength to push its device through all the necessary trials[118] and two respondents consider that Eurocor's DCB would not be effective at all.[119] Eurocor itself considers that the advantages of its DCB are its brand and the fact that it is easy to use while the disadvantages would be the limited availability and that it does not have dedicated sales force for its DCBs.[120]

(222) In Covidien's internal documents, Eurocor is not always considered.[121] Covidien also points to the lack of clinical data for Eurocor's product.[122] It also requires 50% higher dose density for a similar uptake, and has a low crystallinity level which may hamper drug residency and it lacks clinical data.[123] The only competitive strength identified by Covidien of the Eurocor product is the lower price in some EU markets (particularly the United Kingdom).

(223) The Commission notes that, contrary to the Notifying Party's claims, Eurocor does not appear as close an alternative to Medtronic's DCB as Bard. Indeed, if the TLR rate was determinant for the success of a DCB as claimed by Medtronic, Eurocor should have become the second biggest competitor in the market after Medtronic. However, the market share data and the return from the market investigation do not confirm that Eurocor's device has had such success. Similarly, the fact that Eurocor is price competitive does not seem to translate into a strong market presence. This is in line with the finding that price is not the key factor in the choice of DCBs. In this context, in response to the Commission's market investigation, only a handful of customers named price as the most important factor which they take into account when choosing a

---

116 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 91.

117 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 90; replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 51.

118 Minutes of a conference call with key opinion leader on 19 September 2014, paragraph 15. Similarly, the DCBs of both Medtronic and Covidien were initially developed by smaller companies, which could not continue developing them and thus sold them to Medtronic and Covidien, which seem to be large enough to continue innovating.

119 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 90; replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 51.

120 Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 51.

121 Covidien recognises that Eurocor has a *"strong commercial presence in the UK*", (see Form CO, Annex I.16, DCB Strategic Bet Review, EU Developed, January 14', p. 6), however according to the information provided by the Notifying Party, Eurocor does not seem to be stronger than Bard and appears only half as big as Medtronic in the UK. Covidien most often benchmarks its product against Medtronics' or in addition against Bard's.

122 Submission of 22 October 2014, Covidien document, p. 26.

123 Submission of 22 October 2014, Covidien document, p. 26.

specific drug coated balloon with the majority of customers indicating that price is the second or even third or fourth most important factor in their choice.[124]

IV.2.3.6.d.iii.3. Biotronik's Passeo 18

(224) According to the Notifying Party, Biotronik's estimated market share in the EU and the various EEA countries are as follows[125]:

Table 12 - Biotronik's market shares EEA

EU / EEA country	Biotronik's DCB Market share
EU	***[5-10]%***
Czech Republic	[20-30]%
Italy	[10-20]%
Latvia	[10-20]%
Estonia	[10-20]%
Lithuania	[10-20]%
Belgium	[10-20]%
Luxembourg	[10-20]%
UK	[10-20]%
Norway	[10-20]%
Austria, Denmark, Finland, Germany, Greece, Ireland, Netherlands, Poland, Portugal, Spain, Sweden	<10%

Source: Annex III.6 to the Form CO

(225) Medtronic argues that Biotronik established a significant market presence on the DCB market in the EEA, leveraging its brand and experience in coronary devices.

(226) Respondents to the Commission's market investigation did not name Biotronik as the closest competitor to Medtronic in the area of DCBs.[126] Respondents considered that Biotronik's DCB is a new device and is cheaper compared to Medtronic and Bard, however it has a very small clinical data set and no strong data proving safety and efficacy.[127]

(227) As concerns Medtronic's argument that Biotronik could leverage its success in coronary space in to peripheral vascular space, the Commission considers this as unlikely given that the entry points in the hospital are not the same and as explained in Section IV.2.3.6.d.iv, the evidence shows that success (or lack of it) in one area does not guarantee success in another area.

---

124 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 87.

125 The Notifying Party explains that the market shares for competitors are *pro forma* estimates of the current position of the competitors, based on the adoption rates in a given country, Medtronic's own sales and estimates of its position, which hospitals/clinics used DCBs, and customer feedback.

126 Only in rare occurrences was Biotronik named as second or third closest, see replies to Questionnaire Q1 - Customers Peripheral Vascular Devices, Question 72 and replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 42.

127 Replies to Questionnaire Q1 - Customers Peripheral Vascular Devices, Question 90; replies to Questionnaire Q2 - Competitors Peripheral Vascular Devices, Question 51.

IV.2.3.6.d.iii.4. Other DCBs having a CE mark

(228) As for the remaining DCB products on the market, the market investigation further pointed out that these other DCBs are relatively new products which lack sufficient data to prove reliability and efficacy. Some of them are even sometimes considered by some doctors as not effective or working just as well as uncoated balloons. Indeed the remaining six of the existing suppliers have a minimal presence in Europe[128]:

a) Aachen Resonance has merely a [0-5]% EU wide market share and its highest (and only) share of [40-50]% would be achieved in Slovakia,

b) Cardionovum achieved a [0-5]% EU wide market share and its highest (and only) share of [10-20]% was achieved in Slovakia,

c) Cook Medical with a [0-5]% EU wide market share and highest share in Bulgaria of [10-20]% and only other presence in France with [0-5]%,

d) Boston Scientific with a [0-5]% EU wide market share and highest share of [30-40]% in Bulgaria and only other presence in Romania with [20-30]%[129],

e) Atrium Medical and iVascular which together with others achieved a EU-wide share of [0-5]%. The countries where these suppliers have higher market shares are typically those where clinical trials for these devices are conducted, accounted in the market share data as sales.

(229) Medtronic in its internal documents only rarely refers to the devices of these companies.[130] The market investigation confirmed that these devices have currently very little traction in Europe possibly because of the doubts associated with their clinical efficacy.

(230) It follows that these DCBs have a very limited presence on the market at this stage and it is unclear whether any of them will gain traction.

IV.2.3.6.d.iii.5. Conclusion

(231) In light of all available evidence, the Commission considers that Medtronic is a clear market leader in the area of DCBs. Albeit substantially smaller, Bard is so far the closest competitor to Medtronic. The other existing DCB manufacturers with a device currently on the market have an even more limited presence and often lack the clinical

---

128 Annex III.6 to the Form CO.

129 Boston Scientific recently entered the market and undertook IDE Testing. However, in its internal documents, Medtronic itself does not seem to be considering Boston Scientific among the companies from which it would face competition. See for instance Form CO, Annex III.37, Peripheral competitive landscape, slide 14 in which only Bard, Cook, Biotronik, Eurocor, Covidien and Medrad (Bayer) are listed. Boston Scientific appears somewhere else as "future competitor".

130 Medtronic sometimes refers to Cook's DCB. See for instance Form CO, Annex III.37, Peripheral competitive landscape, slide 7 and slide 20.

data necessary to gain adhesion of the surgeons. It therefore appears that the existing competitors would not be in a position to exert sufficient competitive pressure on the merged entity on the DCB market post-Transaction.

IV.2.3.6.d.iv. Covidien's Stellarex: likely a strong contender on the DCB market

(232) Medtronic considers that Covidien's pipeline product Stellarex is more likely to compete with other DCBs (e.g. Biotronik's product) than with Medtronic's DCB. This argument is based on the fact that, according to Medtronic, Stellarex's TLR rate of 12.1% is closer to that of Biotronik (15.4%) than to the one of Medtronic 2.4%. Medtronic also claims that Covidien does not yet have the results of any rigorous IDE Testing but instead has simply had a "first in human" study of 50-80 patients and only for safety (not efficacy or equivalence with marketed products). Accordingly, the Notifying Party submits that Stellarex is not a close competitor to Medtronic's DCBs. In addition, Covidien does not benefit from any track record of success in coronary DCBs and that it does not expect Stellarex to be marketed at premium prices (i.e. Stellarex will not be marketed at prices comparable to Medtronic's IN.Pact products).[131]

(233) The market investigation portrayed a somewhat different picture. First, according to Covidien, Stellarex has a progressive design and is part of the next generation manufacturing process for DCBs.[132] Covidien considers that crystalline coating may facilitate persistence of drug with lower dosage than most competitors.[133] It therefore expects a higher drug uptake at lower dosage than its competitors (in particular Medtronic and Bard). It also considers that Stellarex presents a better coating durability during the balloon's implantation to treatment site of Stellarex than Medtronic's DCB and comparable to Bard's product.[134] Surgeons participating in Covidien's trials seemed to be particularly enthusiastic about this specific coating design, pointing to the novelty and the ensuing advantage for Stellarex compared to competing devices.[135]

(234) Covidien most often compares its Stellarex product with Medtronic's DCBs. Covidien recognises the competitive strength of one of Medtronics' DCBs, in particular due to the balloon platform, the fact that it is the established market leader and that it is the leader in clinical enrollment.[136] However, when compared to Stellarex, Covidien considers that Medtronic uses 50% higher dose density than Stellarex with similar uptake and that it loses significantly more coating in transit to lesion site than Stellarex.

(235) Therefore, in terms of clinical impact, Covidien considers that Stellarex has a number of benefits such as a low rate of drug loss prior to deployment, its crystalline structure which improves duration, a 100% clinical success meaning that all procedures were performed without the occurrence of a material adverse effect and a high patency in

131 Form CO, paragraph 302.

132 Submission of 22 October 2014, Covidien document, p. 25.

133 Marketing plan Covidien 2015, slide 46.

134 Form CO, Annex 16, Stellarex Q2FY14, Franchise Review, p. 59.

135 [*Statements made by surgeons during the clinical trials for Stellarex*]

136 Submission of 22 October 2014, Covidien document, p. 26.

early outcomes, namely a 12 month PPR of 87%[137] compared to Medtronic's 12 month PPR of 83.7%.[138] [Confidential statement regarding Covidien's investments in clinical trials] as Medtronic's and Bard's which are outpacing Covidien in trials.[139] However, Covidien has upscaled their trial series so that at least [number of] patients will be treated with the Stellarex[140]. Covidien expects to spend additional USD […] million on R&D and clinical trials until 2019.[141] The total investment in Stellarex[142] will therefore be comparable with Medtronic's, which spent about USD […] million.[143] Covidien also developed a marketing strategy focusing on activities that will enable them to raise awareness of Stellarex' advantages despite the smaller amount of data currently available.[144]

(236) During the market investigation several key opinion leaders[145] indicated that Covidien's product cannot really be compared with competitors' products and in particular Medtronic's at this stage, as there are no sufficient clinical data and no similar data (based on the same samples)[146]. Nevertheless, on the basis of preliminary results, Covidien's product seems promising and surgeons which indicated that they participate in Stellarex' trials[147] consider that Stellarex is comparable and possibly better than Medtronic's DCB.[148] One surgeon indicates that Stellarex tends to be a better product as, compared to Medtronic's device, it has an homogenous drug coating on the balloon. Others indicate that Stellarex is similar to Medtronic's DCB[149] and that it "*might be the best and safest*"[150], coming close to Medtronic's DCB.[151]

---

137 Submission of 22 October 2014, p. 25, Covidien document. Note that Medtronic provided a PPR of 89.5% for Covidien in response to RFI 8.

138 Form CO, Annex III.37, Peripheral competitive landscape, p. 20, Medtronic document. Note that Medtronic provided a PPR of 89.8% for Medtronic in response to RFI 8.

139 [*Confidential statement regarding Covidien's investments in clinical trials*] (see Form CO, Annex I.16, Presentation entitled Stellarex Q2FY14 Franchise Review (Rev 16) Annex I.16).

140 *[Number of]* patients will be involved overall in these trials, however as some trials are randomized, not all of these patients will receive a treatment with DCB.

141 Response to RFI 7 (revised), question 14.

142 In total, this is expected to amount to USD […] million, including the investment of CV Ingenuity.

143 Response to RFI 7 (revised), question 14 and Form CO, paragraph 296.

144 Form CO, Annex I.16, Franchise Review, slide 18 et seq.

145 Minutes of a conference call with a key opinion leader on 16 September 2014; minutes of a conference call with a key opinion leader on 19 September 2014; minutes of a conference call with a key opinion leader on 19 September 2014, paragraph 10.

146 Minutes of a conference call with a key opinion leader on 19 September 2014, paragraph 11.

147 Minutes of a conference call with a key opinion leader on 19 September 2014, paragraph 11.

148 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 93.

149 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 93.

150 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 94, minutes of a conference call with a key opinion leader on 19 September 2014, paragraph.

151 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 93.

(237) The Commission acknowledges that, given the fact that Stellarex is not yet on the market, a comparison of this product with the other DCBs in terms of its clinical efficacy is not straightforward.[152] However, based on some objective criteria such as the characteristics of the product as well as early returns from trials[153] it appears that both Covidien and the surgeons testing the Stellarex product expect Stellarex to become a serious contender on the market for DCBs. Similarly, when comparing Medtronic's DCBs with those of its competitors, some respondents to the Commission's market investigation named Covidien's pipeline product as the most similar alternative/closest competitor of Medtronic in terms of product characteristics.[154]

(238) Second, the amount of Covidien's clinical data, once completed will be very comparable, if not better than Medtronic's. To obtain the CE mark, Covidien conducted two trials: one in Germany – the Illumenate study and the second as a first-in-human trial which involved [number of] patients treated with a pre-dilation balloon. Additional trials are also taking place primarily for FDA approval, such as the IDE testing involving [number of] patients. The totality of Covidien's clinical tests involves [number of] patients (although a proportion of these will not be treated with a DCB as they form part of a randomised trial).[155]

(239) Third, contrary to Medtronic's claims, it does not appear necessary to have coated balloons in other areas to be a strong player in DCBs for peripheral vascular diseases and vice versa. One customer for example indicates BBraun as market leader for coronary DCBs in cardiology which does not appear to have a DCB in the endovascular space.[156] Likewise Bard, which the Notifying Party considers as the closest competitor to Medtronic, is not a player in coronary DCBs. In addition, Medtronic itself withdrew from the market a DCB for indicated for below-the-knee lesions[157], which further shows that leadership in a close area (even closer than coronary) is not sufficient for success in another area.

(240) In addition, in Medtronic's internal documents, Covidien's DCB is often included among the products which are compared with Medtronic's existing DCB.

(241) Lastly, the claim that Stellarex would not be marketed at prices comparable to Medtronic's DCBs is not supported by the information in Covidien's internal

---

152 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Questions 94-95.

153 For instance, patency rate for Medtronic's DCB the 12 month patency rate was 83.7% while for Covidien's product it was 87%, Covidien's device uses lower amount of paclitaxel for the same result, etc.

154 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 72 and to Questionnaire Q2 - Competitors peripheral vascular devices, Question 42.

155 Response to RFI 7, question 12.

156 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 89.

157 Medtronic formerly marketed In.PACT Amphirion, a below-the-knee product. However, the product has been withdrawn from the market following a failed trial.

documents. Indeed, the average selling price considered by Covidien is similar to Medtronic's average selling price of its DCBs.[158]

(242) Therefore, on the basis of the market investigation, the Commission considers that Covidien's Stellarex has the potential for becoming a very effective DCB, possibly even better than Medtronic's product and thus become a serious challenger to Medtronic's leading position in the EEA.

IV.2.3.6.d.v. Medtronic's intention to stop the development of Stellarex would be detrimental for DCB patients and harm innovation in the market

(243) DCBs are new and innovative products in the area of peripheral vascular devices on which Covidien has traditionally focused. Stellarex was one of Covidien's latest developments and, absent the Transaction, Covidien would have continued to invest in developing the product and completing the trials. In fact, Covidien already invested USD […] million in the development of Stellarex (the biggest cost being the R&D and the trials)[159], hired more than [number of] people in this project, activated [number of] sites, treated more than [number of] patients[160] and expected to invest additional USD […] million in R&D and clinical trial costs until 2019.[161]

(244) In addition, Covidien expected to reach between [0-5]% market shares in the EU in 2014 and up to [20-30]% in 2018.[162] According to the latest internal presentation of Covidien, it expected to gain a market share of [5-10]% in 2015, to sell [number of] units and to gain revenues of USD […].[163] In total on this market, Covidien expected to gain up to EUR […] million in revenues in the EU by 2018.[164] In addition to the most frequent above the knee indication, Covidien also committed resources to develop DCB for below the knee indication showing the commitment to innovation in this space.

(245) In its internal documents, Covidien states that it intends to be a clear first choice for customers, ideas and investment by delivering breakthroughs in the prevention and treatment of vascular diseases worldwide.[165] One building block in such strategy is to "*execute on lower limb breakthrough (DCB,…)*". It expects to become the scientific leader and get ahead of Medtronic and Bard in the field of DCBs[166] and be the "*clear first choice for DCB*".[167]

---

158 Submission of 22 October 2014, Covidien document, p. 11.

159 Response to RFI 7 (revised), question 14.

160 Form CO, Annex 16, Stellarex Q2FY14, Franchise Review, p. 53.

161 Response to RFI 7 (revised), question 14.

162 Form CO, Annex 16, EU DCB, Covidien document, p. 15.

163 Submission of 22 October 2014, Covidien document, p. 11.

164 Form CO, Annex 16, Stellarex Q2FY14, Franchise Review, p. 8 and 53.

165 Form CO, Annex 16, Stellarex Q2FY14, p. 3.

166 Form CO, Annex 16, Stellarex Q2FY14, p. 27.

167 Submission of 22 October 2014, Covidien document, p. 25.

(246) In particular in the SFA treatment, Covidien intended to be the driver in the developing SFA treatment paradigm, build on their innovative power and drive clinical evidence. Its objective was therefore to launch Stellarex by differentiation. While Covidien's product would enter the market later that the other manufacturers, Covidien is ready to launch the product in late 2014 or Q1 2015 with a focus on countries with reimbursement and expected to gain traction in Germany, UK, Italy and Spain.[168]

(247) Once Medtronic acquires Covidien, it appears from Medtronic's internal planning that it is expected that the development of Covidien's product will be put to an end. This means that the Transaction will have as an effect an elimination of a serious future competitor as a result of which DCB patients will be deprived of an innovative and potentially a very effective device.

IV.2.3.6.e. Conclusion

(248) Based on the above the Commission considers that the elimination of Covidien's pipeline product following the proposed Transaction will result in the loss of a credible competitor which absent the Transaction would likely have constrained Medtronic on the market for drug coated balloons in the EEA, where Medtronic is currently the market leader. Furthermore, the Commission considers that the players that are currently on the market would not exert sufficient competitive pressure on the merged entity post-Transaction.

(249) In addition, the Transaction will also have a significant effect on innovation in these markets as Covidien had the ability and incentive to continue innovation by further investing in clinical trials and developing Stellarex into a strong contender on the market including for indications for which Medtronic's device is not currently approved.

(250) Therefore, in light of all available evidence, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market on the market for DCBs.

IV.2.3.7. CTO crossing devices

(251) Medtronic does not currently market a CTO crossing device in the EEA but it has a pipeline product, *TOTAL CTO*, a re-entry device in development.

(252) Medtronic explained that this CTO is a crossing device likely to be indicated for all lesions with CTO, but with a specific focus on larger vessels, such as SFA arteries.

(253) Covidien currently markets two CTOs: (i) Viance, a recanalization device indicated for use in all lesions with CTO, which has a catheter size of 1.75mm, a working length of 150mm and is compatible with a 0.014" guidewire and (ii) Enteer, which is a re-entry device indicated for use in all lesions with CTO, but with a specific focus on below the knee procedures. Enteer has a catheter size of 1.75mm and a working length of 135-300mm and is compatible with a 0.018" guidewire.

---

168 Submission of 22 October 2014, Covidien document, p. 57 and Marketing plan Covidien 2015.

(254) The presence of Covidien on the CTO market in the various EEA countries is rather limited. If all CTO crossing devices are considered, in 2013, its market shares only exceed 20% in Denmark ([30-40]%), Finland ([20-30]%), Norway ([30-40]%) and Sweden ([40-50]%).[169] If a narrower market only for re-entry devices were considered (the CTO crossing devices on which Medtronic's pipeline product and Covidien's existing product overlap), in addition to the countries identified above, in 2013, Covidien's market share would exceed 20% in Austria ([20-30]%), Germany ([40-50]%), Italy ([30-40]%) and Spain ([20-30]%).

(255) Medtronic's entry is rather speculative at this stage. Medtronic has not begun discussions with any EU regulatory agency and has not conducted any clinical trials. It is still only in the design phase of development. In a best case scenario, Medtronic could launch a commercially available CTO device in the EU in 2016 at the earliest.

(256) The Notifying Party submits that the Transaction will not negatively affect Medtronic's CTO crossing devices program. Although Covidien already markets a re-entry CTO crossing device, the products would be complementary: Medtronic's pipeline product is better suited for use in larger vessels (e.g., in SFA procedures) whereas Covidien's is better suited for procedures below the knee. Thus, according to the Notifying Party, there is no plan to discontinue Medtronic's program.

(257) The Commission notes that Covidien does not appear to have a strong presence on the CTO market. In 2013, Covidien generated sales of only EUR […] million in the EEA. The Notifying Party argues that the EU-wide market leader in this area is J&J with a share of [40-50]% followed by Bard and Boston Scientific.

(258) Indeed, other suppliers of CTO devices appear to have a much more established presence in the EEA. The majority of respondents to the Commission's market investigation indicated that other medical device companies and in particular J&J and Boston Scientific would be the leading suppliers of CTOs in the EEA.[170] In addition, when comparing the various CTO devices on the market, respondents indicated that J&J's CTO would be very efficient, safe and leading to good results, compared to Covidien's CTO which is primarily praised for its price rather than technical capability.[171] J&J also identifies price as the advantage of Covidien's CTO, while for its own CTO, J&J considers that it has a precise re-entry capability and high success rate.[172]

(259) Therefore, in view of all these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to CTO crossing devices in the EEA.

---

169 Form CO, Table 59.

170 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Questions 71 and 96 and Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 41.

171 Replies to Questionnaire Q1 - Customers peripheral vascular devices, Question 97.

172 Replies to Questionnaire Q2 - Competitors peripheral vascular devices, Question 56.

IV.3. Electrosurgical devices

(260) Electrosurgical devices are energy-activated devices used in surgery that conduct electrical current through a patient's body to generate heat energy in order to create a desired clinical effect (cut, coagulate, seal, etc.). Electrosurgical devices are commonly used in a broad range of laparoscopic and open surgical procedures instead of mechanical cutting and sealing devices, as they make surgical intervention more effective and reduce patient trauma.

(261) Electrosurgery procedures include the use of a generator, a hand piece, active and return electrodes, cables connecting the generator to the other devices and a switch to activate the procedure. Depending on the polarity of the handpiece used, procedure are monopolar or bipolar. Handpieces may be reusable or disposable.

(262) Through the sale of MicroFrance to Integra Life Sciences Medtronic divested most of its electrosurgical devices. Medtronic will continue to market only few sets of advanced electrosurgical devices, namely PlasmaBlade, Aquamantys and a series of monopolar sealers, which will be added to Covidien's electrosurgical portfolio post-Transaction.

(263) The Notifying Party submits that within the area of electrosurgical devices, the Transaction is likely to lead to horizontal overlaps on the market for electrosurgical pencils and PlasmaBlade and the market for Large Surface Coagulation devices (LSCs).

IV.3.1. Product market definition

(264) The Notifying Party submits that electrosurgical devices could be split in standard electrosurgical devices ("standard ED"s), which constitute commodity devices, and more complex advanced electrosurgical devices ("AED"s).[173]

(265) Moreover, the Notifying Party considers that the market for electrosurgical devices can be further segmented on the basis of the various devices' functionality. Different product markets for electrosurgical pencils, LSCs, open surgery electrosurgical forceps, vessel sealing and dissection devices etc. were thus identified.

(266) During the market investigation the majority of customers and competitors also analysed the market on the basis of the various devices' functionality and were familiar with the above-mentioned product groups.[174]

IV.3.1.1. Electrosurgical pencils and PlasmaBlade

(267) Electrosurgical pencils are very common operating room tools, used to cut and coagulate skin and tissue during the initial incision or in the course of a broad range of procedures. PlasmaBlade can perform the same functions but is a very advanced, non-commoditised device, using pulsed radiofrequency and plasma electrodes. PlasmaBlade

---

173 Form CO, paragraph 535.

174 Replies Questionnaire Q3 – Customers electrosurgical devices, Questions 7-24 and Replies Questionnaire Q4 - Competitors electrosurgical devices, Questions 5-27.

creates much smaller tissue damage when used and is therefore better suited for demanding, high end niche applications, such as cardiac rhythm disease management or plastic surgery procedures. Besides, the cost of PlasmaBlade is not comparable to that of electrosurgical pencils, as it has an average price of EUR [180-300], whereas electrosurgical pencils are priced at EUR 1 to 4.[175]

IV.3.1.1.a. Notifying Party's views

(268) On the basis of a sub-segmentation of the market by functionality, the Notifying Party submits that PlasmaBlade should be on a market of its own. The closest sub-segment to PlasmaBlade in terms of functionality would be that of electrosurgical pencils; Medtronic's product however has distinct characteristics in terms of technology, price and sophistication.[176]

(269) A further sub-segmentation among reusable and disposable electrosurgical pencils is suggested by the Notifying Party, as some electrosurgical pencils are designed for use in a single procedure, whereas others are used multiple times.[177]

(270) Lastly, the Notifying Party examines whether a further sub-segmentation according to the type of procedure in which electrosurgical pencils are used would be of relevance. Since most electrosurgical devices are indicated for many different procedures and since, even when certain degree of specialisation is provided, suppliers offer products for the full range of procedures to address all customers needs, the Notifying Party concludes that there is no need to consider separate markets on the basis of procedure.

IV.3.1.1.b. Assessment of the Commission

(271) During the Commission's market investigation, customers and competitors also characterise PlasmaBlade as a more advanced electrosurgical pencil; responses were however inconclusive as to whether it can in all cases be substituted by standard electrosurgical pencils. In any case, due to the significant difference in pricing, customers tend to use PlasmaBlade mostly in cardiac or plastic surgery procedures.[178]

(272) Regarding further possible sub-segmentations of this market, customers indicate that they tend to purchase either reusable or disposable devices, but do not alternate between the two.[179] Similarly, all responding manufacturers submit that the production

---

175 Replies Questionnaire Q4 - Competitors electrosurgical devices, Question 8 and 21.

176 Form CO, paragraph 539 and 555-576.

177 Form CO paragraph 545.

178 Replies to Questionnaire Q3 - Customers electrosurgical devices, Questions 8, 9, 15, 16; replies to Questionnaire Q4 - Competitors electrosurgical devices, Questions 10 and 11; see also minutes of a conference call with a customer on 31 October 2014, paragraph 7 "*Le PlasmaBlade est en revanche utilisé en cardiologie*", Minutes of a conference call with a competitor on 4 November 2014, paragraph 15 "*ENT and plastic surgeons use this product [i.e. the PlasmaBlade]*."

179 Replies to Questionnaire Q3 - Customers electrosurgical devices, Question 13.

of reusable pencils differs significantly from that of disposable ones and that they produce both types of electrosurgical pencils.[180]

(273) Moreover, no further sub-segmentation was identified as relevant during the market investigation, especially as most customers indicated that they use standardised electrosurgical pencils for all procedures and most competitors confirmed that electrosurgical pencils for various applications follow the same manufacturing and authorisation process.[181]

IV.3.1.1.c. Conclusion

(274) In light of the above, the Commission concludes that PlasmaBlade would indeed most probably form part of the market for electrosurgical pencils. Moreover, a further sub-segmentation among reusable and disposable electrosurgical pencils may be considered. In any event, for the purpose of the present decision it is not necessary to conclude whether the market for electrosurgical devices should include PlasmaBlade or should be further subdivided, as the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to electrosurgical pencils irrespective of the exact product market definition.

IV.3.1.2. Large Surface Coagulation Devices

(275) Medtronic's Aquamantys and monopolar sealers are large surface coagulation devices ("LSC"s). These advanced electrosurgical devices are used in procedures in which significant bleeding control is required, such as in the removal of an organ or portion of an organ, joint replacement revision, etc. LSCs are used to coagulate small vessels of 1-2 mm. LSCs include devices operating through various technologies, such as argon gas plasma-based technology, saline-based technology, gelatin-based technology, air/nitrogen-based technology or hemostatic patches.

IV.3.1.2.a. Notifying Party's views

(276) The Notifying Party submits that there is a sub-segment within the market for electrosurgical devices for LSCs. In addition, Medtronic claims that saline-based and argon-based LSCs are not part of the same market, as further to being based on different technologies, their design and development processes are different, they are priced differently and require different surgeon training.[182]

(277) The Notifying Party does not identify any further relevant sub-segmentation in this market. Different market segments on the basis of the procedure in which LSCs are used could be considered. As however all providers market multi-purpose devices that can be used in all procedures requiring the use of LSCs, the Notifying Party concludes that such further segmentation of the product market would not be of relevance. Even when manufacturers also market specialised LSCs, these operate and are priced

---

180 Replies to Questionnaire Q4 - Competitors electrosurgical devices, Questions 12 and 13.

181 Replies to Questionnaire Q3 - Customers electrosurgical devices, Question 11; replies to Questionnaire Q4 - Competitors electrosurgical devices, Question 10.

182 Form CO, paragraph 585.

similarly, differing only in certain design features. Companies could therefore easily switch production among the various specialised models, should there be sufficient market demand.[183]

(278) The Notifying Party also assesses whether a distinction between monopolar and bipolar LSCs should be made. Since the electrosurgical generators that power the LSCs are equipped with both types of connections and LSC manufacturers are familiar with both types of technology and can easily and quickly shift production from monopolar to bipolar devices, the Notifying Party concludes that such sub-segmentation should not be made.[184]

IV.3.1.2.b. Assessment of the Commission

(279) The suggested division among LSCs based on different types of technologies was investigated by the Commission; responses from the market participants however were non-conclusive as to the exact scope of the relevant product market.

(280) LSCs appear to have different characteristics, depending on the technology, on the basis of which they operate, customers and competitors however did not clearly identify separate markets for argon-based, saline-based or other non-energy based LSCs. Similarly, no other segmentations on the basis of polarity or the procedure for which the various devices are used were considered relevant by market participants in relation to LSCs.[185]

IV.3.1.2.c. Conclusion

(281) In light of the above, the Commission concludes that a market for all LSCs could be considered, as well as narrower markets on the basis of the technology or the procedure on which each device is based. In any event, for the purpose of the present decision it is not necessary to conclude on the exact scope of the market for LSC devices as the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to LSC devices irrespective of the exact product market definition.

IV.3.1.3. Conclusion on product market definition

(282) As no competition concerns would arise as to the compatibility of the Transaction with the internal market under any plausible market definition of electrosurgical devices, it may be left open whether a single market for all electrosurgical devices, separate markets for standard and advanced devices or further sub-segmentations on the basis of functionality and possibly also of durability should be considered.

---

183 Form CO, paragraph 549.

184 Form CO, paragraph 548.

185 Replies to Questionnaire Q3 - Customers electrosurgical devices, Questions 22-26; replies to Questionnaire Q4 - Competitors electrosurgical devices, Questions 17-27.

IV.3.2. Geographic market definition

(283) The Commission has in previous cases defined the geographic market for medical devices as national.[186] Even though from a supply side an EEA-wide market would be of relevance, given the CE mark, the centralised production and rather low transport costs and the lack of national marketing and distribution barriers, there are significant differences among EEA countries in reimbursement schemes, procurement procedures and pricing. Moreover, customers tend to only source products from their own country and in cooperation with national or even local sales offices. A further indication that markets are organised on a national basis is the variation of manufacturers' market shares across the EEA.[187]

(284) The Notifying Party also submits that the geographic scope of the markets for electrosurgical devices is national. The results of market investigation lead to the same conclusion, as customers indicated that they have regional or national contact points, in order to easily follow up should training requirements or problems arise. They also confirmed that they have not and would not consider buying electrosurgical devices from providers outside their country. Similarly, manufacturers explained that they establish their presence on a country basis, either directly or through distributors, in view of customers' buying patterns and of regulatory and linguistic reasons.[188]

(285) In view of these elements and coherently with previous decisions in medical devices cases, the Commission concludes that the relevant geographic markets for the products described in the section of relevant product markets are national.

IV.3.3. Assessment

(286) The market for EDs is growing at a rate of 3-5% per year, because of favourable demographics, the increase of procedures involving the use of EDs and the significant innovation in the sector.

(287) Within the market for EDs the picture however differs for non-advanced devices and for advanced devices. The non-advanced segments of the market (e.g. the market for electrosurgical pencils) are mature, as these products have been used for decades. Market growth in these market segments is rather low, whereas in relation to advanced electrosurgical devices the market has been growing significantly in the last years.[189]

(288) The market for electrosurgical devices, particularly regarding advanced electrosurgical devices, is characterised by innovation and attracts significant R&D spend, as new and improved versions of already existing devices are regularly introduced.[190] In order to

---

186 Case M.3687 Johnson & Johnson / Guidant, recitals 68-69; Case M.3146 Smith & Nephew / Centerpulse, paragraphs 15-16; Case M. 1286 Johnson & Johnson / DePuy, paragraphs 17-20.

187 Case M.3687 Johnson & Johnson / Guidant, recital 68.

188 Replies to Questionnaire Q3 - Customers electrosurgical devices, Questions 25-27; replies to Questionnaire Q4 - Competitors electrosurgical devices, Questions 28-29.

189 Form CO, paragraphs 721 et seq.

190 Response to RFI 9, question 4.

launch a new product, manufacturers start by engaging in R&D, must then acquire the necessary regulatory approval (CE mark and on occasion approval by national authorities), followed by the manufacturing stage and the distribution and servicing. Ensuring new devices' reimbursement can also be a key factor in ensuring their effective market launch.

IV.3.3.1. All electrosurgical devices

(289) Table 13 below sets out the Parties' position in a market for all electrosurgical devices in the countries where their activities overlap and give rise to affected markets:

Table 13 - All electrosurgical devices (2013)

Country	Medtronic (%)	Covidien (%)	Combined shares
Austria	[0-5]%	[50-60]%	[50-60]%
Belgium	[0-5]%	[20-30]%	[20-30]%
Croatia	[0-5]%	[20-30]%	[20-30]%
Czech Republic	[0-5]%	[20-30]%	[20-30]%
Denmark	[0-5]%	[30-40]%	[30-40]%
Finland	[0-5]%	[30-40]%	[30-40]%
France	[0-5]%	[30-40]%	[30-40]%
Germany	[0-5]%	[20-30]%	[20-30]%
Ireland	[0-5]%	[40-50]%	[50-60]%
Italy	[0-5]%	[20-30]%	[20-30]%
Malta	[0-5]%	[50-60]%	[50-60]%
Netherlands	[0-5]%	[30-40]%	[30-40]%
Poland	[0-5]%	[20-30]%	[20-30]%
Portugal	[0-5]%	[40-50]%	[40-50]%
Romania	[0-5]%	[20-30]%	[20-30]%
Slovakia	[0-5]%	[30-40]%	[30-40]%
Slovenia	[0-5]%	[30-40]%	[30-40]%
Spain	[0-5]%	[40-50]%	[40-50]%
Sweden	[0-5]%	[40-50]%	[40-50]%
United Kingdom	[0-5]%	[20-30]%	[20-30]%
EU Total	*[0-5]%*	*[30-40]%*	*[30-40]%*
Norway	[0-5]%	[40-50]%	[40-50]%
EEA Total	[0-5]%	[30-40]%	[30-40]%

Source: Form CO

(290) As can be seen in Table 13 above, the Parties' combined market shares exceed 35% in certain markets; the increment however does not exceed 1.4% in any market. The Transaction does not therefore have an impact on the structure of the market in any of these EEA countries.

(291) The merged entity is likely to continue to face strong competitive pressure from several large multinational suppliers post-Transaction, including J&J/Ethicon ([20-30]%), ERBE ([10-20]%), Olympus ([5-10]%), 3M ([0-5]%) and others, which also have a broad portfolio of electrosurgical devices.

(292) Therefore, the Commission concludes that the Transaction does not therefore raise serious doubts as to its compatibility with the internal market in relation to all electrosurgical devices.

IV.3.3.2. Advanced electrosurgical devices (AEDs)

(293) Table 14 below provides an overview of the Parties' position in a narrower market for all advanced electrosurgical devices in the countries where their activities overlap and give rise to affected markets:

Table 14 - All advanced electrosurgical devices (2013)

Country	Medtronic (%)	Covidien (%)	Combined shares
Austria	[0-5]%	[60-70]%	[60-70]%
Belgium	[0-5]%	[20-30]%	[20-30]%
Bulgaria	[0-5]%	[10-20]%	[10-20]%
Croatia	[0-5]%	[10-20]%	[20-30]%
Czech Republic	[0-5]%	[20-30]%	[20-30]%
Denmark	[0-5]%	[40-50]%	[40-50]%
Estonia	[0-5]%	[10-20]%	[10-20]%
Finland	[0-5]%	[30-40]%	[30-40]%
France	[0-5]%	[30-40]%	[30-40]%
Germany	[0-5]%	[20-30]%	[20-30]%
Greece	[0-5]%	[10-20]%	[20-30]%
Hungary	[0-5]%	[10-20]%	[10-20]%
Ireland	[0-5]%	[70-80]%	[70-80]%
Italy	[0-5]%	[20-30]%	[20-30]%
Latvia	[0-5]%	[10-20]%	[10-20]%
Lithuania	[0-5]%	[5-10]%	[5-10]%
Malta	[0-5]%	[60-70]%	[60-70]%
Netherlands	[0-5]%	[30-40]%	[30-40]%
Poland	[0-5]%	[20-30]%	[20-30]%
Portugal	[0-5]%	[40-50]%	[40-50]%
Romania	[0-5]%	[20-30]%	[20-30]%
Slovakia	[0-5]%	[30-40]%	[30-40]%
Slovenia	[0-5]%	[30-40]%	[30-40]%
Spain	[0-5]%	[40-50]%	[40-50]%
Sweden	[0-5]%	[50-60]%	[50-60]%
United Kingdom	[0-5]%	[20-30]%	[20-30]%
EU Total	*[0-5]%*	*[30-40]%*	*[30-40]%*
Norway	[0-5]%	[50-60]%	[50-60]%
EEA Total	[0-5]%	[30-40]%	[30-40]%

Source: Form CO

(294) As can be seen in Table 14 above, the Parties' combined market shares exceed 35% in few national markets, the increment however is in all cases very limited, not exceeding 2%. The Transaction does not therefore have an impact on the structure of the market in any of these EEA countries.

(295) In addition, the merged entity will continue to face strong competition from several large multinational suppliers post-Transaction, including J&J/Ethicon ([30-40]%), ERBE ([5-10]%), Olympus ([10-20]%), Aesculap ([0-5]%) or Martin ([0-5]%).

(296) In addition hospital customers in the various EEA countries have significant buyer power, as they ensure through tenders or bilateral negotiations the procurement of electrosurgical devices on competitive terms.

(297) Moreover, the Parties' portfolio in this space is highly complementary. As a result, the products of Medtronic are not close competitors to those of Covidien and do not currently exert strong competitive constraint on each other.

(298) In view of these elements, the Commission concludes that the Transaction does not raise any concerns as to its compatibility with the internal market in relation to advanced electrosurgical devices.

IV.3.3.3. Electrosurgical pencils and PlasmaBlade

(299) The Parties' activities overlap in a market for electrosurgical pencils and PlasmaBlade. Medtronic is only present in this space with the PlasmaBlade product line. Covidien on the other hand manufactures standard commodity electrosurgical pencils. Covidien markets both reusable and disposable pencils of different sizes and with some degree of differentiation on their characteristics to better adapt them to the requirements of specific procedures.

(300) Table 15 below sets out the Parties' position in a market for all electrosurgical pencils including PlasmaBlade in the countries where their activities overlap and give rise to affected markets:

Table 15 - Electrosurgical pencils including PlasmaBlade

Country	Market Size (€ m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Austria	2.767	[0-5]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Croatia	0.120	[0-5]%	[30-40]%	[30-40]%	N/A	N/A
Finland	1.673	[5-10]%	[10-20]%	[20-30]%	[20-30]%	[20-30]%
Greece	0.053	[50-60]%	[10-20]%	[70-80]%	[50-60]%	[40-50]%
Italy	10.479	[0-5]%	[10-20]%	[20-30]%	[20-30]%	N/A
Sweden	2.617	[0-5]%	[60-70]%	[60-70]%	[60-70]%	N/A
Norway	1.099	[5-10]%	[10-20]%	[20-30]%	[10-20]%	N/A
EEA Total	66.900	[0-5]%	[10-20]%	[10-20]%	N/A	N/A

Source: Form CO.

(301) The PlasmaBlade handpieces are disposable. Therefore, should a further segmentation of the market for electrosurgical pencils among reusable and disposable be considered, PlasmaBlade would be in direct competition with Covidien's disposable electrosurgical pencils. Table 16 below sets out the Parties' position in a market for all disposable electrosurgical pencils including PlasmaBlade in the countries where their activities overlap and give rise to affected markets:

Table 16 - Disposable electrosurgical pencils including PlasmaBlade

Country	Market Size (€ m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Austria	2.180	[0-5]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Croatia	0.065	[0-5]%	[20-30]%	[30-40]%	N/A	N/A
Finland	1.579	[5-10]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%
Germany	3.677	[5-10]%	[10-20]%	[20-30]%	[10-20]%	[10-20]%
Greece	0.051	[50-60]%	[10-20]%	[70-80]%	[50-60]%	[40-50]%
Italy	9.281	[0-5]%	[20-30]%	[20-30]%	[20-30]%	N/A
Poland	0.819	[0-5]%	[20-30]%	[20-30]%	N/A	N/A
Sweden	2.529	[0-5]%	[60-70]%	[60-70]%	[60-70]%	N/A
Norway	0.870	[10-20]%	[10-20]%	[20-30]%	[10-20]%	N/A
EEA Total	52.970	[0-5]%	[10-20]%	[10-20]%	N/A	N/A

Source: Form CO

IV.3.3.3.a. Austria, Finland, Germany, Italy, Poland, Sweden and Norway

(302) As can be seen in Tables 15 and 16 above, the Parties' combined market shares exceed 35% only in Croatia, if a market for all electrosurgical pencils and PlasmaBlade is considered, and in Greece and Sweden in the market for all electrosurgical pencils and PlasmaBlade as well as in the market consisting only of disposable electrosurgical pencils and PlasmaBlade. In some of these countries, the increment is very small, and therefore the Transaction does not have an impact on the structure of the market.

(303) In addition, the merged entity will continue to face competition from several multinational competitors, such as Fiab, Bovie Medical, ConMed, ERBE, J&J, LiNa Medical and Megadyne in all these EEA countries.

(304) Lastly, given the difference among standard electrosurgical pencils and PlasmaBlade, the products of the two companies are not each other's closest competitors.

(305) In view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the sales of electrosurgical pencils and PlasmaBlade in Austria, Finland, Germany, Italy, Poland, Sweden and Norway. The situation in Greece and Croatia will be assessed separately below.

IV.3.3.3.b. Greece and Croatia

Greece

(306) The Parties' combined market share in Greece is [70-80]%, the market for electrosurgical pencils and PlasmaBlade is however very small, amounting to EUR […].

(307) Also, the fact that PlasmaBlade differs from electrosurgical pencils in terms of function, cost and procedures in which it is used, indicates that the two types of products do not exert significant competitive pressure on each other. Several other competitors are present in the Greek market, such as ERBE ([10-20]%), ConMed ([5-10]%), Fiab SpA ([0-5]%) and are expected to continue exerting competitive pressure

on the merged entity post-Transaction. In addition, hospital customers exert significant countervailing buyer power and typically organise procurements in a manner that secures competitive outcomes.

(308) In view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the sales of electrosurgical pencils and PlasmaBlade in Greece.

Croatia

(309) The Parties' market share in Croatia is [30-40]% in a market for all electrosurgical pencils and PlasmaBlade[191], the market for electrosurgical pencils and PlasmaBlade amounts however to only EUR […].

(310) Given the differences in the Parties' products, they currently exert limited competitive constraint on each other. Also, ERBE ([20-30]%), ConMed ([10-20]%), Fiab ([5-10]%), but also COMEPA, Skintact and KLS Martin are among the Parties' competitors in the Croatian market and are expected to continue exerting competitive pressure on the merged entity post-Transaction. Moreover, hospitals in Croatia have significant countervailing buyer power and typically organise their procurement in ways ensuring competitive outcomes.

(311) Therefore, in view of these elements, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in light of the sales of electrosurgical devices and PlasmaBlade in Croatia.

IV.3.3.4. Large Surface Coagulation devices (LSCs)

(312) Medtronic is active in the market for LSCs through its Aquamantys product line and through its series of monopolar sealers, both of which function on the basis of a combination of radiofrequency and saline in order to seal bleeding vessels during surgery. Covidien markets an argon gas-based coagulator, ForceArgon II that also has a cutting function.

(313) The Notifying Party submits that in a market for all LSCs in the EEA, the share of Covidien would amount to [0-5]% and the share of Medtronic to [0-5]%. It therefore results that post-Transaction, the merged entity would have a market share of [5-10]%.[192] Moreover, the Notifying Party confirms that the Transaction does not give rise to any affected market in the overall LSCs segment.[193]

(314) The Notifying Party also submits that the Parties' activities on LSCs primarily overlap in hepatobiliary and kidney procedures. Table 17 below sets out the Parties' position in

---

191 If a narrower market for disposable electrosurgical pencils including PlasmaBlade is considered, the Parties' combined market shares would be 30% and the increment 2%.

192 The Notifying Party estimates that the size of the EEA LSC market is approximately EUR 55 million, RFI 10, question 3. Medtronic's sales of LSCs were EUR […] million in 2014 and Covidien's sales EUR […] million in 2013.

193 Form CO, paragraph 684; response to RFI 11, question 6.

a market for LSCs in hepatobiliary and kidney procedures in the countries where their activities overlap and give rise to affected markets:

Table 17 - LSCs in hepatobiliary and kidney procedures

Country	Market Size (€ m)	Medtronic Share (%)	Covidien Share (%)	Combined Share (%) 2013	Combined Share (%) 2012	Combined Share (%) 2011
Spain	3.037	[10-20]%	[5-10]%	[20-30]%	[20-30]%	[10-20]%
Norway	0.328	[0-5]%	[20-30]%	[20-30]%	[20-30]%	N/A
EEA Total	29.564	[0-5]%	[0-5]%	[5-10]%	N/A	N/A

Source: Form CO.

(315) The Parties' market shares do not exceed 35% in any national market for LSCs in hepatobiliary and kidney procedures.

(316) Also, the Parties' products use different types of technology, differ significantly in pricing[194] and are therefore not each other's closest competitor. Moreover, a number of other manufacturers are present in this space also offering argon-based devices, such as KLS Martin, Bowa, ConMed, ERBE or Plasma Surgical and are expected to continue exerting competitive pressure on the merged entity post-Transaction.

(317) Therefore, the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to LSC devices.

IV.4. Vertical relationships

(318) In addition to the horizontal overlaps among the Parties' portfolios, the Transaction also gives rise to vertical relationships. Covidien is not a customer of any Medtronic products, Medtronic however procures approximately USD 7 million of supplies from Covidien.

(319) The supplies consist in polyskin dressings, sutures material, electrodes, medical recording and chart paper, syringes and needles that are either consumed or used in the development of certain Medtronic products by Medtronic's US business.

(320) The Notifying Party explains that this vertical relationship does not raise any input foreclosure risk in the EEA market, as several companies other than Covidien produce the same types of equipment. The share of Covidien does not exceed 30% in any of the above markets and in all cases, a number of competitors with significant scale compete with it.

(321) In addition, there appears to be no risk of customer foreclosure in the EEA market, as the volume of sales realised by Medtronic is very low compared to the total sales of

194 Covidien's Force Argon II has an average selling price of EUR [50-100], whereas Aquamantys is on average priced at approximately EUR [200-500].

Covidien in these products. Indeed, the Notifying Party submits that in most cases, these sales do not exceed 1% of the total Covidien sales of the respective product. Moreover, Medtronic already acquires 100% of these products from Covidien. The only change brought by the Transaction will therefore be the internalising of this already existing vertical relationship.

(322) Lastly, the Notifying Party submits that there is a vertical relationship between Covidien and NGC Medical, a provider of managed services to hospitals based in Italy and the UK, which was acquired on 27 August 2014 by Medtronic. Among the services offered by NGC Medical is the management of material and equipment on behalf of the hospitals. In this function, NGC Medical purchases small volumes of surgical technology products from Covidien, accounting to 5% of NGC Medical total sales. As NGC procures also from other providers and on the basis of hospital demand and given that the sales realised by NGC are well below 5% of Covidien's total sales in the EEA, this relationship does not raise any competition concerns.

(323) In light of the above, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the vertical relationships arising because of the Transaction.

IV.5. Conglomerate effects

IV.5.1. Introduction

(324) The Commission investigated whether the proposed Transaction would lead to conglomerate effects within the meaning of its Guidelines on the assessment of non-horizontal mergers (Non-horizontal merger guidelines).[195]

(325) In this context, the Commission received a complaint from a market participant, arguing that, in view of the Parties' broad and complementary product portfolios, and the fact that they would allegedly both hold "must have" products, the Transaction would provide the merged entity with the ability and incentive to engage in anticompetitive bundling and tying practices thereby foreclosing smaller specialised players from the market.

(326) According to the Non-horizontal merger guidelines, while non-horizontal mergers are usually not anti-competitive, the combination of products in closely related markets may confer upon the merged entity the ability and incentive to leverage a strong market position in one market to another by means of tying or bundling.[196]

(327) In the present case, the alleged anti-competitive behaviour could consist in mixed bundling, whereby the merged entity would make its products available separately but at higher prices than if they were bought in a bundle, or in tying practices, whereby the merged entity would ensure that some of its products are only functional when

---

195 Commission's Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings (hereinafter "Non-horizontal merger guidelines"), paragraph 7.

196 Non-horizontal merger guidelines, paragraph 93.

combined with other of its devices. Conversely, it seems rather unlikely that the merged entity would engage in pure bundling activities, whereby devices would be sold only jointly in fixed proportions. Taking into account the specificities of the markets for medical devices, in which the needs for equipment are not always pre-defined and physicians' preference plays a significant role, such practice would risk being unsuccessful.

(328) Specifically, possible conglomerate effects of the Transaction would consist, according to the complainant, in the merged entity leveraging its strong market position in the LigaSure market into electrosurgical devices markets through tying, bundling or other exclusionary practices. The complainant argued that Covidien has already engaged in such practices in the past and would be in a better position to continue doing so post-Transaction, as it would be able to bundle its devices with products from Medtronic's portfolio. More concretely, the alleged practices post-Transaction would be as follows:

a) The merged entity would bundle Covidien's flagship electrosurgical device LigaSure with Medtronic's electrosurgical devices or other products from the Medtronic portfolio, in particular its Aquamantys and PlasmaBlade product (*commercial bundling*), and/or

b) The merged entity would further develop LigaSure's electrosurgical generator ForceTriad to make it compatible with Medtronic's electrosurgical devices; customers would therefore be forced into buying Medtronic's products rather than those of competitors to profit from the special features of ForceTriad (*technical bundling*).

(329) In examining the likelihood of both scenarios, the Commission analyses the ability of the merged entity to foreclose its rivals, the economic incentives to do so and whether such foreclosure would have a significant detrimental effect on competition thus harming consumers through either the commercial bundling strategy (Section IV.5.3) and/or the technical bundling strategy (Section IV.5.4).[197] To proceed to this analysis, the Commission will first set out the concerned product markets (Section IV.5.2).

IV.5.2. Products and markets concerned

IV.5.2.1. Identification of relevant products in Covidien's/Medtronic's portfolio

(330) During the Commission's market investigation and following the complaint, Covidien's leading vessel sealing and dissection device LigaSure, together with its ForceTriad generator were identified as products on which Covidien might have market power which could be leveraged (through bundling or tying) into other electrosurgical devices currently owned by Medtronic, namely PlasmaBlade and Aquamantys. The market investigation did not indicate any other Medtronic devices that could create an attractive bundle for customers and add value to LigaSure.[198]

---

197 Non-horizontal merger guidelines, paragraph 94.

198 Minutes of a conference call with a customer on the 31 October 2014, paragraph 11.

(331) Medtronic also has a significant presence in certain markets, such as the market for cardiac disease rhythm management, for neurology, for spine surgery, for diabetes, etc. The Commission's market investigation however did not indicate that Medtronic has sufficient market power in relation to any of its products that it could leverage in markets, in which other Covidien products are sold. Similarly, no markets in which Medtronic's current position would be strengthened or maintained through a bundle with Covidien products was identified.

(332) In light of the above considerations, the present analysis will focus on assessing whether the merged entity would attempt to increase its position on the market in which it sells PlasmaBlade and Aquamantys, using its power in the LigaSure market.

(333) In Section IV.5.2.2 below, the Commission will define the relevant product and geographic market for the LigaSure device and the ForceTriad generator. For a definition of the markets to which the PlasmaBlade and the Aquamantys device belong, see Section IV.3.1. above.

IV.5.2.2. Definition of relevant product markets

IV.5.2.2.a. Vessel sealing and dissection devices

(334) Within the electrosurgical devices' space, a separate segment for vessel sealing and dissection energy devices can be considered. These devices can be split into two types, namely advanced bipolar RF devices and ultrasonic devices.[199] Covidien's LigaSure is an advanced bipolar RF single use device for vessel sealing and dissection. It can fuse vessels up to 7 mm and is used both in laparoscopic and open surgeries. The average sale price of LigaSure is approximately EUR [300-400].

(335) The complainant argues that advanced bipolar and ultrasonic devices are not substitutable because of their intended use and characteristics,[200] whereas the Notifying Party submits that these two types of devices are substitutable because they both have the same functionality and both can be used for the same procedures.

(336) According to the market participants cutting and sealing devices are necessary in most operating rooms and LigaSure is one of the most popular products in this space.[201] The majority considers that LigaSure is in direct competition with devices using ultrasonic technology and that the main competitor to LigaSure is Harmonic by J&J/Ethicon.[202]

---

199 Minutes of a conference call with a competitor on 4 November 2014, paragraph 1; Minutes of a conference call with a competitor on 4 November 2014, paragraphs 4 and 6.

200 The complainant considers that (i) RF bipolar devices are better at sealing and ultrasonic are better at dissecting, (ii) RF bipolar devices can be used for vessels up to 7mm while ultrasonic can only be used for vessels up to 3mm, (iii) RF bipolar devices do not retain high heat temperatures while ultrasonic become heat very quickly and retain high temperature, hindering their use in certain procedures and (iv) the learning curve for RF bipolar devices is significantly lower than for ultrasonic.

201 Minutes of a conference call with a competitor on 4 November 2014, paragraph 15; Minutes of a conference call with a competitor on 5 November 2014, paragraph 6; Minutes of a conference call with a customer on the 31 October 2014, paragraph 1.

202 Minutes of a conference call with a customer on 31 October 2014, paragraph 6.

Even though the market investigation highlighted that bipolar RF technology and ultrasonic devices have slightly different target use[203] - LigaSure being the most successful sealing device, whereas Harmonic the best dissecting product - customers generally explain that the two types of devices can be used for both purposes and surgeons decide on which product to use on the basis of the procedure they perform and of personal preference.[204]

(337) Covidien's market position differs depending on whether LigaSure is part of an overall market for vessel sealing and dissection devices or a separate market for advanced bipolar RF devices.

IV.5.2.2.b. Generators

(338) As mentioned in Section IV.3., all electrosurgical devices are powered by a generator. The Notifying Party argues that electrosurgical generators are distinguished in two categories: standard generators that are compatible with standard, commodity electrosurgical devices of different manufacturers and generators created in order to power a specific type of advanced electrosurgical devices; these generators are not compatible with other AEDs.[205] This distinction is also reflected in the differences in pricing among standard and advanced electrosurgical generators.

(339) For its LigaSure devices, Covidien uses a generator called ForceTriad energy platform. This is an electrosurgical system that combines electrosurgical cutting and coagulation, bipolar functionality and vessel sealing in a single generator and may be used in open and laparoscopic procedures. ForceTriad is compatible with conventional electrosurgical instruments from Covidien and competitors and all LigaSure instruments. ForceTriad is not compatible with advanced energy devices from other providers.

(340) According to the Notifying Party, it is the functionality of the AED handpiece that drives the choice of one advanced electrosurgical generator over another and competition takes place at the level of the AED.

(341) Generators for advanced electrosurgical devices are not perceived as interchangeable to the standard generators by customers.[206] The market investigation also indicated that advanced electrosurgical generators are either sold together with AED handpieces or placed free of charge in hospitals that undertake acquiring a certain number of handpieces.

---

203 Minutes of a conference call with a competitor on 4 November 2014, paragraph 15.

204 Minutes of a conference call with a customer on 31 October 2014, paragraph 6; Minutes of a conference call with a competitor on 4 November 2014, paragraph 15, Minutes of a conference call with a customer on 31 October 2014, paragraph 4.

205 Minutes of a conference call with a competitor on 3 November 2014, paragraph 12.

206 Minutes of a conference call with a competitor on 4 November 2014, paragraph 18; Minutes of a conference call with a customer on 31 October 2014, paragraph 3; Minutes of a conference call with a customer on 31 October 2014, paragraph 1; Minutes of a conference call with a customer on 6 November 2014, paragraph 3.

(342) In light of the above considerations and the results of the market investigation, it may be considered that advanced electrosurgical generators do not belong to a separate market segment, but are merely accessory to the AED handpieces. Customers will take into account, when selecting handpieces, which generator they work with. There is however no market for advanced electrosurgical generators. For the purposes of the present decision however, the exact scope of the market, to which the ForceTriad belongs may be left open.

IV.5.3. Commercial bundling

IV.5.3.1. Introduction

(343) Bundling practices are not anti-competitive *per se*. However, they may produce anticompetitive effects in cases they result in consumer harm. Therefore, the mere offer of bundles by the merged entity would not raise competition concerns. Even if the total price of the devices sold individually is higher than the price of all devices in the bundle, customers could profit from the offer and acquire the products they need at a lower cost.

(344) The circumstances in which a bundling strategy would be anticompetitive is if the price of the stand-alone products is higher than the price of the same products sold in a bundle post-Transaction and only if this would lead to market foreclosure.

IV.5.3.2. Ability of the merged entity to engage in a foreclosure strategy

(345) For the merged entity to be able to engage in foreclosure strategies it must enjoy market power in a market and be in a position to leverage it in another market through conditioning sales in separate markets.

IV.5.3.2.a. Market power

(346) The complainant argues that Covidien enjoys significant market power in the LigaSure market and/or the market of its ForceTriad generator.

IV.5.3.2.a.i. Vessel sealing and dissection devices

(347) In a market for all vessel sealing and dissection energy devices[207], the Notifying Party estimates that LigaSure would have a market share of [30-40]% in the EEA (and a slightly higher one in some national markets)[208] while the complainant estimates LigaSure's market share in the range of 40-50%.

(348) On a market for advanced bipolar RF devices only, Covidien would have a near monopoly with LigaSure, according to the complainant. The Notifying Party submits

---

207 As explained in Section IV.2.1. above, the market definition for electrosurgical devices was left open. The vessel sealing and dissection devices would be part of the narrower narrower market for advanced electrosurgical devices split by functionality.

208 The main competitors would be J&J/Ethicon with its Harmonic device, which operates with ultrasonic energy ([30-40]%), Olympus with Thunderbeat, a device combining both RF and ultrasonic energy ([10-20]%), ERBE ([5-10]%) and Aesculap ([0-5]%), Response to RFI 8, question 8.d.

that LigaSure would be leading on such narrow product market, with a share of [70-80]% in the EEA and higher than 80% in Austria, Croatia, Denmark, France, Ireland, the Netherlands, Portugal, Slovenia, Spain, Sweden and Norway.[209] The main competitors within the advanced bipolar RF devices' space are J&J with its second product, Enseal, and Olympus with the Thunderbeat.[210]

(349) Irrespective of whether the market is defined broadly or narrowly, Covidien seems to be the market leader and enjoy some degree of market power in the segment of advanced bipolar RF devices.

IV.5.3.2.a.ii. Generators

(350) The complainant argues that ForceTriad generator is dominating the market, as the most popular electrosurgical generator system that can be found in operating rooms across the EEA, because of its additional functionality to accommodate, further to LigaSure, regular standard electrosurgical devices. In addition, once installed, the ForceTriad generator is very costly to replace. This way, Covidien forces its customers to continue purchasing LigaSure in order to avoid purchasing a new standard electrosurgical generator.

(351) In a market for standard electrosurgical generators, the Notifying Party estimates that Covidien's market share with ForceTriad and two more standard generators (ForceFX and Surgistat) is approximately [20-30]%. The market shares of its competitors are estimated at approximately [50-60]% for ERBE, [10-20]% for Martin, [5-10]% for Olympus, [5-10]% for Bowa and [5-10]% for Conmed.[211]

(352) Regarding specifically ForceTriad, customers do not seem to place high value on its ability to also accommodate standard electrosurgical devices. The majority of respondents stated that they acquired the ForceTriad in order to power LigaSure but do not necessarily use it for other devices. Indeed, customers explain that they in principle already have standard electrosurgical generators in their operating rooms and would not buy ForceTriad for this purpose. In most cases operating rooms do not have space limitations that would hinder them from using several generators in a single procedure; the mere fact that ForceTriad offers a synergy is therefore not of major significance in selecting this product.[212]

(353) In addition, competitors explain that they have already launched or intend to launch in the near future AED generators with comparable characteristics to the ForceTriad. Conmed explains that the generator of its vessel sealing and dissection device can be attached on top of its standard generator, thus creating a system with the same

---

209 Response to RFI 10, question 1.

210 Minutes of a conference call with a competitor on 4 November 2014, , Minutes of a conference call with a competitor on 4 November 2014, paragraph 6; Minutes of a conference call with a competitor on 4 November 2014, paragraph 12.

211 Response to RFI8, question 9.

212 Minutes of a conference call with a customer on 31 October 2014, paragraph 3; Minutes of a conference call with a customer on the 31 October 2014, paragraph 1; Minutes of a conference call with a competitor on 6 November 2014, paragraph 8.

functionality as ForceTriad.[213] Olympus' generator can also power both standard monopolar and bipolar devices, as well as Thunderbeat, Olympus' sealing and dissecting device which combines RF and ultrasonic energy.[214] Further, the VIO workstation of ERBE is also used for basic devices, for BiCision, a product developed by ERBE to compete with LigaSure and includes in addition Waterjet technology, which is not provided by any other generator system.[215]

(354) On the other hand, customers confirmed the very broad use of ForceTriad in hospitals and competitors indicated that they experienced a drop in the sales of their standard generators after the entry of ForceTriad.[216]

IV.5.3.2.a.iii. Conclusion on market power

(355) In light of the market investigation, it can therefore be concluded that ForceTriad does not *per se* constitute a flagship product of Covidien. LigaSure could potentially be seen as such, given its high market shares and volume of sales. In any case, these two products are interconnected as LigaSure cannot be used without the ForceTriad and ForceTriad's value lies in its compatibility with LigaSure. Therefore, any market power Covidien may have in the area of vessel sealing and dissection is not restricted to LigaSure only or the ForceTriad only, but consists in the combination of these two products' features.

IV.5.3.2.b. Functioning of the market does not encourage the emergence of bundles

(356) The Commission's market investigation revealed that various aspects of the functioning of these markets do not seem to encourage the emergence of bundles.

(357) First, as regards current bundling practices involving LigaSure, these appear rather limited in the EEA. Covidien offers bundles of LigaSure, ForceTriad and some other devices, however these only represent 0.5% of its total sales of vessel sealing and dissecting devices.[217] In any event, the Parties' products are available, priced and sold individually. Only occasionally and upon customers' request, the Parties sell procedure-specific kits, in which a number of devices required for a particular procedure are included. Customers of Covidien and Medtronic submit that they organise their purchases based on their identified supply needs. Even if a company were to offer sets of products, customers explained that they would not buy devices that they do not need.[218]

---

213 Minutes of a conference call with a competitor on 3 November 2014, paragraph 12.

214 Minutes of a conference call with a competitor on 5 November 2014, paragraph 11-12.

215 Minutes of a conference call with a competitor on 5 November 2014, paragraph 8. Minutes of a conference call with a competitor on 3 November 2014, paragraph 16.

216 Minutes of a conference call with a competitor on 5 November 2014, paragraphs 7-8; Minutes of a conference call with a competitor on 5 November 2014, paragraph 6.

217 Annex X.8 of RFI 10 and response to RFI 10, question 8. The sale of laparoscopic kits corresponds to only 2.5% of Covidien's total sales.

218 Minutes of a conference call with a customer on 31 October 2014, paragraph 15; Minutes of a conference call with a customer on 29 October 2014, paragraph 2; Minutes of a conference call with a

(358) Second, it appears unlikely that merger-specific bundles would emerge post-Transaction. LigaSure appears to be used primarily in urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures. Aquamantys on the other hand appears to be used in orthopaedic, spine, and endoscopic procedures, abdominal and thoracic surgery and PlasmaBlade in soft tissue during otorhinolaryngology, cardiac rhythm disease management applications and plastic surgery.[219] Therefore, Plasmablade and Aquamantys do not appear to share a large customer base with LigaSure, and therefore such bundle would not be easy to sell.[220]

(359) Third, the existing sales patterns do not appear to facilitate bundles in the EEA. In most EEA countries, LigaSure is often sold via tenders[221] while Aquamantys and Plasmablade are in most cases sold through bilateral negotiations. In the other EEA countries, in which also LigaSure is sold via bilateral negotiations, the emergence of bundles would be easier.[222] However, since these devices are not used for the same procedures, they are in principle also not used by the same physicians. As a result, contact persons within a hospital would be different for LigaSure and for the Aquamantys and PlasmaBlade.[223]

(360) Lastly, as regards rebates, both Covidien and Medtronic have different discount policies, amongst which the provision of AED generators free of charge if the customer purchases a minimum number of disposable devices. However, bundled discounts, whereby customers are offered better prices if they buy a specific combination of products do not form part of the Parties' discount policy.[224] The results of the market investigation also indicate that rebates are in principle volume-based and not dependent on the purchase of sets of products together.[225] Therefore it appears that the current discount structure does not impose the acquisition of products which the customers do not want.

---

customer on the 31 October 2014, paragraph 5; Minutes of a conference call with a customer on 31 October 2014, paragraph 9.

219 Medtronic's White Paper on conglomerate effects of 2 November 2014 and response to RFI11.

220 The Notifying Party submits that Plasmablade and Aquamantys are sold to only 4% of the hospitals, which purchase LigaSure and in any case to less than 1% of all EEA hospitals.

221 More than 80% of LigaSure's sales are done through tenders in a majority of European countries (in particular in the UK, Italy and Spain, which represent together more than 40% of LigaSure's sales in Europe), Bulgaria (65%), France (50%).

222 Austria, Belgium, Czech Republic, Germany, Hungary, Netherlands (tenders in less than 30% of the sales).

223 Moreover, the contribution of specialised personnel is required for the purchase of each type of devices. Depending on the function of each device and the procedure for which it is used, different medical and technical staff members would be involved in the purchasing decision. Mirroring this, manufacturers' and distributors' sales forces are also specialised on certain types of products (e.g. on peripheral vascular or electrosurgical devices). This way, they can approach and establish contacts with the medical and technical hospital staff that would be involved in the sale of such products, present them their devices, educate them of their use etc.

224 Response to RFI 11, question 8.

225 Minutes of a conference call with a customer on 29 October 2014, paragraph 2; Minutes of a conference call with a customer on the 31 October 2014, paragraph 5.

IV.5.3.3. Incentives to engage in foreclosure strategies

(361) The Parties' incentive to foreclose competitors through a bundling or tying strategy would depend on the profitability of such strategy.[226]

(362) As analysed in Section IV.5.2, LigaSure is a flagship product of Covidien. Aquamantys and PlasmaBlade however are relatively new, niche products that do not have comparable market traction.

(363) The value of the EEA market for vessel sealing and dissection devices amounts to EUR 450 million and is significantly larger than the value of the EEA markets for electrosurgical pencils and large surface coagulation devices, which together amount to EUR 97 million.[227] While the sales of LigaSure represent around 10% of Covidien's total sales both in the EEA[228] and worldwide[229], Medtronic's sales of PlasmaBlade[230] and Aquamantys[231] are minimal and represent less than 1% of its total sales.

(364) In assessing the likelihood of the merged entity engaging in a foreclosure strategy, it is necessary to compare the profit margins in the various products as well as their relative value.[232] The complainant also claimed that even in the absence of a direct bundling or tying, the merged entity would offer rebates on grouped sales, which would incentivise the customers to buy more products from the merged entity.

(365) In the present case, the profit margins in Aquamantys, PlasmaBlade and LigaSure are fairly similar.[233] However, there are significant differences in size of the markets of LigaSure on the one hand and of Aquamantys and PlasmaBlade on the other and the total revenues they generate.

(366) Therefore, implementing a strategy through which the prices of Aquamantys, PlasmaBlade and LigaSure would increase if the products are sold independently and remain at their current levels or decrease only if customers buy all products in a bundle, is unlikely to be profitable. Absent exclusionary effects, the mere rebates are not likely

---

226 Non-horizontal merger guidelines, paragraph 105.

227 This calculation includes the market for electrosurgical pencils and PlasmaBlade, however as explained above, PlasmaBlade is a much more sophisticated device than a standard electrosurgical pencil, the value of the market for PlasmaBlade and Aquamantys together is therefore likely to be smaller.

228 LigaSure generates sales of EUR […] million in the EEA representing […]% of all Covidien sales in the EEA. In a few European countries, the sales of LigaSure represent more than […]% of Covidien's total sales, namely Austria ([…]%), Finland ([…]%), Malta ([…]%), Portugal ([…]%) and Spain ([…]%).

229 LigaSure has sales of USD […] million, equal to approximately […]% of Covidien's global sales.

230 Sales of PlasmaBlade were less than EUR […] million in the EEA.

231 Sales of Aquamantys were less than EUR […] million in the EEA.

232 Non-horizontal merger guidelines, paragraph 107.

233 The unit margin for LigaSure ranges from EUR […] in Greece to EUR […] in Norway, whereas for PlasmaBlade it is from EUR […] in Croatia to EUR […] in the UK and for Aquamantys from EUR […] in Hungary to EUR […] in Belgium, Medtronic's White Paper on conglomerate effects of 2 November 2014.

to have anticompetitive consequences. In any event, even if the merged entity would engage in such strategies, it is unlikely that it would have any effect on the market, as explained in Section IV.5.3.4 below.

IV.5.3.4. Effects of a bundling strategy on competition

(367) Even if the merged entity would have the ability and the incentive to engage in a bundling strategy, the Commission considers that such strategy is unlikely to have anticompetitive effects in this case.

(368) The results of the market investigation indicated that competitors are likely to have the power to counteract any bundling strategy of the merged entity with LigaSure as the tying product.

(369) As mentioned in Section IV.5.3. above, LigaSure albeit a very successful product with significant market shares, faces competition from a number of other providers such as J&J with the addition of new functionalities in its Harmonic product, Olympus, B.Braun, ERBE but also Aesculap which recently invested in a new energy platform and Applied Medical that is expected to launch a new device in the course of 2015.

(370) Second, other companies are in the position to compete with the ForceTriad generator. Should the merged entity decide to engage in a bundling strategy combining PlasmaBlade and Aquamantys with ForceTriad and LigaSure, companies such as ERBE, ConMed or Olympus would be able to also follow such strategy, offering similar combinations of products. Indeed, ERBE already has a device competing with LigaSure and a device used for coagulation (like Aquamantys) and these two work with its advanced generator, VIO, which is also compatible with standard electrosurgical devices of various suppliers. ERBE is strong in the generator market and it is likely to have the ability to counteract an upgraded ForceTriad. Similarly Conmed, despite its smaller position in Europe has a similar device to Aquamantys and it could also combine this device with its advanced device which competes with LigaSure into one single generator.

(371) Third, in a scenario in which the merged entity would be successful in offering a bundle including LigaSure, Aquamantys and PlasmaBlade (which as explained above is not likely to happen), Covidien's actual or future competitors in the LigaSure market, such as Applied Medical could team up with manufacturers of generators and of devices similar to Aquamantys and PlasmaBlade in order to make competing offers to the merged entity's bundle. The Notifying Party further submits that there are some independent companies that already provide such services, as for example Mölnlyke which sells their own products but also sets up and sells packages of devices from various providers.[234]

(372) Fourth, should the merged entity decide to engage in bundling practices also more widely, including other types of devices, competitors such as J&J could counteract with similar strategies by setting up bundles consisting of different products. Even if a competitor cannot provide the same type of bundle, it may always create a combination

---

234 Response to RFI 9, question 3.

of products from its own portfolio that would be meaningful to customers thus remaining competitive and not compromising its market share in the market of the tying product. Similarly, Abbott and Boston Scientific also produce medical devices that are used in several sectors. Also in this case, companies active in selling packages of medical devices to hospitals could exert a degree of competitive pressure on the merged entity to enable smaller competitors to remain in the market.

(373) More generally, regarding the merged entity's ability to set up bundles containing devices other than only LigaSure, Plasmablade and Aquamantys, such bundles would only be successful if structured in a way that would be meaningful to the customer, e.g. combining products that are used together in a single procedure. Looking into the portfolio of Medtronic and Covidien however, there seems to be a high degree of complementarity, but not closely related areas of activity that would justify a joint sale of different devices. For instance, both companies are active in neurology, but focus on different diseases (brain functioning for Medtronic, neurovascular devices for Covidien). Customers and competitors were asked during the market investigation, but did not identify any other obvious fit between the portfolios of Medtronic and Covidien.[235]

(374) Moreover, besides the complainant, neither customers nor competitors raised specific concerns as to the merged entity's ability to engage in bundling practices.[236]

(375) In light of all available evidence, the Commission considers that even if the merged entity were to engage in tying and bundling strategies, it is unlikely that such practices would lead to a merger-specific anti-competitive effect. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market because of commercial bundling strategies.

IV.5.4. Technical bundling

(376) The complainant argues that in addition to the merged entity's ability to offer LigaSure in a bundle with Medtronic's AEDs, it could also adopt a strategy of technical bundling. In such scenario, the merged entity would update the ForceTriad generator, in order to not only power LigaSure and commodity devices, but also Medtronic's PlasmaBlade and Aquamantys.

(377) By creating such bundle, it would further leverage its position in the LigaSure market to increase the sales of Aquamantys and PlasmaBlade, as these would not require an additional generator to function.

---

235 Minutes of a conference call with a competitor on 5 November 2014, paragraph 13; Minutes of a conference call with a competitor on 31 October 2014, paragraph 42; Minutes of a conference call with a competitor on 4 November 2014, paragraph 19; Minutes of a conference call with a customer on the 31 October 2014, paragraph 11.

236 Out of the total responses from customers and distributors on the issue, only in very few instances were concerns on the possible effect of the Transaction on competition raised, mostly as a general comment of the reduction of competition, the negotiating power of the merged entity and the risk of price increases and cuts on innovation.

(378) In addition, the complainant also argues that through such technical bundling, the merged entity would maintain its high market share in the LigaSure market, by ensuring that the additional functionalities of PlasmaBlade and Aquamantys form part of the LigaSure product line. The merged entity's rivals in the LigaSure market would not be able to compete with this more advanced product and therefore be driven out of the market.

(379) The Commission therefore also assessed the merged entity's ability and incentive to engage in such strategy, as well as its possible effects on the market.

IV.5.4.1. Ability to technically tie ForceTriad to PlasmaBlade and Aquamantys

(380) The Notifying Party submits that in order to create an advanced version of ForceTriad with the ability to also accommodate PlasmaBlade and Aquamantys, a significant investment would be required. More concretely, a period of 4-5 years would be needed for the technical development of such device and approximately another 1.5 year for the acquisition of the regulatory approval. An investment of approximately USD 6-8 million would be necessary according to the Notifying Party, which subsequently would lead to an increase in prices of the various handpieces until its investment is recouped.

(381) The Notifying Party further explains that it currently has no plan in developing such device. Medtronic is already working on a single generator that would accommodate PlasmaBlade and Aquamantys and intends to launch this device in April 2015 – this product is in the pipeline since 2012 and the project costs have been around USD 5-6 million. Similarly, Covidien is currently developing a next generator version of ForceTriad, which will constitute a complex multifunctional system and shall replace ForceTriad after its launch in 2015. Covidien has already invested USD 75 million in this device.

(382) It follows that although technically possible, it would be rather unlikely that the merged entity decides to technically bundle the ForceTriad generator to Aquamantys and PlasmaBlade.

IV.5.4.2. Incentive to engage in foreclosure strategy

(383) As already analysed in relation to commercial bundling, taking into account the relative value of the LigaSure/ForceTriad market and the Aquamantys and PlasmaBlade markets, it is rather unlikely that the merged entity would decide to adopt such strategy.

(384) Indeed, should the merged entity invest in an updated version of the ForceTriad, it would have to recoup its investment by increasing either the price of the generator or of the disposables that are powered by it. Such increase in prices could lead some of the customers of LigaSure/ForceTriad to switch to competing products, resulting in losses for the merged entity. As the markets of Aquamantys and PlasmaBlade are very small, it is quite unlikely that the merged entity would recoup its losses from the decrease in the sales of LigaSure/ForceTriad through the profits generated by the sales of Medtronic's AEDs.

(385) Therefore, it does not appear that the merged entity would have financial incentives to technically bundle its generator with PlasmaBlade and Aquamantys.

IV.5.4.3. Effects on competition

(386) The results of the market investigation indicated that competitors would likely have the ability to counteract such bundling strategy of the merged entity.

(387) As mentioned in Section IV.5.3, other competitors market devices similar to LigaSure and/or ForceTriad in the EEA. Customers would therefore have the possibility to switch to other suppliers, if the merged entity increases the prices of these products.

(388) In addition, other companies have proved that they are in a position to compete with the ForceTriad generator. Therefore, should the merged entity decide to engage in technical bundling that would allow PlasmaBlade and Aquamantys to also be powered by the ForceTriad, companies such as ERBE, ConMed, Olympus are likely to have the ability and incentive to also develop such generators, offering an energy platform that would offer similar functionalities.

(389) Moreover, as already mentioned above, customers have indicated that a combination of LigaSure with Aquamantys and PlasmaBlade is not particularly meaningful, as these devices are not used for the same procedures or by the same physicians. Therefore, even if such technical bundle were offered by the merged entity, it would quite likely not be successful on the market.

IV.5.4.4. Conclusion

(390) In light of the above considerations, it appears unlikely that the merged entity would engage in such technical bundling.

IV.5.5. Conclusion on conglomerate effects

(391) In light of all available evidence, the Commission concludes for the purposes of this decision that the Transaction is unlikely to lead to conglomerate effects which would raise serious doubts as to the compatibility of the Transaction with the internal market.

V. PROPOSED REMEDIES

(392) In order to render the concentration compatible with the internal market, the Notifying Party has modified the notified concentration by entering into the following commitments, which are annexed to this decision and form an integral part thereof.

(393) To address the concerns identified during the market investigation in relation to DCBs, Medtronic committed to divest, or procure the divestiture of, the entire worldwide *Stellarex* DCB business essentially consisting of the research, development, manufacture, marketing, sale and distribution of *Stellarex* DCBs and a license to the Purchaser of certain PTA intellectual property currently owned by Covidien to operate that *Stellarex* DCB business, including (i) to make, have made, use, offer to sell, sell, import, and export any *Stellarex* DCBs, and (ii) the research, development, and manufacture of PTA Products for the incorporation into *Stellarex* DCBs.

(394) The Divestment Business includes (via transfer or license) all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

a) all tangible assets, in particular (i) the lease of the facility located in Fremont (California); (ii) all manufacturing equipment primarily used or held for use in manufacturing *Stellarex* DCBs, including relevant *Stellarex* DCB manufacturing equipment located at the Plymouth (Minnesota) facility and (iii) 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 and packaging of *Stellarex* DCBs;

b) all intangible assets (including intellectual property rights), in particular the assignment of certain U.S. and foreign patents and trademarks to the extent primarily related to the *Stellarex* DCB business. Medtronic will not be permitted to use any of know-how, schematics, trademarks, trade secrets, or copyrights included in the transferred intellectual property in the production or sale of its own drug coated balloons or in any other Medtronic product;

c) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;

d) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business; and

e) the Personnel.

(395) In addition, the Divestment Business includes the benefit, for a transitional period of up to two years after Closing and on terms and conditions equivalent to those at present afforded to the Divestment Business, of all current arrangements under which Covidien or its Affiliated Undertakings supply products or services to the Divestment Business, as detailed in the Schedule, unless otherwise agreed with the Purchaser. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from, such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside Covidien's PTA balloon business.

(396) The Divestment Business includes the entire worldwide *Stellarex* business purchased by Covidien from CV Ingenuity ("CVI") in January 2013, including any improvements and developments done by Covidien since then. According to the Notifying Party, because Covidien only recently purchased *Stellarex*, these assets can be easily severed from the existing Covidien peripheral vascular business without impairing the viability of the DCB program.

(397) The Divestment Business will include all regulatory documentation and clinical data in connection with the pursuit of FDA approval, CE Mark, and any other regulatory approvals that Covidien is currently pursuing anywhere in the world.

(398) On 31 October 2014, Medtronic signed an agreement, pursuant to which the Spectranetics Corporation will acquire Covidien's Stellarex drug coated balloon post-Transaction.

VI. ASSESSMENT OF THE PROPOSED REMEDIES

(399) The Commission analysed the suitability of the proposed commitments to remedy serious doubts in this case against the standard set out in the Commission Notice on Remedies.[237]

VI.1. Framework for the Commission's assessment of the Commitments

(400) Where a notified concentration raises serious doubts as to its compatibility with the internal market, the parties may modify the notified concentration so as to remove the grounds for the serious doubts identified by the Commission with a view to having it declared compatible with the internal market pursuant to Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation.

(401) As set out in the Commission Notice on Remedies, commitments have to eliminate the Commission's serious doubts entirely, they have to be comprehensive and effective from all points of view and they must be capable of being implemented effectively within a short period of time, as the conditions of competition on the market will not be maintained until the commitments have been fulfilled.[238]

(402) In assessing whether or not commitments will restore effective competition, the Commission considers their type, scale and scope by reference to the structure and the particular characteristics of the market in which the Commission has identified serious doubts as to the compatibility of the notified concentration with the internal market.[239]

(403) Divestiture commitments are the best way to eliminate serious doubts resulting from horizontal overlaps of the merging parties' activities.[240] Other commitments (such as licensing) may be suitable to resolve serious doubts if those commitments are equivalent to divestitures in their effects. The divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern.[241]

(404) The business to be divested must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness and all personnel which are currently employed or which are necessary to ensure the business' viability and competitiveness. Personnel and assets which are currently shared between the business to be divested and other businesses of the parties, but which contribute to the operation of the business or which are necessary to ensure its viability and competitiveness, must also be included. Otherwise, the viability and competitiveness of the business to be divested would be endangered. Therefore, the business to be divested

---

237 Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (2008/C 267/01), (the "Commission Notice on Remedies").

238 Commission Notice on Remedies, paragraph 9.

239 Commission Notice on Remedies, paragraph 12.

240 Commission Notice on Remedies, paragraph 17.

241 Commission Notice on Remedies, paragraph 23.

must contain the personnel providing essential functions for the business, at least in a sufficient proportion to meet the on-going needs of the business to be divested.[242]

(405) Furthermore, the intended effect of the divestiture will only be achieved if and once the business is transferred to a suitable purchaser with proven relevant expertise and ability to maintain and develop the business to be divested as a viable and active competitive undertaking.

VI.2. Results of the market test

(406) To assess the suitability of the Commitments to remove serious doubts in this case the Commission launched a market test on 11 November 2014.

(407) The market test indicated that the Commitments proposed in this case are overall suitable in that they contain all the necessary assets, provide for divestiture of a stand-alone business and are likely to lead to an emergence of a new player in the area of DCBs.

VI.3. Suitability of the prosed commitments to remedy serious doubts in the area of DCBs

(408) The Commitments consist of the divestment of all assets necessary for the development and manufacturing of Covidien's DCB Stellarex. Specifically, the divestment contains all assets for the Purchaser to be able to produce DCBs. Indeed, the package contains the manufacturing equipment currently used for paclitaxel coating, the associated technology, IP and know-how as well as the personnel. In addition, to ensure the DCB produced by the Purchaser on the basis of the Commitments has identical characteristics than the DCB currently produced by Covidien the package contains a license to the Covidien's PTA balloon technology. Finally, the commitments contain the entirely regulatory file of Stellarex and the research to date.

(409) In addition, the results of the market test indicated that the divestment package includes all the elements necessary for the Purchaser of the Divestment Business to complete the clinical trials for Stellarex and ultimately effectively and efficiently compete with the merged entity on the market for DCBs in the EEA.[243]

(410) To ensure that the Purchaser, pending it setting up its own capabilities for the production of PTA balloon catheters, is in a position to supply DCBs immediately, the Commitments contain a transitional agreement for a period of up to three years whereby Covidien will continue supplying its PTA balloon catheters to the Purchaser.

(411) The market test confirmed that the proposed commitments are suitable to remedy the serious doubts in this case and to generate a new competitive force in the market. According to the market participants, the package contains all the necessary assets for the purchaser to continue and finalise the trials and bring Stellarex to the market. As concerns the duration of the transitional agreements, most respondents to the market

---

242 Commission Notice on Remedies, paragraphs 25 and 26.

243 Replies to R1 - Market test of the Commitments, Question 3.

test indicated that one to three years would be needed for the Purchaser to set up its own production facilities for PTA balloons and sell DCBs with these balloons incorporated on the basis of the licensed technology.[244] Therefore the duration of the PTA supply agreement of up to three years is sufficient for the Purchaser to begin to produce identical balloons to those of Covidien and enter the market with its own DCB.[245]

(412) On this basis, the Commission concludes that the Divestment business is comprehensive and can be operated on a stand-alone basis by a suitable Purchaser. As such it is therefore suitable to remedy serious doubts identified in this case.

VI.4. Purchaser criteria

(413) Besides the standard criteria for a suitable purchaser contained in section D of the Commitments, the market test revealed that the Purchaser would have to be a company having the ability to finalise the Stellarex clinical trials and the ability to distribute Stellarex throughout Europe.[246] With regards to the latter, the market test pointed in particular to the need of sufficient sales force.

VI.5. Conclusion on the Commitments

(414) On the basis of the above, the Commission concludes that the Commitments are suitable and sufficient to remedy the serious doubts raised by the Transaction in relation to DCBs. Moreover, the Commitments are comprehensive and effective from all points of view, and are capable of being implemented effectively within a short period of time.

(415) The Commitments provide for a full divestment of the competing business and thus remove entirely the future overlap between the Parties in the EEA and the individual Member States as well as worldwide.

(416) Through the Commitments a new player will emerge on the DCB market with a promising device as a result of which patients in need of a DCB will have a new product on the market. In addition, given that all pipeline research is part of the divestment business, the Commitments will contribute to the creation of an innovative competitor who will have the potential to further develop and improve the product, including for new indications.

VII. CONDITIONS AND OBLIGATIONS

(417) Pursuant to the first sentence of the second subparagraph of Article 6(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the internal market.

---

244 Replies to R1 - Market test of the Commitments, Question 8.

245 Replies to R1 - Market test of the Commitments, Question 9.

246 Replies to R1 - Market test of the Commitments, Question 14.

(418) The achievement of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's decision declaring the concentration compatible with the internal market and the EEA Agreement no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(6)(b) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.

(419) In accordance with the basic distinction between conditions and obligations, the decision in this case is conditional on full compliance with the requirements set out in Section B of the final Commitments, which constitute conditions. The remaining requirements set out in the other Sections of the said Commitments are considered to constitute obligations.

(420) The full text of the final Commitments is annexed to this Decision as Annex I and forms an integral part thereof.

VIII. CONCLUSION

(421) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in section B of the commitments annexed to the present decision and with the obligations contained in the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation.

For the Commission

(signed)
Margrethe VESTAGER
Member of the Commission

CASE M.7326 – MEDTRONIC/COVIDIEN
COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2), of Council Regulation (EC) No 139/2004 (the "Merger Regulation"), Medtronic, Inc. ("Medtronic") and Covidien plc ("Covidien") (the "Parties", each a "Party") hereby enter into the following Commitments (the "Commitments") vis-à-vis the European Commission (the "Commission") with a view to rendering the acquisition by Medtronic of sole control over Covidien (the "Medtronic/Covidien Transaction") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Medtronic/Covidien Transaction compatible with the internal market and the functioning of the EEA Agreement (the "Decision"), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "Remedies Notice").

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by Medtronic, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission's Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "Consolidated Jurisdictional Notice").

Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B, paragraph 6 (a), (b) and (c) and described more in detail in the Schedule.

Closing: the transfer of the legal title to the Divestment Business to the Purchaser.

Closing Period: the period of 3 months from the approval of the Purchaser and the terms of sale by the Commission.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Covidien: Covidien plc, 20 on Hatch, Lower Hatch Street, Dublin 2, Ireland.

Divestment Business: the business defined in Section B and in the Schedule which Medtronic commits to divest.

Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Medtronic and who has/have received from

Medtronic the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of […] from the Effective Date.

Hold Separate Manager: the person appointed by Medtronic for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Business, as listed in the Schedule, including the Hold Separate Manager.

Medtronic: Medtronic plc. incorporated under the laws of the State of Minnesota with its registered office at 710 Medtronic Parkway, Minneapolis, MN 55432-5604.

Medtronic/Covidien Transaction: the acquisition by Medtronic of sole control, pursuant to Council Regulation (EC) 139/2004, over Covidien plc, announced on June 15, 2014.

Monitoring Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Medtronic, and who has/have the duty to monitor Medtronic's compliance with the conditions and obligations attached to the Decision.

Parties: Medtronic and Covidien.

Personnel: all staff currently employed by Covidien who are primarily active in the Divestment Business, as well as the additional personnel listed in the Schedule.

PTA Product: (1) Covidien's *EverCross*™ 0.035" percutaneous transluminal angioplasty balloon catheter; (2) Covidien's *NanoCross Elite*™ 0.014" percutaneous transluminal angioplasty balloon catheter; (3) Covidien's *PowerCross*™ 0.018" percutaneous transluminal angioplasty balloon catheter; and (4) Covidien's *RapidCross*™ 0.014" percutaneous transluminal angioplasty balloon catheter.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 15 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing more in detail the Divestment Business.

***Stellarex* DCBs**: Covidien's over the wire percutaneous transluminal angioplasty (PTA) balloon catheters with paclitaxel coated balloons for peripheral vascular use; provided, however, that *Stellarex* DCBs shall not include PTA Products that do not contain a paclitaxel coated balloon.

Trustee(s): the Monitoring Trustee and the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of […] from the end of the First Divestiture Period.

Section B. The commitment to divest and the Divestment Business

Commitment to divest

2. Medtronic commits to divest, or procure the divestiture of, the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 16 of these Commitments. To carry out the divestiture, Medtronic commits to find, or procure Covidien to find, a purchaser and to enter into, or procure Covidien to enter into, a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If Medtronic has not entered into such an agreement at the end of the First Divestiture Period, Medtronic shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 28 in the Trustee Divestiture Period.

3. Medtronic shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, Medtronic or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 16; and

   (b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, Medtronic shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from Medtronic showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 42 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the Medtronic/Covidien Transaction compatible with the internal market.

Structure and definition of the Divestment Business

5. The Divestment Business consists of the entire worldwide *Stellarex* DCB business (currently owned by Covidien) that is related primarily to the research, development, manufacture, marketing, sale or distribution of *Stellarex* DCBs and a license to the Purchaser under certain PTA intellectual property currently owned by Covidien to operate that *Stellarex* DCB business, including (i) to make, have made, use, offer to sell, sell, import, and export any *Stellarex* DCBs, and (ii) the research, development, and manufacture of PTA Products for the incorporation into *Stellarex* DCBs. The legal and functional structure of the Divestment Business as operated to date is described in the Schedule. The Divestment Business, described in more detail in the Schedule, includes (via transfer or license) all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:

   (a) all tangible and intangible assets (including intellectual property rights);

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;

(c) all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business; and

(d) the Personnel.

6. In addition, the Divestment Business includes the benefit, for a transitional period of up to 2 years after Closing and on terms and conditions equivalent to those at present afforded to the Divestment Business, of all current arrangements under which Covidien or its Affiliated Undertakings supply products or services to the Divestment Business, as detailed in the Schedule, unless otherwise agreed with the Purchaser. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from, such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside Covidien's PTA balloon business.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

7. From the closing of the Medtronic/Covidien Transaction until Closing, Medtronic shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise, as far as possible, any risk of loss of competitive potential of the Divestment Business. In particular, Medtronic undertakes:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans; and

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business, and not to solicit or move any Personnel to Medtronic's remaining businesses. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Business, Medtronic shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Medtronic must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.

Hold-separate obligations

8. From the closing of the Medtronic/Covidien Transaction until Closing, Medtronic shall keep the Divestment Business separate from the retained businesses and ensure

that, unless explicitly permitted under these Commitments: (i) management and staff of the business retained by Medtronic have no involvement in the Divestment Business; (ii) the Key Personnel and Personnel of the Divestment Business have no involvement in any business retained by Medtronic and do not report to any individual outside the Divestment Business.

9. From closing of the Medtronic/Covidien Transaction until Closing, Medtronic shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the business which Medtronic is retaining. Immediately after the adoption of the Decision, Medtronic shall appoint a Hold Separate Manager. The Hold Separate Manager, who shall be part of the Key Personnel, shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by Medtronic. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 7(c) of these Commitments. The Commission may, after having heard Medtronic, require Medtronic to replace the Hold Separate Manager.

Ring-fencing

10. From closing of the Medtronic/Covidien Transaction until Closing, Medtronic shall implement, or procure to implement, all necessary measures to ensure that it does not obtain any Confidential Information relating to the Divestment Business and that any such Confidential Information obtained by Medtronic before the Effective Date will be eliminated and not be used by Medtronic. This includes measures vis-à-vis any of Medtronic or Covidien's appointees on the supervisory board and/or board of directors of the Divestment Business. In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. Medtronic may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to Medtronic is required by law.

Non-solicitation clause

11. Medtronic undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Business for a period of one year after Closing.

Due diligence

12. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, Medtronic shall (or has), subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

    (a) provide(d) to potential purchasers sufficient information as regards the Divestment Business;

    (b) provide(d) to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

13. Medtronic shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request) and until Closing. Medtronic shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission, as well as a copy of all the offers made by those potential purchasers within five business days of the Effective Date.

14. Medtronic shall inform the Commission and the Monitoring Trustee on its preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee.

Section D. The Purchaser

15. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

    a. The Purchaser shall be independent of and unconnected to Medtronic and its Affiliated Undertakings (this being assessed having regard to the situation following the divestiture).

    b. The Purchaser shall have the financial resources, proven expertise, and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with Medtronic and other competitors;

    c. The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

16. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When Medtronic or Covidien has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission. Medtronic must be able to demonstrate to the Commission that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets or parts of the Personnel, or by substituting one or more Assets or parts of the Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment procedure

17. Medtronic shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. Medtronic commits not to close the Medtronic/Covidien Transaction before the appointment of a Monitoring Trustee.

18. If Medtronic or Covidien has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Medtronic at that time or thereafter, Medtronic shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

19. The Monitoring Trustee shall:

(i) at the time of appointment, be independent of Medtronic and its affiliated Undertakings;

(ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker, or consultant, or auditor; and

(iii) neither have nor become exposed to a Conflict of Interest.

20. The Trustee shall be remunerated by Medtronic in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by Medtronic

21. No later than two weeks after the Effective Date, Medtronic shall submit the name or names of one or more natural or legal persons whom Medtronic proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, Medtronic shall submit a list of one or more persons whom Medtronic proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 19 above and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

22. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Medtronic shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Medtronic shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Medtronic

23. If all the proposed Trustees are rejected, Medtronic shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 17 and 22 of these Commitments.

Trustee nominated by the Commission

24. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Medtronic shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

25. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Medtronic, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

26. The Monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(ii) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Medtronic with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by Medtronic, in accordance with paragraphs 7 and 8 of these Commitments;

(b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraphs 8 and 9 of these Commitments;

(c) with respect to Confidential Information:

- determine all necessary measures to ensure that Medtronic does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Business,

- in particular strive for the severing of the Divestment Business's participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,

- make sure that any Confidential Information relating to the Divestment Business obtained by Medtronic before the Effective Date is eliminated and will not be used by Medtronic, and

- decide whether such information may be disclosed to or kept by Medtronic as the disclosure is reasonably necessary to allow Medtronic to carry out the divestiture or as the disclosure is required by law;

(d) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and Medtronic or Affiliated Undertakings;

(iii) propose to Medtronic such measures as the Monitoring Trustee considers necessary to ensure Medtronic's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

(iv) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:

(a) potential purchasers receive (or have received) sufficient and correct information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and

(b) potential purchasers are granted (or have been granted) reasonable access to the Personnel;

(v) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(vi) provide to the Commission, sending Medtronic a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Personnel, so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(vii) promptly report in writing to the Commission, sending Medtronic a non-confidential copy at the same time, if it concludes on reasonable grounds that Medtronic is failing to comply with these Commitments;

(viii) within one week after receipt of the documented proposal referred to in paragraph 16 of these Commitments, submit to the Commission, sending Medtronic a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser;

(ix) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

27. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

28. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 15 and 16 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Medtronic, subject to Medtronic’s unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

29. In the Trustee Divestiture Period (or otherwise at the Commission’s request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to Medtronic.

III. Duties and obligations of Medtronic

30. Medtronic shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Medtronic’s or the Divestment Business’s books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Medtronic and the Divestment Business shall provide the Trustee upon request with copies of any document. Medtronic and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

31. Medtronic shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. Medtronic shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. Medtronic shall inform the Monitoring Trustee on possible purchasers approached, submit lists of potential purchasers prepared during the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

32. Medtronic shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing, and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Medtronic shall cause the documents required for effecting the sale and the Closing to be duly executed.

33. Medtronic shall indemnify the Trustee and its employees and agents (each an "Indemnified Party") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Medtronic for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

34. At the expense of Medtronic, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Medtronic's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Medtronic refuse to approve the advisors proposed by the Trustee, the Commission may approve the appointment of such advisors instead, after having heard Medtronic. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 33 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Medtronic during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

35. Medtronic agrees that the Commission may share Confidential Information proprietary to Medtronic with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

36. Medtronic agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

37. For a period of 10 years from the Effective Date, the Commission may request all information from Medtronic that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

38. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

(a) the Commission may, after hearing the Trustee and Medtronic, require Medtronic to replace the Trustee; or

(b) Medtronic may, with the prior approval of the Commission, replace the Trustee.

39. If the Trustee is removed according to paragraph 38 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 17-24 of these Commitments.

40. Unless removed according to paragraph 38 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The review clause

41. The Commission may extend the time periods foreseen in the Commitments in response to a request from Medtronic or, in appropriate cases, on its own initiative. Where Medtronic requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause**.** This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Medtronic. Only in exceptional circumstances shall Medtronic be entitled to request an extension within the last month of any period.

42. The Commission may further, in response to a reasoned request from Medtronic showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Medtronic. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into force

43. The Commitments shall take effect upon the date of adoption of the Decision.

Geoff S. Martha
Senior Vice President, Strategy and Business Development duly authorised for and on behalf of Medtronic, Inc.

SCHEDULE

1 The Divestment Business as operated to date has the following legal and functional structure:

The Divestment Business consists of the entire worldwide *Stellarex* DCB business (currently owned by Covidien) that is related primarily to the research, development, manufacture, marketing, sale or distribution of *Stellarex* DCBs and a license to the Purchaser under certain PTA intellectual property currently owned by Covidien to operate that *Stellarex* DCB business, including (i) to make, have made, use, offer to sell, sell, import, and export any *Stellarex* DCBs and (ii) the research, development, and manufacture of PTA Products for the incorporation into *Stellarex* DCBs.

2 In accordance with paragraph 5 of these Commitments, the Divestment Business includes, but is not limited to:

(a) the following main tangible assets:

- The lease of the facility located in Fremont (California);
- All manufacturing equipment primarily used or held for use in manufacturing *Stellarex* DCBs, including relevant *Stellarex* DCB manufacturing equipment located at the Plymouth (Minnesota) facility;
- 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 and packaging of *Stellarex* DCBs

(b) the following main intangible assets:

The Divestment Business includes the assignment of the following intellectual property owned by Covidien as of the Closing date:

- U.S. and foreign patents and patent applications in each case filed, or in existence, on or before Closing and covered under the patent families listed in Annex 1, and any renewal, derivation, divisions, reissues, continuation, continuations in-part, modifications, or extensions thereof;
- 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 other than patents or patent applications, to the extent primarily related to the *Stellarex* DCB business (see Annex 5 for the list of trademark applications);

Medtronic will not be permitted to use any of know-how, schematics, trademarks, trade secrets, or copyrights included in the transferred intellectual property in the production or sale of its own drug coated balloons or in any other Medtronic product.

(c) the following main license, permits and authorizations:

- Royalty-free, fully paid-up, perpetual, irrevocable, worldwide, non-exclusive license to the Purchaser under certain PTA intellectual property currently owned by Covidien, *i.e.*, (x) U.S. and foreign patents and patent applications in each case filed, or in existence, on or before the Closing and covered under the patent families listed in Annex 3 and (y) copyrights, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, development and other information (other than patents or patent applications) to the extent primarily related to the research, development and manufacture of PTA Products to operate the *Stellarex* DCB business, including (i) to make, have made, use, offer to sell, sell, import, and export any *Stellarex* DCBs and (ii) the research, development, and manufacture of PTA products for the incorporation of such PTA products into *Stellarex* DCBs.

- Royalty-free, fully paid-up, perpetual, irrevocable, worldwide, non-exclusive license to the Purchaser under any background intellectual property, *i.e.* any patents, copyrights, trade secrets or other intellectual property rights owned by Covidien as of the Closing, that is used in or would otherwise be infringed by the *Stellarex* DCB business or the research, development and manufacture of PTA products for incorporation of such PTA products into *Stellarex* DCBs as of the Closing.

(d) the following main contracts, agreements, leases, commitments and understandings

- Product Supply Agreement for the supply of Covidien's *EverCross* .035 PTA balloon catheters and Covidien's *NanoCross Elite* .014 PTA balloon catheters for a period of up to [3 years ...] If the Purchaser requests an extension to the Product Supply Agreement, the Monitoring Trustee shall monitor the progress and implementation of this request and report on it to the Commission.

- The benefit to the maximum extent permissible of all contracts entered into with any third party in the ordinary course of business with suppliers (including paclitaxel suppliers and sterilizers), personal property lessors, personal property lessees, licensors, licensees, consignors, and consignees, and contracts with physicians and hospitals, to the extent primarily related to the research, development, manufacture marketing, distribution of *Stellarex* DCBs.

- 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 *Stellarex* DCBs.

- Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from, such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside Covidien's PTA balloon business.

(e) the following customer, credit and other records;

- All of Covidien's books, records and files to the extent primarily related to the research, development, manufacture, marketing, distribution, or sale of *Stellarex* DCBs and copies of all of Covidien's books, records and files to the extent primarily related to the research, development, and manufacture of PTA Products.

- All *Stellarex* DCB scientific and regulatory material, including 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 *Stellarex* DCBs.

- All R&D, scientific and regulatory material (including regulatory dossiers) concerning *Stellarex* will be transferred along with the Divestment Business.

(f) the following personnel;

The Divestment Business shall include the personnel listed in Annex 2. At the option of the Purchaser, additional personnel with experience in *Stellarex* DCBs will be made available.

(e) the following Key Personnel;

The Key Personnel are:

- […] (R&D Director);

- […] (Program Manager) and

- […] (Clinical Affairs)

3 The Divestment Business shall not include:

- For the avoidance of doubt, the Divestment Business does not include any of the assets, tangible or intangible, businesses or goodwill that relate to any product researched, developed, manufactured, marketed, sold or distributed by Covidien other than Drug-Coated Balloons or to PTA Products, other than as used in the incorporation of such PTA products into *Stellarex* DCBs.

- The Divestment Business shall not include cash or cash equivalents, equity interests in any person, tax assets, or insurance policies.

- **Annex 1 – DCB Business Patents and Patent Applications**

Patent Title	Country	Application No.	Filed Date	Patent No.	Issue Date
[…]	Australia	[…]	[…]	[…]	[…]
[…]	Australia	[…]	[…]		
[…]	Australia	[…]	[…]	[…]	[…]
[…]	Canada	[…]	[…]		
[…]	Canada	[…]	[…]		
[…]	China	[…]	[…]	[…]	[…]
[…]	China	[…]	[…]		
[…]	European Patent	[…]	[…]		
[…]	European Patent	[…]	[…]		
[…]	Hong Kong	[…]	[…]	[…]	[…]
[…]	Hong Kong	[…]	[…]		
[…]	Japan	[…]	[…]		
[…]	Japan	[…]	[…]		
[…]	Japan	[…]	[…]		
[…]	New Zealand	[…]	[…]	[…]	[…]

Patent Title	Country	Application No.	Filed Date	Patent No.	Issue Date
[…]	New Zealand	[…]	[…]		
[…]	Patent Cooperation Treaty	[…]	[…]		
[…]	Patent Cooperation Treaty	[…]	[…]		
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of America	[…]	[…]		
[…]	United States of America	[…]	[…]		
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of	[…]	[…]	[…]	[…]

Patent Title	Country	Application No.	Filed Date	Patent No.	Issue Date
	America				
[…]	United States of America	[…]	[…]		
[…]	United States of America	[…]	[…]		
[…]	United States of America	[…]	[…]		
[…]	United States of America	[…]	[…]		
[…]	Patent Cooperation Treaty	[…]	[…]		
[…]	United States of America	[…]	[…]		

-

Annex 2 – List of Employees

Name	Job Title
[…]	PV Group Management
[…]	Staff Dev Engineer
[…]	Euro Sr. CRA
[…]	Supv Production
[…]	Lead Assembler
[…]	Sr Dev Engineer
[…]	Production Super
[…]	Sr Dev Engineer
[…]	PV Group Management
[…]	Ops Quality Eng II
[…]	Dev Engineer I
[…]	Focus Factory Mgr II
[…]	PV Group Management
[…]	Assembler I
[…]	Euro Clin Project Mgr
[…]	Mgr Clinical Educ
[…]	Sr Dev Engineer
[…]	Assembler I
[…]	PV Group Management
[…]	Prog Mgr Clinical Affairs
[…]	Sr RA Product Spec
[…]	Sr Dir Clinical Affairs
[…]	PV Group Management
[…]	Sr Clinical Research Assoc
[…]	PV Group Management
[…]	Supv Quality Testing
[…]	Euro Clin Field Specialist
[…]	Quality Tech II
[…]	Mgr Clinical Educ
[…]	Mgr Clinical Affairs
[…]	Document Coord I
[…]	Euro Lead CRA
[…]	PV Group Management
[…]	Staff Dev Scientist
[…]	Ops Quality Engineer I
[…]	Proj Mgr Clinical
[…]	Prin Ops Quality Engineer
[…]	Staff Dev Engineer
[…]	Assembler I
[…]	Sr Analytical Chemist
[…]	Chemist I

Name	Job Title
[…]	Proj Mgr Clinical
[…]	Dev Engineer I
[…]	Mgr Clinical Educ
[…]	Dev Eng Tech III
[…]	Analytical Chemist Fellow
[…]	PV Group Management
[…]	Dev Engineer II
[…]	Clinical Research Assoc II
[…]	Clinical Research Coord III
[…]	PV Group Management
[…]	Dev Engineer II
[…]	Quality Tech IV
[…]	Clinical Research Coord III
[…]	Dir Proj Eng
[…]	Chemical Process Tech IV
[…]	Mgr Clinical Research
[…]	Assoc Product Mgr
[…]	Mgr Dev Eng
[…]	Sr Dev Engineer
[…]	Quality Tech IV
[…]	Sr Proj Mgr Prod Dev
[…]	Mgr Proj Eng
[…]	Euro Sr. Clin Tech Field Specialist
[…]	PV Group Management
[…]	Dev Engineer II
[…]	Admin Coord IV
[…]	Sr Clinical Research Assoc
[…]	Dir Ops Quality / Fremont Site Leader
[…]	Mgr Clinical Educ
[…]	Sr Dev Engineer
[…]	Doc Spec II
[…]	PV Group Management
[…]	Euro Sr. Clin Field Specialist
[…]	Prin Dev Engineer
[…]	PV Group Management
[…]	QC Inspector Tech II

Name	Job Title
[…]	Ops Quality Eng II
[…]	Prin Dev Engineer
[…]	Assembler I
[…]	Sr Clinical Research Coord
[…]	AUS/NZ Sr. Clin Field Spe
[…]	PV Group Management
[…]	Assoc Product Mgr
[…]	QC Inspector Tech III
[…]	Sr Ops Quality Eng
[…]	Sr Dev Engineer
[…]	PV Group Management
[…]	Sr Dev Engineer
[…]	Euro Clin Program Mgr
[…]	Euro Clin Field Specialist
[…]	Sr Chemist
[…]	PV Group Management
[…]	Dev Engineer I
[…]	Mgr Clinical Educ
[…]	PV Group Management
[…]	PV Group Management
[…]	RA Ops Spec
[…]	Sr Product Mgr
[…]	Prin Dev Engineer

Annex 3 – PTA License Patents and Patent Applications

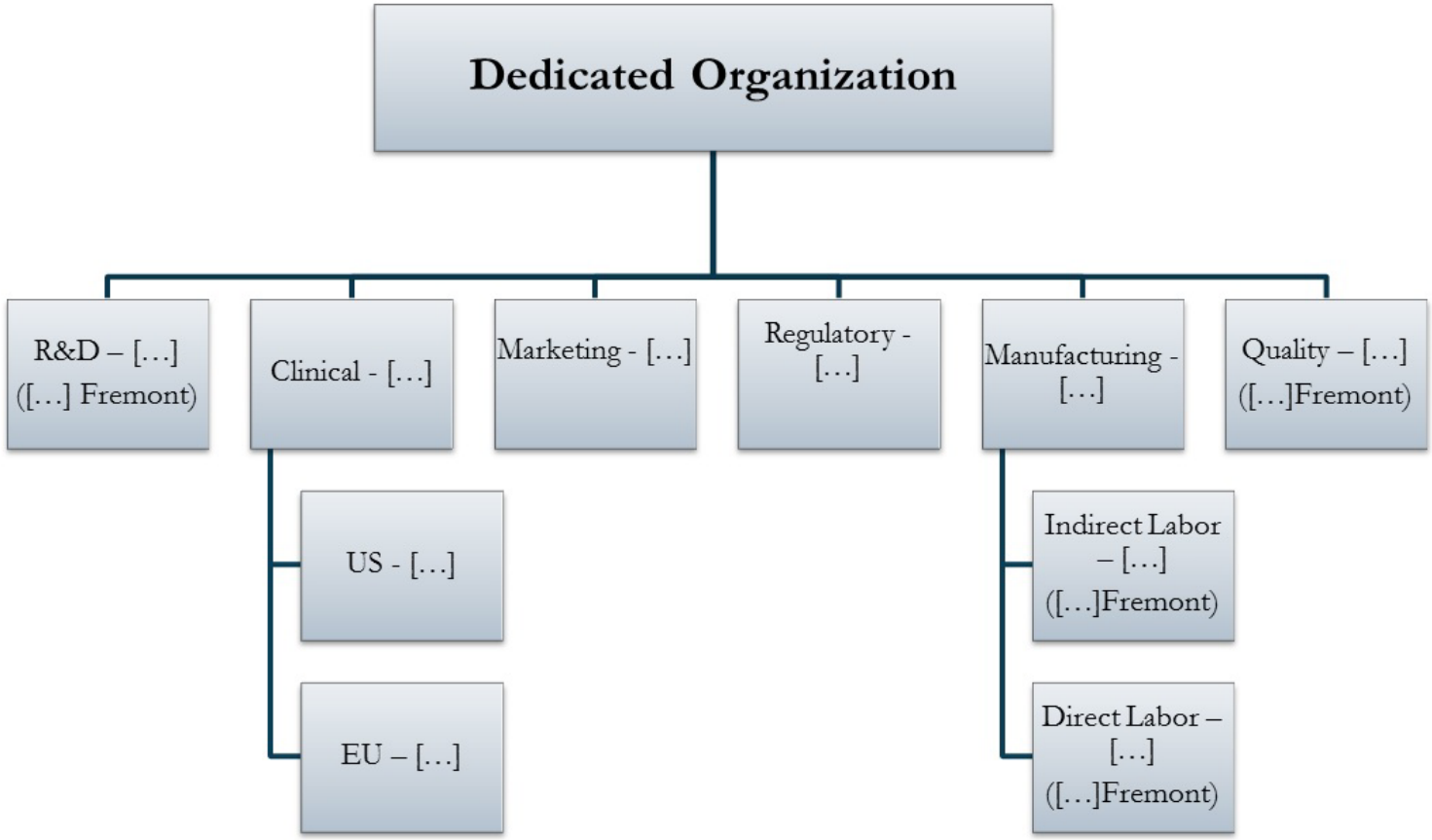
Patent Title	Country/Jurisdiction	Application No.	Filed Date	Patent No.	Issue Date
[…]	United States of America	[…]	[…]		
[…]	Patent Cooperation Treaty	[…]	[…]		
[…]	European Patent	[…]	[…]		
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	France	[…]	[…]		
[…]	Germany	[…]	[…]		
[…]	Ireland	[…]	[…]		
[…]	Italy	[…]	[…]		
[…]	Netherlands	[…]	[…]		
[…]	Spain	[…]	[…]		
[…]	United Kingdom	[…]	[…]		
[…]	United States of America	[…]	[…]	[…]	[…]
[…]	United States of America	[…]	[…]		

Annex 4: Stellarex Organizational Chart

This Annex contains Stellarex Organizational Chart.

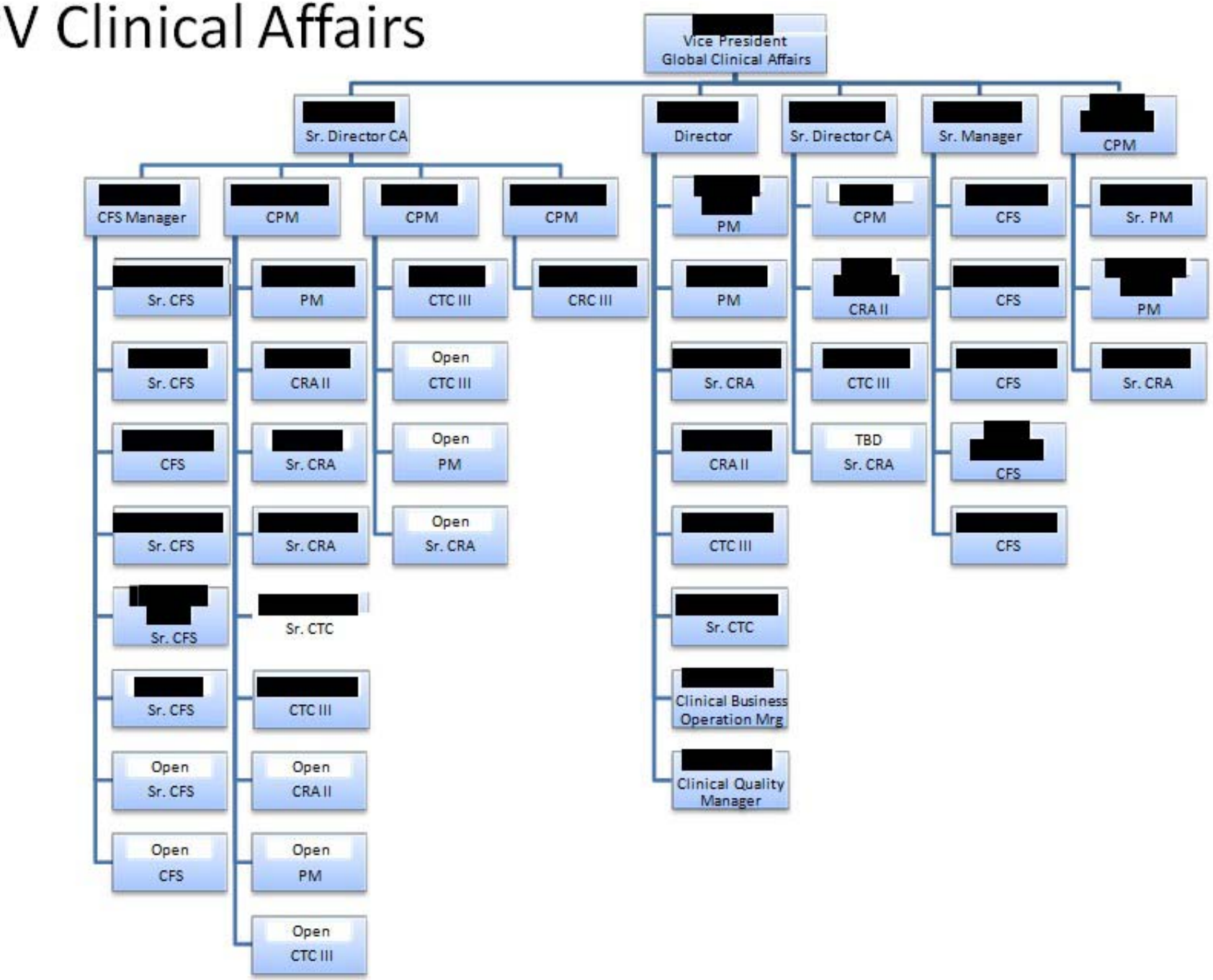
ORGANIZATIONAL CHART

Global Organization – Dedicated Employees



Notes: As of 07/17/14. Currently looking to add 6 temporary assemblers to increase capacity to support launch; other Covidien personnel provide support but are not 100% dedicated (for example, VP of Regulatory will provide support but he works across all Peripheral Vascular projects); Covidien uses 3 part time consultants to provide accounting, safety and IT support

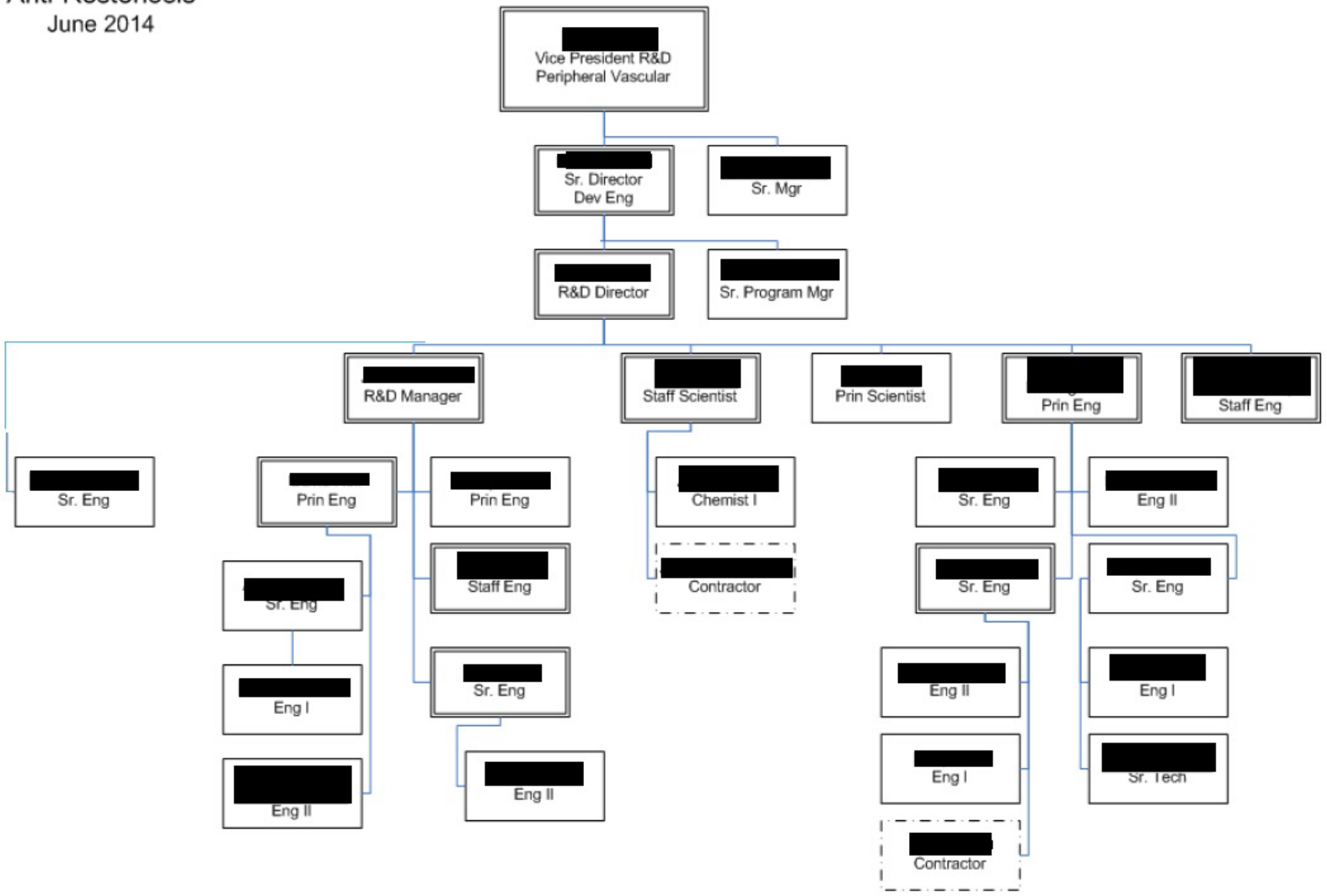
PV Clinical Affairs



Peripheral Vascular R&D

Anti-Restenosis

June 2014



COVIDIEN

Annex 5 - Trademark Applications

Mark	Country	Class Description	Application No.	Filed Date
ENDURACOAT	U.S.A.	5 – Pharmaceutical preparations used for the treatment of cardiovascular disease; Pharmaceutical preparations in the nature of surgical coatings used to treat blockage in blood vessels and arteries; Drug delivery agents in the form of surgical coatings used to treat blockage in blood vessels and arteries 10 – Surgical instruments and apparatus; medical apparatus and instruments for use in treating cardiovascular disease; drug coated angioplasty balloons; drug coated angioplasty balloon system, namely, surgical and medical apparatus and instruments for use in angioplasty surgery; surgical balloons for use in angioplasty surgery	[…]	[…]
ENDURACOAT	European Community	5 - Pharmaceutical preparations used for the treatment of cardiovascular disease; Pharmaceutical preparations in the nature of surgical coatings used to treat blockage in blood vessels and arteries; Drug delivery agents in the form of surgical coatings used to treat blockage in blood vessels and arteries, 10 - Surgical instruments and apparatus; medical apparatus and instruments for use in treating cardiovascular disease; drug coated angioplasty balloons; drug coated angioplasty balloon system, namely, surgical and medical apparatus and instruments for use in angioplasty surgery; surgical	[…]	[…]

		balloons for use in angioplasty surgery		
STELLAREX	U.S.A.	10 – Drug coated angioplasty balloon and drug coated angioplasty balloon system, namely, surgical and medical apparatus and instruments for use in angioplasty surgery	[…]	[…]
Mark	**Country**	**Class Description**	**Application No.**	**Filed Date**
STELLAREX	European Community	10 – Drug coated angioplasty balloon and drug coated angioplasty balloon system, namely, surgical and medical apparatus and instruments for use in angioplasty surgery	[…]	[…]