ANTICIPATED ACQUISITION BY COCHLEAR LIMITED OF THE HEARING IMPLANTS DIVISION OF DEMANT A/S

Issues statement

20 January 2023

The reference

1. On 20 December 2022, the Competition and Markets Authority (**CMA**), in exercise of its duty under section 33(1) of the Enterprise Act 2002 (the **Act**), referred the anticipated acquisition by Cochlear Limited (**Cochlear**) of the hearing implants division (**Oticon Medical**) of Demant A/S (**Demant**) (the **Merger**) for further investigation and report by a group of CMA panel members (the **Inquiry Group**). Cochlear and Demant are together referred to as the **Parties**, and for statements referring to the post-Merger situation, Cochlear and Oticon Medical are referred to as the **Merged Entity**.

2. In exercise of its duty under section 36(1) of the Act, the CMA must decide:

   (a) whether arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation; and

   (b) if so, whether the creation of that relevant merger situation may be expected to result in a substantial lessening of competition (**SLC**) within any market or markets in the United Kingdom (**UK**) for goods or services.

Purpose of this issues statement

3. In this issues statement, we set out the main issues we are likely to consider in reaching a decision on the SLC question (paragraph 2(b) above), taking into account the evidence available to us to date, including the evidence obtained in the CMA's phase 1 investigation, and further evidence that will be obtained during our phase 2 investigation. This does not preclude the consideration of any other issues which may be identified during the course of our investigation.

4. The CMA's phase 1 decision (the **Phase 1 Decision**)[1] contains much of the detailed background to this issues statement. We are publishing this issues statement to assist parties submitting evidence to our phase 2 investigation.

5. As noted above, this issues statement sets out the main issues we are likely to consider in our investigation and we invite parties to notify us if there are any additional relevant issues which they believe we should consider.

Background

The Parties

6. Cochlear is a public company listed on the Australian Securities Exchange and headquartered in Sydney.[2] Cochlear manufactures and supplies hearing devices used by healthcare professionals to treat a range of types of hearing loss, with a particular focus on cochlear implants (**CI**) and bone conduction solutions (**BCS**) (together, **hearing implants**).[3] In the UK, Cochlear's CI products include the Nucleus range, and its BCS products include the Osia 2, Baha Connect, Baha Attract and a softband non-surgical device.

7. The turnover of Cochlear in the financial year 2021 was approximately £878 million worldwide, of which approximately £[✂] million was generated in the UK.[4]

8. Demant is a global hearing healthcare and technology group headquartered in Denmark and listed on the Copenhagen Stock Exchange.[5] Demant develops, manufactures and supplies hearing implants (both CI and BCS) through **Oticon Medical**.[6] Demant also develops and supplies hearing aids, operates clinics providing hearing care solutions, and supplies hearing diagnostic products and audio solutions for enterprise, gaming and air traffic control.[7]

9. Oticon Medical's turnover in the financial year 2021 was approximately £[✂] million worldwide, of which approximately £[✂] million was generated in the UK.[8]

10. The Parties overlap in the supply of hearing implants in the UK.

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[1] Available on the case page: Cochlear / Oticon merger inquiry - GOV.UK (www.gov.uk).
[2] Final Merger Notice (**FMN**), paragraph 45.
[3] FMN, paragraph 45.
[4] FMN, paragraph 46.
[5] FMN, paragraph 48.
[6] FMN, paragraph 49.
[7] FMN, paragraph 49.
[8] FMN, paragraph 53.

The transaction

11. Cochlear and Demant entered into a Put Option Agreement and agreed the form of the Asset Sale and Purchase Agreement on 27 April 2022, which was finalised on 25 May 2022.[9] Cochlear, upon completion of the Merger, would acquire 100% of the shares of Oticon Medical's legal entities, which are:

    (a) Oticon Medical AB, a Swedish private limited liability company;

    (b) Oticon Medical Maroc, a Moroccan limited liability company;

    (c) Oticon Medical, LLC, a US limited liability company incorporated in New Jersey;

    (d) Neurelec S.A.S, a French simplified joint-stock corporation; and

    (e) Oticon Medical A/S, a Danish private limited company.[10]

12. The Merger consideration is DKK 850,000 (a little under £100 million).[11]

13. The Parties initially informed the CMA that the Merger is also the subject of review by competition authorities in Australia and Spain. The Spanish authority subsequently requested the referral of the Merger to the European Commission.[12]

14. Cochlear has submitted that its strategic rationale for the Merger is to gain increased scale to invest in hearing implants technology and clinical trials, which would improve awareness of and access to hearing implants, provide patients with clinical solutions better suited to their needs, and provide long-term support to Oticon Medical's CI and BCS patients, in order to avoid detriment to these patients and reputational damage to the industry.[13]

Our inquiry

15. Below we set out the main areas of our intended assessment in order to help parties who wish to make representations to us.

Jurisdiction

16. We shall consider the question of jurisdiction in our inquiry.

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[9] FMN, paragraph 55.
[10] FMN, paragraph 56; Cochlear will also acquire certain other assets, including the relevant intellectual property and the transfer of current employees employed within the above entities. FMN, paragraph 56(b).
[11] FMN, paragraph 58.
[12] FMN, paragraph 59.
[13] FMN, paragraph 62.

17. In the case of an anticipated merger, a relevant merger situation exists where the following conditions are satisfied:[14]

    (a) Two or more enterprises[15] have ceased to be distinct; and

    (b) Either:

        (i) the value of the target enterprise's UK turnover exceeded £70 million in its last fiscal year (the **turnover test**); or

        (ii) the enterprises ceasing to be distinct have a share of supply in the UK, or in a substantial part of the UK, of 25% or more in relation to goods or services of any description (the **share of supply test**).

18. In its Phase 1 Decision,[16] the CMA found that it had jurisdiction to review the Merger on the basis that it believed that it is or may be the case that:

    (a) each of Cochlear and Oticon Medical is an enterprise, and that these enterprises will cease to be distinct as a result of the Merger; and

    (b) the share of supply test is satisfied on the basis that the Parties overlap in the supply of BCS services in the UK and have a combined share of supply, when measured by either value or volume, of approximately [90–100%] (with an increment of approximately [20–30%] based on volume, and an increment of approximately [40–50%].

Counterfactual

19. We will compare the prospects for competition resulting from the Merger against the competitive situation without the Merger: the latter is called the 'counterfactual'. The counterfactual is not a statutory test but rather an analytical tool used in answering the question of whether a merger gives rise to an SLC.[17]

20. For anticipated mergers the CMA generally adopts the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. The CMA's Phase 1 Decision found that the relevant counterfactual is the prevailing conditions of competition.[18]

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[14] Section 23 of the Act.
[15] An enterprise is defined under section 129(1) of the Act as the activities, or part of the activities, of a business. A business includes a professional practice and any other undertaking which is carried on for gain or reward, or which supplies goods or services otherwise than free of charge.
[16] Phase 1 Decision, paragraphs 28–30.
[17] Merger Assessment Guidelines (CMA129) (March 2021) (**MAGs**), paragraph 3.1.
[18] Phase 1 Decision, paragraph 76.

21. The Parties submitted that the counterfactual to the Merger is that Demant would have inevitably exited the hearing implants segment, while maintaining some limited activities (in-house or outsourced) in order to provide continued support to its installed base of patients, and that there would not have been an alternative purchaser for Oticon Medical.[19] As such, Demant submitted that it would not, absent the Merger, be competing against Cochlear in the supply of BCS and, as a result, the Merger cannot result in any loss of competition.[20]

22. The CMA will consider an exiting firm scenario where it is submitted that one of the merger firms would have exited a market because of financial failure or for other reasons, such as a change in the firm's corporate strategy.[21] As set out in the CMA's Merger Assessment Guidelines (the **MAGs**), in a phase 2 investigation the CMA will select the most likely conditions of competition as its counterfactual against which to assess the merger.[22] In forming a view on an exiting firm counterfactual, the CMA will consider whether it is most likely that absent the merger:

    (a) the firm is likely to have exited (through failure or otherwise) (**limb 1**); and, if so

    (b) there would not have been an alternative, less anti-competitive purchaser for the firm or its assets to the acquirer in question (**limb 2**).[23]

23. Based on the evidence it had received, the CMA in phase 1 believed strategic exit was one of a number of options considered by Demant, and that Demant decided to try to sell Oticon Medical in the first instance. The CMA did not consider that the evidence showed, to the legal standard required in a phase 1 investigation, that Oticon Medical would have exited had Demant not agreed to sell the business to Cochlear. Moreover, the CMA also considered it would have been commercially irrational for Demant to discontinue the entire hearing implant business without at least fully exploring other options given parts of the business were generating profits and worth almost £100 million.[24]

24. The CMA in phase 1 noted that the sales process for Oticon Medical was limited to Demant informally approaching [✂]. Oticon Medical was not marketed to other [✂]. As such, the CMA considered that Demant did not run a sales process that was sufficient to establish whether there would be an alternative, less anti-competitive buyer to Cochlear.[25] The CMA also noted that Demant had submitted that at least one other party ([✂]) had expressed

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[19] FMN, paragraphs 8 and 117.
[20] Phase 1 Decision, paragraph 6.
[21] MAGs, paragraph 3.22.
[22] MAGs, paragraph 3.23.
[23] MAGs, paragraph 3.21.
[24] Phase 1 Decision, paragraph 7.
[25] Phase 1 Decision, paragraph 71.

some interest in acquiring at least some of Oticon Medical but that this interest was not pursued by Demant.[26]

25. In the CMA's assessment in phase 1, the very limited sales process and the possibility that [✂] could have acquired at least some of Oticon Medical did not provide a basis for the CMA to rule out that there could have been an alternative, less anti-competitive purchaser for one or both of the BCS and CI businesses.[27]

26. In view of the above, and subject to further evidence obtained in the phase 2 investigation, our starting point is that our assessment should be based against the prevailing conditions of competition, as the most likely counterfactual to the Merger, but we welcome any further evidence on this part of our assessment.

Assessment of the competitive effects of the Merger

Theory of harm

27. The term 'theory of harm' refers to the hypothesis about how the process of rivalry could be harmed as a result of a merger. Theories of harm provide a framework for assessing the competitive effects of a merger and whether or not it could lead to an SLC relative to the counterfactual.[28]

28. In its Phase 1 Decision, the CMA found that the Merger gave rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of BCS in the UK, given that it would eliminate the strongest competitor and create a near monopoly supplier in the UK.[29]

29. We are minded to focus our competitive assessment on this theory of harm at phase 2.

30. Identifying a theory of harm in this issues statement does not preclude an SLC being identified on another basis following further work, or receipt of additional evidence. However, subject to new evidence being submitted, we do not currently intend to investigate any other theories of harm in relation to this Merger.

[26] Phase 1 Decision, paragraph 73.
[27] Phase 1 Decision, paragraph 74.
[28] MAGs, paragraph 2.11.
[29] Phase 1 Decision, paragraph 129.

Horizontal unilateral effects

31. Unilateral effects can arise in a horizontal merger when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged entity profitably to raise prices or degrade non-price aspects of its competitive offering (such as quality, range, service and innovation) on its own and without needing to coordinate with its rivals. Unilateral effects giving rise to an SLC can occur in relation to customers at any level of a supply chain, for example at a wholesale level or retail level (or both) and is not limited to end consumers.[30]

32. Our assessment of mergers is generally forward-looking, and we will seek to account for the future evolution of competitive conditions when assessing a merger.[31] This includes developments in the merger parties' competitive offering and the competitive offering of third parties.

33. BCS devices can be categorised as passive BCS or active BCS.[32] Passive BCS can further be categorised by transcutaneous BCS or percutaneous BCS.[33] BCS have traditionally been passive. Oticon Medical is currently the leading supplier of passive BCS, with Cochlear the only other option for patients and clinics. During the phase 1 investigation, the Parties submitted that active BCS is becoming more frequently used. Cochlear supplies active BCS as does one other supplier (Med El). Oticon Medical does not currently have an active BCS, but in the Phase 1 Decision the CMA considered that Oticon Medical's efforts to innovate and launch an active BCS product already provide Cochlear with a strong incentive to innovate to defend against this threat.[34].

34. In our assessment we will focus on:

    (a) the potential growth in active BCS and the extent to which it will replace passive BCS;

    (b) whether going forward Oticon Medical's passive BCS would likely exert a sufficient constraint on Cochlear's active PCS;

    (c) the likelihood of Oticon Medical becoming a significant or strong competitor in the supply of active BCS in the future; and

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[30] MAGs, paragraph 4.1.
[31] MAGs, paragraph 4.16.
[32] Passive BCS use an external transducer (ie outside of the skin) whereas active BCS use an implanted transducer, to transmit the necessary vibrations to the inner ear. Non-surgical BCS, are also available primarily for children or for adults with fluctuating degrees of hearing loss.
[33] Transcutaneous BCS implants do not penetrate the skin while percutaneous BCS feature an abutment that penetrates the skin.
[34] Phase 1 Decision, paragraph 131.

(d) the extent to which the threat of Oticon Medical becoming a significant or strong competitor in the supply of active BCS in the future currently constrains Cochlear.

35. We will consider:

(a) shares of supply;

(b) closeness of competition[35] between the Parties taking into account the Parties' internal documents, and the views of the Parties, competitors and customers;

(c) other competitive constraints on the Parties; and

(d) forecasts and projections of the Parties and other competitors.

Market definition

36. Where the CMA makes an SLC finding, this must be 'within any market or markets in the United Kingdom for goods or services'.[36] The CMA is therefore required to identify the market or markets within which an SLC may be expected to result. An SLC can affect the whole or part of a market or markets. Within that context, the assessment of the relevant market is an analytical tool that forms part of the analysis of the competitive effects of a merger and should not be viewed as a separate exercise.[37]

37. In its Phase 1 Decision, the CMA considered that BCS products served distinct clinical patient needs compared to CI, and that other hearing solutions, such as hearing aids, were not good alternatives for BCS products. BCS products are typically prescribed after hearing aids have been tried and failed. They typically seek to correct more serious hearing loss than hearing aids, cost significantly more than hearing aids, and, unlike hearing aids, require surgery. The CMA considered the impact of the Merger on the basis of the supply of (i) BCS and, separately (ii) CI, in the UK.[38]

38. We will use the frame of reference adopted in the Phase 1 Decision as a starting point for our analysis, and our view of market definition will be largely drawn from the same evidence that informs our competitive assessment.

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[35] In line with the MAGs (paragraphs 4.19 and 4.20), with the exception of sponsored entry, which we will consider as part of countervailing factors, we will cover buyer power as part of our assessment of competitive effects. Paragraph 4.20 states 'Most other forms of buyer power that do not result in new entry – for example, buyer power based on a customer's size, sophistication, or ability to switch easily – are unlikely to prevent an SLC that would otherwise arise from the elimination of competition between the merger firms. This is because a customer's buyer power depends on the availability of good alternatives they can switch to, which in the context of an SLC will have been reduced. In that sense, market power and buyer power are two sides of the same coin, and an SLC can be interpreted as a substantial lessening of customers' buyer power'.
[36] Section 36(1)(b), the Act.
[37] MAGs, paragraph 9.1.
[38] Phase 1 Decision, paragraph 5.

Where relevant, we will consider out-of-market constraints and/or any differences in the degree of competitive constraints on the Merged Entity from different suppliers.

Countervailing factors

39. We will consider whether there are countervailing factors which prevent or mitigate any SLC that we may find. Some of the evidence that is relevant to the assessment of countervailing factors may also be relevant to our competitive assessment.

40. We will consider evidence of entry and/or expansion by third parties, including that sponsored by the NHS, and whether entry and/or expansion would be timely, likely and sufficient to prevent any SLC from arising as a result of the Merger.[39]

41. We will also consider any relevant evidence submitted to us by the Parties that the Merger is likely to give rise to efficiencies that will enhance rivalry, such that the Merger may not be expected to result in an SLC.[40]

Possible remedies and relevant customer benefits

42. Should we conclude that the Merger may be expected to result in an SLC within one or more markets in the UK, we will consider whether, and if so what, remedies might be appropriate.

43. In any consideration of possible remedies, we may have regard to their effect on any relevant customer benefits that might be expected to arise as a result of the Merger and, if so, what these benefits are likely to be and which customers would benefit.[41]

Responses to this issues statement

44. Any party wishing to respond to this issues statement should do so in writing, by no later than **17:00 (UK time) on Friday 3 February 2023** by emailing Cochlear.Oticon@cma.gov.uk.

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[39] MAGs, paragraphs 8.28–8.46.
[40] In order to reach a view that such efficiencies prevent or mitigate any SLC found, the CMA must be satisfied that the evidence shows that that the merger efficiencies: (a) enhance rivalry in the supply of those products where an SLC may otherwise arise; (b) are timely, likely and sufficient to prevent an SLC from arising; (c) be merger-specific; and (d) benefit customers in the UK (MAGs, paragraph 8.8).
[41] Merger Remedies (CMA87) (13 December 2018), paragraphs 3.4 and 3.15–3.24.