EUROPEAN COMMISSION
DG Competition

Case M.8060 - ABBOTT LABORATORIES / ST JUDE MEDICAL

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Decision on the implementation of remedies - Art. 6(1)(b) in conjunction with 6(2) - Purchaser approval
Date: 22.12.2016

EUROPEAN COMMISSION

Brussels, 22.12.2016
C(2016) 9014 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

To the notifying party:

Dear Sir/Madam,

Subject: **Case M.8060 – Abbott Laboratories / St Jude Medical**
Approval of Terumo Corporation as purchaser of St Jude Medical's global vessel closure device business and Abbott's entire shareholding in Kalila Medical following your letter of 15 November 2016 and the Trustee's opinion of 15 December 2016

I. FACTS AND PROCEDURE

1. By decision of 23 November 2016 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2), the Commission declared the operation by which Abbott Laboratories (Abbott) acquired control of the whole of St Jude Medical (St Jude) by way of purchase of shares ("the Transaction") compatible with the internal market following modification by Abbott and St Jude, subject to conditions and obligations ("the Commitments").

2. In particular, the Commitments provide that Abbott will divest:

   a) St Jude's global vessel closure device (VCD) business, comprising all assets and staff that contribute to the current operation or that are necessary to ensure the viability and competitiveness of St Jude's *AngioSeal* and *FemoSeal* businesses ("the VCD Business")

   b) Abbott's shareholding in Kalila Medical, an indirect wholly owned subsidiary of Abbott that has developed a steerable introducer sheath for use in electrophysiology (EP), *Vado* ("the Vado Business").

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3. By letter of 15 November 2016, the Parties proposed Terumo Corporation (Terumo) for approval by the Commission as purchaser of both the VCD Business and the Vado Business (together, "the Divestment Businesses") and submitted the proposed Purchase Agreement and related agreements (the "Proposed Agreement").

4. On 15 December 2016, the Trustee Mazars LLP ("the Trustee") submitted an assessment of Terumo's suitability as a purchaser and, in particular, indicated that it fulfils the criteria of the purchaser requirements set out in section D of the Commitments attached to the Decision. In this assessment, the Trustee also indicated that, on the basis of the Proposed Agreement, the Divestment Businesses would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

5. As set out in section D of the Commitments, in order to be approved by the Commission, the purchaser(s) of the Divestment Businesses must fulfil the following criteria:

   a) the purchaser(s) shall be independent of and unconnected to the Parties and their affiliated undertakings (this being assessed having regard to the situation following the divestiture);

   b) the purchaser(s) shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Businesses as viable and active competitive forces in competition with the Parties and other competitors;

   c) the acquisition of the Divestment Businesses by the purchaser(s) must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the purchaser(s) must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Businesses.

6. This section provides a short description of the purchaser and an assessment of its suitability in view of these criteria.

(a) Description of the purchaser

7. Terumo is a global healthcare company active in the development, manufacture and marketing of medical devices and pharmaceutical products. It is headquartered in Tokyo, Japan, and has been present in Europe since 1971. In 2015, it achieved global sales of EUR 4 billion, of which EUR […] million were in the EEA. Terumo has over 26 000 employees worldwide, including […] in Europe.

(b) Independence from the Parties

8. There are no institutional investors that hold shares in Abbott or St Jude, on the one hand, and in Terumo, on the other.[1] Furthermore, Terumo does not have any directors in common with the Parties.

9. The only existing commercial relationships between Terumo and the Parties are as follows:

   a) Terumo previously distributed Abbott's VCDs in Japan, but the agreement was terminated with effect from […]. Terumo is expected to continue selling one of Abbott's VCDs, *Perclose ProGlide*, until stock runs out (estimated to be in […]).

   b) St Jude currently purchases a femoral introducer sheath, *SoloPath*, from Terumo, for sale in Europe in conjunction with its *Portico* TAVI systems. Sales volumes have been very minimal to date (amounting to approximately USD […] to date in 2016). St Jude and Terumo are negotiating an agreement for […]. This is expected to be a non-exclusive agreement.

   c) Terumo's subsidiary, Vascutek, supplies […]to St Jude, and supplies […] to St Jude MCS (formerly Thoratec Corporation), for use in the production of […]. The revenue generated from these agreements represents approximately […]% of Terumo's total revenue.

10. In view of the above, the Commission considers that Terumo is independent of and unconnected to Abbott and St Jude.

(c) Financial resources, proven expertise and incentive to maintain and develop the Divested Businesses as a viable and active competitor

11. In 2015, Terumo generated revenue of EUR 3.9 billion. It has seen revenue growth of 20% since 2013, much of which is attributable to its cardiac and vascular business. Terumo has net debt of 4% of its market value.

12. Terumo has sufficient cash resources on its balance sheet (approximately USD 1.4 billion) to finance the acquisition of the Divestment Businesses (for a purchase price of approximately USD 1.12 billion) using its own resources. It has, however, arranged further debt facilities with Bank of Tokyo Mitsubishi-UFJ, and funding the purchase price will therefore not pose any difficulties.

13. Terumo has significant experience in the research, development and marketing of a range of cardiovascular products, with a portfolio that includes vascular access, coronary, imaging, peripheral and neurovascular devices. It is a leading global supplier in this area and has been active in Europe for over 40 years, during which time it has acquired expertise and market knowledge and has established its reputation as a high quality supplier.

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[1] Whilst it is possible that individuals may hold shares in both Abbott and/or St Jude and in Terumo, their shareholding would be minimal and would not afford any degree of control over any of the entities..

14. The Divestment Businesses will be complementary to Terumo's existing portfolio of cardiovascular products, which includes access products such as guidewires and non-EP sheaths. As a result, Terumo will be well placed to integrate the VCDs and the Vado sheath into its existing product range.

15. Terumo has its own sales force in the major European markets and works with independent distributors to serve other countries.[2] Its presence in markets adjacent to those of the Divestment Businesses means that it is familiar with the product landscape.

16. Terumo plans to sell VCDs directly via its three existing sales teams (interventional cardiology, interventional radiology and peripheral vascular), strengthened by the recruitment of […] new sales staff members (for VCDs and Vado combined).

17. Terumo plans to market Vado in Europe both via direct sales and potentially using distributors. It is in the processing of identifying possible distributors and also expects to receive information from Abbott as to its planned sales strategy and the distributors it had previously identified. As mentioned above, Terumo is also recruiting new sales and marketing staff to strengthen its sales capacity for both VCDs and Vado.

18. Over the last six years, Terumo has successfully completed a number of large acquisitions, and therefore has experience in integrating new products into its portfolio. In particular, it recently acquired two companies active in the cardiovascular area, Harvest Technologies in 2011 and Onset Medical (which produces the *SoloPath* femoral introducer device) in 2012.

The VCD Business

19. Terumo already supplies products to the majority of hospitals and physicians that form St Jude's customer base, and it will thus be well placed to market *AngioSeal* and *FemoSeal*. It should also be noted that St Jude does not have a dedicated VCD sales force.

20. Terumo is already present in the market for small-hole vessel closure, and is therefore already known to a large proportion of physician's using *AngioSeal* and *FemoSeal*.[3]

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[2] Terumo has a direct presence in […] markets ([…]). It is represented via distributors in […] further countries, and is active indirectly in […] countries which are served from neighbouring markets.

[3] Terumo currently markets a closure assist device (CAD). CADs are used for small-hole closure, but exclusively in coronary interventions that have been performed via radial access. Where a coronary intervention is instead performed via femoral access, a VCD would typically be used to achieve vessel closure. Terumo is therefore already marketing products to a physician customer base that largely overlaps with that of St Jude's VCDs, but the products have mutually exclusive indications.

The Vado Business

21. The Vado sheath is not yet being marketed in Europe, and Abbott had only recently entered the EP sector with its rotor mapping product, *Topera*. Abbott was using its existing sales force to market this product, and under Abbott, Kalila Medical had envisaged selling Vado through distributors.

22. Terumo made its first step towards entering the EP sector through the acquisition of Onset Medical (which produces the *SoloPath* femoral introducer device) in 2012. Although its presence in EP is currently minimal, it offers as part of its product portfolio a number of other vascular access products, and has a particularly strong reputation as an access device company. In addition to Abbott, with its *Topera* rotor mapping technology, there are a number of other companies that have succeeded in entering the EP sector with a limited product range, including Endosense and Biotronik.

23. Terumo will have invested significant financial resources to acquire both divestment businesses (for approximately USD 1.12 billion). Furthermore, the acquisition is consistent with Terumo's long-term business strategy, firstly, in terms of strengthening its existing position in access devices and making its portfolio more complete, and secondly, […].[4]

24. The Trustee has reviewed Terumo's business plan and considers that, based on reasonable projections and quite conservative assumptions, the operating margin and the gross profit margin of the Divestment Businesses will be significantly higher than Terumo's current average margins. Both are considered to be stable and profitable businesses, the acquisition of which brings a low financial risk.

25. The Trustee considers that the transitional arrangements are sufficient to ensure manufacturing and supply short term, and that they will provide Terumo with the support needed to complete the transition and start operating independently. The Trustee is also satisfied that Terumo's plans for integrating the Divestment Businesses longer term will allow them to operate as viable and competitive businesses.

26. In view of the above, the Commission considers that Terumo has the financial resources, proven expertise and incentive to maintain and develop the VCD Divestment Business and the Vado Divestment Business as viable and active competitive forces in competition with the Parties and competitors on the market.

(d) Absence of prima facie competition problems

The VCD Business

27. Terumo does not manufacture or sell VCDs in the EEA. (The agreement with Abbott referred to in Section II(b) related exclusively to Japan, and has in any case now been terminated.) Although the company produces a closure assist device (CAD), the *TR Band*, this type of device is indicated solely for the closure of holes at the radial access site, and there is therefore no overlap in indication with VCDs (which are indicated exclusively for femoral access closure).

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4 […].

28. Furthermore, the technology of the two products is entirely different. Terumo's CAD is a bracelet-like device, comprising a pair of balloons that compress the radial artery, allowing the physician to adjust the pressure applied to achieve closure. Both St Jude's VCDs are plug-based devices: *AngioSeal* achieves closure by securing a plug using an absorbable polymer anchor; *FemoSeal* allows the physician to position an inner seal in the artery and to secure an outer discover it using a suture device, whereby a secure seal is created over the hole. There is thus no similarity between the technology used for Terumo's VCDs and either of the devices included in the VCD Business.

The Vado Business

29. Terumo does not manufacture or sell steerable introducer sheaths used in EP procedures in the EEA, and is not developing any such devices. The access sheaths produced by Terumo (the *Glidesheath*, *Radifocus*, *Solopath* and *Pinnacle* families of products) are indicated to be inserted percutaneously for use in interventional procedures, i.e. for introducing diagnostic or therapeutic devices into a blood vessel. They are not, however, indicated for crossing the septum (i.e. transseptal punctures) so as to access the left side of the heart for atrial fibrillation. There is therefore no overlap between the usage of Terumo's existing sheaths and the potential usage of Vado.

30. This prima facie assessment is based on the information available for the purpose of this buyer approval and does not prejudge the competition assessment of the acquisition of the Divestment Businesses by Terumo by a competent competition authority under applicable merger control rules.

III. CONCLUSION

31. On the basis of the above assessment, the Commission approves Terumo as a suitable purchaser for the above-mentioned reasons.

32. On the basis of the Proposed Agreement, the Commission further concludes that the Divestment Businesses are being sold in a manner consistent with the Commitments.

33. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreement. This decision does not constitute a confirmation that Abbott has complied with its Commitments.

34. This decision is based on Section D of the Commitments attached to the Commission Decision of 23 November 2016.

For the Commission

(signed)
Johannes LAITENBERGER
Director-General