Case No COMP/M.4150 - ABBOTT / GUIDANT

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REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(2) NON-OPPOSITION Date: 11/04/2006

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COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 11/04/2006

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 ARTICLE 6(1)b and 6(2) DECISION

To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.4150-Abbott/Guidant

Notification of 23.02.2006 pursuant to Article 4 of Council Regulation

No 139/2004¹

- 1. On 23.02.2006, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Abbott acquires within the meaning of Article 3(1)(b) of the Council Regulation control of Guidant's interventional cardiology and endovascular devices businesses.
- 2. In the course of the proceedings, the notifying party submitted undertakings designed to eliminate competition concerns identified by the Commission, in accordance with Article 6(2) of the Merger Regulation. In the light of these modifications, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

I. THE PARTIES

- 3. Abbott is a broad-based health care company for the supply of pharmaceutical products and medical devices, with €16 billion in revenues in its fiscal year 2004. Abbott develops, manufactures and sells devices used in the interventional cardiology and the endovascular area.
- 4. Guidant is a company incorporated in the USA that is active in the design and development of cardiovascular medical products. Guidant was founded in 1994 from a spin-off from the pharmaceutical company Eli Lilly. Guidant's presence covers four main areas within the fast-growing cardiovascular medical products business: cardiac

¹ OJ L 24, 29.1.2004 p. 1.

rhythm management, interventional cardiology, endovascular devices and cardiac surgery.

II. THE OPERATION

- 5. On 8 January 2006, Abbott entered into a Transaction Agreement, then amended on January 16, 2006, with Boston Scientific, according to which Abbott would acquire all assets, rights and stock related to Guidant's vascular intervention and endovascular businesses.
- 6. As part of this latter transaction, Abbott and Boston Scientific would share the rights to Guidant's Xience V drug eluting stent ("DES") portfolio, as described more in detail below.
- 7. Pursuant to Section 5.08 of the Transaction Agreement, Abbott would grant Boston Scientific a perpetual, exclusive (except for Abbott and its affiliates), royalty-free licence (with no right to sublicense except for "have made" rights but solely on behalf of Boston Scientific and its affiliates) to Guidant's DES intellectual property, including the bare metal and bioabsorbable stents, delivery system, drugs and polymers. This grant includes all intellectual property that is available to Guidant and used in its DES programme, insofar as it has a priority date prior to, or otherwise is existing as of, the date of closing of the Transaction Agreement. The licence would not be limited to the DES area, since intellectual property related to DES may be also used in other medical devices in interventional cardiology (e.g. bare metal stents) or in endovascular devices (e.g. peripheral stents). However, the licence would not extend to improvements that Abbott may make to the Guidant technology post-acquisition.
- 8. Additionally, Boston Scientific would grant Abbott a covenant not to sue Abbott for any infringement or violation of Boston Scientific's intellectual property rights by any Guidant's product manufactured or in a late development stage at the time of closing. The covenant not to sue extends to improvements and iterations of such products, but does not cover changes to such products.
- 9. Pursuant to Section 5.07 of the Transaction Agreement, Abbott would, during an interim period, supply Boston Scientific with the existing Xience V stent. The supply agreement would remain in place in Europe until the latter of these two dates: i) 31 December 2010; ii) one year following the date on which Boston Scientific has received CE Mark for an everolimus eluting stent on a Boston Scientific stent platform. However, the supply agreement would in any event terminate on 30 June 2012.
- 10. The transfer price paid by Boston Scientific to Abbott for each DES supplied by Abbott would be equal to Abbott's cost of manufacturing such stent, as reported by Abbott to Boston Scientific, plus a manufacturing margin equal to 40% of the result obtained by subtracting from the average selling price for DES sold by Boston Scientific the sum of third party royalties payable by Boston Scientific with respect to DES sold, a 7% of the averaging selling price, representing Boston Scientific variable selling costs for the stents and Abbott's manufacturing cost proxy. For an average selling price of less than \$400, the transfer price would be equal to 125% of Abbott's manufacturing cost.
- 11. Finally, as part of the Transaction Agreement, Abbott would correspond \$3,8 billion (€3.14 billion) in cash to Boston Scientific. Additionally, it would provide to Boston Scientific a subordinated loan of \$900 million and would purchase approximately \$1.4

- million of Boston Scientific common stock, representing a minority shareholding of approximately 4% of the company.
- 12. The above Agreement was subject to the bid by Boston Scientific over the whole of Guidant being successful. On 25 January 2006, Boston Scientific and Guidant entered into a definitive Agreement and Plan of Merger pursuant to which Boston Scientific agreed to acquire all the outstanding shares of Guidant for a combination of cash and stock worth \$80 per Guidant share, or \$27 billion in the aggregate. As a result of this agreement Boston Scientific would acquire control, within the meaning of the EC Merger Regulation, over Guidant's activities other than the interventional cardiology and endovascular businesses, comprising its cardiac rhythm management and cardiac surgery businesses. The latter transaction has been separately assessed by the Commission in case M.4076, Boston Scientific/Guidant.

III. CONCENTRATION

13. Following the transaction, Abbott will acquire sole control over Guidant's vascular activities. The transaction constitutes a concentration within the meaning of Article 3 (1)(b) of the Merger Regulation.

IV. COMMUNITY DIMENSION

14. The combined aggregate worldwide turnover of the undertakings concerned exceeds EURO 2,500 million² (in 2004 Abbott €16.66 billion, Guidant €1,1 billion). The aggregate Community-wide turnover of each party exceeds EURO 100 million (in 2004 Abbott €[3-4]billion, Guidant €[200-300] million). In each of at least three Member States, [...], each of the parties has a turnover in excess of EURO 25 million, and in each of those Member States the parties' combined aggregate turnover exceeds EURO 100 million. The undertakings concerned do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

V. RELEVANT PRODUCT MARKET

15. The transaction involves two main areas within the cardiovascular medical products business: i) interventional cardiology devices; ii) endovascular devices. In each of these areas, a number of product markets are concerned.

A. INTERVENTIONAL CARDIOLOGY DEVICES

16. Interventional cardiology is used in the treatment of Coronary Artery Disease ("CAD"): a reduction of the blood flow to the heart muscle due to the gradual build-up of cholesterol against the coronary artery walls. Interventional cardiology involves minimally invasive treatment procedures. The 'core' of the interventional cardiologist's kit is constituted by the stents, expandable wire tubes which are placed in an occluded coronary artery in order to remove the plaque and support the walls of the vessel.

17. In line with Case M.3687, Johnson & Johnson/Guidant, Abbott submits that the following markets are affected in the interventional cardiology devices area: Guiding

Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C 66, 2.3.1998, p 25).

Catheters; Steerable Guidewires ("SGW"), PTCA (meaning Percutaneous Transluminal Coronary Angioplasty) balloon catheters, Bare Metal Stents ("BMS"), and Drug-Eluting Stents ("DES"). These products are described below.

- 1. Coronary Bare Metal Stents (BMS) and Drug Eluting Stents (DES)
- 18. A stent is a small expandable wire tube that is used to support the walls of the coronary artery following an angioplasty procedure. The stent is usually premounted on the balloon so that when the balloon is inflated the stent expands to fit the inner wall of the vessel. The parties submit that two separate product markets for stents exist: BMS and DES. DES are a recent³ evolution of BMS, whereby a drug and a drug-releasing mechanism is added to the basic expandable wire tube. The main advantage of DES over BMS is that it reduces restenosis (excessive cell growth within and near the stented area, probably as a response to the trauma caused by the inflation of the balloon) through the gradual release of the drug. This, in turn, reduces the likelihood that a repeat intervention will be necessary to re-widen the area for blood flow.
- 19. As regards Drug Eluting Stents (DES), the market investigation has confirmed the conclusion in the Johnson & Johnson/Guidant case that DES form a relevant product market, which is separated from the market for Bare Metal Stents (BMS). Indeed, there is no significant price correlation between the two, no supply side substitutability, very significant differences in clinical outcomes, different reimbursement systems in virtually all European countries. Moreover, despite the fact that BMS and DES share the same stent structure and delivery system, a number of crucial components are specifically important to a coronary DES (the drug, drug dosage and rate of release, polymer coatings).

2. The accessories

a. Coronary Guiding Catheters

- 20. A guiding catheter is a long, hollow tube manufactured from a polymer blend that is inserted into the radial or femoral artery and is advanced to the origin of the coronary arteries. Its purpose is to allow the other devices (including SGW, PTCA balloon catheters and stents) to reach the site of the lesion in the coronary artery.
- 21. In line with Johnson & Johnson/Guidant, Abbott submits that all guiding catheters used for IC purposes, regardless of their shape, dimension, length, should be considered to belong to the same relevant market due to supply side reasons. Conversely, coronary guiding catheters would be in different product markets than endovascular guiding catheters. In the market investigation no new evidence has been brought to the Commission's attention pointing to a different conclusion.

b. Coronary Steerable Guidewires

22. A SGW is a very thin and flexible wire which is advanced though the guiding catheter beyond the narrowed area of the artery which requires dilatation. In line with Johnson & Johnson /Guidant, Abbott submits that all coronary SGWs should be included in the same relevant market taking into consideration the high degree of supply side substitutability. In the market investigation no new evidence has been brought to the Commission's attention pointing to a different conclusion.

The first DES, J&J's Cypher, was marketed in Europe in 2002 and in the USA in 2003.

c. Coronary PTCA Balloon Catheters

- 23. A PTCA balloon catheter is a long, flexible, hollow tube with a balloon at the end. It is inserted in the guiding catheter and is advanced to the occluded vessel using the steerable guidewire as a lead. Once the lesion site has been reached, the balloon is inflated a number of times to compress the plaque against the arterial wall, widening the area for blood flow. This procedure is called angioplasty and does not involve the placement of a stent.
- 24. In line with Johnson&Johnson/Guidant, Abbott submits that all PTCA balloon catheters should be included in the same relevant market taking into consideration the high degree of supply side substitutability. In the market investigation no new evidence has been brought to the Commission's attention pointing to a different conclusion.

B. ENDOVASCULAR DEVICES

- 25. As described in the Johnson & Johnson / Guidant case, Endovascular devices are used for the minimally invasive treatment of peripheral vascular (or endovascular) diseases.
- 26. The parties submit that the following markets are affected in the endovascular devices area: Balloon Expandable Stents ("BX"), Endovascular Guiding Catheters, Steerable Guidewires ("SGW"), PTA (meaning Percutaneous Transluminal Angioplasty) balloon catheters, Self-Expandable non-Carotid Stents ("non-Carotid SX"), Self-Expandable Carotid Stents ("Carotid SX") and Embolic Protection Devices ("EPD"). The products are described below.

1. Endovascular Stents

- 27. In the Johnson&Johnson/Guidant case three different product markets were delineated namely Balloon Expandable Stents ("BX"), Self-Expandable non-Carotid Stents ("non-Carotid SX") and Self-Expandable Carotid Stents ("Carotid SX").
- 28. A combination of several factors lead to distinguish between BX and SX stents. First, the degree of substitutability between the two kinds of stents is very limited, indeed they are used predominantly for different applications. Secondly, SX stents are considerably more expensive than BX stents. Finally, there is very limited supply side substitutability between BX and SX stents: they have different design, they are made of different materials, they use different deployment techniques and they require different manufacturing processes.
- 29. Moreover, due to the fact that there is neither demand-side nor supply-side substitutability between carotid and other endovascular stents, a separate market for carotid stents should be defined within the SX stents.
- 30. The parties endorsed the previous findings of the Commission.
- 31. In the current investigation no elements have been brought to the Commission's attention pointing to different conclusions. Based on these elements, the Commission concludes that a relevant product market should be defined for Balloon Expandable Stents ("BX"), Self-Expandable non-Carotid Stents ("non-Carotid SX") and Self-Expandable Carotid Stents ("Carotid SX").

2. The accessories

- 32. Endovascular Guiding Catheters, SGW and PTA balloon catheters are, all of three, sold in different sizes and dimensions. However, due to the high degree of supply side substitutability, a relevant market should be defined for each of these accessories. This conclusion was reached in the Johnson&Johnson/Guidant case and confirmed by the parties in the present case.
- 33. Moreover, in line with the findings from the former decision, the endovascular guiding catheters, SGWs and PTA balloon catheters are in distinct markets from the coronary corresponding products.
- 34. In the current investigation no elements have been brought to the Commission's attention pointing to different conclusions. Based on these elements, the Commission concludes that a relevant product market should be defined for (i) guiding catheters, (ii) SGWs, (iii) PTA balloon catheters.
 - 3. Embolic Protection Devices
- 35. EPDs are small umbrella-type devices that are mounted on a catheter and placed beyond the lesion with the aim of trapping any material or debris dislodged during the angioplasty procedure. EPDs are used predominantly (but not exclusively) in carotid stenting procedures, where the risk of damage to the brain from loose material is highest.

In the current investigation no elements have been brought to the Commission's attention pointing to different conclusion than the Johnson&Johnson/Guidant decision. Based on these elements, the Commission concludes that a relevant product market should be defined for EPD.

VI. RELEVANT GEOGRAPHIC MARKET

- 36. Abbott takes the view that the relevant geographic market for all the products described above is increasingly EEA-wide in scope since there are no significant regulatory barriers to marketing products across EEA countries; production and distribution is organized on a European-wide basis (for several products production is even centralized on a worldwide basis); there are no significant transport costs.
- 37. In *J&J/Guidant* the Commission found that the relevant geographic market for medical devices, including CRM devices, is national. The Commission came to this conclusion essentially because of differences in reimbursement schemes, procurement processes, prices and market shares across countries in the EEA, as well as the fact that most customers allegedly consider a local sales office a necessity and do not source from abroad. No new evidence has been brought to the attention of the Commission, either from Abbott, or from the market investigation, pointing to a different conclusion.

VII. COMPETITIVE ASSESSMENT

A. INTERVENTIONAL CARDIOLOGY DEVICES

38. Interventional cardiology is a fast growing and innovation driven business. The first coronary stent was implanted in a human being in 1987. Following the development of

new techniques and devices, interventional cardiology has become a very effective alternative to open heart surgery for the treatment Coronary Artery Diseases.

- 39. The first drug-eluting stent was put on the market in Europe in 2002 by Johnson & Johnson. Since then, the DES market has experienced a spectacular growth in the United States, where DES have all but replaced Bare Metal Stents in coronary interventions. In Europe penetration of DES has been somehow slower: according to a recent medical survey⁴, in the third quarter of 2005, DES accounted for 56% of all coronary stents used in the European Union. Their share is estimated to grow to more than 75% by 2008. DES sales in Europe were estimated at just under € 1 billion in 2005 and are expected to continue to grow significantly over the next five years, with a compound annual growth rate of around 10%.⁵
- 40. In J&J/Guidant the investigation revealed that the interventional cardiology devices are differentiated products, where quality of performance and innovation are key parameters. This feature is perhaps less accentuated for some of the accessories.
- 41. The interventional cardiology field is characterised by significant barriers to entry. Firstly, it is a highly innovative area with rapidly evolving products, which requires important investments in R&D. Secondly, the major medical devices suppliers hold numerous patents on the essential features of these products. A new entrant, especially if targeting the US market, would have to face litigation risk or enter into licensing agreements with existing suppliers. This aspect, however, as it will be explained further below, is much more predominant in the US than in Europe. Thirdly, the launch of a new innovative product entails very long and costly clinical trials to demonstrate their safety and efficacy. Fourthly, established suppliers are very well known by the customers and have dedicated and technically prepared sales forces. Additionally, they have close relationships with key opinion leaders in the medical profession. Finally, all major suppliers offer a wide range of products in interventional cardiology.
- 42. The demand is constituted by hospitals or hospital groups, national healthcare procurement organisations or joint procurement entities. They generally resort to tendering procedures for the procurement of supplies, although informal negotiations and package deals are also a recurring feature of the market. The scope of the tender is typically limited to specific cardiovascular products or covers a range of cardiovascular products. Hospitals typically multi-source in order to avoid dependence on one supplier.
- 43. As to the competitive landscape, the investigation revealed the existence of two leagues of players. In the top tier, there were large global companies competing on a worldwide level, that can count on the following: i) Top quality devices, primarily the stents; ii) Strong relationships with customers, good reputation and support by key opinion leaders; iii) vast financial capabilities to finance massive R&D programmes; iv) wide geographic reach, that is, a strong and widespread presence in the three most lucrative markets, the US, Japan and Europe; iv) a strong patent portfolio, especially for the purpose of gaining access to the US market and to a lesser extent to Europe; v) broad product range.

Source: Citigroup, "Medical Supplies & Technology – 05/06 DES Outlook – Adding the cards to the mix", 27 September 2005, p. 37.

Source: MEDACorp survey, "Trends In E.U. Stent Utilization", January 2006, reported in "Cardiovascular Industry – EU stent survey", Leerink Swann & Company, 20 January 2006, p. 2.

- 44. The investigation also showed that only J&J, Guidant, Medtronic and Boston Scientific should be considered to belong to the top tier, while Abbott, a big pharmaceutical company was entering the market with the ambition to become a key player in vascular devices.
- 45. The feed back received in the context of the current investigation has confirmed the findings of the previous case.

The market for DES

- 46. The competitive landscape of the interventional cardiology arena and of the DES markets in particular has been extensively analysed in case M.3687, Johnson & Johnson / Guidant. In that investigation, with respect to Guidant's prospect of success, the Commission concluded that "[...] the concentration results in the elimination of one of the strongest new entrants in the market for DES, which, absent the merger, would have acted as a major competitive constraint in such a market. However, the investigation shows as well that the other new entrants, primarily Medtronic and Abbott, and to a lesser extent Sorin and Conor/Biotronik are likely to compensate for the loss of competition resulting from Guidant's exit from the marketplace due to the merger and exert a sufficiently significant competitive constraint in Europe. Based on the above, it is reasonably expected that the concentration will not significantly impede effective competition in the Common market and the EEA for DES." 6
- 47. The current investigation has confirmed the conclusions of the previous analysis, while revealing the importance of events in the DES market that have occurred after the conclusion of the Johnson & Johnson / Guidant investigation and that may have an impact on the assessment of the current transaction.
- 48. First, and most important, Guidant has confirmed to represent a very strong new entrant in the market for DES. On 30 January 2006, Guidant received CE Mark approval for its XIENCE V DES. The XIENCE V utilizes Guidant's cobalt chromium stent platform in conjunction with the Everolimus drug and Guidant's rapid-exchange delivery system. All these components are judged as excellent by market analysts, who consider Guidant's DES a potential best in class product. Guidant could launch its stent on the European markets within the second quarter of 2006. The fact that Guidant interventional cardiology assets will post merger (i.e. following Boston Scientific's acquisition of Guidant and the execution of the Transaction Agreement) be owned by Abbott —which does not sell yet a DES-, means that there is a very high probability that Guidant's DES will be released on the market at the earliest possible date. At the same time, Abbott confirmed that its Zomaxx DES stent will enter [...] in the European markets, probably in [...].
- 49. Second, Medtronic's Endeavour DES has entered the European markets in August 2005 and has had a good initial success, supported by good safety clinical data and very good stent platform, which is considered to offer superior deliverability than Johnson & Johnson's and Boston Scientific's by most medical analysts. However, according to clinical data released in October 2005, Medtronic's endeavour DES missed the primary endpoint of a pivotal clinical trial to obtain approval for marketing its DES stent in the USA. This negative clinical result delayed its US launch by several months. It is not yet

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⁶ See case M. 3786 Johnson & Johnson / Guidant, point 165.

clear what the full impact of this event will be on Medtronic Endeavour's European competitive position. On the one hand, not all interventional cardiologists and analysts consider the parameter that Endeavour failed to achieve as important for the success of a DES; on the other hand, it is possible that the failed clinical trial and the delay in the US launch will dent the reputation of Endeavour in the medical community.

- 50. Third, the outlook for other potential entrants in the DES arena remained substantially in line with the analysis carried out by the Commission in the Johnson & Johnson / Guidant case. In particular, Conor Medsystems received CE Mark for its CoStar DES in February 2006 (slightly later than initially foreseen) and has started marketing the product in partnership with Biosensors of Germany.
- 51. In sum, there have been confirmations of the competitive dynamics in the European DES markets. Post-merger, Abbott will become a strong competitor in the DES arena thanks to Guidant's assets and its Xience V DES, potentially at a level comparable to Johnson & Johnson and Boston Scientific, with Medtronic in a slightly weaker position within the league of major players.
- 52. Against this background, the provisions in the Transaction Agreement relating to the sharing of the Guidant's Xience V DES portfolio and to the supply agreement for the same product between Abbott and Boston should also be considered for the purpose of the assessment of the present transaction.
- 53. The interim arrangements put in place by Abbott and Boston, together with the other links being created as a result of the transaction, including the minority stake that Abbott will own over Boston, can lessen Abbott and Boston incentives to act independently and to compete with each other post merger in the DES market, with spill-over negative implications on competition in the entire market-place for the following reasons.
- 54. Firstly, the sharing between Abbott and Boston of Guidant IP rights and technology in the DES, including its everolimus drug and its renowned stent platform, will enable both Boston and Abbott to have exclusive access to best in class technology which could be developed and improved by each of them separately. While such a sharing of intellectual property rights can have beneficial effects for competition, allowing the beneficiary companies to foster innovation by developing new, improved products, the exclusivity clause implies that Abbott will not be able to licence the intellectual property rights acquired with Guidant's DES program to any other company. This restricts the pool of possible beneficiaries of such body of knowledge to the sole Boston Scientific. Some market players have indicated that the exclusivity clause can have the effect of preventing the cost of entry or expansion of other companies into the markets where such patents are required for the successful development of new products. On this aspect, the market investigation has provided mixed results. While exclusive access to IP rights essential for the purpose of the development of DES can be regarded as a significant barrier to entry, tangible risks of foreclosure remain limited to exceptional circumstances in Europe. As regards in particular the drugs employed in DES, in line with the findings in Johnson&Johnson/Guidant, it appears from the current investigation that a non insignificant number of suppliers have secured access either to Rapamycin analogues belonging to the same family as Everolimus (Sirolimus is being developed by Johnson&Johnson, Biolimus, A9 is being developed by Biosensors and Terumo, ABT-578 is owned by Abbott and licensed to Medtronic, Tacrolimus is being developed by

Sorin, Pimecrolimus is being developed by Conor) or to Paclitaxel (such as Conor and Boston).

- 55. As regards the supply agreement, according to the Transaction agreement Boston Scientific would obtain the right to be supplied Guidant's Xience V stents by Abbott. Such stents would then be marketed independently by Boston Scientific under its brand, while Abbott will market the same product under Guidant brand. Moreover, should Boston, before the expiry of the supply agreement, set up its own manufacturing facilities and produce on its own a Guidant copy-cat DES (the Xience V), it is nonetheless due to pay Abbott the same 40% "profit margin".
- 56. The rationale for the supply agreement is to allow Boston Scientific to supply its customers with a product widely believed to be very promising for a period of time necessary to develop its own *Everolimus* stent benefiting from access to Guidant's DES intellectual property portfolio. However, there are two aspects of the supply agreement that can significantly reduce the incentive for Boston Scientific and Abbott to compete in the DES area.
- 57. To begin with, the remuneration mechanism of the Xience V stents supplied by Abbott to Boston Scientific foresees for the two companies to share internal information on both Abbott's manufacturing costs for the Xience V stent and on Boston Scientific's sales and price data for the same stent. Therefore, this pricing formula, on top of inducing price transparency on the market through exchange of commercially sensitive information, may create for Abbott an incentive to take Boston's profits in the sale of Guidant DES into account when deciding upon its own pricing strategy.
- 58. Moreover, the supply agreement, because of its extensive duration (at least until December 2010 and extending potentially up to June 2012), create a long lasting organic link between Boston Scientific and Abbott in the DES area through the remuneration mechanism, by which Abbott will obtain a share of Boston Scientific's profits for the sale of Xience V DES.
- 59. Additionally, the long duration of the supply agreement coupled with the obligation for Boston to keep sharing with Abbott any profit it makes with respect to sales of Xience V, even in the event Boston manufactures on its own such stents, would "force" Boston to remain dependent upon Abbott supplies of Guidant Xience V DES.
- 60. Finally, the minority interest that Abbott will acquire in Boston Scientific, although it is limited to around 4% and will not give Abbott control under the meaning of the EC Merger Regulation, may contribute to distort Abbott's incentives in competing with Boston Scientific to the extent it creates an incentive in Abbott to care about Boston's profits.
- 61. It is a well established principle under mainstream antitrust economics that the existence of links between two competing undertakings in the form of interest stakes of one in the other, or other commercial ties giving rise to form of profit sharing, may change their incentives to compete. First, such links create a strong financial interest of one firm in its

10

With the only difference that Boston's manufacturing costs, and not Abbott's, will enter in the transfer price formula.

competitor's welfare. This can alter the dynamics of the competitive game as one firm is less interested in competing against the other than in finding a common commercial strategy profitable for both. In addition, such links can secure access to commercially sensitive information. This in turn renders the competitive conduct of each undertaking vis-à-vis the other more transparent and thus susceptible to be easily anticipated and monitored. Also, these links may put one undertaking in a position that enables it to influence the strategic choices of its competitor towards decisions in line with the common interest. All these factors may push the undertakings concerned towards a convergence of their commercial policies. It should be noted that the conduct described above is for each of the undertakings concerned absolutely rational as they are based on a profit maximising perspective.

- 62. In the light of the above, the first adverse effect on competition stemming from the cumulative effects of the above arrangements is that Boston and Abbott's commercial decisions as regards the sale of Xience V will likely converge. The price transparency and the profit sharing mechanism induced by the pricing formula being retained by the parties in the framework of the supply agreement, together with the long lasting organic links being established as a result of the long duration of the agreement and the minority stake are such that intra-brand competition on the Xience V between Boston and Abbott is very unlikely.
- 63. Moreover, the coordination concerning the Guidant products may well cause spill-over effects to Boston's and Abbott's respective and separate DES. In this respect, first, as it was mentioned in J&J/Guidant, Abbott's prospect of success with its own Zomax stent is yet to be proved, thus "it would be rather speculative to predict that Abbott will play a leading role in the DES market" with Zomax. If anything, under the current scenario, additional uncertainty arises [...]. As regards then Boston, in line with what was indicated in J&J/Guidant, the current market investigation has confirmed that its leadership is being more robustly challenged in the market place, because of the outcome of the latest clinical trials indicating a slight preference for the drugs belonging to the Limus family relative to paclitaxel, the compound used by Boston Scientific. All these aspects would deserve further in-depth scrutiny.
- 64. Finally, it should be borne in mind that, despite recent entry, the markets for DES remain fairly concentrated, with only two leading established suppliers, Boston and J&J, plus two new strong entrants, Abbott (both in its own right and all the more after the acquisition of Guidant's assets) and Medtronic (in a somehow weaker position).
- 65. In the light of the above, the interim arrangements and ties put in place by the parties to the transaction may ultimately result in Abbott/Guidant and Boston not acting independently and not competing effectively in the market for DES. The possible lack of competition between two of the DES leading players would in turn entail the removal of an additional significant competitive constraint, thus causing adverse effects for competition in the market for DES. The transaction raises therefore serious doubts as to its compatibility with the common market as regards the market for DES in all the countries of the EEA.

The Intellectual Property rights

- 66. During the investigation, some competitors argued that the sharing of Guidant's intellectual property rights in the DES area may, in conjunction with the covenant not to sue between Boston Scientific and Abbott, cause competitive harm independently of the exclusive nature of the licensing agreement. In particular, it was argued that, on top of the arrangements relating to Guidant DES portfolio, the covenant not to sue between Boston Scientific and Abbott/Guidant would be tantamount to a general, "across the board" cross-licensing covering the whole of their IP rights. The pooling of a very consistent body of intellectual property rights primarily in the US, and to a lesser extent in the EU, would inhibit Boston Scientific and Abbott from licensing key patents to other players, possibly as part of a cross-licensing settlement and would increase their incentive to start litigation with the aim of excluding competitors' products from the market. Therefore, competitors would face an increased threat of litigation from Boston Scientific and/or Abbott which would significantly impede their European operations and, in turn, significantly reduce competition on the market.
- 67. The Commission has first scrutinised these allegations having regard to the features of the European patent landscape. The current investigation has confirmed the findings of the Johnson & Johnson / Guidant investigation, in particular as regards the lower risk that competitor face in Europe (versus the US) to be prevented in their effort to market their products in the EEA following intellectual property rights litigation. Indeed, there are significantly fewer patents granted in Europe than in the US; patent coverage of medical devices tends to be narrower; European courts tend to be less interventionist than their US counterparts and more sensitive to public interest arguments; injunctions are rarer in the EU than in the US and some EU countries offer the option of a compulsory license to an infringer; finally, patent enforcement in the EU requires country-by-country infringement actions. In the light of the above, it can be concluded that the litigation risk in Europe as regards IP rights in the field of vascular devices is by no means comparable to the US, and so far has not prevented competitors in their effort to market their products in the EEA.
- 68. The specific claims of the competitors must be assessed in this general context. Moreover, in order to argue that the transaction may give rise to competition concerns in the markets for IC devices or endovascular devices as a result of the combination of IP rights under the parties' control several conditions must be fulfilled. First, it should be proven that, alongside the sharing of Guidant's DES portfolio, the covenant not to sue allows the parties to take benefit of each other patents; second, that this exchange significantly increases the IP portfolio of the parties; third, that the patents being exchanged cover some form of key technology for the purpose of the development of cardiovascular devices; fourth, that these patents are enforceable in the EU territory; and fifth, that thanks to such blocking patents, the parties or one of them would gain significant market power which could then turn into some form of detriment to consumers.
- 69. With respect to the above, no sufficiently substantiated evidence has been brought showing that the transaction has changed the parties' incentives to license their IP rights to other vascular medical devices suppliers relative to the situation prior to the merger. The arguments put forward by the complainants remain highly speculative and often based on the possibility of European Courts granting injunctions against Boston Scientific and Abbott's competitors based on patents that have not yet been granted in Europe. Also, no account has been taken of the fact that, with the exception of Guidant DES portfolio (which however is addressed by the remedies proposed by the parties), Boston and

Guidant have already cross licensed to each other all of their key IP rights in the context of an older settlement agreement.

- 70. Moreover, and more importantly, the complainants have been unable to point to any specific IP right that the parties would exchange and that should be regarded as essential for the development of any cardiovascular devices, as well as scarcely available.
- 71. Finally, it appears that the complainants tend to equate the detriment that they may well suffer from the transaction to detriment to competition in general. In this respect, it should be stressed that no compelling evidence has been brought to the Commission's attention proving that there are serious doubts that competition may be significantly impeded as a result of the transaction.
- 72. With the exception of the doubts explained above, and taking into account the commitments offered by the parties designed to address the concerns above identified, the current investigation has shown on the contrary that all of the markets affected by the transaction in both IC and Endo will remain sufficiently competitive.

Bare metal stents

- 73. As regards the market for bare metal stents, in J&J/Guidant, the investigation revealed that in the European market a certain degree of competition is recorded and prices have been progressively declining over the last years. Besides the big four, a number of new players (Sorin, Biotronik, Terumo, B.Braun, Angiotech) have entered the market, supplying products of acceptable quality at cheaper price. New entry in the European market has been possible due to the fact patent protection of medical devices is much narrower than in the US. This has enabled the new entrants to have access to Rapid eXchange, the standard technology used by physicians for delivering the stents, as well as design around the major patents owned by the big four which protect the stent platform and design.
- 74. The feedback from the market investigation did not bring to the Commission's attention significant new evidence, except that the rate of penetration of the DES continue to increase in Europe while BMS sales keep declining to a steady pace in both value and volume (see Millennium Report, 2005, p.105).
- 75. As to the impact of the transaction, while Guidant is, together with Medtronic, one of the two leading suppliers in Europe, with a share of [30-40%] in 2004 in the EEA, Abbott has a very limited presence in Europe, with a share on average [<5%]. In fact, in the largest countries of the EU [...], Abbott has a share of generally [<5%], therefore the increment is negligible. The parties' EEA market shares are by and large representative of the situation in most domestic markets of the EEA.
- 76. In the light of the above, it can be concluded that the increment brought about by Abbott to Guidant's position in the BMS market is negligible. Post-transaction, there will remain a number of significant BMS competitors in the EEA, including one of the two leaders, Medtronic, and Boston Scientific, plus some fringe players. Neither these suppliers, nor the many other BMS suppliers face any significant barriers to expansion. The transaction will therefore not result in a significant impediment to effective competition in the common market and the EEA for BMS.

IC accessories

- 77. The market of accessories consists essentially of PTCA balloon catheters, steerable guidewires and guiding catheters. In J&J/Guidant, the investigation revealed that IC accessories tend to be increasingly low margin and "commodity" like items, to the extent they are relatively simple and homogeneous products. The trend towards commoditisation was however less accentuated for guide-wires, where quality remains one of the key criteria driving customers' choice.
- 78. As to the impact of the merger on such markets, guiding catheters are not affected by the transaction as Abbott has discontinued its production in 2004.
- 79. In PTCA balloon catheters, Guidant and Abbott have a share of respectively [15-25%] and around [0-10%], while Boston Scientific is market leader with [35-45%], and J&J has a share of about [5-15%] in the EEA. The above market shares are by and large representative of the situation in virtually all of the countries of the EEA, with one exception [...], where the parties' combined market shares [<30%]. In any event, given the competitive constraints coming from the other players on the market, and in view of the features of the products, no competition concerns arise in any of the national markets of the EEA.

Finally, as regards the market for steerable guide-wires, in J&J/Guidant, the investigation revealed that Guidant was the uncontested market leader with a share in the EEA of [>50%]. However, Abbott is an insignificant player in this area, with a share on average [<5%] in the EEA. And even in those countries of the EEA where Abbott has its highest sales [...], its share [<5%]. Therefore, the transaction does not give rise to any competition concern given the irrelevant incremental market share contributed by Abbott to Guidant.

B. ENDOVASCULAR DEVICES

1. Endovascular Stents

- a. Balloon Expandable stents
- 80. In the market for balloon expandable stents, the J&J/Guidant investigation revealed that the proposed merger between J&J and Guidant would combine the two leading and closest competitors in this market. In the current investigation no new evidence has been brought to the Commission's attention pointing to a different conclusion. Guidant remains number two player with a share of around [20-30%] in the EEA, behind J&J with a share or around [30-40%], while Abbott has a small presence with a share on average of about [0-10%] in the EEA. At national level, the combined entity's market share would be between [40-50%] in [...]. However, the parties' combined market position would mainly be the result of the strong position of Guidant, Abbott's increment [<5%] in [...], and reaching [0-10%] only in [...]. In any event, in all of these markets the combined entity will continue to face a strong competition from the closest and leading player J&J, and other suppliers such as Boston Scientific, Medtronic, and niche competitors.
- 81. In light of the above, it appears that no competitive concerns arise in any of the markets affected in the area of Balloon Expandable Stents, given the tiny market position held by Abbott, and the competitive constraints coming from other major suppliers.

- b. Self-Expandable non-Carotid Stents ("non-Carotid SX")
- 82. In the market for Self-Expandable non-Carotid Stents, Guidant has a share of around [5-15%] in the EEA while Abbott is very small, with a share on average of [<5%] in the EEA. At national level, the only peak is reached in [...], where the merged entity has a share of [25-35%], but with a very small increment of [<5%] from Abbott. For the other affected markets, the market share is below [20-30%] with a maximum increment of [0-10%].
- 83. Given the remaining strong competitive pressure that Boston Scientific, J&J and Bard, will still exert in this market, the proposed concentration is unlikely to significantly impede competition in the common market.
 - c. Self-Expandable Carotid Stents ("Carotid SX")
- 84. In J&J/Guidant, the Commission noted that Abbott's products "have so far failed to gain wide acceptance". The investigation at the time also revealed that the proposed merger of J&J and Guidant would combine the two leading and closest competitors in carotids. In the current investigation no new evidence has been brought to the Commission's attention pointing to a different conclusion. In this market, J&J is number one, Guidant is number two with a share of [20-30%] in the EEA while Abbott is very small, with a share on average of [<5%] in the EEA. Only in [...] the combined market share would exceed [30-40%].
- 85. More specifically, in [...], according to the parties' estimates, the combined Abbott/Guidant entity would be around [50-60%], with Abbott representing an increment of [<5%]. However, Abbott remains a very small player, [...]. The market is in its infancy and is undergoing a non insignificant growth. Most carotid procedures are concentrated in a few centers [...]. Hence, any contract won or lost with that center as a result of a tender will result in dramatic changes in market shares. Finally, post-merger there will remain a number of significant market players which will exercise a competitive constraint on Abbott, such as J&J with a share of [20-30%], and Boston with [5-15%].
- 86. In [...], according to the parties' estimates, the combined Abbott/Guidant entity had a [40-50%] market share in 2004, with Abbott representing an increment of [<5%]. However, Abbott remains very small, [...]. More importantly, there are significant competitors on the market, such as Boston Scientific ([30-40%] market share in 2004), J&J [10-20%], and others.
- 87. In [...], according to the parties' estimates, the combined market share of Abbott/Guidant in 2004 was around [50-60%], with Abbott representing an increment of around [15-25%]. However, the [...] market for carotid stents is very small (around [...]). Moreover, the market is in its infancy and is undergoing a non insignificant growth. Only a handful hospitals handle carotid procedures so that any tender won or lost can produce dramatic changes in market shares. More importantly, post-merger, there will remain a number of significant competitors that will exercise a competitive constraint on Abbott, such as Boston, with an estimated share of [20-30%], J&J, Medtronic and others.
- 88. Finally, in [...], according to the parties' estimates, the combined market share of Abbott/Guidant in 2004 [...] slightly exceeded [40-50%], with Abbott representing a

- negligible increment of only [<5%]. Moreover, there are other significant competitors on the market such as Boston, with a share at [30-40%], and J&J between [5-15%].
- 89. In the light of the above, in all of the affected markets, the proposed concentration is unlikely to significantly impede competition in the common market.
 - b. Endovascular accessories
- 90. For both Endovascular Guiding Catheters and Endovascular Steerable Guidewires ("SGW") markets, the transaction does not lead to any affected market. Indeed Abbott is not present in both product markets.
- 91. With regard to PTA balloon catheters, in [...], which are the only affected markets, the combined entity's market share would not exceed [<20%]. Moreover Abbott's increment in the two affected markets would not exceed [<5%]. Finally, the merged entity will face a strong competition from Bard, Boston Scientific, Johnson&Johnson and other local suppliers.
- 92. In light of the above, the proposed concentration is unlikely to significantly impede competition in the common market in any of the markets for endovascular accessories described above.
 - c. Embolic Protection Devices
- 93. In this market, Guidant has a share in the range of [10-20%] in the EEA, while Abbott is a smaller player, with a share on average of about [5-15%] in the EEA. The above market shares are fairly representative of the situation at national level, with one exception, [...], where, according to the parties' estimates, Abbott/Guidant's combined market share would reach something in the range of [50-60%], with Abbott representing an increment between [10-20%].
- 94. However, first it should be borne in mind that the EPD market in [...] is a market in its infancy and is extremely small. Total sales in 2004 amounted to [...] according to the parties' estimates, with Abbott selling [...] units of EPDs for a total turnover of [...]. Second, market shares are not representative of market power given that the bulk of carotid procedures is concentrated in a very small number of hospitals [...] so that any new contract won or lost after a tender procedure can produce dramatic swings in market shares. Finally, there will remain strong competitors post-concentration, which could easily increase output in case Abbott were to raise prices. More particularly, Boston Scientific's estimated market share in 2005 is between [25-35%]. Other competitors include J&J and Bard.
- 95. In light of the above, it appears that no competitive concerns arise in any of the national markets affected in this area.

VIII. MODIFICATION OF THE PROPOSED CONCENTRATION

96. In order to remove the serious doubts resulting from the proposed transaction, on 23.03.2006 Boston Scientific and Abbott formally submitted joint commitments to the Commission.

97. Following the market test, the parties submitted a final commitment package on 10.04.2006 taking account of the Commission's comments. The detailed text of these commitments is annexed to this decision. The full text of the annexed commitments forms an integral part of this decision.

Interventional Cardiology and Endovascular Businesses

- 98. In order to remove the serious doubts resulting from the proposed transaction in the interventional cardiology and endovascular businesses, and in particular in the DES markets, Boston Scientific and Abbott have proposed the following modifications of the Transaction Agreement:
 - Regarding the sharing of Guidant's DES intellectual property, the licence to Boston Scientific will be on a non-exclusive basis with the exception of the Everolimus drug.
 - Regarding the duration of the supply agreement, Boston Scientific commits to stop
 purchasing DES from Abbott for sale in the EEA three years following the date on
 which Boston Scientific receives from Abbott its first commercial shipment of DES
 for marketing and sale by Boston Scientific in EEA. In addition, Boston Scientific
 commits to stop purchasing DES from Abbott for sale in the EEA no later than 90
 days after receiving CE mark with respect to an everolimus eluting stent on a
 Boston Scientific stent platform.
 - Regarding the remuneration mechanism, for the supply of DES Stents to Boston Scientific by Abbott, the Transaction Agreement will be modified to provide that Abbott's manufacturing costs to be inputted into the remuneration formula will be based on a predetermined manufacturing cost proxy, while Boston Scientific's average selling price will be based on the estimates reported by an independent third party entity.
 - Regarding the minority stake of Abbott in Boston Scientific, Abbott commits (i) to exercise its voting rights proportionately with the votes cast by all other Boston Scientific stockholders, (ii) not to have any representation on the Board of Directors, and (iii) to dispose of the minority stake within 30 months of the date of closing of the transaction.
- 99. The Commission considers that the remedies being proposed by Boston Scientific and Abbott address the serious doubts it identified. In particular, the shortening of the supply agreement between the parties, coupled with the amendment of its remuneration mechanism, as well as the divestiture of Abbott stake in Boston Scientific are meant to severe the links between the parties and ensure that the parties' incentives to compete in the markets for vascular devices are not diminished. The waiver of the co-exclusivity by Boston Scientific with respect to certain Guidant's DES rights may enable other third parties' competitors to be granted the same licenses, thus lowering barriers to entry in the DES and other vascular markets.
- 100. In order to ensure that Abbott and Boston comply with these commitments, the Commission attaches conditions and obligations to this decision. The commitments set out in Sections B-C-D-E of the commitments annexed to the present decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be achieved so as to eliminate the serious doubts identified by the Commission. The other commitments constitute obligations, since they concern the

implementing steps necessary to achieve the structural change intended to eliminate the serious doubts identified by the Commission.

IX. CONCLUSION

101. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement, subject to full compliance with: (i) the conditions in Sections B-C-D-E of the commitments annexed to the present decision; and (ii) the obligations in the other Sections of the said commitments. This decision is adopted in application of Articles 6(1)(b) and 6(2) of Council Regulation (EC) No 139/2004

For the Commission signed Neelie KROES Member of the Commission

CASE No COMP/M.4150 - Abbott/Guidant

Commitments to the European Commission

Pursuant to Article 6(2) of Council Regulation (EEC) No. 139/2004 (the "Merger Regulation"), Boston Scientific Corporation ("BSC") and Abbott Laboratories ("Abbott"), respectively, hereby provide the following commitments (the "Commitments" or "Commitment") in order to enable the European Commission (the "Commission") to declare the acquisition by BSC of Guidant Corporation ("Guidant") and by Abbott of certain Guidant businesses compatible with the common market and the EEA Agreement by its decisions pursuant to Article 6(1)(b) of the Merger Regulation (the "Decisions"). BSC, Abbott and Guidant are hereinafter referred to as the "Parties". For each Commitment, the Party (or Parties) that provide the Commitment concerned has (have) been identified.

The Commitments are submitted to address the potential concerns identified by the Commission in relation to (i) the duration of the interim supply arrangement in the EEA between Abbott and BSC with respect to certain drug eluting stents, (ii) the pricing formula to be applied between Abbott and BSC with respect to the supply of these drug eluting stents, (iii) the grant of certain license rights by Abbott to BSC with respect to drug eluting stents, and (iv) the time period during which Abbott may retain the shares of BSC common stock that it will acquire from BSC and the exercise of voting rights by Abbott with respect to those shares.

The Commitments shall take effect upon the date of adoption of the Decisions. This text shall be interpreted in the light of the Decisions to the extent that the Commitments are attached as conditions and obligations, in the general framework of Community law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EEC) No 139/2004 and under Commission Regulation (EC) No 802/2004.

Section A. Definitions

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

Abbott: Abbott Laboratories. After Closing, the term "Abbott" shall include the Guidant businesses being acquired by Abbott.

Abbott Minority Stake: the shares of common stock of BSC that Abbott shall have received pursuant to the Transaction Agreement.

Abbott Pricing Formula: the pricing formula by reference to which Abbott shall invoice BSC for each DES Stent supplied by Abbott to BSC and sold or otherwise transferred for value to a third party by BSC (which shall not include samples or DES Stents provided at no cost for use in clinical trials) pursuant to Section 5.07 of the Transaction Agreement.

Acquisition: the acquisition by BSC of all the outstanding shares of Guidant pursuant to the definitive Agreement and Plan of Merger between BSC and Guidant, and the acquisition by Abbott of Guidant's vascular intervention and endovascular solutions businesses pursuant to the Transaction Agreement.

BSC: Boston Scientific Corporation. After Closing, the term "BSC" shall include the Guidant businesses being acquired by BSC.

Closing: the date or dates on which the Parties close the Acquisition.

Commission: the European Commission.

Commitments: the commitments herewith provided by BSC and/or Abbott in order to enable the Commission to declare the acquisition by BSC of Guidant and by Abbott of certain Guidant businesses compatible with the common market and the EEA Agreement by its decisions pursuant to Article 6(1)(b) of Council Regulation (EEC) No. 139/2004.

DES Intellectual Property: the intellectual property that Abbott shall license to BSC pursuant to Section 5.08 of the Transaction Agreement.

DES Stents: the everolimus eluting stent system in development by Guidant at the time of Closing as defined in the Transaction Agreement.

DES Supply Arrangement: the interim supply arrangement between Abbott and BSC relating to DES Stents as set out in Section 5.07 of the Transaction Agreement.

Endovascular: the field of use for medical devices designed for the minimally invasive treatment of peripheral vascular (or endovascular) diseases.

Everolimus: the agent having the chemical name 40-O-(2-hydroxyethyl)-rapamycin as defined in Section 5.07(c) of the Transaction Agreement.

Guidant: Guidant Corporation.

Transaction Agreement: the agreement entered into between BSC and Abbott and dated as of January 8, 2006, and amended by Amendments Nos.1 and 2 thereto dated as of January 16, 2006, by Amendment No.3 thereto dated as of February 22, 2006, and by Amendment No.4 thereto dated as of April 5, 2006, pursuant to which, on the terms and subject to the conditions contained in the agreement, Abbott agreed to acquire certain assets and businesses and assume certain liabilities of Guidant prior to BSC's acquisition of Guidant.

Section B. BSC Commitment to stop purchasing DES Stents from Abbott

- 1. In order to address the potential competition concerns identified by the Commission with regard to the duration of the DES Supply Arrangement, BSC commits to stop purchasing DES Stents from Abbott for sale in the EEA no later than 90 days after issuance of the EC design examination certificate (pursuant to which the CE mark may be affixed) with respect to an Everolimus eluting stent on a BSC stent platform.
- 2. In addition, BSC commits to stop purchasing DES Stents from Abbott for sale in the EEA three years following the date on which BSC receives from Abbott its first commercial shipment of DES Stents for marketing and sale by BSC in the EEA.

Section C. BSC and Abbott Commitment relating to the Abbott Pricing Formula

- 3. To address the potential concerns identified by the Commission in relation to the Abbott Pricing Formula, BSC and Abbott have agreed as follows.
 - 4. The Abbott Pricing Formula shall be structured in the following manner:
 - (a) It shall be based on a predetermined manufacturing cost proxy, decreasing over time, agreed upon by BSC and Abbott, plus a manufacturing margin proxy.
 - (b) The manufacturing margin proxy shall be equal to 40% of the result obtained by subtracting the following from the weighted average selling price of DES Stents in the market during the relevant quarter sold by BSC as reported by the

Millennium Research Group ("MRG"), or similar independent market research entity, provided however that such weighted average selling price as it relates to the EEA shall include a discount to the price reported by MRG of 6% to reflect customary rebates and discounts in the territory:

- (a) third party royalties payable by Boston Scientific with respect to DES Stents sold by it based on the MRG price;
- (b) 7% of the MRG price for the DES Stents; and
- (c) the manufacturing cost proxy.
- (c) If the MRG price is less than \$400, then the manufacturing margin proxy shall be equal to 25% of the manufacturing cost proxy, provided however that in no case shall the manufacturing margin proxy be less than zero.
- (d) BSC and Abbott shall have a third party do a lagged "true-up" as to the actual Abbott manufacturing cost, the actual BSC price and the actual royalties paid by BSC to third parties.

Section D. BSC and Abbott Commitment relating to co-exclusivity

- 5. To address the potential competition concerns identified by the Commission in relation to the co-exclusive nature of the license that Abbott grants to BSC to DES Intellectual Property, BSC and Abbott have agreed as follows.
- 6. The license granted to BSC to DES Intellectual Property pursuant to Section 5.08(a) of the Transaction Agreement is non-exclusive, which means that Abbott and its Affiliates (as defined in the Transaction Agreement), as of the Closing, have the right to grant licenses, sublicenses or covenants not to sue or other rights with respect to the DES Intellectual Property, except that the license granted to BSC to DES Intellectual Property is co-exclusive as to Everolimus eluting stent systems, which means that any rights to DES Intellectual Property granted by Abbott to a third party shall not extend to such third party's drug eluting stent system if the drug used in such drug eluting stent system is Everolimus. Notwithstanding the previous sentence, Abbott and its Affiliates, as of the Closing, have the right to grant licenses, sublicences or covenants not to sue or other rights with respect to the DES Intellectual Property in the countries of the EEA within the Endovascular field of use.

Section E. BSC and Abbott Commitment relating to the Abbott Minority Stake

- 7. To address the potential concerns identified by the Commission in relation to the Abbott Minority Stake, BSC and Abbott have agreed as follows.
 - (a) As of Closing and for as long as Abbott or any of its affiliates shall own such shares, with respect to any matter to be voted on by stockholders of BSC, such shares shall be voted proportionately with the votes cast by all other Boston Scientific stockholders entitled to vote and voting on such matter.
 - (b) Abbott shall not have any representation on BSC's Board of Directors as part of the Abbott Minority Stake.
 - (c) Abbott will sell, transfer or otherwise dispose of the Abbott Minority Stake no later than 30 months following Closing.

Section F. The Review Clause

- 8. The Commission may, where appropriate, in response to a request from BSC or Abbott showing good cause:
 - (i) grant an extension of the duration of the DES Supply Arrangement; or
 - (ii) grant an extension of the term of the Abbott Minority Stake; or
- (iii) waive, modify or substitute, in exceptional circumstances, one or more of the conditions or obligations in these Commitments.