EN

Case No COMP/M.4076 - BOSTON SCIENTIFIC / GUIDANT

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 11/04/2006

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11/04/2006

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.4076-Boston Scientific/Guidant
Notification of 23.02.2006 pursuant to Article 4 of Council Regulation No 139/2004[1]

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 Boston Scientific Corporation ("Boston Scientific", USA) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Guidant Corporation ("Guidant", USA), with the exception of Guidant's interventional cardiology and endovascular devices businesses, by way of purchase of shares.

2. 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. Boston Scientific is a US company active in the development, manufacture and sale of medical devices for interventional medical specialties, including interventional cardiology, endovascular and neurovascular intervention, electrophysiology, vascular surgery, endoscopy, radiology/oncology, urology, gynaecology, pulmonary endoscopy

[1] OJ L 24, 29.1.2004 p. 1.

and neuromodulation. Boston Scientific derives most of its revenue from its cardiovascular business […], followed by endosurgery […] and neuromodulation […].

4. Guidant is a company incorporated in the USA that is active in the design and development of cardiovascular medical products. Guidant was funded 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 rhythm management, interventional cardiology, endovascular devices and cardiac surgery.

II. THE OPERATION

5. 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. Boston Scientific will 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.

6. As for Guidant's interventional cardiology and endovascular businesses, Boston Scientific will not acquire control of such assets within the meaning of the EC Merger Regulation. On 8 January 2006, Boston Scientific and Abbott Laboratories entered into a Transaction Agreement pursuant to which Abbott will acquire all assets, rights and stock related to Guidant's interventional cardiology and endovascular businesses. This transaction has been separately notified to the Commission (case M.4150 Abbott/Guidant). As part of this latter transaction, Abbott and Boston Scientific will share the rights to Guidant's Xience V drug eluting stent ("DES") portfolio. The impact on competition of such arrangements between Abbott and Boston are assessed in the context of the case M. 4150, Abbott/Guidant.

III. CONCENTRATION

7. Following the transaction, Boston Scientific will acquire sole control over Guidant's cardiac rhythm management and cardiac surgery businesses and the transaction constitutes a concentration within the meaning of Article 3 (1)(b) of the Merger Regulation.

IV. COMMUNITY DIMENSION

8. The undertakings concerned have a combined aggregate world-wide turnover of more than € 5 billion[2] (in 2004, Boston Scientific of € 4.5 billion and Guidant's cardiac rhythm management and cardiac surgery businesses € [1,5-2,5 billion]). Both companies have a Community-wide turnover in excess of € 250 million (in 2004, Boston Scientific of € [750-850 million] and Guidant's cardiac rhythm management and cardiac surgery businesses € [300-400 million]), but they 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.

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[2] 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).

V. COMPETITIVE ASSESSMENT

RELEVANT PRODUCT MARKET

9. The transaction involves two main areas within the cardiovascular medical products business: i) cardiac rhythm management devices ii) cardiac surgery devices. In each of these areas, a number of product markets are concerned.

Cardiac rhythm management

10. CRM devices are used for the treatment of severe heart rhythm disorders such as bradycardia (abnormally slow heartbeat) and tachycardia (abnormally fast heartbeat). Guidant develops, manufactures and sells three types of CRM products: (i) implantable pacemakers (“pacemakers”); (ii) implantable cardioverter defibrillators ("ICDs"); and (iii) cardiac resynchronization therapy devices ("CRTs"). ICDs are treated below as they constitute the only market in the area of CRM being affected by the concentration.

Implantable Cardioverter defibrillators

11. Implantable cardioverter defibrillators (“ICDs”) are cardiac devices that are used to prevent and control more severe forms of tachycardia (abnormally fast heart rhythms). ICDs monitor the heart and can deliver high or low-energy shocks to stop either extremely rapid and irregular heartbeats, or simply fast heartbeats, and to return the heart to normal rhythm. More specifically:

- If the heart rhythm is regular but fast, the ICD system can deliver a series of small, rapid electrical pacing pulses (anti-tachycardia pacing or "ATP"). This ATP is used to interrupt the arrhythmia and return the heart to its normal rhythm.

- If the arrhythmia is regular but very fast, the ICD can deliver a low-energy shock (cardioversion). This can stop the arrhythmia and return the heart to its normal rhythm.

- If the arrhythmias are very fast and irregular, high-energy shocks are delivered to the heart to stop the arrhythmia (defibrillation) and prevent SCD. Then the heart can return to its normal rhythm.

- ICDs can also function like pacemakers, providing regular, low energy pulses for the treatment of bradycardia.

12. The ICD works with leads (insulated wires) connected to the heart's chambers, which monitor the heart's contractions, check the rate of heartbeats, and deliver necessary electrical impulses to the heart. ICDs can be single or dual-chamber, connecting the defibrillator device via leads with the right atrium and/or the right ventricle. An implantable defibrillator system is comprised of three principal components: (i) the defibrillator device (also known as the pulse generator); (ii) leads; and (iii) the programmer.

13. Some suppliers are developing an innovative leadless ICD which would only require its implantable pulse generator to be implanted into the subcutaneous fat beneath the breast. This generator is solely responsible for receiving electrical impulses from the

heart to differentially diagnose specific rhythm abnormalities that are known to lead to cardiac arrest. The generator then would provide an electric shock to restore normal cardiac rhythm. This technology is being tested in the context of clinical trials and has not yet reached the market.

14. As it was stated in the previous case J&J/Guidant, the parties submit that all of ICDs, regardless of the specific technology being used, would constitute a single market, and it would not be appropriate to further segment the market by individual components. The components comprising each type of system are custom-designed for each type of system, and are only very rarely sold on a stand-alone basis. As a result, each type of ICD is priced and sold as an integrated system. No evidence has emerged from the market investigation indicating any different conclusion.

15. As to pipeline leadless ICDs, since they have not yet reached the market, the issue of whether the products incorporating such a new technology will compete head on with standard ICDs is extensively treated further below in the section on the *competitive assessment*.

Cardiac surgery

16. Surgery of the heart is typically carried out to correct and repair multiple heart conditions, including coronary artery disease and congenital heart disease. There are three principal types of cardiac surgery: heart valve surgery, to replace heart valves; cardiac ablation, to treat serious cases of atrial fibrillation; and Coronary Artery Bypass Graft surgery ("CABG"), to treat coronary artery disease. With CABG, the blocked artery is "bypassed" by sewing ("grafting") another blood vessel to the aorta at one end and to the coronary artery beyond the damaged area the other end. After the operation, blood flows through the new grafted vessel to the heart muscle. The vessel used for the bypass is removed ("harvested") from the leg ("saphenous vein graft"), chest or arm.

17. The parties submit that the following markets are affected in the cardiac surgery area: i) beating-heart stabilisation systems ii) accessories as blowers/misters); iii) cardiac surgey systems. The products are described below.

Beating-Heart Stabilisation Systems

18. Beating-heart CABG stabilisation systems enable the perform CABG surgery on the heart while beating. A stabilisation system usually consists of a retractor, a stabiliser and a positioner. According to the parties, the three parts are usually sold together, but can also be purchased separately. The retractor is composed of a rack and two rails that are inserted into the chest after a sternotomy to keep the ribcage open and allow access to the heart. The stabiliser is a device that reduces cardiac motion in the target area through either suction or compression, thus enabling the surgeon to carry out the operation. The stabiliser is the most important component of the stabilisation system and accounts for approximately 75% of the total price. The positioner is a device used to manipulate the beating heart and to provide access to coronary arteries located at the back of the heart.

19. In *J&J/Guidant*, the Commission investigation broadly endorsed the claim that stabilisation systems should be treated as a single product, essentially due to the fact that there is no interoperability between the components of different suppliers. This means that customers normally purchase all components from one supplier, even if in

different quantities. The choice of the stabiliser is the main factor that determines the choice of supplier.

20. 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 beating-heart stabilisation systems.

Blowers/Misters

21. Blowers/misters are ancillary products that are used in conjunction with the stabilisation systems. Blowers/misters are low technology products used to clear blood away from and to deliver saline mist to the target vessel. The sales of blowers/misters are closely related to the sale of stabilisation systems.

22. In *J&J/Guidant,* the Commission concluded that a relevant product market should be defined for blowers/misters. In the current investigation no elements have been brought to the Commission's attention pointing to different conclusions.

Surgical ablation systems

23. Surgical ablation procedures are generally performed as a secondary (or concomitant) intervention, when the patient is already having cardiac surgery for another medical condition (valve or bypass surgery). In a small number of cases, surgical ablation is performed as the primary (or stand-alone) procedure. Surgical ablation is performed by cardiac surgeons and involves the following basic steps:

- The patient's breastbone is separated while the patient is under general anaesthesia.

- The surgeon makes small lines of ablated (i.e. destroyed) tissue in the heart. One of several energy sources may be used to create the lines: laser, radio-frequency, microwave, cryothermy (cold temperature) or ultrasound.

When the heart heals, scar tissue will interrupt the conduction of abnormal impulses from travelling through the heart and will promote the normal conduction of impulses through the normal pathway.

24. The market definition as regards cardiac ablation systems can be left open given that, irrespective of the segmentation being retained, the transaction will not give rise to competition concerns.

RELEVANT GEOGRAPHIC MARKET

25. Boston Scientific takes the view that the relevant geographic market for all the products mentioned 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.

26. 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 Boston Scientific, or from the market investigation, pointing to a different conclusion.

COMPETITIVE ASSESSMENT

Cardiac rhythm management

27. Guidant is a worldwide leading supplier of cardiac rhythm management ("CRM") devices that monitor and regulate the heart's rhythm through electrical stimuli. CRM devices represent approximately […] of Guidant's total revenues.

28. Boston Scientific does not manufacture or sell CRM devices. As a consequence, the merger does not give rise to any direct overlaps in the above markets. However, Boston Scientific holds a minority stake of [<15%] of the issued share capitals of the US company Cameron Health, Inc. ("Cameron"), coupled with a purchase option to be exercised within a defined option period[3]. Boston Scientific is not represented on the Board of Directors of Cameron but may attend Board meetings as an observer. Cameron is developing a new generation of Implantable Cardioverter Defibrillator ("ICD"), a technology that differs from existing ICD technology in that Cameron's product will eliminate the need for leads to be surgically implanted into the intracardiac and intravascular spaces, thus permitting implantation through a less invasive procedure. Cameron is expected to receive pre-market approval ("PMA") application in [2007] in the U.S. and obtain CE Mark [mid 2006-mid 2007] in Europe.

29. Under the terms of the Securities Purchase Agreement between Cameron and Boston Scientific, the latter is allowed privileged access to Cameron's sensitive information pertaining to its pipeline leadless ICD [including information on clinical trials, the status of regulatory fillings and information on Cameron's financial performance].

As to Boston Scientific's influence over Cameron

30. Boston Scientific argues that it does not own Cameron; it has only a minority investment with no ability to direct the Cameron R&D programme. When and if Cameron's ICD product comes to market, Boston Scientific will not have any control over the business decisions or management (e.g., pricing or output level decisions) of Cameron's business in any way.

31. The evidence in the file does not support Boston Scientific's claim. Although the minority stake owned by Boston Scientific over Cameron coupled with a purchase option do not give rise to a situation of *de iure* control, it should be considered whether the cumulative effects of the contractual arrangements put in place between Boston Scientific and Cameron enable the former to exercise decisive influence over the latter.

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[3] [The Option Period runs for a determined period which is amongst other dependent on Cameron's receipt of the US FDA's approval of its PMA application for the leadless ICD for substantive review, provided certain conditions are satisfied]

Under article 3.2 of the ECMR, control is defined as the possibility of exercising decisive influence on an undertaking on the basis of rights, contracts or any other means, taken separately or in combination. In the Commission practice as set out in its notice on Concentration, existence of an option right can be taken into account as an element which, together with other elements, may lead to the conclusion there is sole control.

32. In the case at stake, there are a number of factors indicating that Boston Scientific may be able to exercise decisive influence over Cameron. First, Boston Scientific holds a non insignificant stake over Cameron coupled with a purchase option. As a result of that, Boston Scientific is one of the major investors in Cameron and plays an important role in deciding whether or not financially to support Cameron's plans of development. In fact, under the terms of the Agreement Boston Scientific is due not only to finance but also give commercial support to Cameron for the purpose of the distribution of the product. Moreover, and more importantly, Boston Scientific enjoys, based on the provisions of the agreement, very extensive *information* rights about the content and the stage of development of Cameron's pipeline programme on leadless technology. The possibility for Boston Scientific to have privileged access to highly sensitive and valuable information crucial for the success of Cameron's advanced pipeline programme, combined with the above described investor's role, gives Boston Scientific an extensive power to decisively influence the outcome of the most valuable if not the only asset owned by Cameron.

33. This reading is corroborated by the findings of the market investigation. In its submission to the Commission, Cameron itself stated that Boston Scientific can *control Cameron's business decisions* by virtue of the relevant provisions of the Securities Purchase Agreement between the two. In particular, Cameron argued that under the terms of this agreement Boston Scientific has access to all sort of commercially sensitive information pertaining to the development of Cameron leadless technology, including the content of the program, the result of the clinical trials, the stage of development etc. Moreover, Cameron argued that the purpose of the agreement with Boston Scientific was to ensure that the latter would provide with the financial, marketing and distribution resources to allow Cameron to continue to develop its products, as well as regulatory expertise, sales forces and distribution channels to allow Cameron's products to reach the market as quickly as possible.

34. Other respondents to the market investigation also confirmed that in this industry a non negligible minority stake coupled with a purchase option and the right to have access to highly commercially sensitive information, give the strategic investor considerable influence over the participated company.

35. In any event, the issue of the control by Boston over Cameron can be left open given that, even assuming that Boston has decisive influence over Cameron, there would be no competition concerns in the market for ICDs stemming from the transaction, due to the following reasons.

The impact on competition of the combination Guidant/Cameron

36. According to Boston Scientific, even if one were to analyse the competitive effects of the combination of Guidant's ICD business and Cameron, no competitive concerns would be raised. There would be other traditional ICD competitors, notably Medtronic and St. Jude, whose products are much closer competitors to Guidant's existing ICD products than would be Cameron's product.

37. Moreover, according to Boston Scientific, development of leadless ICDs will expand the market rather than cannibalise existing sales. For ICDs currently penetrate only a small portion of the population that could potentially benefit from a device. Physicians and doctors are deterred from using the device because of the highly invasive nature of traditional ICDs. Since Cameron's leadless ICD is less invasive than traditional ICDs due to a simplified device and implant procedure, this could result in the reduction of acute surgical risk and future clinical complications because of lead failures. Therefore, there would be great potential for less invasive ICDs to expand the use of ICDs, for example, into usage by primary prevention patients that have not experienced sudden cardiac arrest, VT or VF but exhibit certain elevated risk factors. In any event, Boston Scientific argues that there is uncertainty as to whether this technology will ever become successful. Finally, several other players developing leadless ICDs would be closer competitors to Cameron's product. In particular, according to Boston Scientific Medtronic, Synecor/IRM[4] and St. Jude are all developing a leadless or subcutaneous ICD technology.

38. The market investigation has provided the following picture. The market for ICDs is fairly concentrated. In Europe there are two leaders, Medtronic with a market share in the EEA of around [35-45%], followed by Guidant with a share of about [30-40%]. St. Jude is a distant third with about [10-20%], followed by smaller players like Biotronik (around [5-15%]) and ELA/Sorin (around [0-10%]).

39. As to the importance of the new technology being developed by Cameron in the field of leadless ICD, the impact of this technology on the traditional ICDs is difficult to measure. From the investigation, it appears that Cameron has an advantage over the other suppliers as regards the stage of development of its leadless technology. Cameron is planning to receive EC mark approval of its defibrillators in [mid 2006-mid 2007]. None of the other leadless or subcutaneous ICDs' potential suppliers are working on a similar timeline, since their technology has not reached yet the same advanced stage of development. Only one player seems to be closer to Cameron in terms of time to market, while for the rest of the operators, on average, the time gap with Cameron is in the range of two years if not longer. In fact, Boston Scientific itself states in its submission that Cameron's leadless ICD product will likely be the first to market in the EEA within the general time frame of [mid 2006-mid 2007]. IRM would follow with its product in 2007, followed by Medtronic in 2008, and then potentially by St. Jude.

40. As to the possibility that this technology would be competing head on with standard ICDs, the findings are more mixed. One operator is little worried, and argues that subcutaneous devices will require more invasive surgical procedures as compared to traditional ICD implantation techniques. This claim is however in contradiction with what other respondents contend, including Boston Scientific, namely that leadless would entail less invasive interventions.

41. Another respondent finds that the success of a leadless technology will depend on the technological ability of such a system. Therefore, the argument goes, leadless may become a prophylactic device rather than replacing altogether a system with leads, unless the sensing ability of the system would be very accurate.

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[4] […]

42. A couple of respondents, instead, voice concerns to the extent the leadless technology would serve by and large the same functions as the standard ICDs, thus the merger would remove the most credible new entrant capable of exerting a significant competitive constraint towards the established players with a new technology potentially disruptive and capable of displacing at least to some extent standard ICDs. These claims, however, remain generic and are not corroborated by some piece of factual evidence.

43. Cameron expects that leadless ICD will compete directly with existing ICDs, as well as expand the market through enabling new users not currently served by current competitors and their technologies. Cameron further claims that the acquisition of Guidant by Boston Scientific may significantly affect the incentives of the latter when taking decisions likely to impact on the development of Cameron. In essence Cameron fears that Boston Scientific's access to Cameron's competitively sensitive information pertaining to its ICD leadless technology, combined with the important role Boston Scientific was supposed to play in the financing of the development of this new product, would enable the latter to extract competitive advantages and exploit them with a view to strengthening Guidant position in the market place detrimental to consumers. This could be done essentially by delaying and obstructing the advent to the market of a new technology potentially disruptive for traditional suppliers of ICDs like Guidant.

44. In the light of the above, it appears that while the leadless technology may well become a competitive constraint for standard ICDs, the issue of the potential impact of the technology being developed by Cameron on the market for ordinary ICDs remains to be seen. .

45. In conclusion, based on the evidence in the file, it appears that, given the stage of development of the ICD leadless technology and its time to market, as well as its potential impact on the ordinary ICDs, it cannot be established, based on sufficiently cogent evidence, that Cameron would be a new entrant capable of exerting a significant competitive constraint in the market for traditional ICDs.

Cardiac surgery

46. Guidant supplies a range of cardiac surgery devices, while Boston Scientific does not operate in these markets. As a consequence, the merger does not give rise to any direct overlaps in the above markets. However, Boston Scientific holds a minority stake of [<15%] of the issued share capitals of the US company **Estech**, coupled with a purchase option to be exercised within a defined period[5]. **Boston Scientific is permitted only to be a non-voting observer at Estech Board meetings. Under certain circumstances, however, such as when the matters being discussed are so competitively sensitive with respect to Boston Scientific that disclosure would be materially adverse to Estech, the observer can be excluded.** […]**.**

[5] […]

As to Boston Scientific's influence over Estech

47. Boston Scientific argues that it does not own Estech; it has only a minority investment with no ability to direct the Estech businesses.

48. In any event, according to Boston, even if one were to attribute Estech's sales to Boston Scientific, following the combination of Guidant, there would be no competitive concerns arising in any of the markets affected in the area of cardiac surgery. More specifically, in the market for stabilisation systems, based on the parties' estimates, it appears that Medtronic is the market leader with a share of about [55-65%] in the EEA, followed by Guidant with a share of around [20-30%], and others with the remainder, including Estech with an estimated share of less than 5%. And although in some countries of the EU Guidant has a more significant share, reaching and sometimes exceeding [35-45%] (see Germany, Spain, Austria), Estech remains tiny in all these countries.

49. In the market of blowers and misters, based on the parties' estimates, it appears that Medtronic is the leading supplier for blowers/misters with a share of around [45-55%] in the EEA, followed by Guidant with about [15-25%], Terumo with around [5-15%], J&J with 5-10% share and others with the remainder, including Estech with an estimated share of [0-10%] or less. The combined market share of Gudiant and Estech is a good proxy of their market share at national level.

50. In the market for surgical ablation systems, based on the parties' estimates, it appears that Medtronic is clearly the market leader in the EEA with an estimated share of [50-60%]. followed by Atricure with **[15-25%]** share, Guidant with **[5-15%]**, CryoCath with **[5-15%]** and others with the remainder, including Estech with a share of around **[0-10%]** share at EEA level in 2005. At national level, in no countries the combined market shares would exceed 15-20%.

Assessment

51. Although the minority stake owned by Boston Scientific over Estech coupled with a purchase option do not give rise to a situation of *de iure* control, it should be considered whether the cumulative effects of the contractual arrangements put in place between Boston Scientific and Estech enable the former to exercise decisive influence over the latter.

52. In this respect, Boston Scientific holds a non insignificant stake over Estech coupled with a purchase option. As a result of that, Boston Scientific is one of the major investors in Estech and plays an important role in deciding whether or not to financially support Estech plans of development. However, neither is Boston allowed access to Estech' s commercially sensitive information, nor can it exercise any direct influence on the major business decisions of Estech, as it has no representation in Estech's Board.

53. Moreover, the market investigation did not bring to the Commission's attention any piece of compelling evidence indicating that Boston can exercise decisive influence over Estech.

54. Finally, it should be noted that even attributing Estech's sales to Boston Scientific, following the combination of Guidant, in the current investigation no elements have been brought to the Commission's attention pointing to possible competition concerns

arising out of the transaction in the area of cardiac surgery, given the very limited market position held by Estech in all of the markets for cardiac surgery devices in which Estech is present.

VI. CONCLUSION

55. 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. This decision is adopted in application of Articles 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission
signed
Neelie KROES
Member of the Commission