



DETERMINATION OF MERGER NOTIFICATION M/15/050 - GREATBATCH / LAKE REGION MEDICAL

Section 21 of the Competition Act 2002

Proposed acquisition by Greatbatch of Lake Region Medical

Dated 21 October 2015

Introduction

1. On 11 September 2015, in accordance with section 18(1) of the Competition Act 2002, as amended¹ (“the Act”), the Competition and Consumer Protection Commission (“the Commission”) received a notification of a proposed transaction whereby Greatbatch, Inc. (“Greatbatch”) would acquire sole control of Lake Region Medical Holdings, Inc. (“Lake Region Medical”).

The Undertakings Involved

The Acquirer

2. Greatbatch², which is listed on the New York Stock Exchange, develops and manufactures medical device products, including the following:
 - a. Cardiac / Neurostimulation / Neuromodulation products: batteries, capacitors, filtered and unfiltered feedthroughs, enclosures, engineered components and some implantable stimulation leads used in implantable medical devices (“IMDs”).
 - b. Vascular products: off-the-shelf introducers, steerable sheaths, and certain shaft components for high performance specialty catheters that deliver minimally invasive therapies to treat disease states such as coronary, neurovascular and peripheral vascular disease.
 - c. Orthopaedic / Advanced Surgical products: hip and shoulder joint reconstruction implants, bone plates and spinal devices, and instruments and delivery systems used in hip replacement, trauma fixation, extremity and spine surgeries.

¹ It should be noted that the Competition and Consumer Protection Act 2014 made a number of important amendments to the merger review regime set out in the Competition Act 2002.

² www.greatbatch.com



- d. Portable Medical, Energy, Military and Environmental products: customised batteries and battery management systems, charging and docking stations, and power supplies.
3. Greatbatch does not have a manufacturing or research facility in Ireland. Greatbatch generates Irish turnover through making sales to original equipment manufacturers (“OEMs”) in the State (e.g. [...]) who in turn supply Irish hospitals and other healthcare providers. For the financial year ending 02 January 2015, Greatbatch had worldwide turnover of approximately €518 million and turnover in the State of approximately €[...].³

The Target

4. Lake Region Medical⁴, incorporated in Delaware, USA, develops and manufactures medical device products. Many of its products are components which are supplied to OEM customers, including the following:
 - a. Cardio-Vascular / Neurostimulation / Neuromodulation products: guidewires, steerable sheaths, diagnostic catheters, electrophysiology (ablation catheters for atrial fibrillation, electrophysiology catheters), cardiac rhythm management and neurostimulation (molded headers, machined components, conductor wire and cable, conductor coils, shocking coils, fixation helices, polymer extrusions, and lead delivery systems.)
 - b. Orthopaedic / Advanced Surgical products: energy based products (harmonic scalpels, advanced bipolar energy delivery devices), electromechanical products (endoscopes and laparoscopes), arthroscopy (shaver blades and burrs), spine and interventional spine (fusion plates, screws and artificial discs), reconstructive implants (hip stems and sleeves and femoral components), biopsy and drug delivery (implantable seeds, tubes, catheters and delivery systems), and electrical and optical mechanical devices
5. Lake Region Medical has manufacturing facilities in County Wexford and in Galway, where it manufactures guidewires, wire assemblies and hypotubes. Lake Region Medical also carries out certain research and development activities in Ireland.
6. Lake Region Medical generates Irish turnover through sales to OEMs based in the State.
7. For the financial year ending 31 December 2014, Lake Region Medical had worldwide turnover of approximately €[...] and turnover in the State of approximately €[...].⁵

The Vendor

8. Lake Region Medical is currently controlled by Accellent Inc, which is in turn indirectly controlled by funds managed by KKR & Co LP (“KKR”), a US-based global investment firm.

³ Converted from dollars using ECB 2014 annual average exchange rate of 1.3285.

⁴ www.lakeregionmedical.com

⁵ Converted from dollars using ECB 2014 annual average exchange rate of 1.3285.



9. After the proposed transaction, [...]. As noted above, the result of the proposed transaction will be that Greatbatch acquires sole control of Lake Region Medical.

Rationale for the Proposed Acquisition

10. The notification states:

“Greatbatch’s primary objectives are:

- *More comprehensive portfolio of solutions and services to OEM customers: both companies have highly-regarded positions with OEM customers in different sub-segments of the cardiac rhythm management, neuromodulation, vascular, orthopaedics and advanced surgical market segments. As a result, the newly combined company will be able to offer a substantially more comprehensive portfolio for customers utilising the best technologies, providing a single point of support, and driving optimal outcomes.*
- *Added scale and diversification: the combination creates a company with operations in the USA, Latin America, Europe and Asia-Pacific. The combination also broadens proprietary technologies and high volume, world-class manufacturing capabilities. In addition, it diversifies Greatbatch into the advanced surgical, vascular and interventional cardiology segments of medical technology.*
- *Enhanced customer access and experience: both Greatbatch and Lake Region [Medical] bring decades of innovation, R&D design excellence, operating excellence and committed partnerships with customers. Greatbatch expects to leverage the expanded R&D resources, manufacturing capabilities and reputation for innovation, quality and reliability to increase partnership opportunities with legacy customers. The combined company in partnership through OEM customers is ultimately expected to help hospitals, physicians and the healthcare systems improve patient outcomes in a cost-effective manner.*
- *Stronger financial profile and solid earnings accretion: 2014 combined revenues of Greatbatch and Lake Region Medical were approximately \$1.5 billion. The transaction is expected to be double-digit accretive to cash earnings per share in 2016, the first full fiscal year post-closing and meaningfully more accretive thereafter. The combined company expects to achieve net annual synergies at the operating profit level of \$25 million in 2016 which is expected to increase to at least \$60 million in 2018.”*

Third Party Submissions

11. No submission was received.

Competitive Analysis

12. Both Greatbatch and Lake Region Medical (collectively “the Parties”) are medical component manufacturers (“CMO”) for major OEM customers. CMOs such as the Parties offer outsourced manufacturing services that allow OEMs to generate efficiencies and benefit from greater focus and specialisation.



13. On the island of Ireland, there is a horizontal overlap between the Parties' activities in relation to the sale of certain orthopaedic implants, namely (i) instruments for use in conjunction with hip implants, and (ii) component parts of orthopaedic hip implants (collectively, the "Overlap Products").
14. The Commission defines markets to the extent necessary depending on the particular circumstances of a given case. In this instance, the Commission considers that it is not necessary to define precise relevant markets. However, since there is a horizontal overlap between the Parties, the Commission has reviewed the competitive impact of the proposed transaction on the market for the provision of the Overlap Products identified above.
15. The Overlap Products, which are sold on the island of Ireland, are manufactured by the Parties in the USA.
16. Lake Region Medical's sales of Overlap Products on the island of Ireland are made to [...] and in the 2014 financial year returned a turnover of €[...], or approximately [...]% of Lake Region's Irish turnover. These sales consist primarily of hip implant components.
17. Greatbatch's sales of Overlap Products on the island of Ireland are made to [...] ([...] having facilities in Ireland). Virtually all of the sales ([...]%) go to [...]. Greatbatch's 2014 sales to [...] were hip implant instruments totalling €[...]. For the financial year ending 02 January 2015, Greatbatch's total sales of Overlap Products on the island of Ireland generated turnover in the amount of €[...], or approximately [...]% of its turnover in the State.
18. According to the Parties, it is not possible to estimate Irish turnover generated by competitors of the Parties from sales of the Overlap Products in the most recent financial year. None of the CMO⁶ competitors is publicly-traded and there is no industry group or publication that publishes this financial information. Accordingly, the specified information is not publicly available and for the same reason it is difficult to calculate market shares in the State for the Overlap Products. The Parties estimate the worldwide market shares, including those of CMO companies, as set out in Table 1 below:

Table 1 – Estimated Worldwide Market Shares for Overlap Products

Competitor	Estimated Market Share % ⁷
OEMs	[40-50]%
Tecomet / Symmetry	[0-10]%
Orchid / Sandvik	[0-10]%
Greatbatch	[0-10]%

⁶ See para. 12 above

⁷ Percentages rounded to nearest round figure.



Competitor	Estimated Market Share % ⁷
Lisi Medical	[0-10]%
Marle	[0-10]%
Lake Region Medical	[0-10]%
Others	[20-30]%

Source: The Parties⁸

19. Apart from the fact that the proposed transaction will give rise only to a small accretion of market share, the proposed transaction is also unlikely to raise any competition concerns for the following reasons:

- OEM companies (such as Stryker, Zimmer, Smith & Nephew and DePuy) currently self-manufacture approximately [40-50]% of all hip implants worldwide, and have the equipment and capability to make their own implant components and instruments and as such they compete directly with specialist component / contract manufacturers.
- The dynamics in the market for the supply of Overlap Products in the State are such that the horizontal overlap between the Parties will not lead to a substantial lessening of competition. In particular:
 - OEMs have many CMOs to choose from when they seek to have an implant and/or instrument manufactured on an outsourced basis. Product quality, price competitiveness, delivery time, development engineering capability and service are some of the factors that are considered.
 - The Parties' current and potential future customers have numerous alternative CMOs to whom they can turn if they wish to outsource manufacturing processes.
 - Price competition for the Overlap Products regularly occurs in the context of tenders / bids for supply contracts to large OEMs.
 - OEMs generally choose to benefit from long term supply agreements that guarantee competitive and consistent pricing. However, switching suppliers can occur because of quality or delivery issues or production constraints preventing a supplier from meeting demand.

⁸ The parties' estimates are derived from "A Strategic Analysis of Contract Manufacturing in Orthopaedics", Avicenne Research 2012.



- The Parties' sales of Overlap Products in the State are generally pursuant to long-term agreements that establish a set price for the term and protect the customer.
 - Most OEMs have production and assembly locations throughout North America, Europe and Asia. Neither Greatbatch nor Lake Region Medical produces the Overlap Products in the State currently, suggesting that Irish customers do not regard proximate manufacturing facilities as a critical preference / requirement.
 - There are a large and varied (in size) number of competitors whose presence will constrain the activities of the merged entity post-transaction.
 - The Proposed Transaction does not give rise to a vertical overlap within the island of Ireland. (For completeness, the Parties notified a vertical overlap between the Parties' worldwide activities outside the island of Ireland, where Greatbatch purchases (from outside of the island of Ireland) guidewires manufactured in Lake Region's New Ross facility for use in the manufacture of introducers and other cardiovascular device products outside of the island of Ireland. Greatbatch also purchases connector blocks, set screws, connector pins, tubing shafts and other catheter components from Lake Region's non-Irish facilities.)
20. In light of the above the Commission considers that the proposed acquisition will not substantially lessen competition in any market for goods or services in the State.

Ancillary Restraints

21. No ancillary restraints were notified.



Determination

The Competition and Consumer Protection Commission, in accordance with section 21(2)(a) of the Competition Act 2002, as amended, has determined that, in its opinion, the result of the proposed acquisition whereby Greatbatch, Inc. would acquire sole control of Lake Region Medical Holdings, Inc., will not be to substantially lessen competition in any market for goods or services in the State, and accordingly, that the acquisition may be put into effect.

For the Competition and Consumer Protection Commission

Gerald FitzGerald
Member
Competition and Consumer Protection Commission