Anticipated acquisition by Cochlear Limited of the hearing implants division of Demant A/S

Final report

22 June 2023

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The Competition and Markets Authority has excluded from this published version of the report information which the Inquiry Group considers should be excluded having regard to the three considerations set out in section 244 of the Enterprise Act 2002 (specified information: considerations relevant to disclosure). The omissions are indicated by [✂]. Some numbers have been replaced by a range. These are shown in square brackets.

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Summary

Overview of our findings

1. The Competition and Markets Authority (**CMA**) has found that Cochlear Limited's (**Cochlear**'s) proposed purchase of the hearing implants division (**Oticon Medical**) of Demant A\S (**Demant**) (the **Merger**) may be expected to result in a substantial lessening of competition (**SLC**) in the supply of bone conduction solutions (**BCS**) in the UK.[1] This could lead to poorer patient outcomes, with patients potentially facing less choice, reduced quality or reduced product innovation, as well as the potential for higher prices for the NHS.

2. Having found that the Merger may be expected to result in an SLC in the supply of BCS, we have concluded that a partial prohibition of the Merger, that is prohibiting the sale of the BCS business of Oticon Medical to Cochlear, would be an effective and proportionate remedy to address our concerns.

Who are the businesses and what products do they provide?

3. 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 BCS (together, **hearing implants**).[2]

4. Demant develops, manufactures and supplies hearing implants (both CI and BCS) through Oticon Medical.[3] Demant also supplies hearing aids, operates clinics providing hearing care solutions, and supplies hearing diagnostic products and audio solutions for enterprise, gaming and air traffic control.[4]

5. BCS are used in the treatment of conductive, mixed and single-sided hearing loss. They bypass damaged parts of the ear by using a sound processor that converts sounds into vibrations that are sent directly to the inner ear.[5] There are two types of BCS products: Passive and Active. They differ in the way they connect the transducer (that translates sounds into vibrations transmitted through the bone) to the sound processor.

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[1] We refer to Cochlear and Demant collectively as 'the **Parties**', and post-Merger to Cochlear and Oticon Medical collectively as 'the **Merged Entity**'.
[2] Final Merger Notice (FMN), paragraph 45.
[3] FMN, paragraph 49.
[4] FMN, paragraph 49.
[5] FMN, page 2.

Our assessment

Why did we review this merger?

6. The CMA's primary duty is to seek to promote competition for the benefit of consumers.[6] It has a duty to investigate mergers that could raise competition concerns in the UK, provided it has jurisdiction to do so.[7]

7. In this case, the CMA has jurisdiction over the Merger because the Parties' overlapping activities meet the 'share of supply' jurisdictional test: the Parties have a combined share of supply of BCS products in the UK of [90-100%].

What evidence have we looked at?

8. In assessing the competitive effects of the Merger, we looked at a wide range of evidence that we considered in the round to reach our findings.

9. We received submissions and responses to information requests from the Parties and held hearings with each of Cochlear and Demant. We also examined a significant volume of the Parties' own internal documents, which show how they run their businesses and how they view their rivals in the ordinary course of business. These internal documents were also helpful in understanding the Parties' thinking at the time of the proposals for the Merger and their plans for the future of their businesses.

10. We spoke to and gathered information from NHS purchasing authorities, clinics that are responsible for selecting these products on behalf of patients, competitors and other interested parties to understand the competitive landscape and get their views on the impact of the Merger.

11. We also considered evidence from the Parties and third parties received during the CMA's phase 1 investigation into the Merger.

[6] Section 25(3) Enterprise and Regulatory Reform Act 2013.
[7] In relation to anticipated mergers, sections 33 and 36 Enterprise Act 2002.

What did the evidence tell us …

… about what would likely have happened had the Merger not taken place?

12. In order to determine what (if any) impact the Merger may be expected to have on competition, we have considered what would likely have happened had the Merger not taken place. This is known as the counterfactual.

13. Demant told us that it had taken a decision to exit the business for the supply of hearing implants and that if it had been unable to sell the business, it would have closed it down, while maintaining some services to people who already had been fitted with its hearing implants, such as servicing and repairs of their implants. Demant said that the Oticon Medical business had been loss-making for some time; it was only a small proportion of Demant's overall business; and it was an unwelcome distraction from Demant's core business in hearing aids.

14. The Parties told us that Cochlear was the only potential purchaser who had the scale needed to cover fixed costs, would be able to invest in the required level of R&D, and would be able to provide an appropriate level of long-term support for Oticon Medical's existing patients.

15. We considered whether it was likely that Demant would have closed the implant business, if it was unable to sell the business to Cochlear.

16. Oticon Medical has been loss-making. This was exacerbated by a product recall for its CI product in 2021 and by the Coronavirus (COVID-19) pandemic, which effectively stopped most implant surgeries. There is no evidence from the time the Merger was agreed of a decision to close the Oticon Medical business. Demant provided evidence, which was prepared after the announcement of the Merger, describing discussions at Board level about a desire to exit the hearing implant business with a solution that would ensure the best lifelong support for its patients.

17. Internal Demant management accounts from the time show the BCS business to have been profitable and growing, a trend that has continued since the announcement of the Merger. Internal Oticon Medical documents also show that the development of a new Active BCS product (Sentio) to rival Cochlear's Osia product was continuing, despite challenges along the way.

18. The Parties provided evidence which was produced after the announcement of the Merger to show that the BCS profitability may have been supported to some extent by services from the wider Demant group and may have

benefitted from some costs shared with the CI side of the business. Our view is that this type of cross-business support is quite common for large, multi-product businesses and is not evidence that Demant would necessarily have had an incentive to close the business. In response to the Remedies Notice, Demant produced further analysis showing the BCS business (separate from the CI business, but retained within the Demant Group) to be profitable. Moreover, the growing revenues in Oticon Medical's existing Passive BCS implants and processors, along with a potentially valuable IP asset in Sentio, would have made Oticon Medical's BCS business potentially attractive to alternative purchasers, whether as a standalone business or as part of the wider Oticon Medical business.

19. Alternative purchasers expressed interest in Oticon Medical, particularly, but not solely, in the BCS business. These potential purchasers continue to express interest in the business.

20. We conclude that if the Merger did not go ahead, the most likely counterfactual is that Oticon Medical would have continued to operate in the BCS business, either as part of Demant or having been sold to an alternative purchaser.

… about the effects of the Merger?

21. We considered the degree of rivalry between the Parties in the supply of BCS products. The Parties are the two largest BCS suppliers in the UK with a combined market share of [90–100%] in 2022. MED-EL UK Limited (**MED-EL**) is the only other supplier in the UK.

22. The Parties told us that the sector is shifting from Passive BCS to Active BCS at a significant rate. Oticon Medical does not currently have an Active BCS product and the Parties told us that the future of Sentio is unclear.

23. The evidence from clinics and from the Parties' internal documents shows that Passive BCS products will continue to be prescribed to a significant percentage of patients over the next two to three years, despite the increasing use of Active BCS.

24. The evidence shows that the Parties are each other's closest competitor in relation to Passive BCS and competition from MED-EL's Active BCS product is significantly weaker. Our view is that the Merger would likely lead to a reduction in competition in Passive BCS by bringing together the only two suppliers of Passive BCS products in the UK.

25. Our view is that the Merger would also likely lead to a reduction in competition for Active BCS products. Cochlear is by far the larger of the only two existing suppliers of Active BCS products in the UK: MED-EL being the other supplier. The evidence from Oticon Medical shows that the development of Sentio, Oticon Medical's new Active BCS product, is progressing. If launched, both Parties expect Sentio to compete with Cochlear's Osia product. In our view, internal documents show that Cochlear views Sentio as a competitive threat and is already responding to that threat. Our view is that the Merger would likely result in the loss of that competition from Sentio.

26. Contrary to the Parties' view that BCS suppliers compete with providers of other hearing solutions, our view is that the evidence from clinics and internal documents shows that competition from other hearing solutions is limited.

27. Our view is that the Parties currently impose an important competitive constraint on each other that would be lost as a result of the Merger. The market is already highly concentrated, and the Merged Entity would face limited competition from other suppliers post-Merger.

…. about the extent of buyer power against the Parties?

28. The Parties told us that the NHS is the main buyer of BCS products in the UK and has significant buyer power. With the exception of entry, which we cover below, a customer's buyer power depends on the availability of good alternative suppliers it can switch to which in our view would be likely substantially reduced as a result of the Merger.

…. about any countervailing factors?

29. We considered whether there are any actions which customers and/or potential entrants could take to prevent or mitigate any SLC arising from the Merger in the supply of BCS products in the UK.

30. We have not received any evidence on whether there are any Merger-specific, rivalry enhancing efficiencies which benefit UK customers that would be timely, likely and sufficient to prevent an SLC.

31. Nor have we received evidence from the Parties or third parties that entry or expansion, including that sponsored by the NHS, would be timely, likely and sufficient to prevent an SLC.

… about the overall impact of the Merger on consumers and the NHS?

32. Our statutory duty is to assess whether the Merger may be expected to result in an SLC within any market or markets in the UK for goods or services. Any such reduction in competition can have a potential impact on consumers.

33. In this case, we are concerned that the Merger could lead to poorer patient outcomes, with patients potentially facing less choice, reduced quality or reduced product innovation, as well as the potential for higher prices for the NHS.

Conclusion

34. Our view is that the Merger will eliminate a major BCS competitor from the market, that in addition to the Merged Entity only one BCS supplier would remain, and that the competition from that supplier and other hearing solutions would not be sufficient to offset the effects on competition of the Merger. The loss of this competitor would significantly reduce the alternatives available to the NHS and patients. We do not consider that entry or expansion would be likely, timely and sufficient to prevent an SLC from arising.

35. For the reasons above, we conclude that the Merger may be expected to result in an SLC in the supply of BCS products in the UK.

How will we address the competition concerns we have found?

36. Where we conclude that an anticipated merger may be expected to result in an SLC, we are required to decide what, if any, action should be taken to remedy, mitigate or prevent that SLC, or any adverse effect resulting from the SLC. In assessing possible remedies, we have sought to identify remedies that will be effective in addressing the SLC and resulting adverse effects we found and then selected the most proportionate remedy that we consider to be effective.

37. Following consultation with the Parties and third parties, we have decided that a partial prohibition of the Merger, that is prohibiting the sale of the BCS business to Cochlear, is the least costly or restrictive remedy out of the remedies that we consider to be effective in addressing the SLC and its adverse effects that we have found.

38. We acknowledge that there are possible risks associated with a partial prohibition, such as those arising from the need for an ongoing relationship between the two key competitors in the market for BCS products, for a transitional period, while Demant supports the CI business's transfer to Cochlear. In order to ensure that the effectiveness of a partial prohibition remedy is not undermined, the terms of the separation process and sale of the CI business will require our approval before the transaction may complete.

What happens next?

39. The CMA will now take steps to implement the remedy described above. In line with statutory requirements, the CMA will implement its remedy decision within 12 weeks of publication of the final report, which may be extended once by up to six weeks if there are special reasons for doing so.[8]

40. If the CI business is sold to Cochlear, we will require that a monitoring trustee or equivalent independent expert is appointed to assist our assessment of the separation process and ensure that the effectiveness of the remedy is not undermined. The Parties will only be able to complete the transfer of the CI business to Cochlear subject to our approval of the terms of all agreements related to the separation. In the event that we do not approve the terms of the transaction, it will not be permitted to go ahead, and in that case the entire transaction would be prohibited.

[8] Section 41A of the Enterprise Act 2002; see also Merger remedies guidance (CMA87), paragraph 4.68.

Findings

1. The reference

1.1 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 (the **Merger**) by Cochlear Limited (**Cochlear**) of the hearing implants division (**Oticon Medical**) of Demant A/S (**Demant**) for further investigation and report by a group of CMA panel members (the **Inquiry Group**).

1.2 Cochlear and Demant are together referred to as the **Parties**. For statements referring to the future, Cochlear and Oticon Medical are referred to as the **Merged Entity**.

1.3 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.

1.4 Our terms of reference are set out at **Appendix A**. We are required to publish our final report by 31 July 2023.[9]

1.5 This document, together with its appendices, constitutes the CMA's findings published and notified to Cochlear and Demant in line with the CMA's rules of procedure.[10] Further information relevant to this inquiry can be found on the CMA case page.[11]

2. The Parties, the products and the Merger

The Parties

2.1 Cochlear is a public company listed on the Australian Securities Exchange and headquartered in Sydney.[12] Cochlear manufactures and supplies hearing

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[9] The statutory deadline was extended by eight weeks pursuant to section 39(3) of the Act. For further information, see Appendix B on the conduct of the inquiry.
[10] CMA rules of procedure for merger, market and special reference groups (CMA17), Rule 11.
[11] Cochlear/Oticon merger case page.
[12] Final Merger Notice dated 7 October 2022 (**FMN**), paragraph 45.

products globally, which treat a range of types of hearing loss, with a particular focus on cochlear implants (**CI**) and bone conduction solutions (**BCS**).[13] Cochlear's worldwide turnover in its 2021 financial year was approximately £878 million, of which approximately £[✂] million was generated in the UK.[14]

2.2 Demant is a global hearing healthcare and technology group headquartered in Denmark and listed on the Copenhagen Stock Exchange.[15] Demant develops, manufactures and supplies hearing implants (both CI and BCS) through Oticon Medical.[16] Oticon Medical's worldwide turnover in its financial year 2021 was approximately £[✂] million, of which approximately £[✂] million was generated in the UK.[17]

The products

Cochlear Implants

2.3 CI are electronic products designed to replace a patient's damaged inner ear or cochlea. Unlike hearing aids, which amplify sounds, CI bypass the functions of the middle and inner-ear structures and stimulate auditory nerves directly.[18] CI consist of an external processor which contains a microphone to pick up sound, a sound processor to convert those sounds into electrical signals, and an internal implant which sends signals to the inner ear.[19]

2.4 CI are typically used for patients experiencing severe or total hearing loss.[20] CI are classified as 'Class III' medical devices in the UK, [21] and the surgery typically requires a general anaesthetic.

Bone Conduction Solutions

2.5 BCS are used in the treatment of conductive, mixed and single-sided hearing loss. They bypass damaged parts of the ear by using a sound processor that converts sounds into vibrations that are sent directly to the inner ear.[22] BCS rely on the stimulation of bones in the patient's skull to bypass damaged outer

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[13] FMN, paragraph 45.
[14] FMN, paragraph 46.
[15] FMN, paragraph 48.
[16] FMN, paragraph 49.
[17] FMN, paragraph 53.
[18] FMN, paragraph 140.
[19] FMN, paragraph 141.
[20] FMN, paragraph 142(a).
[21] FMN, paragraph 263; In the UK, medical products are classified into four risk levels (I, IIa, IIb and III), with Class III devices being the highest risk. See Chapter 2: Classification - GOV.UK for further information.
[22] FMN, page 2.

or middle ear structures.[23] This is achieved through an external sound processor which converts sounds into vibrations that are sent through the skull to the inner ear.[24] BCS products can be subcategorised into:[25]

(a) *Passive BCS:* These rely on vibrations created by an external transducer which are transmitted to an internal implant before travelling to the inner ear.[26] Passive BCS products generally use an abutment which penetrates the skin to hold the sound processor in place.[27] Passive BCS products are usually categorised as Class II medical products in the UK, and the surgery typically involves a 10-20 minute procedure under local anaesthetic.[28]

(b) *Active BCS:* These use an internal implant or transducer to create the necessary vibrations to stimulate bones in the inner ear to produce sound. These products do not require an abutment and leave the skin intact.[29] Similar to a CI, active BCS products are classified as Class III products in the UK and typically require a general anaesthetic during surgery.[30]

(c) *Non-Surgical BCS*: These are typically used for children who are too young for surgery, patients who cannot have surgery or patients who want to sample BCS before adopting a surgical solution.[31] These products typically use a headband to hold an external sound processor in place which will generate vibrations through the skin to the skull without an implant.[32]

2.6 BCSs are suitable for patients with mild, moderate, moderately severe, or severe hearing loss.[33]

The Merger

2.7 On 25 May 2022, Cochlear agreed to acquire Oticon Medical for DKK 850 million (approximately GBP 100 million).[34]

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[23] FMN, paragraph 146.
[24] FMN, paragraph 146.
[25] FMN, paragraph 147
[26] FMN, paragraph 147.
[27] FMN, paragraph 147.
[28] FMN, paragraphs 3 and 263.
[29] FMN, paragraph 148.
[30] FMN, paragraph 29; Third party responses to the CMA's questionnaire.
[31] FMN, paragraph 186.
[32] FMN, paragraph 155.
[33] FMN, paragraph 146.
[34] FMN, paragraphs 55 and 58. The GBP figure is derived from a conversion of DKK based on the Bank of England exchange rate as of 12 September 2022 (GBP 1 = DKK 8.95920) (FMN, footnote 79).

Merger rationale

2.8 Cochlear submitted that the strategic rationale for the Merger is to gain increased scale to invest in hearing implants technological 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.[35]

3. Relevant merger situation

3.1 This chapter addresses the first of the two statutory questions which we are required to answer under section 36 of the Act and pursuant to our Terms of Reference (see Appendix A), namely: whether arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

3.2 The concept of a relevant merger situation has two principal elements: two or more enterprises cease to be distinct enterprises within the statutory period for reference;[36] and the turnover test and/or the share of supply test is satisfied.[37]

Enterprises

3.3 The Act defines an 'enterprise' as 'the activities or part of the activities of a business'.[38] A 'business' is defined as including 'a professional practice and includes any other undertaking which is carried on for gain or reward or which is an undertaking in the course of which goods or services are supplied otherwise than free of charge'.[39]

3.4 Each of Cochlear and Oticon Medical is active in the supply of BCS products in the UK and generates turnover worldwide and in the UK (see Chapter 2 above). Our view is therefore that each of Cochlear and Oticon Medical is a 'business' within the meaning of the Act and that, accordingly, the activities of each of Cochlear and Oticon Medical are an 'enterprise' for the purposes of the Act.

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[35] FMN, paragraph 62.
[36] Sections 23 and 24 of the Act.
[37] Section 23 of the Act.
[38] Section 129(1) of the Act.
[39] Section 129(1) and (3) of the Act.

Ceasing to be distinct

3.5 The Act provides that two enterprises cease to be distinct if they are brought under common ownership or common control.[40]

3.6 The Merger concerns the acquisition by Cochlear of the entire issued share capital 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.[41]

3.7 On completion of the Merger, Oticon Medical will be under the common ownership and control of Cochlear.[42] Our view is therefore that arrangements are in progress or in contemplation which, if carried into effect, will result in the enterprises of Cochlear and Oticon Medical ceasing to be distinct.

3.8 The Merger has not yet completed, so Cochlear and Oticon Medical remain independent enterprises. Our view is therefore that the four-month time limit (the statutory period for reference) for a relevant merger situation under the Act is not engaged in the present circumstances.[43]

Turnover test

3.9 The turnover test is satisfied where the value of the turnover in the UK of the enterprise being taken over exceeds £70 million.[44] In this case, the turnover test is not satisfied as the turnover in the UK of Oticon Medical does not exceed £70 million (see Chapter 2 above). Our view is therefore that the turnover test in section 23 of the Act is not met.

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[40] Section 26 of the Act.
[41] 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)).
[42] On completion of the Merger, Cochlear will have a 'controlling interest' in the Oticon Medical enterprise within the meaning of that term in section 26 of the Act.
[43] Section 24 of the Act. In summary, the four-month time limit applies only where the enterprises *have ceased* to be distinct.
[44] Section 23(1)(b) of the Act.

Share of supply test

3.10 The share of supply test is satisfied where the merger would result in the creation or enhancement of at least a 25% share of supply or acquisition of goods or services of any description in either the UK or in a substantial part of the UK.[45]

3.11 Cochlear and Oticon Medical overlap in the supply of BCS products in the UK, with a combined share of supply, by value, of approximately [90–100%], with an increment arising from the Merger of approximately [40–50%].[46] Therefore as a result of the Merger, the Merged Entity would have a combined share of supply of more than 25% and the Merger would result in an increment in the share of supply. Accordingly, we have found that the share of supply test in section 23 of the Act is satisfied.

Conclusion on the relevant merger situation

3.12 In view of the above, we have found that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

4. Counterfactual

4.1 Determining whether there is an SLC in the assessment of a merger involves a comparison of the prospects for competition with the merger against the competitive situation without the merger (which is referred to as the counterfactual).[47]

4.2 This chapter sets out our conclusion on the appropriate counterfactual to apply in our assessment of the effect of the Merger on the supply of BCS products in the UK.

4.3 Our conclusion is that, absent the Merger, the appropriate counterfactual is the prevailing conditions of competition, ie that Oticon Medical would most likely have continued to operate in the market for the supply of BCS products in the UK (whether the BCS business of Oticon Medical continued to operate

[45] Section 23 of the Act and paragraph 4.60 of Mergers: Guidance on the CMA's jurisdiction and procedure (CMA2 revised). The concept of goods or services of 'any description' is very broad. The CMA is required by the Act to measure shares of supply by reference to such criterion or such combination of criteria as the CMA considers appropriate (section 23(5) of the Act).
[46] Based on 2021 figures. See Table 5.5: Share of supply estimates for BCS products in the UK.
[47] Merger Assessment Guidelines (CMA129), paragraph 3.1.

under Demant's ownership or under the ownership of an alternative purchaser).

4.4 This chapter considers:

(a) the CMA's framework for the assessment of the counterfactual;

(b) the Parties' submissions on the relevant counterfactual; and

(c) our assessment of the appropriate counterfactual.

The CMA's framework for the assessment of the counterfactual

4.5 The counterfactual is an analytical tool used in answering the question of whether a merger gives rise to an SLC.[48] It provides the basis for a comparison of the competitive situation with the merger against the competitive situation absent the merger.[49]

4.6 The counterfactual is not, however, intended to be a detailed description of those conditions of competition that would prevail absent the merger.[50] The detailed consideration of those conditions is relevant to our overall conclusions, but they are better considered in the sections that deal with our competitive assessment.[51] The CMA also seeks to avoid predicting the precise details or circumstances that would have arisen absent the merger.[52]

4.7 In a phase 2 merger investigation, the CMA will select the most likely conditions of competition as its counterfactual against which to assess the merger.[53] In its assessment of the counterfactual, the CMA may need to consider multiple possible scenarios, before identifying the relevant counterfactual.[54] As part of this assessment, the CMA will take into account whether any of the possible scenarios make a significant difference to the conditions of competition; if they do, the CMA will ultimately select the most likely conditions of competition absent the merger as the counterfactual.[55] The counterfactual assessment will often focus on significant changes affecting competition between merger firms, such as entry into new markets in

[48] Merger Assessment Guidelines (CMA129), paragraph 3.1.
[49] Merger Assessment Guidelines (CMA129), paragraph 3.1.
[50] Merger Assessment Guidelines (CMA129), paragraph 3.7.
[51] Merger Assessment Guidelines (CMA129), paragraph 3.7.
[52] Merger Assessment Guidelines (CMA129), paragraph 3.11.
[53] Merger Assessment Guidelines (CMA129), paragraph 3.13.
[54] Merger Assessment Guidelines (CMA129), paragraph 3.13.
[55] Merger Assessment Guidelines (CMA129), paragraph 3.13.

competition with each other, significant expansion by the merger firms in markets where they are both present, or exit by one of the merger firms.[56]

4.8 The CMA recognises that evidence relating to future developments absent the merger may be difficult to obtain.[57] Uncertainty about the future will not in itself lead the CMA to assume the pre-merger situation to be the appropriate counterfactual. As part of its assessment of the counterfactual, the CMA may consider the ability and incentive (including but not limited to evidence of intention) of the merging parties to pursue alternatives to the merger, which may include reviewing evidence of specific plans where available.[58]

4.9 The CMA may examine several possible scenarios to determine the appropriate counterfactual, one of which may be the prevailing, or pre-merger, conditions of competition, or conditions of competition that involve stronger or weaker competition between the merger firms than under the prevailing conditions of competition.[59] An example of a situation where the CMA may select a counterfactual different from the prevailing conditions of competition is where the target is likely to exit the market absent the transaction under review (the 'exiting firm scenario').[60]

4.10 In forming a view on an exiting firm scenario, the CMA will apply the following framework of cumulative conditions (and, as noted in paragraph 4.7, at phase 2 it will ultimately select the most likely conditions of competition absent the merger as the counterfactual):

(a) **Limb 1 – likelihood of exit**: the firm is likely to have exited (through failure or otherwise); and, if so

(b) **Limb 2 – no alternative purchaser**: there would not have been an alternative, less anti-competitive purchaser for the firm or its assets to the acquirer in question.[61]

4.11 The time horizon considered by the CMA when describing the counterfactual will depend on the context and will be consistent with the time horizon used in the competitive assessment.[62]

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[56] Merger Assessment Guidelines (CMA129), paragraph 3.8.
[57] Merger Assessment Guidelines (CMA129), paragraph 3.14.
[58] Merger Assessment Guidelines (CMA129), paragraph 3.14.
[59] Merger Assessment Guidelines (CMA129), paragraph 3.2.
[60] Merger Assessment Guidelines (CMA129), paragraphs 3.16 and 3.21.
[61] Merger Assessment Guidelines (CMA129), paragraph 3.21.
[62] Merger Assessment Guidelines (CMA129), paragraph 3.15.

The Parties' submissions on the relevant counterfactual

Summary of the Parties' submissions

4.12 The Parties submitted that the relevant counterfactual for the CMA's assessment of the Merger is not the prevailing conditions of competition.[63] In particular, they submitted that:

(a) Demant would, on the balance of probabilities, have exited the 'market' for hearing implants while maintaining some limited activities (in-house or outsourced) in order to provide continued support to its installed base of patients; and

(b) there was no alternative purchaser that would be able to take on obligations to provide continuous lifetime support to Oticon Medical's installed patient base or to make the necessary investments in research and development (**R&D**) and in obtaining regulatory approvals to ensure the cross-compatibility of Oticon Medical's installed implants with the latest processors and platforms in a manner which provides ongoing and future support and upgrades to patients.[64]

The Parties' submissions in relation to Limb 1 (likely exit of Oticon Medical from the market absent the Merger)

4.13 The Parties submitted that Demant's exit from the hearing implants business was rational and inevitable, and that several factors influenced its strategic decision to exit.[65]

The valuation of Oticon Medical and the BCS business

4.14 The Parties submitted that the value attributed by Cochlear to Oticon Medical did not reflect Oticon Medical's value to Demant under its continued ownership. In the Asset Sale and Purchase Agreement (**ASPA**), the BCS business was attributed an Enterprise Value (**EV**) of DKK [✂] million, equivalent to almost GBP [✂] million (as set out in Appendix D).

4.15 The evidence provided to us indicates that Cochlear's valuation was based in part on its assessment that the BCS business was growing and profitable.[66] The Parties told us that the transaction value did not equate to the value of

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[63] Parties' response to Issues Statement, 3 February 2023, paragraph 1.1.
[64] Parties' response to Issues Statement, 3 February 2023, paragraph 1.1.
[65] Parties' response to Issues Statement, 3 February 2023, paragraphs 1.2 and 1.4.
[66] See Appendix D.

the assets transferring,[67] but rather demonstrated what Cochlear was willing to pay to (i) 'protect its investments in upholding the reputation of the hearing implants sector' and (ii) 'increase scale and thereby generate better clinical evidence needed' to educate healthcare professionals (**HCP**s) on the benefits of hearing implants, and grow the hearing implants market.[68] The Parties submitted that [✂].[69]

The BCS business is not a significant part of Demant's wider activities

4.16 The Parties submitted that it was commercially rational for Demant to decide to discontinue the hearing implants business in its entirety, rather than only its CI business.[70] Demant's core business is the supply of hearing aids, a market which the Parties told us is 'fiercely competitive', with hearing aids manufacturers needing to invest significantly in R&D in order to develop competitive products.[71] The hearing implants business (Oticon Medical), however, amounted to 3% of Demant's total revenues in 2021. Demant considered that continued investment in a loss-making business was an 'unwelcome distraction' from its core business in terms of costs, management time, and risks, particularly given the requirement to provide lifetime support to implant patients.[72]

Oticon Medical was loss making as a whole; the BCS business was not profitable on a standalone basis

4.17 The Parties submitted that Oticon Medical had incurred [✂] financial losses.[73] These losses are concentrated in the CI business. However, Demant told us that the profitability of the BCS business is overstated:[74] this part of the business is not sustainable on a standalone basis (ie outside of Demant), and it is not possible to 'profitably split up and retain' parts of the Oticon Medical business,[75] were Demant to exit the CI business.

4.18 More specifically, the Parties told us that an exit from the loss making CI business would have a negative impact on the BCS business, both in the short and long term, and would result in the BCS business being unprofitable.[76] In particular, the BCS business benefits from significant

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[67] Parties' response to Issues Statement, 3 February 2023, paragraph 1.3.
[68] Parties' response to Issues Statement, 3 February 2023, paragraph 1.3.
[69] Parties' response to Issues Statement, 3 February 2023, paragraph 1.3.
[70] Parties' response to Issues Statement, 3 February 2023, paragraph 1.4.
[71] Parties' response to Issues Statement, 3 February 2023, paragraph 1.4.
[72] Parties' response to Issues Statement, 3 February 2023, paragraph 1.4.
[73] FMN, paragraph 9(a).
[74] Parties' response to Issues Statement, 3 February 2023, paragraph 1.5(d).
[75] Parties' response to Issues Statement, 3 February 2023, paragraph 1.1.
[76] FMN, paragraph 28.

resources and staff that are provided from Demant's core hearing aid business, while the total shared capacity cost paid by the CI business is approximately DKK [✂] million. In the short term, a significant proportion of these costs would persist which would likely result in the BCS business being unprofitable.[77]

4.19 Demant submitted that no player in the hearing implants business restricts its activities to BCS and the players are all present in CI in order to achieve the scale needed to succeed.[78]

Oticon Medical's products lag behind rivals in respect of quality and other factors

4.20 The Parties submitted that Oticon Medical's products lag behind those of its rivals on many performance metrics, and this gap has increased over time.[79] Innovation is key to competition in the hearing implants space and, over the course of more than a decade of significant investment, Oticon Medical had never been 'first to market' with a key innovation and 'could not deliver products that had additional quality, cost, or price benefits over existing competing technologies'.[80] While Oticon Medical had invested in R&D with respect to the BCS business, it had focussed on 'synergies' between sound processors and its wider hearing aids business. Demant's Active BCS product, Sentio, would be '[✂]' compared to Cochlear's existing product, and [✂] with MED-EL's.[81]

Oticon Medical was 'behind the curve' in innovation and would not have the ability to compete in future as the market transitions towards Active BCS products

4.21 The Parties submitted that the market-wide transition from Passive BCS products to Active BCS products represented a 'paradigm shift' in three critical aspects that have heavily influenced Demant's decision to exit the market:[82]

(a) First, it entails a move from producing a Class II to a Class III medical device which significantly increases quality assurance and regulatory burdens, resulting in significantly higher regulatory approval and compliance costs for Class III compared to Class II.[83]

(b) Second, bringing Oticon Medical's Active Sentio product to market would have required Demant to maintain relevant 'know-how' and its approved

[77] Parties' response to Issues Statement, 3 February 2023, paragraph 1.1.
[78] Parties' response to the AIS and WPs, 23 March 2023, paragraph 2.5.
[79] Parties' response to Issues Statement, 3 February 2023, paragraph 1.5(c).
[80] Parties' response to Issues Statement, 3 February 2023, paragraph 1.5(c).
[81] Parties' response to Issues Statement, 3 February 2023, paragraph 1.5(c).
[82] Parties' response to Issues Statement, 3 February 2023, paragraph 1.6.
[83] Parties' response to Issues Statement, 3 February 2023, paragraph 1.6(a).

Class III manufacturing facility in Nice (which currently largely relates to CI business).[84] If the BCS business was operating on a standalone basis, this would '[✂] reduce its gross margins'.[85]

(c) Third, the transition to Active, transcutaneous BCS products means: (i) lost synergies with Demant's hearing aids business and (ii) the BCS business will take on a key feature of the CI business in that patients will require lifelong support from Demant.[86]

4.22 The Parties told us that Sentio was a 'stranded asset' as Demant was not prepared to make the lifelong commitment to support future potential patients. The Parties told us that the project developing the Sentio product has [✂] and costs had '[✂]'.[87]

The decision to exit has been announced and is final

4.23 The Parties submitted that Demant made public its decision to exit the hearing implants market at the time of the announcement of the transaction,[88] with the news having been communicated to and accepted by staff, investors, customers and HCPs.[89]

Demant's decision-making process

4.24 On the basis of the above considerations, Demant told us that it had ultimately concluded that the size of the 'profit pool' for hearing implants, the constraints applied by national health systems and the demands and expectations of HCPs 'make it difficult for the market to sustain a fourth player that does not bring significant qualitative, cost or price benefits'.[90] It therefore determined to exit the hearing implants sector.[91] Demant told us that it wanted a solution which would protect it from future customer claims, and it therefore needed to find a buyer, for legal and moral reasons, who would continue supporting patients.[92]

4.25 Demant's board operates under a two-tier system made up of an Executive Board (including the CEO and CFO) which is responsible for the day-to-day

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[84] Parties' response to Issues Statement, 3 February 2023, paragraph 1.6(b) and Cochlear's partial written response to P2 s109 of 8 February 2023.
[85] Parties' response to Issues Statement, 3 February 2023, paragraph 1.6(b).
[86] Parties' response to Issues Statement, 3 February 2023, paragraph 1.6(c).
[87] Parties' response to Issues Statement, 3 February 2023, paragraph 1.7.
[88] Parties' response to Issues Statement, 3 February 2023, paragraph 1.8.
[89] Parties' response to Issues Statement, 3 February 2023, paragraphs 1.8-1.10.
[90] Parties' response to Issues Statement, 3 February 2023, paragraph 1.11.
[91] Parties' response to Issues Statement, 3 February 2023, paragraph 1.11.
[92] Parties' response to Issues Statement, 3 February 2023, paragraphs 1.11-1.12.

management of the business and a Board of Directors, which consists of eight non-executives ([✂]).

4.26 Demant submitted that, to avoid the risk of leakage and destabilisation of Oticon Medical given that [✂], the Executive Board believed that it must present an orderly exit strategy before presenting the exit decision to the Board of Directors – 'this would reassure both [Oticon Medical]'s employees and its customers (including HCPs) that the business has a sustainable future'.[93]

4.27 Therefore, Demant submitted, prior to concluding that the best solution was to exit the market via a sale, the Executive Board kept the decision to exit the market strictly confidential, resulting in 'the paucity of documentation around the decision to exit as well as the straightforward and swift exercise to find a suitable buyer'.[94] Demant's Board of Directors subsequently authorised the Executive Board (and more specifically Demant's CEO, Søren Nielsen) to initiate discussions with other hearing implant manufacturers.[95]

Demant's submissions in relation to Limb 2 (no alternative, less anti-competitive purchaser)

4.28 Demant told us that there was no alternative purchaser that would have been able to take on obligations to provide continuous lifetime support to Oticon Medical's installed patient base, now or in the future.

4.29 The marketing of Oticon Medical was limited to other players active in the hearing implants space (ie [✂] and Cochlear), and Demant submitted that this was as a result of its need to keep its decision to exit the hearing implants sector strictly confidential. Had Demant conducted a public or more open bidding process, it told us that this would have severely undermined the confidence of HCPs and patients in using Oticon Medical's implants.[96]

4.30 Demant told us that the pool of potential acquirers was necessarily small given the loss-making nature of Oticon Medical as a whole, and the 'subscale' nature of the hearing implants segment. Demant also told us that non-specialist industry acquirers or financial buyers were considered inappropriate for the following reasons:[97]

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[93] Parties' response to Issues Statement, 3 February 2023, paragraph 1.13.
[94] Parties' response to Issues Statement, 3 February 2023, paragraph 1.15.
[95] Parties' response to Issues Statement, 3 February 2023, paragraph 1.15.
[96] Parties' response to Issues Statement, 3 February 2023, paragraph 1.17.
[97] Parties' response to Issues Statement, 3 February 2023, paragraph 1.19.

(a) Companies outside of the hearing technology industry would be highly unlikely to be successful in maintaining the required level of care for Oticon Medical's patients (assuming they were interested in acquiring Oticon Medical).

(b) Hearing aid manufacturers not already active in the hearing implants sector would not have had the necessary competencies, resources or distribution networks to continue supporting Oticon Medical's patients or to manufacture and seek regulatory approval for Class III devices.

(c) Financial acquirers would not be prepared to make the necessary investments in R&D to support Oticon Medical's patient base. Oticon Medical's business model is not attractive to a financial buyer, which would ultimately look to exit its investment. Financial investors are generally unwilling to commit for the long-term to support patients on a lifetime basis.

4.31 Of the potential acquirers approached as part of the sales process, the Parties submitted that:

(a) [✂].

(b) [✂].

(c) Cochlear, therefore, was the only acquirer who could appropriately support Oticon Medical's patients.

Demant's submissions on its plans, should the Merger not proceed

4.32 In respect of the BCS business, Demant told us that, should the Merger not proceed, it planned to discontinue its activities in the BCS market including [✂]. Demant has told us that it would discontinue the development of its Sentio product and would not launch this in the market.[98]

4.33 In respect of future sales, Demant told us that there may be some [✂] in the sale of current BCS products going forwards, provided that [✂]. These activities would take place against the backdrop of a market-wide shift towards Active BCS products.[99]

4.34 Demant told us that Oticon Medical's installed BCS patient base will be [✂]. Demant submitted that there was a strong public interest to be considered by

[98] Parties' response to Issues Statement, 3 February 2023, paragraph 1.24.
[99] Parties' response to Issues Statement, 3 February 2023, paragraph 1.25.

the CMA in terms of the future long-term wellbeing of Oticon Medical's BCS patients.[100]

Our assessment of the counterfactual

4.35 The Parties have submitted that the counterfactual should be considered under the 'exiting firm scenario'.[101] As set out above, in forming a view on an exiting firm scenario, the CMA will apply the following framework of cumulative conditions:

(a) **Limb 1 – likelihood of exit**: the firm is likely to have exited (through failure or otherwise); and, if so

(b) **Limb 2 – no alternative purchaser**: there would not have been an alternative, less anti-competitive purchaser for the firm or its assets to the acquirer in question.[102]

4.36 In relation to the exiting firm scenario at phase 2, the CMA will consider what conditions of competition are most likely to have prevailed absent the merger.[103]

Limb 1: would Oticon Medical likely have exited the market absent the Merger?

4.37 This section considers the evidence provided to us in relation to Limb 1 and the key aspects of the Parties' submissions. We first consider whether the Oticon Medical business as a whole would have been likely to have exited the market. We then consider what would likely have happened to the BCS business of Oticon Medical.

Demant's financial incentive to exit the hearing implants business

4.38 Appendix E sets out the financial performance of Oticon Medical, as a whole and segmented for the CI and BCS businesses, in the period 2019-2022.

4.39 The analysis shows that Oticon Medical (as a whole) has faced challenges over this period associated with declining revenues and increasing operating costs, particularly in [✂] spend. We note this is largely as a result of the performance of the CI business, which has seen [✂] declines in revenue and more marked increases in R&D costs over recent periods.

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[100] Parties' response to Issues Statement, 3 February 2023, paragraphs 1.26-1.27.
[101] Merger Assessment Guidelines (CMA129), paragraph 3.21.
[102] Merger Assessment Guidelines (CMA129), paragraph 3.21.
[103] Merger Assessment Guidelines (CMA129), paragraph 3.23.

4.40 This overall assessment is illustrated by the following more detailed observations:

(a) The BCS business saw relatively stable revenue performance over the period included in our analysis (showing average annual growth[104] over the period of [✂]%), while the CI business's revenue saw an average annual decline of [✂]% over the period (including a [✂]% decline from 2021-22).

(b) The proportion of Oticon Medical's total revenue arising from the BCS business has increased over time. The BCS business's revenue comprised [✂]% of Oticon Medical's revenue in 2019, compared with [✂]% in 2022 (2021: [✂]%).

(c) While the BCS business has provided the majority of Oticon Medical's revenue, the CI business has generated the majority of certain categories of operating costs, in particular R&D. In 2019, the CI business generated [✂]% of Oticon Medical's total R&D spend, and this rose to [✂]% by 2022 (2021: [✂]%).

(d) Most significantly, the BCS business has consistently been profitable at an EBIT[105] level over the period included in our analysis and, despite a dip in 2021, has shown growth in profitability over the period. The BCS business's EBIT grew on average from 2019 to 2022 by [✂]%, and by [✂]% from 2021 to 2022. Conversely, the CI business has seen [✂] losses, which have increased at an annual average of [✂]% (in total by [✂]%) from 2019 to 2022. In 2021, the CI business saw an EBIT loss of DKK [✂] million, largely as a result of increasing [✂] expenditure as shown in Figure 1 in Appendix E.

4.41 In response to the Remedies Notice,[106] Demant provided a further financial model which showed that it expected the BCS business (separate from the CI business but retained within the Demant group) to continue to be profitable.[107] We discuss this further in Chapter 7.[108]

4.42 The Parties have not submitted, and we do not have supporting evidence to show, that Oticon Medical would likely have exited the hearing implants

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[104] Where we refer to 'average annual growth' in this chapter, we have used compound annual growth rate (**CAGR**) to measure performance over several periods. CAGR gives an average yearly growth metric which aids comparability across different companies by dampening the effect of volatility in performance over several periods (as compared to a standard arithmetic mean).
[105] EBIT means Earnings Before Interest and Tax and, in Demant and Oticon Medical's presentation, is equivalent to operating profit.
[106] Notice of possible remedies, (**Remedies Notice**), published on 20 April 2023.
[107] Demant's response to CMA's Notice of Possible Remedies – Annex 1.
[108] See paragraphs 7.45 to 7.53.

business as a whole as a result of financial failure. As noted below, the evidence provided to us to date implies that Oticon Medical would likely have been profitable without the CI business.

Demant's ability and incentive to support Oticon Medical

4.43 When assessing whether a firm would likely have exited the market because of financial failure, we will also, where that firm is part of a larger corporate group, consider the parent company's ability and incentive to provide continued financial support.[109]

4.44 Appendix E also provides a brief overview of the financial performance of the Demant group. As noted at Figure 4.1, the majority of Demant's revenue is generated across its other activities, including in its 'Hearing Healthcare' division (which includes Diagnostics, Hearing Aids, Hearing Care and formerly Hearing Implants or Oticon Medical), and its separate 'Communications' division, which focusses on audio and video solutions for business professionals and gamers.[110] Demant has significant scale in the hearing technology industry, has seen recent revenue growth, and is consistently profitable over the period included in our analysis.

4.45 Based on the information provided to us, both (i) on the size and financial performance of the Demant group and (ii) on the integration of Oticon Medical within Demant, we consider that Demant had and is likely to continue to have the ability to continue supporting the activities of Oticon Medical.

4.46 With respect to incentive, we note that, as illustrated in the Parties' submissions, Demant considered it had a responsibility to the patients of its CI and BCS businesses to continue providing vital technology. As noted below, it considered several options to sustain the future of the Oticon Medical business, including [✂]. We do not therefore have evidence of an incentive for Demant to close the whole of the Oticon Medical business.

4.47 With respect to Demant's incentive to support the BCS business in particular, we note that the BCS business has a leading market position in the UK and a prominent market position globally.[111] Based on the information Demant had available to it on the performance of the BCS business, Demant is likely to have considered it to have been generating income for the group. We

[109] Merger Assessment Guidelines (CMA129), paragraph 3.28.
[110] Demant Annual Report 2022.
[111] FMN – Table 14B.

therefore consider that Demant was unlikely to have had the incentive, in late 2021, to pursue a strategy of closing down the BCS business.

Extent of evidence of decision to exit the hearing implants business

4.48 At phase 1, Demant provided the CMA with board members' recollections of board meetings leading up to the decision to exit, as well as copies of board minutes and notices produced between 1 June 2021 and 30 June 2022.[112] The board's summary of its recollections was produced in November 2022, after the announcement of the Merger. We note, in this respect, that when considering any exiting firm argument, the CMA will usually attach greater weight to contemporaneous evidence in relation to the events at issue and evidence that has not been prepared in contemplation of the merger.[113]

4.49 We note further that a large part of the comments in these recollections of discussions relate to concerns around the [✂]. In a board meeting in August 2021, Demant submitted that [✂].[114] [✂].[115] Demant noted that, in these discussions, [✂].[116] We also note that concerns around the Oticon Medical business were discussed in the context of exploring a range of solutions, including the possibility of [✂].[117] Demant submitted that no decision was taken at this time, and so this discussion was not recorded in the minutes to this board meeting.[118]

4.50 In a meeting of October 2021, the Demant board was briefed on an issue relating to the CI business's Neuro Zti implants, which could result in a voluntary field corrective action (essentially a product recall).[119] Demant submitted that the board resumed the discussion of the challenges associated with [✂], and it now became clear in the long term that Demant could not be [✂].[120] Demant told us that no decisions were made and this discussion was therefore not recorded in minutes or in any other written communications.[121]

4.51 Following these discussions Demant submitted that, at a Chairmanship meeting in October 2021, the Executive Board was given [✂] to conclude on the future of the Hearing Implants (Oticon Medical) business area, and that:

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[112] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022.
[113] Merger Assessment Guidelines (CMA129), paragraph 3.24.
[114] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 2.
[115] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 2.
[116] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 2.
[117] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 2.
[118] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 2.
[119] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 3.
[120] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 3.
[121] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 3.

'[✂]'.[122]

4.52 It was, therefore, decided that:

'[✂]'.[123]

4.53 The minutes of a board meeting of December 2021 record that the CEO of Demant gave an update on the financial performance of Oticon Medical.[124] [✂].[125] The management had therefore '[✂]'.[126]

4.54 We note that the recollections of discussions centred around various transactions that might be entered into as an intended solution for Oticon Medical's difficulties (ie [✂] or divesting the Oticon Medical business), rather than any plans to close down the Oticon Medical business, or in particular the BCS business. When considering evidence from board minutes, we observe that discussions are in the context of Demant's attempts to divest the Oticon Medical business, and do not provide evidence of any decision to close the business down.

The valuation of Oticon Medical and the BCS business

4.55 The valuation by Cochlear of the BCS business (see paragraph 4.14) and Oticon Medical is explored in more detail in Appendix D. This appendix shows that the BCS business was seen by Cochlear[127] to be valuable, growing, and profitable.

4.56 Further, we note that [✂] provided the CMA with valuation analysis ([✂]) which assessed the financial profile and potential performance of the BCS business, describing the BCS business as '[✂]',[128] finding the BCS business to be [✂][129] and [✂].[130] This assessment of value by a competitor of Oticon Medical, on the face of it, is not consistent with the position that Demant would have a financial incentive to close the business down without exploring other options.

4.57 The CMA recognises that any valuation exercise necessarily assesses the value of a business to the acquirer, and that the assessment of value to that acquirer when considering the prospects for the business under its ownership

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[122] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 3.
[123] Annex A to the Parties Response to the P1 CMA Issues Letter of 10 November 2022 – page 4.
[124] Response to CMA P1 s109 of 30 September 2022 – [✂] – page 5.
[125] Response to CMA P1 s109 of 30 September 2022 – [✂] – page 5.
[126] Response to CMA P1 s109 of 30 September 2022 – [✂] – page 5.
[127] In addition, at phase 1, the CMA was informed by [✂].
[128] '[✂]
[129] [✂] response to CMA RFI dated 15 August 2022 – Annex B – page 2 '[✂].
[130] [✂] response to CMA RFI dated 15 August 2022 – Annex B. [✂].

is generally likely to be greater than the price the acquirer is willing to pay (in order to make the transaction financially attractive to an acquirer). Further, we note that the value of Oticon Medical to a competitor of Demant would not necessarily correspond to the strategic value of that business to Demant.

4.58 The Parties submitted that valuation analysis is not an appropriate basis to judge whether Demant would have a financial incentive to exit the market by way of closing the business.[131] However, our view is that the external perspective offered by assessments by Demant's competitors (including those assessments, underpinned by various due diligence exercises, which influenced Cochlear's decision to acquire Oticon Medical) offer insight into other market participants' perceptions of the business and its prospects. These can be considered together with Demant's own assessments of Oticon Medical's recent financial performance and strategic potential.

4.59 In Cochlear's assessment of the value of the Oticon Medical business, it consistently attributed value to the ongoing Passive BCS business without regard to [✂].[132,133] Cochlear also [✂].[134]

4.60 Cochlear submitted that its consideration of [✂], and that Cochlear's assessments do not hold evidential weight in determining Demant's actual decision-making absent the Merger.[135] Cochlear further submitted that the key financial aspects of its rationale focused on (i) increased investment in BCS to enable it to better compete with alternative treatments and improve patient access and (ii) [✂].[136]

4.61 As further explored in Appendix D we note, in this respect, that [✂].[137]

4.62 As noted above, the assessments of other market participants, although not determinative of Demant's decision-making process, do nonetheless offer insight into others' perceptions of: (i) Oticon Medical's operational performance and (ii) the value of the assets of Oticon Medical (for example, its intellectual property (**IP**) or strategic knowhow). We consider therefore that these assessments provide insight into Demant's likely incentives to close the business without exploring alternatives. Contemporaneous evidence of external perspectives on valuation is particularly helpful in enabling us to form a judgement in a context where there is no contemporaneous evidence from

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[131] Parties' response to Annotated Issues Statement and Working Papers – paragraph 2.34.
[132] EBITDA means Earnings Before Interest, Tax, Depreciation and Amortisation.
[133] In Cochlear's analysis and presentation, it conducted Net Present Value (NPV) analysis, assessing future forecasts of the BCS business. This appears to be broadly equivalent to discounted cashflow (DCF) analysis.
[134] For more detail, please refer to Appendix D.
[135] Parties' response to AIS and WPs – paragraph 2.37.
[136] Parties' response to AIS and WPs – paragraph 2.38.
[137] Cochlear response to P1 s109 request of 21 July 2022, [✂].

within Demant itself of incentives to close the business or a decision to that effect.

Significance of Oticon Medical (and the BCS business) to Demant's wider activities

4.63 The Oticon Medical business was created by Demant through a series of acquisitions and subsequent investment, including:

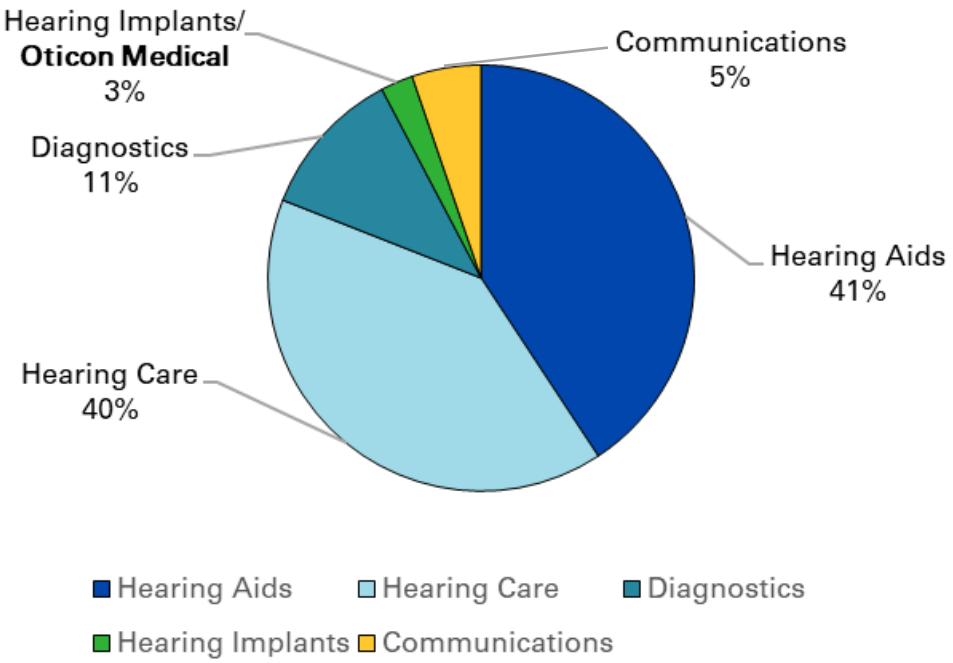
(a) In the case of the BCS business: the acquisition of the IP relating to BCS technology in 2006 from Otorix, a Swedish innovation company which focused on bone conduction R&D.[138] The first Oticon Medical BCS product (Ponto) was launched in 2009 following this acquisition, and the Parties told us that Oticon Medical was an early innovator in BCS products;[139] and

(b) In the case of the CI business: the acquisition of Neurelec SA (**Neurelec**), a French CI specialist, in 2013.[140] Owing to its origins, the Parties told us that the CI business has a strong legacy presence in France, and French-speaking North Africa, and has subsequently expanded into emerging markets.[141]

4.64 In Demant's financial year ending in December 2021 (**FY21**), Oticon Medical comprised 3% of Demant's total revenues. In Demant's reporting of the financial year ending in December 2022 (**FY22**), it classified Oticon Medical as a discontinued operation and did not present its results. However, our analysis is that Oticon Medical's contribution to Demant's total revenue will have remained largely consistent at 3% in 2022 (see Figure 4.1).

[138] FMN, paragraph 51.
[139] FMN, paragraph 51(a).
[140] Oticon Medical – CMA teach-in presentation, 23 January 2023, page 9.
[141] FMN, paragraph 51(b).

Figure 4.1: Demant's FY22 revenues across its business divisions



Sources: Demant Annual Report 2022. Hearing Implants (Oticon Medical) performance was re-incorporated into the data, as these are no longer presented in Demant's reporting figures. This was incorporated using CMA analysis of Demant Internal Document, Annex 5.1 to the Partial Response to P2 s109 notice of 8 February 2023, '[✂]'.
Notes:

a) The chart above is a pie chart showing the proportions of Demant's total revenue that it earned across its separate activities in the year ending December 2022 (**FY22**).
b) Oticon Medical's revenue (the Hearing Implants division) comprised approximately 3% of Demant's total revenue in FY22, shown in green.
c) The Communications division comprised approximately 5% of Demant's total revenue in FY22, shown in yellow.
d) The Hearing Aids division comprised approximately 41% of Demant's total revenue in FY22, shown in dark blue.
e) The Hearing Care division comprised approximately 40% of Demant's total revenue in FY22, shown in light blue.
f) The Diagnostics division comprised approximately 11% of Demant's total revenue in FY22, shown in teal.

4.65 We recognise that the Oticon Medical business comprised a small proportion of Demant's total revenues and was distinct in its activities (which involved higher risk medical intervention), and so Demant would likely have considered it to have been non-core to the wider corporate group.

4.66 In addition, Oticon Medical was loss-making as a whole (when accounting for the CI and BCS businesses together) and, given the nature of the hearing implants sector and the requirement to provide lifetime support to implanted patients, the 'cost' in terms of management time, regulatory burden, and commitment would likely have outweighed financial 'benefits'.

4.67 We recognise that Demant's board might have sought strategically to pivot away from the significant time and resource investment required for the continuing operation of Oticon Medical (including the BCS business). Demant described its board having 'lost patience' with Oticon Medical and 'belief' in its future prospects having spent [✂]% of management time on 3% of its

business.[142] Demant told us that it faced 'fierce competition in its core [hearing technology] business', and that this required 'significant investment' to remain successful.[143] It therefore no longer wanted to divert important resources away from its core activities. MW&L Capital Partners (**MW&L**), Demant's lead advisers in the transaction process, told us that the sale of Oticon Medical was [✂]'.[144] Further, as noted by the Parties' submissions and illustrated in Figure 4.1 above, the BCS business, while profitable, makes only a modest contribution to Demant's overall financial position.[145]

4.68 We acknowledge that Oticon Medical represents a small part of Demant's overall operations, and was posing various challenges for Demant's management team. However, we do not consider that these factors by themselves would have been likely to provide sufficient incentive for Demant to close down Oticon Medical (and in particular the BCS business) absent the transaction given (i) the nature of the business in terms of Demant's responsibilities with respect to patient care, and (ii) the data Demant had available to it at the time the Merger was agreed showing that the BCS business was growing and profitable. We do consider that this combination of factors could have motivated Demant to pursue a sale of the business, and there is evidence of a decision-making process to this effect and outcome taking place in late 2021.

The financial performance of the BCS business

4.69 As set out above at paragraphs 4.17 to 4.19, Demant told the CMA that the BCS business's profitability was not reflective of its true performance, and that the BCS business would not be profitable on a standalone basis (ie separate from the Demant group and without the CI business). In response to the Remedies Notice, Demant stated that it did believe that the BCS business would be profitable on a standalone basis (ie separate from the CI business) but retained within the Demant group.[146]

The extent of the BCS business's dependence on the Demant group

4.70 The evidence, from internal documents and views of third parties, shows that the BCS business relies to some extent on resources from the Demant group:

[142] Demant Main Party Hearing Transcript – page 8, lines 9-14.
[143] Parties' response to the AIS and WPs, 23 March 2023, paragraph 2.10.
[144] Note of call with third party - MW&L Capital Partners [✂], paragraph 3.
[145] Parties' response to Annotated Issues Statement and Working Papers – paragraph 2.9.
[146] Demant response to CMA's Notice of Possible Remedies, paragraph 1.4(c).

(a) MW&L told us that there is significant overlap in BCS products' [✂] and [✂], and that this benefits the BCS business [✂].[147]

(b) Cochlear's financial due diligence (**FDD**) report for the Merger prepared by Ernst & Young (**EY**) [✂].[148]

(c) Documents in the transaction virtual data room demonstrate that Demant group entities act as [✂] for the BCS business.[149]

(d) Demant's internal documents show that the BCS business benefits from numerous Demant group benefits, particularly, as mentioned, in R&D and in marketing and distribution.[150]

4.71 As explored further below, Demant also submitted additional analysis during the course of our investigation to outline benefits that Oticon Medical gains from being a part of the Demant group, including:

(a) 'Non-cash benefits', which are difficult to quantify, such as brand association with Demant's hearing aid division (known as Oticon);[151]

(b) Intragroup shared services (eg legal, facilities management, knowledge sharing);[152]

(c) Specific cost benefits in relation to [✂];[153] and

(d) As noted at paragraph 4.69(a), R&D by Demant's hearing aid division benefiting the sound processor and other types of technology used by Oticon Medical.[154]

4.72 We note that these types of interdependencies between a larger corporate group and a subsidiary are a standard aspect of the way in which most large companies operate. Many large corporate groups benefit from, and strategically seek to maximise, cost synergies across their business activities and product portfolios. While these group benefits could mean the BCS business might be less profitable on a standalone basis (ie outside of Demant), we do not consider the potential realisation and maximisation of cost synergies demonstrates a need to close the business. As noted at paragraph 4.46, Demant is likely to have considered the BCS business to

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[147] Note of call with third party - MW&L Capital Partners [✂], paragraphs 19-24.
[148] Annex 435 to Cochlear's response to P2 s109 notice of 8 February 2023 – [✂].
[149] Annex 8.10 to Demant's response to P2 s109 notice of 8 February 2023 - [✂].
[150] Demant's response to P2 s109 notice of 8 February 2021, Q 1, [✂] – slides 1 -3.
[151] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, pages 1 and 2.
[152] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, page 2.
[153] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, page 2.
[154] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, page 2.

have been generating income for the Demant group in late 2021 (perhaps partially as a result of favourable pricing arrangements and realised group benefits), by way of revenue and profits.

The dependence of the BCS business on the CI business

4.73 As noted at paragraph 4.18, Demant told us that only exiting from the loss-making CI business would have a negative impact on the BCS business in the short and long term, and would result in the BCS business being unprofitable.[155]

4.74 With respect to this submission, evidence from internal documents and third parties shows there is currently some operational and financial reliance by the BCS business on the CI business (and vice versa). For example:

(a) Demant's internal documents note significant shared employee costs between the two business segments.[156]

(b) At an operating cost level, MW&L told us that distribution and administrative expenses for the two businesses can be difficult to separate, particularly because of staff costs (eg [✂]) and with costs associated with Oticon Medical's [✂] which are used by both the CI and BCS businesses.[157]

(c) [✂] described compatibility considerations around a business being active in both CI and BCS markets from a revenue generation point of view, noting that clinicians generally work across both CI and BCS products (ie, for patients, CI and BCS products have the same 'call point'), and sales teams therefore tend to work across both hearing implant devices. However, in respect of the potential separability of the CI and BCS businesses, [✂] of Oticon Medical that the CI and BCS businesses had begun as separate businesses before being brought into one brand through Demant's acquisitions.[158] [✂] noted that the two businesses had largely separate manufacturing facilities and largely separate R&D operations (which is reflected in our wider evidence).[159] It considered therefore that, [✂].[160]

(d) MED-EL explained to the CMA that a market participant offering only CI or BCS products may be commercially viable, but it may be perceived by

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[155] FMN, paragraph 28.
[156] Demant's response to P2 s109 notice of 8 February 2021, Q 1, [✂] – page 9.
[157] Note of call with third party – MW&L Capital Partners, [✂].
[158] Note of a call with a third party: [✂] – paragraph 15.
[159] Note of a call with a third party: [✂] – paragraph 15.
[160] Note of a call with a third party: [✂] – paragraph 15.

customers as having too 'narrow' an offering, and this may impact its performance over the long term.[161]

4.75 In the course of our investigation, we asked Demant for further evidence of the extent of the BCS business's financial dependence on the CI business in order to determine whether this had allowed the BCS business to appear to be profitable 'at face value' across Demant's management accounting data but would mean the BCS business would not be profitable independent of the CI business.[162] In response to our request, Demant provided the CMA with a single high level analysis prepared by Demant following the announcement of the Merger.

Figure 4.2: Demant's analysis of the BCS business's financial performance should CI-related costs be factored into its operating model

[✂]

Source: Annex [✂] to Demant's response to P2 s109 notice of 8 February 2023. [✂].

4.76 Figure 4.2 shows that, as a result of increased operating costs originating from the CI business, the BCS business would have incurred additional costs of DKK [✂] million in 2021 if the CI business had been divested and would therefore not have been profitable in 2021. Demant did not provide any methodology, explanation, or data as to how these figures were calculated. We are therefore not in a position to determine, on the basis of this evidence, whether the BCS business would likely have remained profitable should Demant have closed the CI business only.

4.77 Further, when considering any exiting firm argument, the CMA will usually attach greater weight to evidence that has not been prepared in contemplation of the merger.[163] The Parties told us that this analysis, in particular, was first prepared in July 2022, after the Parties had notified the CMA of the Merger and after Demant had announced its decision to exit. When presented for discussion with the CMA, Demant's representatives were unable to provide further detail as to how the analysis was produced.[164] We therefore consider that this analysis was unlikely to have been significant for Demant's decision making, or to have influenced any decision by Demant to exit its activities in hearing implants, including in the market for BCS products, in late 2021.

4.78 During the course of our investigation, Demant submitted further analysis of why it considers BCS, within Demant, would not be profitable without the CI

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[161] Note of a call with a third party: MED-EL – 8 February 2023 – paragraph 13.
[162] We asked for this because of Demant's initial submissions to us that the BCS business would not be profitable absent the CI business, as a result of approximately DKK [✂] million of shared capacity costs.
[163] Merger Assessment Guidelines (CMA129), paragraphs 3.24 and 2.29.
[164] Demant Main Party Hearing transcript – page 24, lines 19-25.

business. This related to employee costs across the BCS and CI businesses (see Table 4.1).

Table 4.1: Demant's estimation of additional employee costs that would be allocated to the BCS business if CI were divested

(DKKm)

Category	*Estimated additional cost*
[✂]	
[✂]	[✂]
[✂]	[✂]
[✂]	[✂]
[✂]	
[✂]	[✂]
[✂]	[✂]
[✂]	[✂]
[✂]	
[✂]	[✂]
[✂]	[✂]
[✂]	[✂]
[✂]	[✂]
[✂]	[✂]
[✂]	[✂]

Source: Table 1 of the Parties' response to the AIS and WPs, 23 March 2023, based on Oticon Medical's 2021 employee data.

4.79 Table 4.1 sets out Demant's current view of additional staff costs of the CI business which would be attributable to the BCS business if Demant were to exit CI only. This analysis implies that the BCS business, within Demant but absent the CI business, would have incurred additional staff costs in 2022 of around DKK [✂] million. This would have reduced the BCS business's 2022 EBIT from DKK [✂] million to around DKK [✂] million, representing an [✂]% EBIT margin, which is above Demant's group performance.[165]

4.80 This analysis, based on Oticon Medical's 2021 employee data, was produced in early 2023 for the purposes of our investigation. As previously noted, when considering any exiting firm argument, the CMA will usually attach greater weight to evidence that has not been prepared in contemplation of the merger.[166]

4.81 However, we do not consider, on the basis of this evidence, that overlapping staff costs of the existing Passive BCS business and CI business would have incentivised Demant to close the BCS business at the time the Merger was agreed.

4.82 The Parties have not provided any evidence of documents or discussions taking place at any level in Demant, either prior to the contemplation of the

[165] As shown in Table 1 of Appendix E, Demant achieved an EBIT margin of [✂]% in FY22. From FY19 to FY22, EBIT margins ranged between [✂]% to [✂]%, averaging [✂]%.
[166] Merger Assessment Guidelines (CMA129), paragraph 3.24.

Merger or since then (with the exception of the analysis prepared for the purposes, and during the course, of our investigation), which raise concerns about the apparent profitability of the BCS business or question the validity of the financial data prepared at the time of the Merger and presented at Appendix E. As noted, the evidence of Board discussions leading up to the Merger, prepared for us based on recollections at the time, focuses on [✂] and does not mention BCS directly.

4.83 As noted above, and set out in Chapter 7,[167] Demant submitted an analysis of the profitability of the BCS separate from the CI business but retained within the Demant group in response to the Remedies Notice. This model forecast the BCS business remaining profitable and increasing in profitability even in its 'lower bound' assessment for the period to 2025.

The potential shift towards Active BCS products and Oticon Medical's Sentio product

4.84 As set out at paragraph 4.21 and 4.22, the Parties submitted that a move from a Class II to a Class III device significantly raises the regulatory approval and compliance requirements on medical device manufacturers, particularly in light of the recent Medical Device Regulation. Demant also told us that bringing the Sentio product to market would have required Demant to maintain its current Class III manufacturing facility (which relates to the CI business), and that a move into the space for Active BCS products results in the BCS business taking on a fundamental characteristic of the CI business, in that patients will require more substantial lifelong support.[168]

4.85 More generally, Demant told us that it considered Sentio a 'stranded asset', as any eventual launch was highly uncertain, and [✂].[169] Demant submitted that, absent the Merger, it has no intention of continuing to invest in the project and will not bring the product to market.[170]

4.86 As set out in Chapter 5, we have concluded that it is likely that a significant proportion of patients will continue to receive Passive BCS products in future and, consequently, sales of Passive BCS products are likely to remain relevant for the Oticon Medical BCS business going forwards.

4.87 Nonetheless, Demant has submitted that presence in the market for Active BCS products would be 'crucial' for the BCS business to remain a 'credible competitor'.[171] As considered in the Competitive Assessment chapter, we

[167] See paragraphs 7.45 to 7.53.
[168] Parties' response to Issues Statement, 3 February 2023, paragraph 1.6(c).
[169] Parties' response to Issues Statement, 3 February 2023, paragraph 1.7.
[170] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 2.26.
[171] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, page 3.

have found evidence that the Sentio project faces some challenges.[172] However, we also see evidence that, since its launch of a sales process (in late 2021) and its announcement of the Merger, Demant continued to invest in the Sentio project for commercial release, including:

(a) A development plan for the Sentio project, produced in October 2022 shows that the project remains well developed, since it refers to the practical steps to be taken ahead of launch, including ensuring that the system is [✂], and ensuring that the product gains necessary regulatory approvals.[173]

(b) A forward-looking strategy document from around August 2022 shows that, at a local management level, the Oticon Medical BCS business expects to launch Sentio in [✂] and that it has several plans for sales of its Passive BCS products.[174]

4.88 During the early stages of our investigation, we received limited contemporaneous evidence from Demant that the shift from Passive to Active BCS products increases the reliance by the BCS business specifically on the CI business's Class III manufacturing facility in Nice. Demant initially provided a simple historical breakdown of spending by the BCS business which relates to this facility (see Table 4.2), but no evidence of how the BCS business would rely on this facility if it were to launch Sentio.

Table 4.2: historical spend by the BCS business on the Nice manufacturing facility

(DKK '000)

	FY21	*FY22*	*FY23*
R&D	[✂]	[✂]	[✂]
Distribution	[✂]	[✂]	[✂]

Source: Annex 2.1 to Demant's response to P2 s109 of 8 February 2023 – [✂].

4.89 As set out in Table 4.2, over the period from 2021 to 2023 there is [✂].

4.90 Demant subsequently produced analysis for the CMA which estimated the cost of establishing a separate Class III manufacturing facility to allow the BCS business to develop Sentio for commercial release absent the CI business. As this was produced following the announcement of the Merger and for the purposes of our investigation, it is unlikely to have influenced a pre-Merger decision or provided a pre-Merger incentive for Demant to exit from BCS products.

[172] See paragraphs 5.101 to 5.106.
[173] Demant's response to P2 s109 notice of 10 January 2023, Q 11, [✂], page 3.
[174] Demant's response to P2 s109 notice of 10 January 2023, Q 11, [✂].

4.91 Demant estimates the cost of establishing a Class III facility to be around EUR [✂] million (including all equipment costs, space for stock/ logistics, office space, and a specialist 'clean room').[175] This is equivalent to approximately DKK [✂] million of upfront costs (which would be spread over a ten year period to represent around DKK [✂] million cost to the Statement of Profit or Loss (**P&L**)[176] each year).[177] Demant also estimates an additional [✂] specialist employees would be required, at an average annual cost of DKK [✂], resulting in an additional DKK [✂] million of annual costs.[178] These costs are set out at Table 4.3.

Table 4.3: Demant's expected yearly costs required to establish a Class III facility

(DKKm)

	2023 forecast	*2024 forecast*	*2025 forecast*
Depreciation and amortisation of facility and equipment	[✂]	[✂]	[✂]
Cost of additional employees needed	[✂]	[✂]	[✂]
Total yearly cost of a Class III facility	[✂]	[✂]	[✂]

Source: Parties' response to the AIS and WPs, 23 March 2023, Table 2.
Demant assumes staff costs increase each year in line with European Commission inflation predictions for Denmark (4.4% in 2023, 2.5% in 2024, held at 2.5% thereafter).
While capital expenditure (ie upfront investment) is represented by depreciation, it appears that these are also assumed to be a 'proxy' for ongoing capital expenditure, as these are assumed to increase in line with European Commission inflation predictions similarly with staff costs.

4.92 Demant submitted that, as a result of the additional costs shown at Table 4.3, combined with the uncertainty of the timing of Sentio's release, it would have 'no incentive' to continue running the BCS business absent the CI business (ie if it exited the CI business alone).[179]

4.93 Our view is that any new development project would require an up-front investment in the short to medium term to generate future returns, as Demant experienced when it first launched the BCS business.[180] While any investment in a product launch would be unlikely to generate cash in the short term, we do not consider that this alone would incentivise Demant to discontinue the BCS business or halt the development of Sentio.

4.94 As noted in the CMA's Merger Assessment Guidelines, the CMA seeks to avoid predicting the precise details or circumstances that would have arisen

[175] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, page 3.
[176] 'P&L', or Statement of Profit or Loss, is a measure of a business's performance which assesses its income and expenditure over a period of time.
[177] Annex 433 to the Parties' response to the AIS and WPs, dated 23 March 2023, page 3.
[178] Annex 432 to the Parties' response to the AIS and WPs, dated 23 March 2023, [✂].
[179] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 2.18.
[180] Demant Annual Report 2011 – pages 4, 6 and 12 describe the success of the newly established BCS business and how the BCS business has started contributing positively to group earnings following two years in the market.

absent the Merger,[181] such as the extent to which Sentio is likely to be a commercially successful product.

4.95 However, on the basis of the analysis presented to us, we consider that Demant is unlikely to have been disincentivised to continue with the Sentio project. Demant subsequently told the CMA that, should the Merger not proceed, it plans to continue investing to complete the Sentio development project (ie ensure the product is ready for commercial release) but would 'keep it in the box'.[182] The analysis presented to us implies that a move into Active BCS products would increase the reliance of the BCS business on the CI business as it exists today (ie it would forego additional costs of establishing a separate facility). However, Demant's updated analysis exploring the potential costs of establishing a separate Class III facility to develop the product (i) does not imply that such a plan would be unfeasible, and (ii) envisages the BCS business establishing this facility absent the CI business, reducing the BCS business's ongoing reliance on the former.

4.96 In summary, while there are regulatory hurdles, costs and other investments associated with (i) a move from a Class II to a Class III device, and (ii) any long-term R&D project, we have seen significant evidence that Demant would have continued to develop Sentio, including with a view to commercial release, and that this would likely have been the case irrespective of the position in relation to the CI business. Further, as evidenced by third party feedback[183], demand for Passive BCS products is likely to continue to provide income for the BCS business in the period before Sentio is ready for commercial release.

Perceptions of the separability of the CI and BCS businesses

4.97 While the views of the Parties and their advisers are not determinative for the CMA's assessment of the separability of the two businesses and whether they could compete effectively on a standalone basis, Cochlear and Demant appeared to consider that [✂]. In particular, they agreed to certain [✂].

4.98 [✂].[184] [✂].[185]

4.99 The Parties have submitted that these provisions [✂],[186] [✂].[187] The Parties also submitted that [✂], as contemplated by the Asset Sale and Purchase

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[181] Merger Assessment Guidelines (CMA129), paragraph 3.11.
[182] Demant – Main Party Hearing Transcript – page 63, line 1.
[183] Please see Chapter 5, including paragraphs 5.77 to 5.93.
[184] FMN, Annex 201 – Agreed Form Asset and Share Purchase Agreement – Executed version, [✂].
[185] FMN, Annex 201 – Agreed Form Asset and Share Purchase Agreement – Executed version, [✂].
[186] Parties response to AIS and WPs – paragraph 2.40.
[187] Parties response to AIS and WPs – paragraph 2.39.

Agreement (**ASPA**), was agreed before Cochlear was able to conduct any meaningful due diligence on the financial performance of Oticon Medical.[188]

4.100 However internal documents (including internal and external due diligence reports) do not provide any evidence of a change in assessment of the feasibility of [✂]. By contrast, the following evidence indicates that the Parties and their advisers considered that [✂] was feasible and would likely remain so:

(a) Most significantly, Demant considered these provisions to be viable at the time the Merger was agreed (simultaneous with its announcement that it would exit the hearing implants sector).

(b) The financial due diligence report commissioned by Cochlear and conducted by EY notes [✂].[189]

(c) MW&L told the CMA that it was not aware of any change in the Parties' position with respect to the [✂] since the signing of the transaction documents.[190] MW&L told us that these provisions were put in place [✂].[191]

4.101 In response to the Remedies Notice, Demant agreed that there were no composition[192] or asset risks[193] associated with separating the CI business from the BCS business and the Demant group.[194]

The position of Oticon Medical's products relative to rivals in respect of quality and other factors

4.102 As set out in Chapter 5, the evidence from internal documents and third parties, including clinics and industry experts, does not suggest that Oticon Medical's BCS products are viewed as lagging behind competing products in respect of quality or other factors, and are preferred by some market participants. For example, as set out in the competitive assessment chapter, when asked whether they had a preferred or 'go-to' supplier for percutaneous Passive BCS products, around two-thirds of clinics which expressed a

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[188] FMN, paragraph 32.
[189] Annex 435 to Cochlear's response to P2 s109 notice of 8 February 2023 – [✂] – page 9.
[190] Note of a call with a third party – MW&L Capital Partners [✂].
[191] Note of a call with a third party – MW&L Capital Partners [✂].
[192] Composition risks are risks that the scope of the divestiture package may be too constrained or not appropriately configured to attract a suitable purchaser or may not allow a purchaser to operate as an effective competitor in the market (Merger remedies guidance (CMA87), paragraph 5.3(a)).
[193] Asset risks are risks that the competitive capability of a divestiture package will deteriorate before completion of the divestiture, for example, through the loss of customers or key members of staff (Merger remedies guidance (CMA87), paragraph 5.3(c)).
[194] Demant response to CMA's Notice of Possible Remedies, paragraph 1.4 (b).

preference preferred Oticon Medical products.[195] Further, when asked about their views on the likely impact of the Merger, ten clinics described the positive impact which Oticon Medical's entry into the market had on factors such as price and innovation.[196]

Demant's decision to exit the market and its public commitment to this decision

4.103 Demant told us that the decision to exit has been announced, is final, and has been communicated to and accepted by staff, investors, customers and HCPs.[197] Demant also told us that it would be 'irrational' not to follow through with this decision given potential 'reputational damage' among customers and investors.[198]

4.104 As noted above, when considering any exiting firm argument, the CMA will usually attach greater weight to evidence that has not been prepared in contemplation of the merger. [199] The corollary of this is that the CMA will usually attach relatively less weight to evidence relating to the operation of the merged businesses after a merger agreement has been entered into. The performance of a target business may, at least to some extent, reflect the fact that a merger agreement has been entered into (notwithstanding that the merger agreement, reflecting various legal obligations, will typically make provision for that business to continue to be run in the same way between signing and closing).

4.105 Notwithstanding this general approach, for completeness and in addition to the evidence set out above on the ongoing development of Sentio, we set out below evidence regarding Demant's continued investment in the BCS business since the announcement of the Merger and decision to exit.[200]

4.106 We note in particular:

(a) Strong sales growth in the Passive BCS business and continued investment by Demant in the BCS business's operating cost spend (see Figure 3 in Appendix E).

(b) This sales growth is partially attributed to Passive BCS product launches which were subsequent to the announcement of the Merger.

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[195] Competitive assessment
[196] Response to the CMA questionnaire from a number of third parties, January 2023, question 12 [NHS clinics].
[197] Parties' response to Issues Statement, 3 February 2023, paragraphs 1.8-1.10.
[198] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 2.2.
[199] Merger Assessment Guidelines (CMA129), paragraph 3.24.
[200] We note that Demant has been subject to an Initial Enforcement Order since November 2022 which requires that it maintains the competitive capability and viability of Oticon Medical.

(c) Internal documents subsequent to the announcement of the Merger which show that the BCS business is planning for the future and maintaining its momentum of business activities, rather than planning for a market exit and product discontinuation should the transaction with Cochlear not proceed.[201]

(d) Demant's financial advisers (**MW&L**) for the transaction process, in their own opinion, considered it [✂].[202]

(e) When we questioned Demant, it was unable to give any clear time horizon or outline for a proposed exit from the market for BCS products (absent the Merger), indicating an exit could take 'months or years'.[203]

Conclusions on Limb 1: would Oticon Medical likely have exited the market absent the Merger?

4.107 Our conclusion is that Demant was not likely to have closed down Oticon Medical absent the Merger. In particular, we do not consider it likely that Demant would have closed the BCS business absent the Merger. This is for the following reasons.

4.108 First, we have seen no evidence that Demant had decided to close the business absent the Merger.

4.109 Second, we have seen no evidence (and the Parties have not submitted) that Oticon Medical would likely have exited the market for reasons of financial failure. While, on the basis of the financial information provided to us, Oticon Medical appeared to be loss-making as a whole, the scale of the reported losses of Oticon Medical are very small compared to the Demant group's profitability and Demant had the ability to continue to support the business. We therefore do not consider it likely that Oticon Medical (as a whole) would have been unable to meet its financial obligations in the near future, and the BCS business itself did not require Demant to fund any losses.

4.110 Third, we have seen no evidence of an incentive for Demant to exit the market for BCS products. The BCS business is shown to be growing and profitable in Demant's management accounts, in its presentation of the BCS business to potential purchasers and in financial due diligence commissioned by Cochlear. It was also considered to be an attractive and growing business by third parties in the transaction process. Given this, in late 2021, we consider

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[201] Demant's response to P2 s109 notice of 10 January 2023, Q 11, [✂].
[202] Note of a call with a third party – MW&L Capital Partners [✂].
[203] Demant – Main Party Hearing Transcript, page 47 – lines 24-25, page 48, lines 20-23.

that Demant was likely – based on the information available to it – to have considered the BCS business to be generating income for the group. We note the analysis which was produced by Demant's advisers for the purposes of our investigation,[204] positing that a hypothetical BCS business operating within Demant, but without the CI business, may not have been profitable. Taking this analysis at face value, we observe that the BCS business would likely have remained profitable in 2022 factoring in the additional costs. However, in response to the Remedies Notice, Demant produced further analysis showing the BCS business as profitable separate from the CI business but retained within the Demant group.[205] In any case, both these analyses were produced after the agreement of the Merger, and so cannot have influenced any decision to exit the market for BCS products in late 2021.

4.111 Fourth, Demant agreed to provisions in the ASPA [✂], implying that it considered at the time of its announcement that this would be a viable option for the BCS business. Demant has indicated to us that it plans to continue with development projects of the BCS business (including Sentio) should the Merger not proceed.

4.112 Our conclusion is therefore that Demant was not likely to have closed Oticon Medical (including the BCS business) and was likely to have had the ability and incentive to continue supporting the BCS business in the short to medium term.

Limb 2: would there not have been an alternative, less anti-competitive, purchaser for the BCS business?

4.113 In forming a view on an exiting firm scenario, the CMA requires that both limbs of the test are met. As our conclusion with respect to Limb 1 is that it is likely that Demant would not have exited the market for BCS products, it is not necessary to address Limb 2. Nevertheless, for completeness, we consider below Demant's submissions on the absence of alternative purchasers for Oticon Medical as a whole or for the BCS business separately.

4.114 As noted at paragraph 4.12(b), Demant submitted that there would not have been an alternative purchaser who would have been able to provide adequate support to Oticon Medical's installed patient base, now or in the future.[206]

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[204] Merger Assessment Guidelines (CMA129), paragraph 3.24 provides that when considering any exiting firm argument, the CMA will usually attach greater weight to evidence that has not been prepared in contemplation of the merger.
[205] Demant response to CMA's Notice of Possible Remedies, Annex 1.
[206] Parties' response to Issues Statement, 3 February 2023, paragraph 1.1.

4.115 As noted at paragraphs 4.29 and 4.30, Demant told us that the process for the sale of Oticon Medical was necessarily limited because: (i) Demant wanted to avoid the risk of any information leakage on the sale which might raise concerns of staff, professionals in the industry, or Oticon Medical's patient base; and (ii) the business as a whole was not [✂], and so wouldn't have interested financial acquirers,[207] trade acquirers in the hearing technology industry or trade acquirers outside of the hearing technology space.[208]

4.116 Demant told us that it therefore considered it appropriate to only run a limited sales process and approach a small number of potential purchasers. This limited sales process does not provide sufficient evidence for us to conclude on whether or not other purchasers would have been interested in Oticon Medical's business (as a whole) if it had been more widely marketed at the time, including to hearing technology firms outside of the specialist hearing implants sector. The CMA in its phase 1 investigation sent brief high-level questions to some broader hearing technology firms assessing their interest in the Oticon Medical business as a whole, and none expressed interest. However, we do not consider this to have significant evidentiary value given that in this context these firms did not have access to financial or operational data regarding Oticon Medical (and would not therefore have been in a position to assess a potential acquisition).

4.117 Within the hearing implants specialism, two alternative purchasers have informed us that they would have been interested in acquiring Oticon Medical as a whole:

(a) [✂].[209] [✂].[210]

(b) Envoy Medical told us that it would have been interested in acquiring the business as a whole or in part and remains so.[211]

4.118 Additionally, because Demant sought to divest the whole of Oticon Medical (ie, the CI and BCS businesses together, which were loss-making as a combination), it was unable to test whether a hearing technology industry purchaser may have been interested in the BCS business on its own. As noted at paragraph 4.62, Demant itself started to supply BCS products, as a non-specialist hearing technology manufacturer, through the acquisition of IP from a Swedish innovation company in 2006. A standalone BCS business,

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[207] Demant submitted analysis to the CMA considering why the BCS business would be unattractive to a financial acquirer if sold on a 'standalone' basis.
[208] Parties' response to Issues Statement, 3 February 2023, paragraph 1.19.
[209] Note of a call with a third party – [✂] – paragraph 14.
[210] Note of a call with a third party – [✂] – paragraph 14.
[211] Note of a call with a third party – Envoy Medical – 9 March 2023 – paragraph 18.

which was demonstrated to be growing, profitable and had a well-developed project for the release of an Active BCS product, may have proven attractive to a player in the wider industry. MW&L told us that, in their opinion, [✂].[212]

Conclusion on Limb 2: would there not have been an alternative, less anticompetitive, purchaser for the BCS business?

4.119 We note that the BCS business is growing and profitable, and as such may have generated greater interest had Demant approached a broader pool of potential purchasers. We also note that businesses in the wider hearing technology sector have entered the hearing implants sector inorganically (ie through an acquisition) in recent history, including Demant and Sonova.

4.120 One alternative purchaser told us that it had been interested in acquiring all of Oticon Medical, or only the BCS business, during the transaction process. Another third party told us that, had it been approached, it would have been interested in Oticon Medical (as a whole or the BCS business only).

4.121 Our conclusion is that, absent the Merger, it is most likely not the case, for the BCS business, that there would not have been an alternative, less anti-competitive purchaser (either on a stand-alone basis or together with the CI business).

Conclusion on the counterfactual

4.122 In view of the above, our conclusion is that the most likely conditions of competition to be taken as the appropriate counterfactual in the present case are the prevailing conditions of competition, ie that Oticon Medical would most likely have continued to operate in the market for the supply of BCS products in the UK (whether the BCS business of Oticon Medical continued to operate under Demant's ownership or under the ownership of an alternative purchaser).

5. Competitive assessment

5.1 This chapter sets out our assessment of the competitive constraints which exist on the Parties' supply of BCS products. We assess whether the Merger may be expected to lead to a significant reduction in competition between the Parties by removing a competitor which previously provided a significant competitive constraint and, in doing so, whether the Merged Entity would likely have the ability and incentive to worsen or not improve its offering when

[212] Note of a call with a third party – MW&L Capital Partners, [✂]– paragraph 13.

assessed against the position absent the Merger. This is a horizontal unilateral effects theory of harm.

5.2 We first set out the background on how competition works in the supply of BCS products in the UK before setting out the evidence we have gathered regarding the existing and potential competitive constraints on the Parties, and our assessment of the effects of the Merger on competition.

5.3 This chapter should be read in conjunction with Appendix C.

Nature of competition for the supply of BCS products

5.4 The assessment of whether a merger gives rise to an SLC must be in terms of an SLC 'within any market or markets in the UK for goods or services'.[213] An SLC can affect the whole or part of a market or markets. The Parties overlap in the supply of BCS products in the UK,[214] and we consider that it is appropriate to assess the competitive effects of the Merger by reference to this relevant market as it comprises the most important constraints on the Parties' overlapping products.[215] In particular, we consider this to be the case because:

(a) As shown below, the internal documents of the Parties and the views of clinics show that the most important competitive constraints on the Parties come from those providers supplying BCS products.[216] In particular, as outlined in paragraphs 5.54 and 5.55 below, clinics consider other hearing solutions (including hearing aids, reconstructive or middle ear surgery, middle-ear implants, CROS hearing aids, and non-surgical products) to be relatively weaker substitutes for the Parties' BCS products. References to these other hearing solutions also feature considerably less than references to BCS products in the Parties' internal documents, in many cases the former being referenced by way of context rather than as competitive alternatives to the latter (see paragraphs 5.42 to 5.49 below and Appendix C).

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[213] The Act, section 36(1)(b) in relation to an anticipated merger; see also Merger Assessment Guidelines (CMA129), paragraph 9.1.
[214] In technical terms, this overlap is our market definition. The assessment of the relevant market(s) 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 (Merger Assessment Guidelines (CMA129), paragraph 9.1). In view of the nature of the competitive constraints assessed in this chapter, we think it is appropriate to take a simple approach to market definition in this case and focus on assessing the strength of the most important (current and likely future) constraints from different competitors or categories of competitors as part of the competitive assessment (Merger Assessment Guidelines (CMA129), paragraph 9.5).
[215] Merger Assessment Guidelines (CMA129), paragraph 9.5.
[216] We have included non-surgical products (as well as surgical products) on the grounds that, as outlined in paragraphs 5.13 to 5.33, the conditions of competition for non-surgical products are broadly the same as for surgical products, namely that these products are provided by the same three suppliers as for surgical products.

(b) Although the BCS products which are available to patients are those which are offered in each clinic in line with the applicable national framework, as outlined in paragraphs 5.13 to 5.33, the competitors and competitive dynamics are broadly similar across the UK nations. In addition, the Parties' internal documents show that the Parties consider competitive dynamics and shares of supply at a UK level, rather than on a nation-by-nation basis.

5.5 In assessing the competitive effects of the Merger, where relevant, we take into account constraints outside the relevant market, segmentation within the relevant market, and other ways in which some constraints are more important than others.[217]

5.6 We discuss in the next section how competition works in the supply of BCS products. We first consider how the NHS procures BCS products; before assessing the factors on which BCS suppliers compete.

How the NHS procures BCS products

5.7 The Parties primarily supply BCS products at the wholesale level, with sales to the NHS accounting for over [✂]% of the Parties' sales.[218] The remaining sales are made to private hospitals, retailers or private patients, and the Parties have told us that this proportion is not expected to change in the future.[219] As such, the NHS procurement process is important for understanding the nature of competition in the supply of these products.

5.8 To supply BCS products to NHS hospital trusts, suppliers must go through a process to be listed on an NHS framework. Each UK nation is responsible for maintaining its own procurement framework for BCS products which are overseen by central procurement bodies, namely NHS Supply Chain (in England), NHS Wales, the Procurement and Logistics Service of Northern Ireland Health and Social Care (PaLS), and NHS Services Scotland (NSS). These bodies are referred to collectively as Central Procurement Bodies.

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[217] Merger Assessment Guidelines (CMA129), paragraph 9.4.
[218] Cochlear's response to P2 s109 notice of, 10 January 2023, Q3 and 5, Annex 209 and Annex 210; and Demant's response P2 s109 notice of 10 January 2023, Annex 2.1 and Annex 3.1.
[219] Cochlear's response to P2 s109 notice of 10 January 2023, question 4 and Demant's response to s P2 s109 notice of 10 January 2023, question 4.

5.9 Clinicians then decide which specific products from the applicable framework to prescribe to a patient by considering a range of factors, including the patients' needs and preferences.[220]

5.10 NHS England procures BCS products on a nationally centralised basis through NHS Supply Chain.[221] Whilst in theory, individual hospital trusts can purchase BCS products directly from suppliers (ie rather than going through NHS Supply Chain), in practice this is uncommon.[222]

5.11 BCS products are categorised as high-cost, tariff-excluded devices which means that the cost of these products is funded centrally by NHS England. Whilst individual clinics pay for these products, they are reimbursed by NHS England.[223] Under the current visible cost model, which was introduced in 2021, clinics can see the cost of BCS products and can take this into account in their decision-making.[224] This represented a change from the previous zero-cost model where clinics could not see the cost of BCS products.[225] The Clinical Commissioning Policy for BCS implants produced by NHS England in 2016 states that, where a patient is suitable for more than one BCS product, the most cost-effective option must be selected by the clinician with patient involvement.[226] The guidance does not, however, set out how clinics should do this in practice.

5.12 In the other UK nations, funding is not centralised, and therefore the cost of the BCS products which individual trusts/clinics purchase comes out of their individual budgets.[227]

The factors on which BCS suppliers compete

5.13 As set out in the CMA's guidance, the CMA will, in its merger assessments, develop a general understanding of the competitive process, including of the

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[220] Note of a call with a third party, January 2023, paragraph 6 [NHS Supply Chain]. Separately a clinic in England told us that their hospital had a Commissioning Group which made decisions about which products from the framework they were able to prescribe to patients. Note of a call with a third party, January 2023, paragraph 17 [Bristol Hospital].
[221] FMN, paragraph 241.
[222] Note of a call with a third party, January 2023, paragraph 6 [NHS Supply Chain].
[223] Note of a call with third party, January 2023, paragraph 6 [NHS Supply Chain] and Demant's response to P2 s109 notice of 10 January 2023, question 9, 'Business Review Meeting Q1 2021 UK Medical v2.6.pptx' [✂], slide 38.
[224] Demant's response to P2 s109 notice of 10 January 2023, Q7, 10, 11, 17, [✂].pptx, slide 33.
[225] Note of a call with third party, January 2023, paragraph 6 [NHS Supply Chain] and Cochlear's response to the CMA's P2 s109 notice of 10 January 2023, Q9 230120 Response to S.109.pdf.
[226] Clinical Commissioning Policy: Bone conducting hearing implants (BCHIs) for hearing loss (all ages) (Reference: NHS England: 16041/P), page 18.
[227] FMN, paragraph 259; Business Services Organisation, Procurement and Logistics Service (BSO PaLS) [Northern Ireland regional procurement body]'s response to the CMA's RFI of 24 January 2023, question 2; and Note of a call with a third party, February 2023, paragraph 3 [Scottish Regional Procurement Body].

competitive parameters that are most important to the process of competition in the relevant industry.[228]

5.14 We have therefore considered the factors on which BCS suppliers compete: first, to be listed on the framework agreement, and then, to be selected by clinicians.

Competition to be listed on the framework

5.15 As outlined above, to supply BCS products to clinics, suppliers must be listed on the NHS framework. Each UK nation is responsible for maintaining its own framework:

(a) In England, the current framework initially ran from 1 August 2020 until 1 July 2022 when it was extended for a further 24 months until 1 August 2024.[229]

(b) The current framework in Northern Ireland runs from 1 January 2023 to 1 January 2025, with the option to extend for up to 24 months to 1 January 2027.[230]

(c) In Scotland, the current framework initially ran from 31 May 2018 until 30 May 2021. It was initially extended for a further 12 months until May 2022, before subsequently being extended again until 31 May 2023. It is now expected to be extended again until 31 May 2024.[231]

(d) In Wales, the current framework runs from 1 January 2021 to 31 December 2023, with an option of an additional 12-month extension until 31 December 2024.[232]

5.16 In England, the tender process for the framework is run by NHS Supply Chain, with input from professionals with direct experience of BCS, and operates as follows:

(a) Suppliers must meet a set of minimum criteria. This includes factors such as whether the suppliers have demonstrated their economic and financial standing and technical and professional ability and that no people

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[228] Merger Assessment Guidelines (CMA129), paragraph 2.3.
[229] FMN, paragraph 229(a).
[230] Business Services Organisation, Procurement and Logistics Service (BSO PaLS)'s Response to the CMA's RFI, 24 January 2023, question 4 and 7.
[231] Contract: NP667/17 Award of Bone Conduction - https://www.publiccontractsscotland.gov.uk/Contracts/Contracts_View.aspx?id=543216; and Note of a call with a third party, February 2023, paragraph 5 and 6 [Scottish Regional Procurement Body].
[232] FMN, paragraph 229(c) and NHS Wales Shared Services Partnership's response to the CMA's RFI of 24 January 2023, question 4.

connected with the organisation have been convicted of a serious offence.[233]

(b) NHS Supply Chain then scores suppliers according to three factors: quality, customer support and prices. In 2020, when the last tender process was run, price was given a relative weighting of 70%, quality 19% and customer service 11%. Those suppliers whose total score met or exceeded the threshold of 50% were listed on the framework.[234]

5.17 We understand that the framework process is broadly similar in the other UK nations.[235] We also understand that this process is not likely to materially change in the future.[236]

5.18 NHS Supply Chain told us that it seeks to maximise the number of suppliers on the framework to increase clinicians' choice of products.[237]

5.19 Three suppliers participated in the last tender process for BCS products in each UK nation, namely Cochlear, Oticon Medical, and MED-EL, with all three being successful.[238] The Central Procurement Bodies told us that they were not aware of any other suppliers who were likely to participate in future tenders.[239]

5.20 In addition, the Central Procurement Bodies told us that it was important for them to ensure that Cochlear and Oticon Medical were on the framework. NHS Supply Chain told us that if either Oticon Medical or Cochlear were not on the framework, there would be 'huge patient impact'.[240] This was echoed by NHS Wales which noted there would be short-term disruption if Cochlear, the main supplier in Wales, was no longer available.[241] PaLS noted that, if there was a supply issue with both Parties, the only alternative to the Parties

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[233] NHS Supply Chain's Response to the CMA's RFI, 24 January 2023, question 5b and Note of a call with a third party, January 2023, paragraph 8 [NHS Supply Chain].
[234] Note of a call with a third party, January 2023, paragraph 8 [NHS Supply Chain]; and FMN, paragraph 229(a), footnote 287: Supplies - 181042-2020 - TED Tenders Electronic Daily (europa.eu).
[235] FMN, paragraph 230.
[236] Business Services Organisation, Procurement and Logistics Service (BSO PaLS)'s Response to the CMA's RFI, 24 January 2023, question 7; NHS Wales Shared Services Partnership's Response to the CMA's RFI, 24 January 2023, question 7; and Note of a call with a third party, January 2023, paragraph 16 [NHS Supply Chain].
[237] Note of a call with a third party, July 2022, paragraph 3 [NHS Supply Chain].
[238] Note of a call with a third party, January 2023, paragraph 16 [NHS Supply Chain] and NHS Supply Chain's Response to the CMA's RFI, 24 January 2023, question 5a.
[239] Note of a call with a third party, January 2023, paragraph 16 [NHS Supply Chain]; Business Services Organisation, Procurement and Logistics Service (BSO PaLS)'s Response to the CMA's RFI, 24 January 2023, question 6 and 8; NHS Wales Shared Services Partnership's Response to the CMA's RFI, 24 January 2023, question 6 and 8; and Note of a call with a third party, February 2023, paragraph 7 [Scottish Regional Procurement Body].
[240] Note of a call with a third party, January 2023, paragraph 17 [NHS Supply Chain].
[241] NHS Wales Shared Services Partnership's response to the CMA's RFI of 24 January 2023, question 9.

on the framework would be MED-EL.[242] The NSS told us that it would prefer at least one of Cochlear or Oticon Medical to be involved going forward.[243]

5.21 Once on the framework for BCS products in England, suppliers are unable to unilaterally increase prices. To increase prices suppliers must provide a justification and seek the consent of NHS Supply Chain.[244] Each party to the framework (ie either NHS Supply Chain, on behalf of clinics, or suppliers) can approach the other to discuss discounts, value added offerings and commitment or bulk buy deals.[245] We understand that this has not happened between 2020 and 2022. However, volume-based discounts may become more common in the future with the implementation of a National Pricing Matrix (NPM) in England as this will provide clinics with the option to purchase BCS products at pre-agreed and transparent lower prices if they commit to make a certain volume of purchases over a 12-month period.[246]

5.22 The frameworks in Northern Ireland, Scotland and Wales contain similar provisions to allow for renegotiations.[247] We understand that renegotiations are relatively uncommon in Northern Ireland and Scotland but have occurred in Wales.[248]

5.23 Overall, the evidence shows that the NHS procurement processes are designed to create incentives for suppliers to compete on price, quality, and customer support in order to be listed on the frameworks.

Competition to be selected by clinicians

5.24 We now consider the key factors which suppliers compete on to get their products selected by clinicians. We first consider evidence from clinicians before turning to our review of the Parties' and third parties' internal documents.

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[242] Business Services Organisation, Procurement and Logistics Service (BSO PaLS)'s response to the CMA's RFI of 24 January 2023, question 9.
[243] Note of a call with a third party, February 2023, paragraph 10 [Scottish Regional Procurement Body].
[244] Cochlear's response to P2 s109 notice of 10 January 2023, Q9 230120 Response to S.109.pdf.
[245] Cochlear's response to P2 s109 notice of 10 January 2023, Q9 230120 Response to S.109.pdf and Note of a call with third party, January 2023, paragraphs 11-13 [NHS Supply Chain].
[246] NHS Supply Chain's response to the CMA's RFI of 24 January 2023, question 3, also NHS SC RFI response to Q1 CMA Response Document 2022_09_09.docx.
[247] Cochlear's response to P2 s109 notice of 10 January 2023, Q9 230120 Response to S.109.pdf.
[248] Business Services Organisation, Procurement and Logistics Service (BSO PaLS)'s response to the CMA's RFI of 24 January 2023, question 3; Note of a call with a third Party, February 2023, paragraph 4 and 5 [Scottish Regional Procurement Body]and NHS Wales Shared Services Partnership's response to the CMA's RFI of 24 January 2023, question 3.

Clinician engagement

5.25 When asked to specify how important certain factors are to them when choosing which BCS product to prescribe, the evidence from responses to our clinic questionnaire shows that clinics consider the most important factor to be the suitability of the product to address the patient's hearing loss (see Table 5.1). This was followed by the reliability and performance of the product. Clinicians considered price to be least important, with only 16 out of 50 giving it a score of 3 or more.[249]

Table 5.1: Relative importance of factors to clinicians when deciding what BCS products to prescribe (1=not important, 5=very important)

Factors	*Average score*	*Total number of scores >3*
Suitability to address specific patient's hearing loss	4.91	48
Reliability of the product	4.66	47
Performance or failure rate of the abutment / implant	4.57	44
Perceived ease of use	4.29	42
Innovation in product features	3.90	33
Compatibility [connectivity with other devices, such as phones, TV]	3.84	33
Aesthetic of product	3.82	33
Customer support [post-implantation support and availability/frequency of upgrades]	3.67	31
Cross-compatibility of the implant with other manufacturers' processors	3.44	24
Reputation of the brand	3.44	24
Familiarity with technology or brand	3.30	23
Price/cost of specific product	2.87	16

Source: CMA's questionnaire to clinics (50 responses).

5.26 A number of clinicians also told us that patient preferences play an important role in their decision about which BCS product to prescribe.[250]

Internal documents and submissions

5.27 Both Parties' internal documents show that patient outcomes, innovation, customer service, quality and performance are important dimensions of competition.

(a) An October 2022 Cochlear internal slide deck compares its Passive Percutaneous BCS product with Oticon Medical's Passive BCS product and MED-EL's Active BCS product on factors such as [✂]. In the same document Cochlear compares its non-surgical BCS product with rivals according to dimensions such as [✂].[251]

[249] Response to the CMA questionnaire from a number of third parties, January 2023, question 3. [✂].
[250] Note of a call with third party, January 2023, paragraph 5 [Northern Care Alliance]; Note of a call with third party, January 2023, paragraph 10 [Bristol Hospital]; and Note of a call with third party, January 2023, paragraph 7 [Auditory Implant Centre, Belfast].
[251] Cochlear's response to the P2 s109 notice of 10 January 2023, Q7, Annex 220: '[✂], pages 3, 5, 8-20, 22-25, 27-34.

(b) A June 2019 Oticon Medical internal slide deck compares Oticon Medical's BCS products to those offered by Cochlear and MED-EL on factors including [✂].[252]

(c) A December 2020 Cochlear strategy slide deck compares Cochlear's product to MED-EL's Bonebridge product according to factors including [✂].[253]

(d) A [✂] Cochlear document setting out its marketing and launch strategy in relation to Osia describes how it expects health care professionals to select Osia for reasons including [✂].[254]

(e) An Oticon Medical internal document from 2019 identifies '[✂]'.[255] Similarly, another Oticon Medical internal document from 2020 notes that the '[✂]'.[256]

(f) An Oticon Medical internal document from 2019 notes that its [✂].[257] In another Oticon Medical internal document from 2021, it compares its BCS business to Cochlear and MED-EL on [✂].[258]

5.28 The importance of innovation as a competitive factor is also reflected in submissions made by the Parties. The Parties submitted that, in the hearing implants segments, the ability to innovate is the key parameter of competition, more so than price.[259] Cochlear told us that, to date, it had spent more than $2bn AUD in research and development.[260] Oticon Medical also told us that it considered innovation to be key and had been spending [✂]% of its revenues on R&D.[261]

5.29 Internal documents from MED-EL also show that it compares its performance with Cochlear's Active product (Osia) on factors such as size, battery life, whether a patient can safely use an MRI, and reliability.[262]

5.30 Price is mentioned within the Parties' internal documents to some extent, but comparatively less than other factors:

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[252] Demant's response to P2 s109 notice of 10 January 2023, Q7, [✂], slides 12-15, 22-27, 32-35.
[253] Cochlear's response to P2 s109 notice of 12 August 2022, Q10a, '[✂].
[254] Cochlear's response to P2 s109 request of 10 January 2023, [✂]. [✂].
[255] Demant's response to P2 s109 notice of 10 January 2023, Q7, [✂], slide 14.
[256] Demant's response to P2 s109 notice of 10 January 2023, Q12, 17, [✂], slide 1.
[257] Demant's response to P2 s109 notice of 10 January 2023, Q7 and 8, [✂], slide 28.
[258] Demant's response to P2 s109 notice of 10 January 2023, Q7, 12, 17, [✂], page 19.
[259] Parties' response to the Issues Statement, 3 February 2023, paragraph 1.5(c).
[260] Cochlear teach in presentation, 23 January 2023, slide 3 [✂].
[261] Demant teach in presentation, 26 January 2023, slide 23 [✂].
[262] MED-EL's response to P2 s109 notice of January 2023, [✂] and [✂].

(a) An Oticon Medical slide deck relating to its budget for 2020 contains a SWOT analysis which, amongst the threats identified, [✂].[263]

(b) Another Oticon Medical internal document from October 2021 [✂].[264] The document goes on to outline Oticon Medical's future strategy, but this has a greater focus on [✂].

5.31 Overall, the evidence shows that, suppliers compete to be selected by clinicians on a range of dimensions of quality – including functionality, reliability, and performance, as well as through innovating to improve quality. Whilst there is some evidence that price is a competitive dimension, this seems relatively less important than other parameters. As noted in paragraphs 5.15 to 5.23, competition to be on the frameworks takes place based on price, quality, and customer support, with price being the most important factor.

5.32 The Parties submitted that the Merger would not impact price, quality or innovation:

(a) In response to the AIS and WPs, the Parties told us that these factors are impacted by commercial and contractual factors other than competition from Oticon Medical.[265] In response to our Provisional Findings, Cochlear reiterated that any attempt to diminish patient outcomes would be commercially irrational as it would damage Cochlear's reputation and actively discourage patients from implant surgery.[266]

(b) In response to the AIS and WPs, the Parties told us that price has been locked in by the NHS[267] and that they [✂].[268] Cochlear made a similar point in response to our Provisional Findings: it told us that the NHS is able to exert significant downward pressure on pricing and can (and does) resist price increases for existing products and refuse to pay for new products.[269]

5.33 In relation to these submissions, we consider that:

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[263] Demant's response to P2 s109 notice of 10 January 2023, Q7, 8, [✂], slide 28.
[264] Demant's response to P2 s109 notice of 10 January 2023, Q7, 9, 12, 17, 18, [✂], slide 20.
[265] Parties' response to the AIS and WPs, dated 23 March 2023, paragraphs 3.30, 3.31 and 3.41. The Parties submitted that Cochlear has a commercial incentive to look after Oticon Medical's patient base and protect its reputation as well as a contractual commitment to [✂]. They also submitted that innovative sound processors and accessories are also crucial for Cochlear's non-surgical segment. Recipients of which then are likely to flow through to its Osia product.
[266] Cochlear's response to the Provisional Findings, dated 11 May 2023, paragraph 10.
[267] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.28. This was also reiterated in Cochlear's response to the Provisional Findings, dated 11 May 2023, paragraph 13.
[268] Notes of a hearing with Cochlear, 21 March 2023, page 7 lines 19-25 and page 8 lines 1-2.
[269] Cochlear's response to the Provisional Findings, dated 11 May 2023, paragraph 11.

(a) Effective competition provides incentives for firms to compete to improve price, quality and innovation and, as such, drives commercial conduct. Any other commercial or contractual factors are likely to be imperfect and insufficient to mitigate the impact of any likely deterioration of competition arising from the Merger.

(b) Price is only one dimension of competition which could be impacted by the Merger. Furthermore, the [✂] for existing technology does not mean that this could not happen in the future as a result of the Merger, or that the Merger could not impact the prices of new products. We have also not seen evidence of the NHS exerting downward pressure on the price of BCS products.

5.34 As a result, if the Merger were to give rise to an SLC, this could lead to poorer patient outcomes, with patients potentially facing less choice, reduced quality or reduced product innovation as well as the potential for higher prices for the NHS relative to the position absent the Merger. In the remainder of this chapter, we assess whether the Merger may be expected to result in an SLC.

Framework of assessment

5.35 Horizontal unilateral effects can arise in a merger where one firm merges with a competitor that previously provided a competitive constraint, allowing the merged entity profitably to increase prices or degrade non-price aspects of its competitive offering (such as quality, range and innovation).[270] This involves a comparison of the prospects for competition with the merger against the counterfactual,[271] which in this case, as set out in Chapter 5, is the prevailing conditions of competition.

5.36 The concern under horizontal unilateral effects essentially relates to the elimination of a competitive constraint by removing an alternative to which customers could switch. The CMA's main consideration is whether there are sufficient remaining good alternatives to constrain the merged entity post-merger. Where there are few existing suppliers, the merger firms enjoy a strong position or exert a strong constraint on each other, or the remaining constraints on the merger firms are weak, competition concerns are likely. Furthermore, in markets with a limited likelihood of entry or expansion, any given lessening of competition will give rise to greater competition concerns.[272]

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[270] Merger Assessment Guidelines (CMA129), paragraph 4.1.
[271] Merger Assessment Guidelines (CMA129), sections 3 and 4.
[272] Merger Assessment Guidelines (CMA129), paragraph 4.3.

5.37 The Parties submitted that 'there is no realistic prospect that the merged entity would be able to profitably raise prices or degrade non-price aspects of its competitive offering (such as quality, range, service and innovation post-merger)',[273] because:

(a) Oticon Medical is not a competitive constraint because the market is shifting rapidly to Active BCS products, and Oticon Medical does not have a current Active BCS product offering nor a proven proof of concept;[274] Oticon Medical is generally a diminishing competitor in BCS that has failed to innovate in respect of implants technology and was losing market share as the pandemic hit.[275]

(b) Sentio, the Active BCS product which Oticon Medical has been developing [✂] and it is currently yet to [✂] or receive any regulatory clearance.[276] Even if it was released, Sentio would not [✂].[277] Oticon Medical no longer plans to bring Sentio to market because it is not prepared to make the lifelong commitment to support future potential patients and because it would require Oticon Medical to maintain relevant know-how and its Class III approved manufacturing site in Nice, which would [✂] the gross margin of its BCS business;[278]

(c) MED-EL is a significant competitive constraint, with a broad product portfolio and an established track record of significant innovation;[279]

(d) BCS products are a small sub-set of a broader range of hearing products that treat mild to moderate hearing loss, including hearing aids, reconstructive (or middle ear) surgery, middle-ear implants, contralateral routing of signal (**CROS**) hearing aids, and non-surgical products.[280] If the merged entity were to seek to increase prices or reduce the pace of innovation in the BCS segment, this would deter patients and health care professionals from switching away from other hearing solutions.[281] There is a significant opportunity for growth in hearing implants, as they account for a small proportion of the total global revenue from hearing solutions;

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[273] Parties' response to Issues Statement, 3 February 2023, paragraph 3.3.
[274] Parties' response to Issues Statement, 3 February 2023, paragraphs 3.25 and 3.35.
[275] Parties' response to Issues Statement, 3 February 2023, paragraphs 3.19-3.23.
[276] Parties' response to Issues Statement, 3 February 2023, paragraph 1.7.
[277] Parties' response to Issues Statement, 3 February 2023, paragraph 3.35.
[278] Parties' response to Issues Statement, 3 February 2023, paragraphs 3.36 and 3.39.
[279] Parties' response to Issues Statement, 3 February 2023, paragraph, 3.34.
[280] Parties' response to Issues Statement, 3 February 2023, paragraphs 3.12-3.17. To support their submission, the Parties provided an audiogram showing that there is overlap between the indications and fitting ranges of BCS products and other hearing solutions, and data showing that BCS volumes are small compared to other solutions. The Parties also referenced internal documents which they submitted demonstrate that they monitor other hearing solutions.
[281] Parties' response to Issues Statement, 3 February 2023, paragraph 3.18s.

this growth potential is a powerful constraint.[282] Innovation will continue to be driven by the commercial incentive to expand the hearing implants segment and these efforts are independent of any competitive pressure exerted by Oticon Medical;[283] and

(e) The very significant majority of BCS sales are via the NHS which has substantial purchasing power due to existing alternatives – including MED-EL's BCS products and the wide range of hearing products that can treat the same hearing loss as BCS products – and the lack of significant costs of switching between these solutions.[284] The NHS also has the option of refusing to pay.[285] Cochlear repeated this point in response to our Provisional Findings: it said that we had not properly assessed buyer power as we had not considered the range of solutions available for adults with mild to moderately severe hearing loss or the ability of the NHS to exert downward pricing pressure.[286]

5.38 We consider the Parties' submissions as part of our assessment. However, we make three initial comments on these submissions which relate to the overall framework of assessment:

(a) Where the CMA finds evidence that competition mainly takes place among few firms, any two would normally be sufficiently close competitors such that the elimination of competition between them would raise competition concerns, subject to evidence to the contrary. The smaller the number of significant players, the stronger the prima facie expectation that any of the two firms are close competitors. In such a scenario, the CMA will require persuasive evidence that the merger firms are not close competitors in order to allay any competition concerns.[287] In this case, there are only three firms currently active in the supply of BCS products in the UK.

(b) We agree with the Parties that the strength of the NHS's buyer power is related to the alternatives it has available. We note that most 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.[288] This is because a customer's

[282] Parties' response to Issues Statement, 3 February 2023, paragraph 3.4.
[283] Parties' response to Issues Statement, 3 February 2023, paragraphs 4.2 and 4.6.
[284] Parties' response to Issues Statement, 3 February 2023, paragraphs 5.1-5.3.
[285] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.42.
[286] Cochlear's response to the Provisional Findings, dated 11 May 2023, paragraph 11.
[287] Merger Assessment Guidelines (CMA129), paragraph 4.10.
[288] Merger Assessment Guidelines (CMA129), paragraph 4.20.

buyer power depends on the availability of good alternatives it 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.[289] Therefore, in assessing the strength of the competitive constraints between the Parties that would be lost as a result of the Merger, and the strength of the competitive constraints on the Parties from other suppliers that would remain after the Merger, we are effectively taking account of customers' buyer power. In this chapter, we have undertaken a detailed and evidence-based assessment of the constraints on BCS products which we consider to be the main factor in determining the NHS's buyer power in relation to BCS products. We consider Cochlear's submission about the NHS driving down prices in paragraph 5.33.

(c) Oticon Medical's development of Sentio represents potential competition to Cochlear from an Active BCS product. Unilateral effects can arise from the elimination of potential or dynamic competition.[290] The CMA's assessment of competitive effects from the loss of future competition between the merger firms is similar to its assessment when the merger firms are existing suppliers, except the CMA's assessment will reflect the future competitive conditions.[291] The impact on competition is likely to be more significant when there are fewer strong existing competitive constraints on the other merger firm; where the other merger firm would already have market power absent the merger; and/or where there are few other potential constraints.[292]

5.39 Our assessment is structured as follows:

(a) We assess the closeness of competition between the BCS products currently supplied by the Parties, the constraint from MED-EL and the constraint from other hearing solutions.

(b) We then describe the Active BCS products which have emerged and assess how the relative importance of Active BCS and Passive BCS products is likely to evolve in the future.

(c) We then assess the competitive constraint from Sentio.

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[289] Merger Assessment Guidelines (CMA129), paragraph 4.20.
[290] Merger Assessment Guidelines (CMA129), paragraph 5.1.
[291] Merger Assessment Guidelines (CMA129), paragraph 5.14.
[292] Merger Assessment Guidelines (CMA129), paragraph 5.15.

(d) Finally, we consider whether there are any countervailing factors that could prevent an SLC arising from the Merger.

5.40 In undertaking our assessment, we have taken account of a wide range of evidence including: the Parties' submissions, internal documents we received from the Parties, and evidence from our engagement with the Parties, competitors, the NHS (including clinics) and other third parties.

Competitive constraints

5.41 This section considers the closeness of competition between the BCS products currently supplied by the Parties, the constraint from MED-EL and the constraint from other hearing solutions. We structure this by the type of evidence which we have received, as follows:

(a) We first outline evidence from our analysis of the Parties' internal documents.

(b) We then consider the views of clinics, including the responses from our questionnaire to them.

(c) We then outline evidence from MED-EL and other third parties.

(d) We finally set out the shares of supply of the Parties and their competitor, MED-EL.

5.42 At the end of each sub-section, we summarise the inferences we are drawing from that evidence source. At the end of the section, we then consider all the different sources of evidence together in the round.

Parties' internal documents

5.43 In this section we present our findings based on evidence from the Parties' internal documents. We begin by presenting our findings based on Cochlear's documents, before doing the same for Oticon Medical's documents. The evidence is set out in Appendix C. We also address the points made in the Parties' response to the AIS and WPs.

Cochlear's internal documents

5.44 Cochlear's internal documents show that it considers a wide range of hearing solutions across both Active and Passive BCS products, including other BCS products, MED-EL's Bonebridge product and other types of hearing solutions, and that:

(a) In relation to its Passive BCS product, as set out in paragraph 4 of Appendix C, Cochlear views Oticon Medical's Passive BCS product [✂], MED-EL's Bonebridge product is a [✂] and that the constraint from other hearing solutions is limited.

(b) In relation to its Active BCS product, as set out in paragraph 5 of Appendix C, Cochlear views MED-EL's Bonebridge product to be [✂] and, [✂], Oticon Medical's Ponto product. The constraint from other hearing solutions is limited.

5.45 In the Parties' response to the AIS and WPs, they submitted that the constraint from other hearing solutions is not limited and that:

(a) Cochlear's internal documents show that it has a longstanding core strategic priority to grow the hearing implant market.[293] In the significant majority of Cochlear's internal documents, other hearing solutions are referred to as competitors, rather than market context, and do not always feature in less detail than BCS products.[294]

(b) The fact that Cochlear assesses its technology against other BCS products in more detail than other hearing solutions does not in itself mean that these pose a more limited competitive constraint.[295]

5.46 In response to our Provisional Findings, Cochlear reiterated that competition and innovation are driven by the opportunity to penetrate the addressable market rather than taking marginal market share from existing direct competitors.[296] It reiterated that it is [✂] that BCS products offer many more patients a better solution than middle-ear surgery and hearing aids,[297] and that implant manufacturers have to innovate to keep up with the dynamic pace of innovation in the hearing aids sector.[298] It also reiterated that there are numerous hearing solutions which overlap across the range of hearing solutions, especially for mild and moderately severe hearing loss that characterises those patients referred to BCS specialists.[299]

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[293] Parties' response to the AIS and WPs, dated 23 March 2023, paragraphs 3.3-3.8. To support their submission further, the Parties referred to analysis undertaken by Cochlear showing that for almost [✂]% of patients eligible for a cochlear implant, these had not been discussed or raised by their audiologist and separately state that Cochlear is [✂] Osia offers better performance over middle-ear surgery. The Parties also provided evidence showing that hearing aid manufacturers spend significant amounts on improving factors such as performance, features, and remote care and stated that whilst globally around 200,000 patients have received a BCS implant, 6.5 million have had middle-ear surgery.
[294] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.18.
[295] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.19 and paragraph 1.4.
[296] Cochlear's response to the Provisional Findings, 11 May 2023, paragraph 7.
[297] Cochlear's response to the Provisional Findings, 11 May 2023, paragraph 8.
[298] Cochlear's response to the Provisional Findings, 11 May 2023, paragraph 9.
[299] Cochlear's response to the Provisional Findings, 11 May 2023, paragraph 8.

5.47 In relation to these submissions, we consider that the products and competitors which firms reference, monitor and respond to in internal documents provides evidence on competitive conditions, and the detail in which this is undertaken will invariably reflect their perceptions of the competitive importance of rivals. Where firms identify specific competitors, undertake detailed monitoring of them, and outline plans to react to these, we consider this shows that these competitors are viewed as providing (or potentially providing) a strong competitive constraint. Conversely, where, within the same or similar documents, firms do not consider other competitors or do not do so in the same level of detail, this is consistent with those competitors being viewed as providing no, or a weaker, constraint.

5.48 As set out in paragraphs 7 to 14 of Appendix C, Cochlear's internal documents contain references to other hearing solutions and show that its strategic objectives include gaining market share as well as growing the market. However, the evidence also shows that, across a wide range of types of documents, Cochlear undertakes detailed monitoring of BCS competitors (including their product features, strengths and weaknesses and expected future strategies) and outline plans to react to these. This is not the case for other hearing solutions which, by contrast, are referenced in many cases by way of context rather than as competitive alternatives to BCS products. We therefore consider that this evidence shows that the competitive constraint from other hearing solutions is limited. This view is supported by other evidence, including Oticon Medical's internal documents and evidence from clinics.

5.49 As set out in paragraphs 15 and 16 of Appendix C, Oticon Medical's internal documents show that:

(a) It considers Cochlear to be its [✂] competitor for Passive BCS products and, to a [✂], MED-EL.

(b) MED-EL and other hearing solutions have some [✂] including that MED-EL's BCS product line [✂].

(c) Other hearing solutions are very rarely mentioned within Oticon Medical's internal documents and provide very limited constraint.

5.50 In response to the AIS and WPs, the Parties submitted that Oticon Medical's internal documents do not focus on the competitive constraint from hearing aids and the competitive interaction between hearing aids and BCS products because Oticon Medical is a small part of Demant's corporate group that

focuses on hearing aids.[300] However, we have not seen any evidence from Oticon Medical's internal documents of it referring to hearing aids as a competitor in relation to BCS products or drawing on Demant's expertise in hearing aids.

5.51 The Parties also submitted that Bonebridge [✂]. They submitted that it is a strong constraint in Active BCS which is supported by evidence from Cochlear's internal documents and clinics, as well as MED-EL stating its intention to grow. They also submitted that MED-EL's second-generation processor makes [✂] and that MED-EL is actively recruiting in the UK to drive growth for Bonebridge.[301] In relation to these submissions, we consider that MED-EL does constrain Cochlear's Osia Active BCS product, but that this is weakened by the fact that the Parties' documents show that it has [✂] and that this is reflected by MED-EL's share of supply which has remained relatively low for the last four years.

Our assessment of the evidence from internal documents

5.52 Our assessment of the evidence from internal documents is that:

(a) In relation to Passive BCS products, the Parties view each other as their closest competitors and the constraint from MED-EL is limited.

(b) The Parties have submitted that their internal documents demonstrate that MED-EL's Bonebridge product has [✂].[302] Our review of internal documents shows that whilst MED-EL's Bonebridge product has advantages and disadvantages [✂] the Parties view it [✂]. However, we have found that that MED-EL's Bonebridge product provides some constraint on Cochlear for Active BCS products. Oticon Medical's Passive BCS products also provide some constraint on Cochlear's Osia product.

(c) Other hearing solutions, like hearing aids and middle-ear implants generally provide limited constraint on both Passive and Active BCS. The Parties have submitted that their internal documents demonstrate that they operate in a market where the most significant competitive constraints include patients which do nothing, hearing aids, and other forms of hearing solution.[303] However, we have found that these other solutions feature considerably less in their internal documents than the

[300] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 1.9 of Annex.
[301] Parties' response to the AIS and WPs, dated 23 March 2023, paragraphs 3.33-3.36.
[302] Parties' response to the Issues Statement, 3 February 2023, paragraphs 3.34 and 3.35.
[303] Parties' response to the Issues Statement, 3 February 2023, paragraph 2.6.

other merging party or MED-EL and, in many cases, they are referenced as market context rather than as competitors.

Clinics' views

5.53 In this section, we present evidence from clinics, including from their responses to our questionnaire.[304] We begin by presenting results about which suppliers clinics use, before outlining evidence about the alternatives they have available and their views on the impact of the Merger.

Current suppliers of BCS products

5.54 In our questionnaire to clinics, we asked them which BCS products they provide to patients. As shown in Table 5.2:

(a) Most clinics provide Passive BCS products to patients and the Parties are the only suppliers of these.[305] The vast majority of clinics provide BCS products supplied by both Cochlear and Oticon Medical.[306]

(b) Only about half of clinics provide Active BCS products to patients.[307] Of these, about half provide products supplied by both MED-EL and Cochlear,[308] around a quarter provide only Cochlear's product,[309] and the remaining clinics only provide MED-EL's product.[310]

(c) About half of clinics provide non-surgical BCS products from more than one supplier,[311] and about a quarter of clinics provide products from all three.[312] 13 out of 38 clinics only provide non-surgical BCS products from MED-EL.[313]

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[304] This questionnaire was sent to 208 clinics who are customers of the Parties. We received 54 usable responses (26% response rate), but not all clinics responded to every question. Response to the CMA questionnaire from a number of third parties, January 2023, [✂].
[305] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂].
[306] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂].
[307] Response to the CMA questionnaire from a number of third parties, January 2023, question 2, [✂].
[308] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂].
[309] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂].
[310] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂].
[311] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂].
[312] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [[✂].
[313] Response to the CMA questionnaire from a number of third parties, January 2023, question 2 [✂]. Additionally, eight clinics who responded to the question about their current non-surgical BCS suppliers named a supplier other than Cochlear, MED-EL or Oticon Medical, namely Starkey, Siemans, Bruckhoff, Autel and Shotz [✂].

Table 5.2: Active and Passive BCS products provided by UK clinics

Suppliers used	Passive BCS	Active BCS	Non-surgical BCS
Cochlear only	6	6	5
Oticon Medical only	5	-	1
MED-EL only	-	8	13
Both Cochlear and Oticon Medical	36	-	5
Both Cochlear and MED-EL	-	12	2
Both Oticon Medical and MED-EL	-	-	3
Cochlear, Oticon Medical and MED-EL	-	-	9
Total	**47**	**26**	**38**

Source: CMA's analysis of questionnaire to clinics (50 responses).

5.55 We asked clinics whether they had a 'preferred' or 'go-to' supplier for BCS products.[314] As shown in Table 5.3, we found that:[315]

(a) 19 out of 27 clinics said that Cochlear was their preferred supplier for transcutaneous Passive BCS products.[316] Six clinics noted that this was the only product available.[317]

(b) A third of clinics did not have a preferred supplier of percutaneous Passive BCS products.[318] Oticon Medical was preferred by about two-thirds of those who expressed a preference.[319] Ten clinics told us they preferred Oticon Medical's percutaneous Passive BCS product as it had a universal abutment and could work with both Oticon Medical and Cochlear processors.[320] Three clinics thought that Cochlear was best for mild hearing loss and Oticon Medical was better for severe hearing loss.[321]

(c) About a third of clinics did not have a preferred supplier of Active BCS products.[322] Of the remaining 22 clinics, 15 preferred Cochlear's product,[323] and seven preferred MED-EL's product.[324] Across all the clinics who responded, irrespective whether they had a preferred supplier or not, five told us that Cochlear's product benefits from better fitting

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[314] This was an open-ended question. In our analysis, we excluded cases where clinics either indicated that the question was not applicable to them because they did not offer these products or did not answer the question. The number of clinics who said the question was not applicable to them was three for percutaneous Passive BCS [✂], 17 for transcutaneous Passive BCS [✂], 13 for Active BCS [✂] and one for non-surgical BCS [✂]. The number of clinics who did not answer the question was one for percutaneous Passive BCS [✂], five for transcutaneous Passive BCS [✂], four for Active BCS [✂] and six for non-surgical BCS [✂].
[315] Some clinics said in their response that their choice would depend on the patient's hearing loss and/or preferences. This was mentioned by ten clinics for percutaneous Passive BCS products [✂], four clinics for transcutaneous Passive BCS products [✂], five clinics for Active BCS products [✂], and 14 clinics for non-surgical BCS products [✂].
[316] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[317] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[318] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[319] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[320] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[321] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[322] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[323] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[324] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].

options,[325] and connectivity and two said it had a higher fitting range.[326] One clinic noted that Bonebridge had a better battery life,[327] and another said it was better for patients who prefer easier options with wireless technology.[328]

(d) Over half of clinics did not have a preferred supplier of non-surgical BCS products.[329] Of those who did, about half preferred Oticon Medical,[330] and just under a half preferred Cochlear.[331] A minority said they preferred MED-EL.[332]

Table 5.3: Clinics' 'preferred' or 'go-to' suppliers of BCS products

Preferred supplier	*Passive Transcutaneous*	*Passive Percutaneous*	*Active*	*Non-surgical*
Cochlear	19	9	15	6
Oticon Medical	1	21	-	7
MED-EL	-	-	7	2
No preference	7	15	10	24
Total	**27**	**45**	**32**	**39**

Source: CMA's analysis of questionnaire to clinics (51 responses)

Alternatives to BCS products

5.56 We asked clinicians what products they would prescribe if one or more features of a BCS product that they had prescribed in the last 12 months worsened significantly (see Table 5.4).[333] We referred to patients who had been prescribed BCS products as we wanted to know what alternatives were

[325] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[326] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[327] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[328] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[329] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[330] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[331] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
[332] Response to the CMA questionnaire from a number of third parties, January 2023, question 4 [✂].
Additionally, nine clinics who responded to the question about preferred non-surgical BCS supplier named a supplier other than Cochlear, MED-EL or Oticon Medical, namely Starkey, Bruckhoff and BHM Tech [✂]. A further nine clinics that told us that they only use MED-EL for non-surgical BCS products named MED-EL and another supplier as their preferred suppliers [✂] and two clinics that told us that they only use MED-EL for non-surgical BCS products named another supplier as their preferred supplier [✂].
[333] The question asked 'Thinking about the patients that you have recently prescribed a (name of BCS product) and the factors you told us were important in your decision, if one or more of these factors worsened significantly (eg significant reduction in quality) please specify (a) what product you would prescribe instead and from which supplier and (b) the basis for your response in (a). Please only answer this question if you have prescribed a (name of BCS product) in the previous 12 months'. This was an open-ended question. We did not ask this question for non-surgical products because we see little reason why switching from Ponto / Baha for non-surgical patients would be substantially different to that for surgical patients. In our analysis we excluded cases where clinics either indicated that the question was not applicable to them because they did not offer these products or did not answer the question. The number of clinics who said the question was not applicable to them was 33 for Baha Attract [✂] 11 for Baha Connect [✂], seven for Ponto [✂], and 28 for Osia [✂]. The number of clinics who did not answer the question was two for Baha Attract [✂], nine for Baha Connect [✂], five for Ponto [✂], and two for Osia [✂].

available for these patients, and clinicians were able to indicate multiple alternatives.[334] The responses show that:

(a) For percutaneous Passive BCS products, most clinics considered the Parties to be each other's closest competitors. 24 of the 29 clinics who identified alternatives to Cochlear's Baha Connect identified Oticon Medical's Ponto BCS product as an alternative.[335] 32 out of the 37 who identified alternatives to Oticon Medical's Ponto identified Cochlear's BCS products (Baha Attract or Baha Connect).[336]

(b) Fewer clinics identified Active BCS products as alternatives to percutaneous Passive BCS products. Six of the 29 clinics who identified alternatives to Cochlear's Baha Connect identified an Active BCS product, and the same number named MED-EL's Bonebridge[337] and Cochlear's Osia products.[338] Three of the 37 clinics who identified alternatives to Oticon Medical's Ponto identified an Active BCS product, with all of these clinics explicitly identifying MED-EL's Bonebridge.[339]

(c) Eight of the ten who identified alternatives to Cochlear's transcutaneous Passive BCS product (Baha Attract) identified another Passive BCS product.[340] A similar number (seven out of ten) identified an Active BCS product,[341] with four of these explicitly stating that they consider Cochlear's Osia product to be a potential alternative.[342]

(d) The overall number of clinics who identified other (ie non-BCS) hearing solutions as being potential alternatives to percutaneous and transcutaneous Passive BCS products was generally low. One out of the ten clinics who identified alternatives to Cochlear's Baha Attract identified other hearing solutions,[343] four out of the 29 clinics who identified

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[334] A number of clinics which responded to this question said that their choice would depend on the patient's hearing loss and/or preferences. This was mentioned by one clinic identifying alternatives to Cochlear's Baha Attract product [✂], three clinics identifying alternatives to Cochlear's Baha Connect product [✂], four clinics identifying alternatives to Oticon Medical's Ponto product [✂], and three clinics identifying alternatives to Cochlear's Osia product [✂].
[335] Response to the CMA questionnaire from a number of third parties, January 2023, question 7 [✂].
[336] Response to the CMA questionnaire from a number of third parties, January 2023, question 8 [✂]. Additionally, six out of 37 clinics said that they would select a Cochlear BCS processor as this was compatible with the Oticon Medical Ponto implant [✂].
[337] Response to the CMA questionnaire from a number of third parties, January 2023, question 7 [✂].
[338] Response to the CMA questionnaire from a number of third parties, January 2023, question 7 [✂].
[339] Response to the CMA questionnaire from a number of third parties, January 2023, question 8 [✂].
[340] Response to the CMA questionnaire from a number of third parties, January 2023, question 6. Of the eight who identified alternatives to Cochlear's transcutaneous Passive BCS product (Baha Attract), four explicitly stated Cochlear Passive BCS [✂], two said Oticon Medical's Ponto [✂], and two stated Unspecified Percutaneous Passive BCS [✂].
[341] Response to the CMA questionnaire from a number of third parties, January 2023, question 6. Of the seven who identified an Active BCS product as an alternative, two explicitly stated MED-EL Bonebridge [✂] and one said Unspecified Active BCS [✂].
[342] Response to the CMA questionnaire from a number of third parties, January 2023, question 6 [✂].
[343] Response to the CMA questionnaire from a number of third parties, January 2023, question 6, [✂].

alternatives to Cochlear's Baha Connect identified other hearing solutions,[344] seven out of the 37 clinics who identified alternatives to Oticon Medical's Ponto identified other hearing solutions.[345] With regard to Osia, six out of the 16 clinics who identified alternatives identified other hearing solutions as alternatives.[346]

(e) Ten out of 16 clinics who identified alternatives to Cochlear's Osia product identified MED-EL's Bonebridge product.[347] Seven out of 16 identified Passive BCS products as an alternative (with two naming Cochlear's Passive products,[348] three Oticon Medical's Ponto,[349] and two not specifying[350]). Five out of 16 clinics stated that middle-ear implants were an alternative to Cochlear's Osia product,[351] with four mentioning MED-EL's Soundbridge product.[352]

Table 5.4: Clinics' alternatives to the Parties' BCS products

	Passive Transcutaneous	Passive Percutaneous		Active BCS
Best alternative	Cochlear Baha Attract	Cochlear Baha Connect	Oticon Medical Ponto	Cochlear Osia
Passive BCS	**8**	**24**	**32**	**7**
Cochlear Passive BCS	4	-	32	2
Oticon Medical Ponto	2	24	*N/A*	3
Unspecified percutaneous Passive BCS	2	-	-	2
Active BCS	**7**	**6**	**3**	**10**
Cochlear Osia	4	3	-	N/A
MED-EL Bonebridge	2	3	3	10
Unspecified Active BCS	1	-	-	-
Other solutions	**1**	**4**	**7**	**6**
Unspecified middle ear implant	1	-	-	1
MED-EL Soundbridge (middle-ear implant)	-	2	3	4
Hearing aids	-	1	1	1
Cochlear Implants	-	1	2	-
Non-surgical BCS	-	-	1	-
Unspecified solutions	**0**	**1**	**2**	**0**
Unspecified Cochlear product	-	-	1	-
Unspecified Oticon Medical product	-	1	-	-
Unspecified MED-EL product	-	-	1	-
No alternative	-	-	3	1
Total	**10**	**29**	**37**	**16**

Source: CMA's analysis of questionnaire to clinics (total number of responses shown in the Total row of the Table).

[344] Response to the CMA questionnaire from a number of third parties, January 2023, question 7 [✂].
[345] Response to the CMA questionnaire from a number of third parties, January 2023, question 8. Of the seven who identified other hearing solutions as alternatives to Oticon Medical's Ponto, three said MED-EL Soundbridge Middle Ear Implant [✂], one said Hearing Aids [✂], and one said Non-Surgical BCS [✂].
[346] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].
[347] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].
[348] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].
[349] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].
[350] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].
[351] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].
[352] Response to the CMA questionnaire from a number of third parties, January 2023, question 5 [✂].

5.57 In our calls with clinics, they provided further details on why non-BCS solutions, such as hearing aids and middle-ear implants, may not be viable alternatives for patients who are typically prescribed BCS products:

(a) Two clinics told us that they did not consider standard hearing aids to be a good alternative as patients referred to them for BCS products have typically already tried standard hearing aids and they have not helped.[353]

(b) One clinic told us that most BCS patients would also be eligible for middle-ear implants but that the clinic would always offer less invasive treatments in the first instance as middle-ear implants require invasive surgery and are riskier for patients. The clinic told us that its middle-ear implant programme is very small, providing about three to four implants in 2022 (compared to 50 for BCS).[354] The clinic also told us that, in some cases, reconstructive surgery may be an alternative option, but the clinic similarly tried to avoid this solution, if possible, as it is more invasive. The clinic also told us that it may be able to explore CROS or bi-contralateral routing of sound (**BI-CROS**) options for single-sided hearing patients.[355]

5.58 In response to the AIS and WPs, the Parties submitted that:

(a) It is to be expected that clinics performing hearing implant surgeries will report that two Passive BCS products are closest competitors, just as two Active BCS products are closest.[356] The question the CMA asked clinics did not assess the extent to which, prior to patients being referred for BCS products, clinics would be willing to recommend alternative hearing solutions. Clinics were also not asked whether other hearing solutions would be potential alternatives in the hypothetical event that, for example, all surgical BCS products worsened significantly (or, conversely, if hearing aids significantly improved).[357]

(b) The low awareness around hearing implants means that clinicians do not have complete visibility of the full range of hearing solutions and their benefits, are unable to provide patients with holistic advice on a patient's

[353] Note of a call with a third party, January 2023, paragraph 9 [✂]; and Note of a call with a third party, January 2023, paragraph 5 [✂]. One of these clinics was also included in our questionnaire, the other was not.
[354] Note of a call with a third party, January 2023, paragraph 9 [✂]. The other clinic [✂] indicated that it was not a middle-ear implant site so its knowledge around this was more limited. Note of a call with a third party, January 2023, paragraph 9 [✂].
[355] Note of a call with a third party, January 2023, paragraph 6 [✂]. This clinic was not included in our questionnaire.
[356] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.22.
[357] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.22.

range of options and will be hesitant to promote solutions they are not familiar with.[358]

5.59 In response to our Provisional Findings, Cochlear made similar points: it submitted that the clinic questionnaire did not explore the unmet demand for BCS products. In particular, Cochlear told us that the questionnaire did not consider whether there were patients who could have been referred for BCS products but were not and the products these patients ultimately received.[359]

5.60 In relation to these submissions, we consider that the question which we asked clinics (ie what product they would prescribe if one or more of aspects of their chosen BCS product worsened significantly) was the most relevant to understanding the competitive constraints on each Party and assessing the likely impact of the Merger (see paragraph 5.54). We also consider that the clinicians who responded are those who prescribe BCS products, and their awareness and views of other hearing solutions are reflective of how the market functions and the options which they would be aware of and willing to recommend to patients post-Merger.

Impact of the Merger

5.61 When asked about their views on the likely impact of the Merger, 42 out of 54 clinics told us that they thought the Merger would worsen competition.[360] 28 said they were concerned that the Merger would lead to less innovation,[361] 15 cited concerns about the impact on price[362] and 13 expressed concerns about the impact on choice.[363] Ten clinics described the positive impact which Oticon Medical's entry into the market had on factors such as prices and innovation.[364]

5.62 In the Parties' response to the AIS and WPs, they submitted that clinics did not articulate exactly how price, choice or innovation would be negatively impacted.[365] We consider that this likely reflects the fact that clinics were not asked to describe how the Merger would impact market outcomes but that, as outlined above, several clinics cited the positive impact of Oticon Medical's presence as the basis for their views.

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[358] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.24.
[359] Cochlear's response to the Provisional Findings, 11 May 2023, paragraph 6.
[360] Response to the CMA questionnaire from a number of third parties, January 2023, question 12 [✂].
[361] Response to the CMA questionnaire from a number of third parties, January 2023, question 12 [✂].
[362] Response to the CMA questionnaire, January 2023 from a number of third parties, question 12 [✂].
[363] In addition, two clinics [✂] who said that they felt the merger would have no impact on competition also said that they were concerned that the merger would lead to a reduction in choice. Response to the CMA questionnaire, January 2023 from a number of third parties, question 12.
[364] Response to the CMA questionnaire from a number of third parties, January 2023, question 12 [✂].
[365] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 3.24.

Our assessment of the clinics' evidence

5.63 The evidence provided by clinics shows that:

(a) For Passive BCS products, the Parties are each other's closest competitors and that Active BCS products (including MED-EL's Bonebridge product) currently represent a weaker constraint than other Passive BCS products.

(b) MED-EL's Bonebridge product provides a constraint on Cochlear's Active BCS product. In addition, some clinics regard Passive BCS products as a good alternative to Active BCS products and Oticon Medical's Passive BCS products provide some constraint on Cochlear's Active BCS product.

(c) Across both Active and Passive BCS products, the constraint from other hearing solutions, such as hearing aids and middle-ear implants, is limited.

Evidence from MED-EL and other third parties

5.64 The evidence provided by MED-EL shows that it considers Cochlear's Osia product to be a significant competitor as well as Cochlear and Oticon Medical's Passive BCS products.

(a) MED-EL told us that Oticon Medical's Ponto product is a major competitor with the majority of market share, followed by Cochlear's BAHA product.[366] MED-EL has also told us that it believes that the launch of Cochlear's Osia 2 product has affected its market share as it has some connectivity features that candidates may prefer to MED-EL's Bonebridge product.

(b) MED-EL stated that it considers that Active and Passive BCS implantable devices target broadly similar patient groups.[367] This is because both products' primary use is for the treatment of conductive or mixed hearing loss. MED-EL considers that, when BCS products are used to treat patients with conductive hearing loss, Passive BCS products are more suitable than Active BCS products for those with higher degrees of hearing loss.

(c) A MED-EL internal document compares its Bonebridge product to Cochlear's Active BCS and Passive BCS products and Oticon Medical's Passive BCS product. The document notes that MED-EL considers its

[366] MED- EL Internal document, Annex 14 to RFI [1],18 January 2023.
[367] MED-EL's response to P2 s109 notice of 18 January 2023, Q11, 13, Annex 19, [✂], 20 January 2023.

Bonebridge product and Cochlear's Osia product to address a similar candidate population and [✂], but states that other percutaneous BCS options lack modern advantages and should not be considered the best option.[368] In another document, MED-EL notes that its Bonebridge product has strengths compared to Cochlear's Osia processor, including its battery life and cost-effectiveness as well as possible weaknesses, such as a lower fitting range yet to be proven in clinical practice.[369]

5.65 The British Society of Audiology (BSA), an industry body, told us that if hypothetically one Party's percutaneous Passive BCS product was not available, the other Party's Passive BCS product would be prescribed instead. It also told us that if Cochlear's Active BCS product (Osia) was not available, MED-EL's Active BCS product (Bonebridge) would be prescribed and if Cochlear's transcutaneous Passive BCS product was not available, either Osia or Bonebridge would be prescribed instead.[370]

5.66 MED-EL told us that it considers that BCS products provide distinctive benefits to patients and, therefore, in most cases other hearing solutions are not good alternatives to BCS products:

(a) MED-EL told us that it does not consider that BCS products are generally substitutable with other hearing solutions, such as conventional acoustic hearing aids.[371]

(b) MED-EL also told us that there is limited substitutability between BCS products and middle-ear implants. It stated that its Soundbridge middle-ear implant is more suitable for patients with sensorineural hearing loss, or where ear-specific stimulation is required, whilst its Bonebridge BCS product is more suitable for those with mixed or conductive hearing loss. It told us that, whilst there may be some patients who may be considered for both products, most clinics would likely prefer to use a BCS product where possible, as middle-ear implants require more extensive surgery.[372]

(c) MED-EL stated that it does not consider that patients could be considered for both BCS products and cochlear implants because the latter are suitable for patients that have little function in the inner ear whereas BCS products rely on the inner ear being at least partially intact.[373] MED-EL

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[368] MED-EL's response to P2 s109 notice of 18 January 2023, Q4, 5, 6, 8, 11, Annex 21, [✂], 28 February 2022, slide 10.
[369] MED-EL's response to P2 s109 notice of 18 January 2023, Q4, 5, 6, 8, 11, Annex 22, [✂], 7 January 2020.
[370] British Society of Audiology's response to the CMA's RFI, 18 January 2023, question 2. (RFI 18 January 2023).
[371] MED-EL's response to P2 s109 notice of 18 January 2023, Q4, 5, 9, Annex 15, [✂].
[372] Note of call with MED-EL, 8 February 2023, paragraph 18.
[373] Note of call with MED-EL, 8 February 2023, paragraph 21.

stated that whilst cochlear implants could be used instead of BCS products in the case of single-sided deafness, such use is not currently funded by the NHS.[374]

5.67 MED-EL also told us that it plans to increase its market share across all hearing solutions.

(a) MED-EL has told us that its aim is to increase its market share to [✂]% across all hearing solutions, including BCS products. However, MED-EL was not able to specify the timeframe over which it expected to achieve this growth or the extent to which BCS products would contribute to this and plans to achieve this aim are not evidenced in internal documents.[375]

(b) MED-EL told us that it expects to be able to grow its market share by promoting [✂]. In addition to [✂], it intends to renew its focus on [✂], and promoting the unique benefits and features of its products. However, it has also noted this process will [✂].[376] It also told us that it expects its second generation Bonebridge product (which was released in 2019) to contribute to this growth, noting that this has a reduced drilling depth compared to its predecessor, which increases the suitability of its product for a greater number of patients.[377]

5.68 Our assessment of the evidence from MED-EL and other third parties is that Active BCS products compete most strongly with each other, although they do compete, to a lesser degree, with Passive BCS products. We also consider that the evidence from MED-EL and other third parties shows that other hearing solutions, including hearing aids, provide limited competitive constraint.

Shares of supply in BCS products

5.69 We have estimated shares for the supply of BCS products by requesting sales data from the Parties and MED-EL for the past four years. The sales data encompassed sales of implants, processors, and accessories for BCS products to all clinics in the UK.[378] Our share of supply estimates are presented in Table 5.5.

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[374] Note of call with MED-EL, 8 February 2023, paragraphs 23 and 24.
[375] Note of call with MED-EL, 8 February 2023, paragraphs 8 and 9.
[376] MED-EL's response to P2 s109 notice of 18 January 2023, [✂].
[377] Note of call with MED-EL, 8 February 2023, paragraph 15.
[378] We have also calculated market shares based upon the sales of implants and processors separately and this show similar results.

Table 5.5: Share of supply estimates for BCS products in the UK

	Revenue (£m)				*Share of supply (%)*			
Entity	*2019*	*2020*	*2021*	*2022*	*2019*	*2020*	*2021*	*2022*
Cochlear	[✂]	[✂]	[✂]	[✂]	[40-50]	[30-40]	[40-50]	[40-50]
Oticon Medical	[✂]	[✂]	[✂]	[✂]	[50-60]	[50-60]	[40-50]	[40-50]
Merged Entity	[✂]	[✂]	[✂]	[✂]	*[90-100]*	*[90-100]*	*[90-100]*	*[90-100]*
MED-EL	[✂]	[✂]	[✂]	[✂]	[5-10]	[5-10]	[10-20]	[5-10]
Total	[✂]	[✂]	[✂]	[✂]	**100**	**100**	**100**	**100**

Source: CMA's calculations based on the Parties' and competitors' sales data.

5.70 Our estimates show the following:

(a) The Merger combines the two largest suppliers of BCS products in the UK to create a Merged Entity with a share of supply in 2022 of [90–100%].

(b) The two Parties each held relatively similar shares of supply in 2022, of just under [40–50%].

(c) The only other competitor in the market is MED-EL which has a share of supply of [5–10%] in 2022. MED-EL's share of supply has never exceeded [5–10%] over the last four years.

(d) The total size of the BCS market has been increasing. Between 2021 and 2022 it increased by almost 50%.

5.71 Therefore, from this share of supply evidence we consider that the supply of BCS products is highly concentrated with the Parties accounting for the vast majority of sales. MED-EL's share of supply has remained relatively low over the last four years.

Conclusions on competitive constraints

5.72 Our overall conclusions are that:

(a) The BCS market is heavily concentrated, with the two Parties having a combined share of supply of [90–100%] in 2022.

(b) The Parties are each other's closest competitor in relation to Passive BCS products. Whilst MED-EL provides some competitive constraint, this is significantly weaker. The constraint from other solutions, such as hearing aids and middle-ear implants, is limited.

(c) MED-EL is a constraint on Cochlear's Osia Active BCS product. Passive BCS products provide some constraint to Active BCS products and, Oticon Medical's Passive BCS products provide some constraint on Osia.

(d) While the Parties submitted that BCS products are a small sub-set of a broader range of hearing products that treat mild to moderate hearing loss, including hearing aids, reconstructive (or middle ear) surgery, middle-ear implants, CROS hearing aids, and non-surgical products, the documentary evidence and evidence from third parties shows that this constraint is limited.

Evolution of Active and Passive BCS

5.73 This section describes the Active BCS products which have emerged before setting out our assessment of how the relative importance of Active BCS and Passive BCS products is likely to evolve in the future.

The emergence of Active BCS products

5.74 We first considered the Active BCS products currently supplied in the UK and how they emerged. We then describe the differences between Active BCS and Passive BCS products. Lastly, we assess the sales of Active BCS products and how this has changed over time.

Emergence of currently available Active BCS products

5.75 BCS products can be categorised as Passive BCS or Active BCS.

(a) Passive BCS implants use an external transducer (ie outside of the skin). These can be either percutaneous (such as Cochlear's Baha Connect and Oticon Medical's Ponto) or transcutaneous BCS (such as Cochlear's Baha Attract). Percutaneous Passive BCS implants use an abutment which penetrates the skin to hold the transducer and the external sound processor in place. Transcutaneous Passive BCS implants use internal and external magnets to hold the external transducer and sound processor in place.[379]

(b) Active BCS implants use an implanted transducer to transmit the necessary vibrations to the inner ear. All Active BCS products are transcutaneous, thus the sound processor is kept in place by magnets rather than an abutment.[380]

5.76 There are currently two Active BCS products available in the UK. MED-EL developed the first Active BCS product, Bonebridge, and introduced this to the UK in 2012. A second generation Bonebridge product was launched in the UK

[379] FMN, paragraph 182.
[380] FMN, paragraph 3.

in 2019. Alongside this, Cochlear has released its Osia product which received regulatory approval in the United States in December 2019 and subsequently received approval in the EU.[381]

5.77 The evidence shows that MED-EL has faced a number of challenges in increasing take-up of its Bonebridge product:

(a) In a [✂] competitive update document, Cochlear notes that it considers that Bonebridge requires complex surgery, is not compatible with MRI scans (in the US), has a lower clinical fitting range (compared to Cochlear's Passive BCS products), and has had issues around reliability.[382] One clinic told us that it prefers not to offer Bonebridge as the surgery is intrusive.[383] Oticon Medical noted in a 2021 internal document that it considers that Bonebridge has [✂]. It, however, notes that there had been a 50% reduction in its size which has made it [✂].[384]

(b) MED-EL has also submitted that the strong position of the Parties in BCS means that clinical staff are afforded fewer opportunities to develop or maintain skills with different BCS products, which, it considers can increase their reluctance to adopt rivals' products.[385]

(c) MED-EL also told us that, until 2022, it only had [✂] sales representatives actively selling its products to customers in the UK, which limited its ability to gain market share.[386] This was also identified in an Oticon Medical internal document from 2021.[387]

(d) MED-EL told us that the way in which the NHS procurement process works has restricted its ability to grow. In particular, it stated that it understands some NHS trusts have agreements with suppliers outside the standard tender process that commit them to buy specific volumes of a supplier's BCS products in exchange for discounts on these. Where clinics have these volume-based agreements in place which, for example, commit them to purchase [✂]% of its volume from one supplier, MED-EL stated that it can only compete for the remaining [✂]% of the clinic's business.[388] However, as set out in paragraphs 5.21 to 5.22, the evidence

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[381] The UK will accept the EU regulatory approval until July 2023. FMN, paragraph 185.
[382] Cochlear's response to P2 s109 notice of 10 January 2023, [✂].
[383] Note of a call with a third party, January 2023, paragraph 16 [Bristol Hospital].
[384] Demant's response to P2 s109 notice of 10 January 2023, Q7, 9, 12, 17, 18. [✂], slide 21.
[385] MED-EL's response to P2 s109 notice of 18 January 2023, Annex 15
[386] MED-EL's response to P2 s109 notice of 18 January 2023, Annex 14 [], [], paragraph 2.
[387] Demant's response to P2 s109 notice of 10 January 2023, Q7, 9, 12, 17, 18: [✂], Oct 2021. [✂], slides 21 and 22.
[388] MED-EL's response to P2 s109 notice of 18 January 2023, Annex 15, and Note of a call with MED-EL, February 2023, paragraph 5.

available to us does not show that this practice is widespread for BCS products.

5.78 In 2019, Cochlear introduced an Active BCS product, Osia.[389] Cochlear submitted that it took over a decade to develop its Osia product.[390] In addition Osia cost about [✂] million SEK to develop (which is about £[✂] million), compared to Baha which cost about [✂] million SEK to develop (about £[✂] million).[391] Cochlear has faced a number of challenges in launching Osia, including:

(a) A clinic told us that COVID-19 resulted in it choosing to fit fewer patients with Cochlear's Active BCS products as they require general anaesthetic.[392] However, in an internal document from 2021 Cochlear notes that, despite the pandemic, it thought that Osia was a success as, since its launch, Cochlear had sold more than [✂] systems, trained more than [✂] staff, received orders from [✂] clinics and gained a [✂]% share of acoustic system sales.[393]

(b) A Cochlear internal document from 2021 noted that [✂]. In relation to the UK, the document states that Osia is reimbursed but notes that a risk is that Cochlear [✂] and that NICE has not yet reviewed this.[394]

(c) The same internal document outlined that [✂].[395]

5.79 We understand that Cochlear's Osia product and MED-EL's Bonebridge products differ in several ways. For example, the products use different technologies, have different fitting ranges, and differ in terms of their aesthetics.[396] The extent to which one product is a good alternative for the other is considered further in the Competitive Constraints section of this chapter.

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[389] Cochlear teach-in slides, 23 January 2023, page 18. [✂].
[390] Parties' response to Issues Statement, 3 February 2023, paragraph 3.37 and Parties' response to s.109.
[391] Cochlear's response to P2 s109 notice of 10 January 2023, response, Q15, page 9. Cochlear / Oticon Medical phase 2 51160-2 – 230120 Response to S.109 .pdf – Documents
[392] Note of a call with a third party, January 2023, paragraph 11 [Auditory Implant Centre, Belfast].
[393] Cochlear's response to P1 s109 request of 21 July 2022, Q8e, Annex 014, [Phase 1] ([✂]) page 9 (slide 85).
[394] Cochlear's response to P1 s109 request of 21 July 2022, Q10a, [✂], slide 3 [October 2021].
[395] Cochlear's response to P1 s109 request of, 21 July 2022, Q10a, slide 3 [October 2021], [✂].
[396] According to submissions from MED-EL and the Cochlear teach-in Osia uses piezoelectric technology in its transducer whereas Bonebridge uses an electromagnetic transducer which means that Bonebridge is suitable for those with a hearing loss of up to 45db whereas Osia has a fitting range up to 55db. In addition, Osia is attached which a single screw whereas Bonebridge requires two screws and Bonebridge requires the drilling of a well in the skull which Osia does not.

Comparison of Active BCS products and Passive BCS products

5.80 Active BCS products can have several advantages relative to Passive BCS products, including:

(a) Reduced likelihood of complications, such as wound infections and skin growth around the abutment. This was identified as an advantage by 22 out of 40 clinics in response to our questionnaire,[397] as well as within a recent academic study.[398]

(b) Improved cosmetic outcomes. This was mentioned by 20 out of 40 clinics in response to our questionnaire,[399] as well as within Oticon Medical's internal documents.[400]

(c) Better sound quality. This was mentioned by 12 out of 40 clinics in response to our questionnaire.[401] Five out of 40 told us that Active BCS products have less feedback.[402]

(d) Less ongoing care of the surgical site. This was mentioned by seven out of 40 clinics in response to our questionnaire.[403]

5.81 The Parties submitted that Active BCS products are generally considered a better option for paediatrics as an abutment may not be the best option for a young child whose head is still growing and who may be prone to accidents that damage the abutment and exacerbate the wound.[404] However, this was not mentioned by any of the clinics in our questionnaire as an advantage of Active BCS products. Indeed, one clinic said that a disadvantage of Active BCS products was that it could not be fitted to children under the age of 5.[405] Cochlear also states in internal documents that it [✂].[406]

5.82 However, Active BCS products can also have disadvantages compared to Passive BCS products, including:

(a) Active BCS products require more invasive surgery. This was mentioned by 21 out of 40 clinics in response to our questionnaire,[407] as well as

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[397] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[398] Cochlear / Oticon Medical phase 2 51160-2 - Annex 380 - Longitudinal economic analysis of Bonebridge 601 versus percutaneous bone-anchored hearing devices over .pdf - (academic study submitted by Cochlear).
[399] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[400] For example, slide 26. Demant's Internal Document '[✂]', January 2022, [✂] in response to P2 s109 notice of 10 January 2023, Questions 10, 11, 12, 14, 15, 17, 18.
[401] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[402] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[403] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[404] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.2.
[405] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[406] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, [✂].
[407] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].

within Oticon Medical's internal documents.[408] The surgery for Active BCS typically involves a general anaesthetic and takes up to one hour, whereas a Passive BCS can be implanted in 10-20 minutes under local anaesthetic.[409] The Parties told us that that one hospital (Manchester) has recently obtained approval to perform Active BCS implant surgery in an outpatient setting in less than 30 minutes under local anaesthetic. The Parties also told us that they expected this development to be followed by other clinics quite quickly as the community of specialist ENT surgeons carrying out hearing implants is small and well-connected.[410] We consider that this development could reduce the significance of this disadvantage in the future, and note that one clinic told us that it has started to offer Osia under local anaesthetic.[411] However, it is unclear the extent to which this is likely to gain significant traction within the next two to three years. The Parties submitted that this was overly cautious given the resource constraints that the NHS is under.[412]

(b) Passive BCS products are more powerful than Active BCS products. Passive BCS products have a fitting range of up to 65dB, whereas Active BCS products only go up to 55dB. This was mentioned as a disadvantage by 14 out of the 40 clinics in our questionnaire.[413] In relation to this:

(i) The Parties submitted that only an estimated 5% of suitable patients with conductive or mixed hearing loss fall into the 55dB to 65dB range at the time of fitting.[414] The evidence from clinics indicated that this may underestimate the number of patients who may be better suited to Passive BCS products. This is because clinics told us that when deciding which product to prescribe, a relevant consideration is the fact that, as people are living longer and hearing typically deteriorates with age, Active BCS products may not be strong enough for certain patients in the longer term. This is especially the case for patients who have particularly progressive hearing loss.[415] The implication of this is that clinics may consider Passive BCS products more suitable for patients who are currently towards the upper end of the Active BCS range. In the Parties' response to the AIS and WPs, they told us that, even if this were true, it would only impact a small number of

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[408] For example, slide 22 Annex 115 - [✂] (response to Merger Notice Q10) and slide 26. Demant's Internal Document [✂], January 2022. [✂] in response to P2 s109 notice of 10 January 2023, Questions 10, 11, 12, 14, 15, 17, 18.
[409] FMN, paragraph 3.
[410] Parties' response to Issues Statement, 3 February 2023, paragraph 3.30.
[411] Note of a call with a third party, January 2023, paragraph 9 [✂].
[412] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.4.
[413] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[414] Parties' response to Issues Statement, 3 February 2023, paragraph 3.25.
[415] For example, Note of a call with a third party, January 2023, paragraph 15 [✂].

patients (as only about 10% of Baha patients are in the 50 to 64db range) and that Osia can actually be a better solution for patients with degenerative hearing loss.[416]

(ii) The Parties also told us that it is likely that, in the near future, Active BCS products will have the same range as Passive BCS products.[417] One reason for this is that [✂].[418] In the Parties' response to the AIS and WPs, they referred to [✂].[419] However, the document [✂] with the implication being that it is subject to uncertainty. We have not seen this timeline mirrored in other documents. The extent to which this development is likely to take place within the next two to three years is therefore unclear.

(c) Active BCS implants can result in distortive shadow effects on MRI images when the head is scanned. This is a particular disadvantage for patients who require frequent MRIs. Clinicians told us that they do not consider Active BCS products to be suitable for such patients.[420] This was mentioned by 15 out of the 40 clinics in our questionnaire.[421] However, the Parties submitted that this only impacts those patients who require frequent head-based MRIs, and this only impacts a very small number of patients (around one or two per 100,000 persons). They also submitted that patients who do require frequent MRIs have the option of Active BCS products where the internal magnet is replaced with a non-magnetic plug and where a retainer disk (adhesive) is used to keep the external sound processor in place.[422]

(d) Active BCS products have higher initial costs than Passive BCS products. In the UK, the current prices of the Parties' Passive BCS implants and processors are around £[✂], Cochlear's Active BCS Product (Osia) costs around £[✂] and MED-EL's Active BCS Product (Bonebridge) is around £[✂].[423] This was mentioned by three out of the 40 clinics in our questionnaire.[424] However, a study by the Hearing Implant Centre at Guy's and St Thomas' NHS Foundation Trust undertaken in 2022 (and

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[416] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.5(a).
[417] Parties' response to Issues Statement, 3 February 2023, paragraph 3.25.
[418] The Parties told us that [✂]. [✂]. Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.5.
[419] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.5(b).
[420] Note of a call with third party, January 2023, paragraph 13 [✂] and Note of a call with third party, January 2023, paragraph 15 [✂].
[421] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].
[422] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.6.
[423] Cochlear's response to P2 s109 notice of 10 January 2023, Q1 Annex 205 [✂]; Demant's response to P2 s109 notice of 10 January 2023: Annex 1.1 [✂]; and MED-EL's response to P2 s109 notice of 18 January 2023 [✂] (Question 2.
[424] Response to the CMA questionnaire from a number of third parties, January 2023, question 9 [✂].

submitted by the Parties) found that whilst the short-term costs to the NHS of Active BCS products are greater than Passive BCS products, over the longer-term the costs to the NHS are similar.[425]

5.83 The above shows that Active BCS products have both advantages and disadvantages compared to Passive BCS products. It also implies that the relative significance of these advantages and disadvantages for a given patient, and therefore by extension the most appropriate BCS product for them, will depend on their individual circumstances.

Sales of Active BCS products

5.84 As shown in Table 5.6, the number of Active BCS implants sold annually has increased by over 300% between 2019 and 2022, and this has been driven mainly by the release of Cochlear's Active BCS product (Osia):

(a) MED-EL experienced an approximately [0–5%] increase in sales of its implants between 2021 and 2022, whereas Cochlear's Osia implant sales increased by about [✂]% between 2021 and 2022.

(b) Annual sales of Cochlear's Osia implants represent about [70–80%] of all Active BCS implant sales in 2022. Despite being released more recently, the annual sales of Cochlear's Osia implants are [✂] the annual sales of MED-EL's Bonebridge implants.

(c) Active BCS implants account for about [✂]% of all Cochlear's BCS implants sold in 2022. We note that this figure is broadly consistent with the Parties' submissions as to how Cochlear's Active BCS implant share as a proportion of its total BCS implant sales has changed over time.[426]

5.85 However, despite the significant increase in the number of Active BCS implants, there are still considerably more annual sales of Passive BCS implants in the market. Active BCS implants accounted for only about [10–20%] of all implants in 2022 (up from about [10–20%] in 2021, and about [5–10%] in 2020).

[425] The Parties' reiterated these views in their response to the AIS and WPs (Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.7). Cochlear follow-up response to teach-in, 23 January 2023, Annex 380, [✂].
[426] Parties' response to Issues Statement, 3 February 2023, paragraph 3.29.

Table 5.6: Sales of Active and Passive BCS implants, 2019-2022

	2019	*2020*	*2021*	*2022*
Active implants				
Cochlear	[✂]	[✂]	[✂]	[✂]
MED-EL	[✂]	[✂]	[✂]	[✂]
Total	[✂]	[✂]	[✂]	[✂]
Passive implants				
Cochlear	[✂]	[✂]	[✂]	[✂]
Oticon Medical	[✂]	[✂]	[✂]	[✂]
Total	[✂]	[✂]	[✂]	[✂]

Source: CMA's estimates based on the Parties' and competitors' Active BCS and Passive BCS implant sales volume data.

5.86 These results are broadly consistent with our clinic questionnaire. 26 out of 38 clinics told us that Active BCS products currently account for less than 25% of their total BCS implants.[427] Three clinics reported that Active BCS products accounted for 25-50% for BCS implants,[428] eight said they were 50-75%,[429] and only one told us they were more than 75% of their total implants.[430]

5.87 The Parties submitted that the growth in Active BCS implants has occurred in a period when, as a result of Coronavirus (COVID-19), healthcare systems have been under significant pressure, BCS surgery has been deprioritised and clinics have been working through waiting list backlogs.[431] The Parties also told us that sales of Osia passed [✂] in December 2022 which makes it the fastest growing hearing implant system in history.[432]

5.88 The Parties also submitted data for how sales of Cochlear's Osia implants had increased in recent years at four leading hospitals.[433] This evidence does not provide a complete view of how the proportion of Active BCS implant sales and Passive BCS implant sales have been changing over time in these clinics as it only captures sales of Cochlear's Passive BCS product and not Oticon Medical's. In addition, it only captures trends within a relatively small number of clinics.[434] For these reasons we consider that our analysis above better captures trends in the proportion of sales of Active BCS implants and Passive BCS implants.

[427] Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[428] Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[429] Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[430] Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[431] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.12.
[432] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.11.
[433] Parties' response to Issues Statement, 3 February 2023, paragraph 3.32.
[434] We also note that across 3 of the 4 clinics the proportion of Active BCS as a percentage of all BCS implants has not been consistently increasing across time but has fluctuated. These clinics accounted for [✂]% of Osia implant sales, [✂]% of Baha implant sales and [✂]% of all Osia and Baha implant sales in 2022.

Conclusions on the emergence of Active BCS products

5.89 The evidence considered above shows that whilst Active BCS products have advantages as compared to Passive BCS products, they also have drawbacks. Over the last couple of years, there has been a significant increase in sales of Active BCS implants. This has been driven by the introduction of Cochlear's Osia product, whilst MED-EL's sales growth has been limited. However, Passive BCS implants continue to account for a considerably greater proportion of BCS implant sales than Active BCS implants.

Projected future evolution of Active BCS products in relation to Passive BCS products

5.90 In this section we consider how sales of Active BCS products as a proportion of sales of all BCS products are expected to change in the future. We first consider evidence from internal documents and then from our third-party engagement.

Parties' internal documents and submissions

5.91 Oticon Medical's internal documents show that, whilst it believes that sales of Active BCS products will increase in the future, it still expects there to be a role for Passive BCS products:

(a) In a 2022 internal document, Oticon Medical says that it expects there to be a [✂]% move away from percutaneous to transcutaneous Active in new patients' surgeries in the UK [✂].[435] However, it notes that limiting factors include [✂]. This is mirrored in another internal document which estimates the [✂].[436]

(b) In a 2020 internal document, Oticon Medical states that globally '[✂]'. It goes on to explain that this is because of factors such as the [✂]. However, Oticon Medical states that it is its strong belief that more patients will choose active transcutaneous solutions when these solutions and the surrounding ecosystem have matured.[437]

(c) In a 2022 internal document, Oticon Medical states that it expects transcutaneous Active BCS products to become a preferred choice globally but that this depends on it having a widened indication and

[435] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂], slide 22.
[436] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, [✂] slide 9.
[437] Demant's response to P2 s109 notice of 10 January 2023, Q10, [✂] pages 5 and 6.

reimbursement being established. Oticon Medical also notes that it expects transcutaneous Active BCS to be a growth driver alongside the percutaneous segment.[438] Several other Oticon Medical documents show that it views Active BCS products as existing alongside Passive BCS products.[439]

5.92 Cochlear's internal documents also show that it expects there to be a global increase in the sale of Active BCS products:[440]

(a) In a 2022 internal document, Cochlear states that it expects Osia to be a driver of growth between 2022 and 2026. [✂].[441]

(b) In a 2022 internal document, Cochlear states that in Q1 of the 2021 financial year it sold, on average, approximately [✂] Osia and [✂] Baha products per day. It estimates that in Q4 2023 it will sell approximately [✂] Osia and [✂] Baha products per day.[442]

(c) In a 2019 internal document, Cochlear states it expects sales of Osia to increase from [✂] units in 2020 to [✂] units in 2024, whilst sales from Baha Connect will fall [✂] from [✂] units in 2020 to [✂] units in 2024. [✂]. However, it still expects that, by 2024, Baha will make up [✂]% of its total revenue from processors.[443]

5.93 In the Parties' response to the AIS and WPs, the Parties stated that the internal documents referred to above show that Cochlear expects there to be a significant global increase in the sale of Active BCS products, and any remaining business for its Passive BCS products will be focused on emerging markets.[444]

5.94 To demonstrate this the Parties referred to a 2021 Cochlear internal document which shows that Cochlear expected sales of Osia to increase [✂] between [✂] (from [✂] to [✂]).[445] However, it also shows that Cochlear expected sales of Baha to fall more modestly over the same timeframe (from [✂] to [✂]) and does not show that these sales are only expected to be in

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[438] Demant's response to P2 s109 notice of 10 January 2023, Q11, [✂] slide 8.
[439] Demant's response to P2 s109 notice of 10 January 2023, Questions 7, 10, 11, 12, 15, 17, 18, [✂] slide 27; Demant's response to P2 s109 notice of 10 January 2023, Questions 7, 10, 11, 18, [✂] slide 7; Demant's response to P2 s109 notice of 10 January 2023, Questions 7, 10, 11, [✂] slides 7 and 9; and Demant's response to P2 s109 notice of 10 January 2023, Questions 7, 12, 17, 18, [✂] slides 3, 15, and 20; Demant's response to P2 s109 notice of 10 January 2023, Q11, [✂], slide 9.
[440] We note that a limitation of this evidence is that it relates to global sales rather than sales in the UK, and that there could be differences across countries.
[441] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, [✂].
[442] Cochlear's response to P2 s109 notice of 10 January 2023, Q10, [✂].
[443] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, [✂] Annex 221 – [✂].
[444] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.11.
[445] Annex 151 to the FMN, Q10, '[✂]', slide 42.

emerging markets. We consider this document provides further evidence that Cochlear expects there to be growth in the sale of Active BCS products, but there to still be a role for Passive BCS products.

Evidence from third parties

5.95 Clinics have told us that that they expect there to be an increase in the use of Active BCS products in the next two to three years. However, most clinics think that they will still be prescribing more Passive BCS products than Active BCS products in the future. As shown in Table 5.7:

(a) 28 out of 38 clinics told us that, out of the BCS products they currently prescribe, 50% or more are Passive BCS products.[446] 26 out of 38 told us that in two to three years' time they expected that Passive BCS products would continue to account for 50% or more of the BCS products they prescribe.[447]

(b) 16 out of 38 clinics expect Active BCS products to account for less than 25% of all BCS products prescribed in the next two to three years.[448]

Table 5.7: Clinicians estimates of the proportion of prescribed BCS products which are Active and Passive currently and how they expect this to change in the next 2-3 years.

	Currently/latest year		*In next 2-3 years*	
Proportions	*Passive*	*Active*	*Passive*	*Active*
<25%	4	26	7	16
25%-50%	6	3	5	7
50%-75%	4	8	11	11
>75%	24	1	15	4

Source: CMA's questionnaire to clinics (38 résponses).

5.96 Consistent with this 43 out of 46 clinics told us they expected there would still be a need for Passive BCS products in the future.[449]

(a) 16 out of 46 clinics told us that this was because Passive BCS products will continue to be more suitable for some patients with more severe hearing loss as they have a greater fitting range.[450]

[446]Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[447] Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[448] Response to the CMA questionnaire from a number of third parties, January 2023, question 11, [✂].
[449] Response to the CMA questionnaire from a number of third parties, January 2023, question 10 [✂]. Additionally, six clinics told us that they expected the use of transcutaneous Passive BCS products to reduce over time [✂] with two stating that this was because they do not have any benefits overactive BCS products [✂].
[450] Response to the CMA questionnaire from a number of third parties, January 2023, question 10, [✂].

(b) 14 out of 46 clinics said that Passive BCS products will be required for patients who require regular MRI scanning.[451]

(c) 11 out of 46 clinics said that they see a continued role for Passive BCS products as these can be done under local anaesthetic and in a shorter time scale, therefore putting less strain on hospital beds.[452]

(d) Four out of 46 clinics told us that some patients will prefer Passive BCS products.[453]

5.97 In the Parties' response to the AIS and WPs, the Parties told us that:

(a) The reasons identified by clinics as to why they expected there would still be a need for Passive BCS products align with the disadvantages of Active BCS products outlined in paragraph 5.79, which only impact a small proportion of potential patients and/or are expected to be mitigated within the next two to three years.[454]

(b) Many clinics have yet to provide Active BCS products to their patients or receive training in these. The Parties submitted that clinics that have not been trained on Active BCS implants were likely to be too conservative in their estimates on the pace of the switch from Passive BCS to Active BCS.[455]

5.98 In relation to these submissions, we consider that the evidence from clinics is consistent with the Parties' own internal documents in showing that, whilst use of Active BCS products is expected to increase in the next two to three years (including as training is rolled out and Active BCS products improve), there will continue to be a significant proportion of patients who receive Passive BCS products.

5.99 The British Society of Audiology, an industry body, told us that there would be some patients better suited to Passive BCS products than Active BCS products for years to come.[456] The Royal National Institute for Deaf People, a patient group similarly also told us that there would be a small number of patients who may benefit more from Passive BCS and would be unsuitable for

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[451] Response to the CMA questionnaire from a number of third parties, January 2023, question 10, [✂].
[452] Response to the CMA questionnaire from a number of third parties, January 2023, question 10, [✂].
[453] Response to the CMA questionnaire from a number of third parties, January 2023, question 10, [✂].
[454] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.9.
[455] The Parties also told us that the evidence on sales to four clinics provided in response to the issues statement (and summarised in 5.85) shows that, once trained, clinics have rapidly switched from Baha to Osia implants. Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.12.
[456] Responses to the CMA questionnaire from the British Society of Audiology, Questions 4 and 5.

Active BCS products due to risks of surgery, underlying health issues and anatomical anomalies.[457]

5.100 MED-EL told us that it expects there to be a market transition away from percutaneous Passive BCS products towards Active BCS products, although there could be some inertia. MED-EL also told us that in the short- to medium-term, it expects there will continue to be demand for percutaneous Passive BCS products. This is because Active BCS products are currently more limited in audiometric fitting range than Passive products, although it expects that this could change in the medium- to long-term as technology improves.[458]

Conclusions on projected future evolution of Active BCS products in relation to Passive BCS products

5.101 Our conclusion is that, whilst it is likely that there will be a material increase in the use of Active BCS products in the next two to three years, there will continue to be a significant proportion of patients that continue to receive a Passive BCS product.

Conclusions on the evolution of Active BCS products and Passive BCS products

5.102 Our overall conclusions are, given Active BCS products have both advantages and disadvantages relative to Passive BCS products, the choice of whether an Active BCS product or Passive BCS product is most suitable for a given patient depends on their individual circumstances. The differences between the products mean that whilst Active BCS product sales have grown significantly since 2019, and it is likely that there will be a material increase in the use of Active BCS products in the next two to three years, the evidence from the Parties and clinics shows that there will still be a significant proportion of patients who will continue to receive Passive BCS products in the UK in the next two to three years.

Competitive constraint from Sentio

5.103 This section considers the competitive constraint from Oticon Medical's Active BCS product (Sentio). We first present evidence from Oticon Medical's internal documents before considering evidence from internal documents and our engagement with Cochlear and MED-EL.

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[457] Responses to the CMA questionnaire from the Royal National Institute for Deaf People, Q5.
[458] Note of call with MED-EL, 8 February 2023, paragraph 16.

Oticon Medical's internal documents

5.104 Oticon Medical's internal documents show that in September 2022 it was aiming to launch Sentio in the UK in [✂].[459] Oticon Medical's internal documents show that it considers that Sentio would compete with Osia and Bonebridge, and have some advantages over these solutions:

(a) In a September 2020 Oticon Medical business review slide deck, Oticon Medical compares Sentio with Osia and Bonebridge. According to this assessment, Sentio would be a [✂].[460] Other Oticon Medical internal documents from between August 2020 and September 2022 similarly note that Sentio is expected to be [✂] than Osia and Bonebridge.[461]

(b) In an internal document from May 2021, Oticon Medical describes the competitive strategies which Cochlear and MED-EL are adopting in relation to Osia and Bonebridge. The document states that Oticon Medical expects [✂].[462]

(c) In an internal document from February 2022, Oticon Medical states that its target group for Sentio is [✂]. Oticon Medical states that it also aims to supply Sentio to [✂].[463]

5.105 Oticon Medical's internal documents also show that it expected [✂]:

(a) In a 2022 internal document, Oticon Medical states that it expects the average sales price [✂]. Based on this, Oticon Medical calculates that [✂]. Oticon Medical describes that it expects [✂] and that this would significantly contribute to its profits.[464]

(b) Oticon Medical reiterates in a number of other internal documents that it expects [✂].[465]

5.106 In the Parties' response to the AIS and WPs, they submitted that:

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[459] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂], slide 20.
[460] Demant's response to P2 s109 notice of 10 January 2023, Question 7, 10, 11, [✂], September 2020, [✂] (phase 1) slide 26; and Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 12, 15, 17, 18, [✂], page 30.
[461] Annex 110 to the FMN – [✂], slide 8; Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂]slides 10 and 15; Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 12, 15, 17, 18, [✂] slide 30; and Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, [✂] slide 13 and 31, Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂] slides 14-15.
[462] Demant's response to P1 s109 request of 10 January 2023, Q17a, [✂], slide 19.
[463] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, slide 37, [✂].
[464] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂], slide 25.
[465] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 12, 15, 17, 18, [✂] slide 31; Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂] slide 25, Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂] slide 25.

(a) The profitability estimates in Oticon Medical's internal documents are overstated. They state that this is because these estimates rely on full reimbursement from public health systems and do not reflect the costs that would be shared with the wider Demant group.[466]

(b) Oticon Medical's internal documents, and views, do not necessarily reflect the views of Demant in relation to the BCS business. Oticon Medical is predisposed to present a more optimistic view of the future of the BCS business to justify investment by Demant.[467]

5.107 We address the point about cost sharing with the wider Demant group in the Counterfactual chapter. With regard to the other points, the Parties did not provide any evidence to support their position that these documents are viewed by Demant as being overly optimistic and do not reflect its views.

5.108 The Parties also submitted that Oticon Medical's internal documents track the development of Sentio (as they would for any ongoing R&D), and they show that Sentio has continued to [✂] and its eventual launch remains highly uncertain.[468] In relation to this submission, we have found evidence that there have been challenges associated with Sentio:

(a) A 2022 internal document identifies several [✂] which Oticon Medical faces in relation to Sentio, including [✂]. However, the same document states that [✂].[469] This is consistent with another 2022 internal document where Oticon Medical notes that Sentio's sound processor has [✂].[470]

(b) In another internal document from 2022, Oticon Medical also discusses [✂] associated with Sentio, including around its commercial launch.[471]

(c) In an internal document from September 2022, Oticon Medical identifies [✂] associated with Sentio, including that [✂].[472]

(d) An internal document from 2021 reports that Sentio is [✂].[473]

5.109 However, despite these challenges, in the hearing, Demant told us that Sentio was [✂]. It stated that the current expectation was that Sentio would receive

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[466] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 2.24.
[467] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 2.25.
[468] Parties' response to Issues Statement, 3 February 2023, paragraph 1.7. The Parties reiterated these views in their response to the AIS and WPs, dated 23 March 2023, paragraph 2.24.
[469] Demant's response to P2 s109 notice of 10 January 2023, Q7, 11, 18, [✂], page 1.
[470] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, [✂] slides 20 and 21.
[471] Demant's response to P2 s109 notice of 10 January 2023, Q 11, [✂] slides 4 and 6.
[472] Demant's response to P2 s109 notice of 10 January 2023, Q 7, 10, 11, 18, [✂] slide 30.
[473] Demant's response to P2 s109 notice of 10 January 2023, Q11, [✂], slide 2.

regulatory clearance in [✂] and would be able to be launched in the UK from [✂]. However, Demant stated that this timeline was subject to uncertainty.[474]

Evidence from Cochlear and MED-EL

5.110 We consider that our review of Cochlear's internal documents shows that it has been monitoring the development of Sentio and views this as a competitive threat:

(a) In internal documents from 2021 and 2022, [✂].[475] [✂].[476]

(b) A Cochlear internal document notes that a [✂].[477]

(c) In several internal documents, Cochlear compares its Active BCS product to Bonebridge and Sentio.[478] Several documents also state that Cochlear expects Sentio to [✂].[479]

(d) A Cochlear internal marketing and launch strategy document for Osia from 2021 states that a [✂]. The document goes on to describe [✂].[480]

5.111 In the Parties' response to the AIS and WPs, they submitted that they do not consider that these documents demonstrate that Sentio is a competitive threat or that the potential release of Sentio has had any impact on Cochlear's innovations.[481] In particular the Parties told us that:

(a) The risk document referred to in paragraph 5.107(a)[482] shows that, [✂].[483]

(b) The document referred to in paragraph 5.107(b)[484] refers to Sentio as part of a broader presentation and the focus of the presentation is on Cochlear's proposals and strategies to address unmet patient need and grow the hearing implants segment. Similarly, the document referred to in

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[474] Notes of a hearing with Demant, 22 March 2023, Page 61, lines 17-23, [✂].
[475] Cochlear's response to P2 s109 notice of 10 January 2023, Q7: COT-000000009 – Annex 212 – [✂]. [November 2021]; & COT-000000011 – Annex 214 – [✂] [August 2019], COT-000000010 – Annex 213 [✂]. [November 2022]; & COT-000000012 – Annex 215 – [✂] [December 2022].
[476] Cochlear's response to P2 s109 notice of 10 January 2023, Q7: Annex 214, [✂].
[477] Annex 151 to the FMN – [✂].
[478] Annex 108 to the FMN – [✂].
[479] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, 17, 18, Annex 231, [✂] 9 November 2021 and Cochlear's response to P2 s109 notice of 10 January 2023, Q7, 17, 18, Annex 235, [✂], June 2022 [✂].
[480] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, 17, 18, Annex 231, [✂], 9 November 2021.
[481] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.13.
[482] Cochlear's response to P2 s109 notice of 10 January 2023, Q7: COT-000000009 – Annex 212 – [✂] [November 2021]; & COT-000000011 – Annex 214 – [✂] [August 2019], COT-000000010 – Annex 213 – [✂] [November 2022]; & COT-000000012 – Annex 215 – [✂] December 2022].
[483] Parties' response to the AIS and WPs, dated 23 March 2023, paragraph 4.14.
[484] Annex 151 to the FMN – [✂].

paragraph 5.107(d)[485] does not show Cochlear responding to the threat of Sentio but instead seeking to grow the market.[486]

5.112 In relation to these submissions, we consider that Cochlear's internal documents show that it perceives Sentio as a risk which it is seeking to respond to:

(a) [✂].[487]

(b) The document in paragraph 5.107(b) shows that one of Cochlear's three must-win areas was to retain market leadership and that it regarded [✂] to this. The document also provides updates on Cochlear's other must-win areas, namely growing the hearing implant market and delivering consistent revenue and earnings growth.[488] We consider that this document shows that Cochlear views Sentio as a threat to one of its key strategic objectives.

(c) In the document in paragraph 5.107(d) Cochlear states that one of its key business objectives with the Osia system release is to achieve market growth and states elsewhere that the main competitor for Osia except 'do nothing' is middle-ear surgery and hearing aids. The document also states that another objective is to [✂]. Cochlear also describes the features it expects Sentio to have (noting that this was subject to uncertainty).[489] We consider that this document therefore shows that protecting its market share in response to the threat of Sentio was one of Cochlear's main drivers to innovate.

5.113 The Parties have also submitted that:

(a) the fact that Cochlear monitored a potential product does not in itself provide an indication that the product, if launched, would constrain it; and

(b) such internal documents were based on assumptions and estimates rather than concrete evidence, and more recent documents reflect that Cochlear does not consider Sentio to be a threat.[490]

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[485] Cochlear's response to the CMA's S109, 10 January 2023, Q7, 17, 18, Annex 231, '[✂], 9 November 2021.
[486] Parties' response to the AIS and WPs, dated 23 March 2023, paragraphs 4.15-4.16.
[487] Cochlear's response to P2 s109 notice of 10 January 2023, Q7: COT-000000009 – Annex 212 – [✂] – [November 2021]; & COT-000000011 – Annex 214 – [✂] [August 2019], COT-000000010 – Annex 213 – [✂] [November 2022]; & COT-000000012 – Annex 215 – [✂] December 2022].
[488] Annex 151 to the FMN – [✂].
[489] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, 17, 18, Annex 231, [✂], 9 November 2021.
[490] Parties' response to Issues Statement, 3 February 2023, para 3.38. The Parties reiterated these views in their response to the AIS and WPs, dated 23 March 2023, paragraphs 4.13 and 4.16.

5.114 In respect of these submissions, we consider that the fact that Cochlear monitors the development of Sentio, assesses how this product compares to its own and regards [✂] demonstrates that it views it as a potential competitive threat. We consider that we can place weight on this evidence, notwithstanding that: (a) these internal documents rely on assumptions, since it is to be expected that (in the absence of full information about its rivals) a competitor will make various assumptions in relation to competitive threats; and (b) ultimately, whether Sentio will constrain Osia in the future is inherently uncertain and will depend on how the product performs if and when it is launched – the presence of some uncertainty in how a market is likely to develop in future does not in itself preclude a finding that there are competition concerns on the basis of all the available evidence.[491] In addition, the evidence set out in paragraph 5.107(d)[492] shows that Sentio is already constraining Cochlear as Cochlear is responding to this competitive threat, including through innovation.

5.115 In relation to their submission that more recent documents reflect that Cochlear no longer consider Sentio to be a threat, the Parties identified a marketing and launch document from 2022. This notes that Sentio is [✂] and the announcement that Cochlear could purchase Oticon Medical makes Sentio 'highly unsecure'.[493] We note that Cochlear's perception of Sentio within this document differs from its view in other documents from 2022 (as outlined in paragraph 5.107) and, in part, is impacted by the proposals for the Merger.

5.116 MED-EL told us that based on its understanding of Sentio, it considers that it could be a major competitor. However, it noted that the extent of its competitive threat is presently unclear and dependent on its performance in clinical trials.[494]

Conclusions on the competitive constraint from Sentio

5.117 The evidence considered above shows that:

(a) Oticon Medical considers that Sentio will compete with Osia and Bonebridge. Whilst the development and potential market launch of Sentio is inherently uncertain, the evidence shows that Oticon Medical believes that it has several advantages relative to competing Active BCS

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[491] Merger Assessment Guidelines (CMA129), paragraph 2.10.
[492] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, 17, 18, Annex 231, [✂], 9 November 2021.
[493] Cochlear's response to P2 s109 notice of 10 January 2023, Q7, 17, 18, Annex 237, [✂], June 2022.
[494] MED-EL's response to P2 s109 notice of 18 January 2023, Document 14, and Note of call with MED-EL, 8 February 2023, paragraph 17.

solutions and, if launched, Sentio would ultimately [✂] than Oticon Medical's Passive BCS product.

(b) Cochlear and MED-EL are monitoring Sentio and consider it a competitive threat, and Cochlear is already taking steps to respond to this threat.

Countervailing factors

5.118 In this section, we consider whether there are any countervailing factors that prevent or mitigate an SLC arising from the Merger.[495] We note that we have not received any submissions on efficiencies, and therefore we have not considered them at this stage.

5.119 This section therefore examines whether entry or expansion of rivals, including that sponsored by the NHS, would be timely, likely and sufficient to prevent an SLC.[496]

Framework of assessment

5.120 If effective entry or expansion occurs as a result of a merger and any consequent adverse effect (for example, a price rise), the effect of the merger on competition may be mitigated, the CMA might conclude that no SLC arises as a result of the merger.[497]

5.121 As set out in the Merger Assessment Guidelines, the framework used by the CMA to determine whether entry or expansion would prevent an SLC is that it must be timely, likely and sufficient.[498] These conditions are cumulative and must be satisfied simultaneously.[499]

5.122 The CMA considers that entry or expansion preventing an SLC from arising would be rare.[500]

Parties' submissions

5.123 The Parties submitted that:

(a) If the BCS segment were to grow, or if the Merged Entity were to attempt to raise prices or decrease its innovation efforts, new competitors may be likely to launch competing BCS products. They identified potential

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[495] Merger Assessment Guidelines (CMA129), paragraph 8.1.
[496] Merger Assessment Guidelines (CMA129), paragraph 8.31.
[497] Merger Assessment Guidelines (CMA129), paragraph 8.28.
[498] Merger Assessment Guidelines (CMA129), paragraph 8.31.
[499] Merger Assessment Guidelines (CMA129), paragraph 8.32.
[500] Merger Assessment Guidelines (CMA129), paragraph 8.29.

entrants as being Medtronic, Envoy Medical, BHM Tech and the big tech companies (especially Apple, Samsung and Google).[501]

(b) Given the anticipated growth of the implantable segment, and notwithstanding the regulatory barriers and concerns of clinics around long-term reliability, potential entry by those able to provide innovative or high-quality solutions must be viewed as likely.[502]

(c) The Parties did not provide submissions regarding potential expansion of existing firms.

5.124 We consider the Parties' submissions as part of our assessment.

Our assessment

5.125 There has not been successful entry into the UK BCS market since MED-EL entered in 2012. As noted in paragraphs 5.67 and 5.68, MED-EL's market share has remained fairly stable over the last four years and was [5–10%] in 2022. Medtronic acquired Sophono, a BCS supplier, in 2016,[503] but Sophono subsequently stopped supplying BCS products in 2019.[504] Medtronic told us that [✂].[505]

5.126 Third parties have described challenges with entry and expressed the view that entry would become more difficult as a result of the Merger.

(a) Envoy Medical told us that key a barrier to entry was the limited size of the market and it considered that it would be challenging for a new entrant to compete with the Merged Entity if the Merger were to proceed. It also told us that, in order to be competitive, any market entrant would need to develop a completely new solution which addressed the same hearing loss in a different and improved way. However, Envoy Medical noted that it considered that new entrants should eventually be able to overcome regulatory barriers and intellectual property issues.[506]

(b) [✂].[507]

5.127 The Parties have also submitted that entry may not be either likely or timely:

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[501] Parties' response to Issues Statement, 3 February 2023, paragraph 6.1.
[502] Parties' response to Issues Statement, 3 February 2023, paragraph 6.2.
[503] Note of a call with a third party, [✂] March 2023, paragraph 3.
[504] FMN, paragraph 121.
[505] Note of a call with a third party, Medtronic March 2023, paragraph 5.
[506] Note of a call with a third party-Envoy Medical, 9 March 2023, paragraphs 27-29.
[507] Note of a call with a third party, [✂], paragraph 8.

(a) In the hearing, Demant told us that it considered that there could be innovation by smaller new entrants. However, it also told us that that any entrant would be unlikely to gain a large market share unless their product was very different. It noted that in its view such entry was possible rather than likely.[508]

(b) In the hearing, Cochlear told us that it considered that the limited size of the BCS segment meant that it was difficult for the BCS segment to sustain more suppliers. However, it considered that if sales were to grow then over time there would be more opportunity for entry.[509]

5.128 The Parties' internal documents are consistent with a long lead time to develop products, conduct clinical trials and gain regulatory approval to launch products, such that organic entry in the next 2 - 3 years would be unlikely.[510]

5.129 In addition, the evidence shows that entry is likely to become more difficult as the use of Active BCS products increases. The Parties have also submitted that the transition from Passive BCS products to Active BCS products entails a move from Class II to Class III medical devices which will significantly increase the need for reliability and internal quality assurance procedures, and will require them to comply with the EU Medical Device Regulation.[511] The complexity and cost of developing Active BCS products is also reflected in internal documents.[512] In the hearing, Cochlear told us that that the move towards Active BCS products increases the need for scale.[513]

5.130 We have not received any evidence from the Parties or through our enquiries of any large-scale entrant who would likely enter in a timely manner, including as a result of sponsored entry by the NHS.

5.131 The only evidence which we have received of potential expansion is from MED-EL. MED-EL told us that its aim is to increase its share to [✂]% across all hearing solutions, including BCS products. However, MED-EL was not able to specify the timeframe over which it expected to achieve this growth or the extent to which BCS products would contribute to this and its plans to achieve this aim are not evidenced in its internal documents.

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[508] Note of a hearing with Demant, 22 March 2023, page 72 lines 4-15.
[509] Notes of a hearing with Cochlear, 21 March 2023, pages 74-75 lines 21-4.
[510] For example, Oticon Medical's documents show the considerable time taken to develop Sentio, including Demant's response to P2 s109 notice of 10 January 2023, Q7, Q10, Q11, Q18, '[✂]', September 2022, slide 20, [✂], page 2.
[511] FMN, paragraph 9(f).
[512] For example, Demant's response to the CMA's S109, 10 January 2023, Q7, Q10, Q11, Q12, Q17, Q18, [✂], 31 January 2022, [✂], slide 22 of [✂]; slide 5 of: [✂]; and slide 10 of [✂].
[513] Notes of a hearing with Cochlear, 21 March 2023, pages 71-72.

5.132 We therefore do not consider that either entry or expansion, including that sponsored by the NHS, would be timely, likely and sufficient to prevent an SLC in the supply of BCS products in the UK.

Conclusion on the competitive assessment

5.133 Our assessment of the evidence shows that:

(a) The BCS market is heavily concentrated, with the two Parties having a combined share of supply of [90–100%] in 2022.

(b) The Parties are close competitors in Passive BCS products, which only the two Parties supply, and the constraint from other competitors and hearing solutions is limited.

(i) The Parties' internal documents show that both Parties see each other as a close competitor. Clinics and third parties also see the Parties as each other's closest competitors.

(ii) The evidence from internal documents, clinics and third parties shows that the constraint from MED-EL is limited. Contrary to the Parties' statements, the evidence also shows that the constraint from other hearing solutions is also limited.

(iii) The evidence from internal documents, clinics and third parties also shows that whilst it is likely that there will be a material increase in the use of Active BCS products in the next two to three years, there will continue to be a significant proportion of patients that continue to receive a Passive BCS product.

(c) Oticon Medical is a competitive constraint on Cochlear's Active Product (Osia). MED-EL also imposes a competitive constraint, but the constraint from other hearing solutions is limited.

(i) The Parties' internal documents and clinic evidence show that MED-EL is an important competitive constraint on Osia, and that, Oticon Medical's Passive BCS product provides some constraint on Osia.

(ii) The Parties' internal documents show that whilst the development and potential market launch of Oticon Medical's Active BCS product (Sentio) is inherently uncertain, both Parties consider that, if launched, it would have several potential advantages over Osia. The evidence from Cochlear's internal documents also shows that it perceives Sentio as a competitive threat and is already taking steps to respond to this.

(iii) The evidence from clinics, the Parties' internal documents and third parties shows that the constraint from other hearing solutions is limited.

5.134 On this basis our view is that the Merger will eliminate a major BCS supplier from the market, that in addition to the Merged Entity only one BCS supplier (MED-EL) would remain, and that the competitive constraint from that supplier and other hearing solutions on the Merged Entity would not be sufficient to offset the effects that may be expected to result from the Merger. The loss of this competitor (Oticon Medical) would significantly reduce the alternatives available to the NHS and patients. We do not consider that entry or expansion, including that sponsored by the NHS, would be timely, likely and sufficient to prevent an SLC from arising.

5.135 The Parties have told us that the market is transitioning rapidly to Active BCS products and Oticon Medical does not intend to launch an Active BCS product. Our view is that, even if this were the case, the Merger would still result in the loss of the competitive constraint which Oticon Medical's Passive BCS product exerts on Cochlear's Active BCS product. Even though this constraint is weaker than the constraint from MED-EL, the loss of it would be significant given that there would only be two suppliers of Active BCS products in the UK.

5.136 We therefore conclude that the Merger may be expected to result in an SLC in the market for the supply of BCS products in the UK. This may be expected to result in poorer patient outcomes, with patients potentially facing less choice, reduced quality or reduced product innovation as well as the potential for higher prices for the NHS relative to the position absent the Merger.

6. Conclusions

6.1 As a result of our assessment, we conclude that the anticipated acquisition by Cochlear of Oticon Medical constitutes arrangements in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

6.2 We also conclude that the creation of that situation may be expected to result in an SLC in the supply of BCS products in the UK.

7. Remedies

Introduction

7.1 This chapter sets out our assessment of, and decision on, the appropriate remedy to the SLC and resulting adverse effects we have found. In particular, this chapter discusses:

(a) our remedy consideration process;

(b) the framework for the assessment of remedies;

(c) overview of remedy options;

(d) the effectiveness of a full prohibition of the Merger;

(e) the effectiveness of a partial prohibition of the Merger;

(f) the effectiveness of a behavioural remedy submitted by the Parties;

(g) consideration of the proportionality of effective remedies; and

(h) our decision on remedies.

Our remedy consideration process

7.2 On 20 April 2023, we provisionally found an SLC in the market for BCS products in the UK. On the same date, we published a Notice of Possible Remedies (the **Remedies Notice**) to set out, and seek views on, possible remedies to the SLC or any adverse effects resulting from the SLC.

7.3 Demant, Cochlear, and one third party separately responded to the Remedies Notice.[514] A response hearing was held with Demant on 10 May 2023. Cochlear informed the CMA that it did not wish to take up the opportunity of having a response hearing. In addition, we held calls with seven third parties to discuss potential remedy options, sent questionnaires to 54 NHS clinics active in prescribing BCS products and received questionnaire responses from five NHS clinics.

[514] See Demant response to the Remedies Notice, 4 May 2023, and Cochlear response to the Remedies Notice, 4 May 2023. We also received a response to the Remedies Notice on 20 April 2023 from University Hospitals Plymouth NHS Trust.

7.4 These calls and questionnaire responses informed our remedies working paper (the **Remedies Working Paper**) which we shared with the Parties setting out our provisional decision on remedies.[515]

CMA remedies assessment framework

7.5 Pursuant to section 36(2) of the Act, where the CMA decides that an anticipated merger may be expected to result in an SLC, we must decide the following:

(a) whether the CMA should itself take action under section 41(2) of the Act for the purpose of remedying, mitigating or preventing the SLC concerned or any adverse effect which may be expected to result from the SLC;

(b) whether the CMA should recommend the taking of action by others for the purpose of remedying, mitigating or preventing the SLC concerned or any adverse effect which may be expected to result from the SLC; and

(c) in either case, if action should be taken, what action should be taken and what is to be remedied, mitigated or prevented.

7.6 The Act provides that the CMA, when considering possible remedial action, 'shall, in particular, have regard to the need to achieve as comprehensive a solution as is reasonable and practicable to the substantial lessening of competition and any adverse effects resulting from it'.[516]

7.7 To fulfil this requirement, the CMA will seek remedies that are effective in addressing the SLC and any resulting adverse effects. The effectiveness of a remedy is assessed by reference to its:[517]

(a) impact on the SLC and the resulting adverse effects – the CMA views competition as a dynamic process of rivalry between firms seeking to win customers' business over time – restoring the process of rivalry is a key aim of a remedy;

(b) duration and timing – remedies need to be capable of timely implementation and address the SLC effectively throughout its expected duration;

(c) practicality in terms of implementation, monitoring and enforcement; and

[515] The Remedies Working Paper was sent to the Parties on 30 May 2023.
[516] Section 36(3) of the Act.
[517] Merger remedies guidance (CMA87), paragraph 3.5.

(d) risk profile, relating in particular to the risk that the remedy will not achieve its intended effect. Although the effect of any remedy is always likely to be uncertain to some degree, the CMA will seek remedies that have a high degree of certainty of achieving their intended effect.

7.8 The CMA first considers which remedy options would be effective in addressing the SLC and resulting adverse effects and, following this, the CMA will then consider the costs of those remedies which it has identified would be effective.[518] The CMA may have regard, in accordance with the Act,[519] to the effect of any remedial action on any relevant customer benefits (**RCB**s) arising from the merger. In order to ensure that any remedy is proportionate and reasonable, the CMA will seek to select the least costly and intrusive remedy, or package of remedies, of those remedy options that it considers would be effective.[520] The CMA will also seek to ensure that it does not select a remedy that is disproportionate in relation to the SLC and its adverse effects.[521]

Overview of remedy options

7.9 As set out in the CMA's Merger Remedies Guidance,[522] remedies are conventionally classified as either structural or behavioural:

(a) Structural remedies, such as divestiture or prohibition, are generally one-off measures that seek to restore or maintain the competitive structure of the market by addressing the market participants and/or their shares of the market.

(b) Behavioural remedies are normally ongoing measures that are designed to regulate or constrain the behaviour of merger parties with the aim of restoring or maintaining the process of rivalry absent the merger.

7.10 The choice of remedy will reflect the particular circumstances of each case. However, the CMA prefers structural remedies over behavioural remedies, because:[523]

(a) structural remedies are more likely to deal with an SLC and its resulting adverse effects directly and comprehensively at source by restoring rivalry;

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[518] Merger remedies guidance (CMA87), paragraph 3.6.
[519] Section 36(4) of the Act.
[520] Merger remedies guidance (CMA87), paragraphs 3.4 and 3.6.
[521] Merger remedies guidance (CMA87), paragraphs 3.4 and 3.6.
[522] Merger remedies guidance (CMA87), paragraph 3.34.
[523] Merger remedies guidance (CMA87), paragraph 3.46.

(b) behavioural remedies are less likely to have an effective impact on the SLC and its resulting adverse effects, and are more likely to create significant costly distortions in market outcomes; and

(c) structural remedies rarely require monitoring and enforcement once implemented.

7.11 In the Remedies Notice, we set out the following structural remedy options:[524]

(a) prohibition of the Merger (ie of any sale of Oticon Medical to Cochlear) (**full prohibition**); and

(b) prohibition of the sale of the BCS business of Oticon Medical to Cochlear (**partial prohibition**).

7.12 We also invited views on whether a structural remedy other than a full or partial prohibition (ie a form of divestiture) would be effective, and if so:

(a) what would need to be included in such a package of assets to attract a suitable purchaser and allow it to operate as an effective competitor in the market; and

(b) who might be a suitable purchaser for such a package of assets.

7.13 In the Remedies Notice, we set out a preliminary view that a behavioural remedy was very unlikely to be an effective remedy to the SLC or any resulting adverse effects that we had provisionally found, but that we would consider any behavioural remedies put forward as part of our consultation process.

7.14 Shortly prior to the publication of our provisional findings, the Parties submitted a behavioural remedy in which Cochlear would commit to continuing to provide, for a period of five years, Oticon Medical's existing passive BCS sound processors and accessories (**SP**s) to customers without increased prices, apart from an allowance for inflation, or reduced functionality (the **SP Remedy**).

7.15 As noted in the CMA's Merger Remedies Guidance, the CMA will generally only select behavioural remedies as the primary source of remedial action where one or more of the following apply:[525]

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[524] Remedies Notice.
[525] Merger remedies guidance (CMA87), paragraphs 3.48 and 7.2.

(a) divestiture and/or prohibition is not feasible, or the relevant costs of any feasible structural remedy far exceed the scale of the adverse effects of the SLC;

(b) the SLC is expected to have a relatively short duration; or

(c) behavioural measures will preserve substantial RCBs that would be largely removed by structural remedies.

7.16 While none of the circumstances in which the CMA would typically select a behavioural remedy as the primary source of remedial action in a merger investigation appeared to be present, we nonetheless considered the SP Remedy as a possible remedy and sought the views of market participants on it during our remedy consultation process.

Effectiveness of full prohibition

Description of remedy

7.17 A full prohibition would involve prohibiting the Parties from completing the Merger in its entirety. The Merger between Cochlear and Oticon Medical would, therefore, not take place, and the competitive dynamics currently present in the market would continue. As set out in Chapter 4, we have concluded that the competitive dynamics currently present in the market would likely prevail – specifically that, absent the Merger, Oticon Medical would most likely have continued to operate in the market for BCS products, whether under the ownership of Demant or of an alternative purchaser.

7.18 A full prohibition would be effected by accepting undertakings under section 82 of the Act or making an order under section 84 of the Act, prohibiting the Merger and preventing Cochlear and Oticon Medical from merging for a further period. Our ordinary practice would be to prevent a future merger between Cochlear and Oticon Medical for the next ten years,[526] absent a change in circumstances.

Views of the Parties and third parties

Views of the Parties

7.19 In relation to the possible structural remedies canvassed in the Remedies Notice, Cochlear submitted a preference for a partial prohibition. Cochlear

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[526] Merger remedies guidance (CMA87), paragraph 5.10.

expressed 'grave doubts as to the sustainability of Oticon Medical business in the medium term'[527] and submitted that, in relation to any potential buyers of the Oticon Medical business, '[t]here must be a serious question mark as to whether any other company has the ability and the willingness to provide continuous support to the existing installed Oticon Medical patient base over the course of their lifetime'.[528]

7.20 Demant submitted that full prohibition would not be 'reasonable' and would be disproportionate to the SLC provisionally found in relation to BCS products. Demant further submitted that a full prohibition 'would result in Demant having to close down its significantly loss-making [Cochlear Implants (**CI**)] business', and that, while Demant would take measures to minimise the impact of this on its patient base, this would leave patients 'worse-off' as compared to a transfer of the CI business to Cochlear.[529]

7.21 In its response to the Remedies Working Paper, Demant reiterated its view that, following a full prohibition, Demant would not re-enter the CI segment and that this would be the worst-case scenario for CI patients.[530]

Views of third parties

7.22 Third parties expressed mixed views on the potential effectiveness of full prohibition, with most third parties saying it would be effective. One third party said there was little difference between full and partial prohibition. Two third parties expressed a preference for a full prohibition, pointing to possible concerns about the viability of the standalone BCS business, while others had concerns that full prohibition could incentivise Demant to close the business in its entirety. Another said that full prohibition may not be sufficiently specific to the SLC provisionally found, but would be preferable to the Merger proceeding, if the CMA had no alternative effective remedies available.

7.23 One third party told us that the difference between a full and partial prohibition was minimal from a commercial perspective, because the market position of the CI business could be seen as negligible, and it may be valued negatively on the basis of its financial performance.[531]

7.24 Another third party told us that full prohibition may not be sufficiently specific to the SLC provisionally found. However, this third party told us that, if the CMA determined that there were no alternative effective remedies, a full

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[527] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 4.
[528] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 8.
[529] Demant response to the Remedies Notice, 4 May 2023, paragraph 1.4.
[530] Demant response to Remedies Working Paper, 6 June 2023, paragraph 3.2.
[531] Note of call with third party [✂].

prohibition would be effective in preventing a monopolistic market dynamic and would be preferable to the Merger proceeding.[532]

7.25 Two third parties told us that, of the structural remedies under consideration by the CMA, a full prohibition would be the preferred option.

(a) The first third party submitted that a full prohibition would allow Demant to revisit its decision as to its presence in hearing implants or, alternatively, would allow an alternative purchaser to compete more effectively in the market for hearing implants (ie CI and BCS products) going forward.[533]

(b) The second third party had a preference for full prohibition because it was concerned that the BCS segment operating alone may not provide a viable business model for Demant in the long term. However, this third party acknowledged that these comments were based on limited access to information, and that Demant was better placed to make these judgements.[534]

7.26 Two third parties questioned whether a full prohibition would incentivise Demant to close Oticon Medical in its entirety, and if this would ultimately lead to a poor outcome for hearing implant patients.[535] One of these third parties noted that it could not give a view on the likelihood of this potential outcome.[536]

7.27 Of the 54 questionnaires sent to NHS clinics, we received five responses, with one individual responding specifically on a personal basis and the remainder responding on behalf of their respective NHS trusts.[537] One NHS clinic stated that it had no comments to make on potential remedies.[538] The remaining four responses stated that clinicians would see a full prohibition as an effective remedy. One response stated that 'any kind of merger would not be acceptable', implying a preference for full prohibition.[539] Others expressed a preference for partial prohibition over full prohibition, with two clinics noting that Cochlear would continue to face competition from other incumbents in CI products, in the event that it acquired the CI business.[540]

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[532] Note of call with third party [✂].
[533] Note of call with third party [✂].
[534] Note of call with third party [✂].
[535] Note of call with third party [✂]; Note of call with third party [✂].
[536] Note of call with third party [✂].
[537] Response to the CMA questionnaire to clinics, May 2023, [✂].
[538] Response to the CMA questionnaire to clinics, May 2023 [✂].
[539] Response to the CMA questionnaire to clinics, May 2023 [✂].
[540] Response to the CMA questionnaire to clinics, May 2023 [✂].

Effectiveness of full prohibition

7.28 The CMA's Merger Remedies Guidance states that full prohibition of an anticipated merger is an effective remedy as it necessarily maintains the competitive structure of a market that would have otherwise been changed by the merger.[541]

7.29 In this case we consider that a full prohibition would be effective in comprehensively preventing an SLC in the market for BCS products in the UK, as it would maintain the current competitive structure of the market. A full prohibition would also prevent risks, which we consider further below, relating to (i) interdependencies between the CI business under the ownership of Cochlear and the BCS business under the ownership of Demant, and (ii) ongoing 'dotted line' links between Cochlear and Demant following an acquisition by Cochlear of the CI business in the event of a partial prohibition.

7.30 We therefore conclude that full prohibition would be an effective remedy which would comprehensively address the SLC that we have found, by preventing the SLC from arising and consequently preventing any of its adverse effects from arising.

Effectiveness of partial prohibition

Description of remedy

7.31 A partial prohibition remedy would prohibit Cochlear from acquiring any of the BCS business (including all relevant corporate entities and assets) of Oticon Medical. A partial prohibition would be limited in scope to the SLC found and so would, in principle, prevent the SLC from arising.

Views of the Parties and third parties

7.32 As previously noted, of the CMA's two proposed structural remedies, Cochlear expressed a preference for a partial prohibition and urged the CMA to approve this as quickly as possible.[542] Cochlear expressed 'grave doubts' as to the sustainability of the Oticon Medical business and the availability of alternative purchasers who could provide adequate long-term support to hearing implant patients.[543]

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[541] Merger remedies guidance (CMA87), paragraph 3.35.
[542] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 4.
[543] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 4.

7.33 Demant submitted that it favoured a partial prohibition over any form of divestment remedy, pointing to reduced risks of the remedy (in the form of composition, asset and purchaser risks).[544] In contrast with its earlier submissions relating to the counterfactual (as set out in Chapter 4),[545] Demant submitted in response to the Remedies Notice that a partial prohibition would create a stronger BCS business which it would be incentivised to continue supporting.[546] Elaborating on this, Demant referenced the CMA's provisional findings in relation to the size and financial performance of the Demant group, and the profitability of the BCS business, stating that the sale of the CI business would 'only serve to make the retained BCS business more financially robust'.[547]

7.34 In relation to potential revenue synergies between the CI and BCS businesses, Demant commented that it had [✂],[548] and therefore, at a revenue level, the divestment of the CI business would have minimal impact. In relation to shared costs, Demant submitted that operational synergies between the CI and BCS businesses are limited to employees and certain assets,[549] and the loss of these synergies may be 'readily overcome' by the additional profitability generated by the divestment of the CI business combined with the continued support of the Demant Group.[550]

7.35 In the following section we first set out views on the separability of BCS business from the CI business that might undermine the effectiveness of the partial prohibition, we then set out views related to the future competitiveness of a standalone BCS business (whether owned by Demant or another purchaser).

Separability of the BCS business

7.36 As identified at Chapter 4, both the Parties and third parties have referred to interdependencies between the CI and BCS businesses in the course of our investigation:

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[544] Composition, purchaser and asset risks typically refer to the effectiveness of a divestiture remedy. Composition risks encompass risks that the scope of a divestiture package may be too constrained or not appropriately configured to attract a suitable purchaser or may not allow a purchaser to operate as an effective competitor in the market. Purchaser risks encompass risks that a suitable purchaser may not be available or that the Parties dispose to a weak or otherwise inappropriate purchaser. Asset risks describe risks that a divestiture package will deteriorate before completion of a divestiture, for example through loss of customers or key staff members. For more information, see Merger remedies guidance (CMA87), paragraphs 5.3–5.5.
[545] See, for example, Demant's submissions as set out at 4.15 to 4.19 of Chapter 4.
[546] Demant response to the Remedies Notice, 4 May 2023, paragraph 1.4(a)–(c)
[547] Demant response to the Remedies Notice, 4 May 2023, paragraph 1.4(a)–(c)
[548] Transcript of Demant response hearing, 10 May 2023, page 23, lines 21-25.
[549] Demant response to the Remedies Notice, 4 May 2023, paragraph 3.4.
[550] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.3.

(a) At a 'revenue' level the Parties and third parties referred to shared key opinion leaders, clinicians and procurement professionals across CI and BCS products (ie activity in both products, therefore, may improve the performance and perception of a brand in the hearing implants segment and increase its potential for strong sales performance);[551] and

(b) At a 'cost' level, Demant told us, prior to the publication of our provisional findings, that divesting the CI business and retaining only the BCS business would have a 'material impact' on the profitability of the BCS business.[552] In particular, Demant raised concerns around staff costs shared between the CI and BCS business.

Potential impact of 'revenue synergies' on separability

7.37 Several third parties discussed likely revenue synergies across the CI and BCS businesses (indicating that purchasing bodies may have a preference for sourcing implants from one supplier), but none submitted that lack of access to these would materially reduce Oticon Medical's future competitive capability:

(a) As noted above, one third party said that the BCS business was 'highly successful' and that (given the CI business's limited performance and market share) there was minimal practical difference between a full and partial prohibition.[553] This third party noted that there were likely to be some synergies between the CI and BCS businesses at a revenue level, but that these were more prevalent if considering synergies between Active BCS products (such as Sentio and Osia) and CI products, as CI products are also 'active' hearing devices.

(b) Another third party, when asked about revenue synergies between the two businesses, commented that the BCS business has been successful over recent periods. This third party expressed a preference for full prohibition, however it expected that the BCS business would continue to generate healthy sales and earnings (with reference to EBITDA) absent the CI business.[554]

(c) Referring to potential 'revenue synergies', one third party commented that both Cochlear and Oticon Medical had a strong reputation for BCS products amongst key opinion leaders and clinicians. This third party noted that its opinion of Oticon Medical's products had not changed, in

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[551] See paragraph 4.74(c), and Transcript of Demant main party hearing, 22 March 2023, page 38, lines 6-13.
[552] Parties' response to AIS and WPs, paragraph 2.12.
[553] Note of call with third party [✂].
[554] Note of call with third party [✂].

this respect, since the announcement of the Merger, and considered that if Oticon Medical were to sell only BCS products (and not CI) going forward, this would be unlikely to significantly impact these positive market perceptions.[555]

(d) Two third parties noted that some purchasing bodies may prefer to procure CI and BCS devices from a single source, and this may impact the sales of the BCS business in the future.[556] Commenting on the potential future sales performance of the BCS business, however, one of these third parties said that the BCS business may in all likelihood continue its trajectory going forward, partly because of ongoing pent-up demand for medical devices and procedures following the pandemic.[557]

(e) A further third party commented, making reference to the CMA's provisional findings, and Demant's public statements, that losses were concentrated in the CI business.[558]

Potential ongoing links

7.38 Two third parties commented that, in the case of a partial prohibition remedy, safeguards would need to be in place to ensure that no material ongoing relationship would remain between Cochlear and Demant.[559] One third party referred to the potential for ongoing 'dotted line' links between the companies, continuing as a result of one half of Oticon Medical (the CI business) transferring to Cochlear.[560] Another third party expressed concern about ongoing supply, distribution, or brand arrangements which may have similar negative competitive effects to the Merger proceeding in its entirety, and which may heighten barriers to entry in the industry.[561]

7.39 Another third party expressed some concern about what might be included in a 'CI-only' transaction. This party told us that, if Cochlear were able to access Sentio in some form as a result of a transaction, this would further strengthen Cochlear's 'dominating' position in active hearing implants and devices.

[555] Note of call with third party [✂].
[556] Note of call with third party [✂]; Note of call with third party [✂].
[557] Note of call with third party [✂].
[558] Note of call with third party [✂].
[559] Note of call with third party [✂]; Note of call with third party [✂].
[560] Note of call with third party [✂].
[561] Note of call with third party [✂].

The capabilities and incentives of a standalone BCS business to compete

7.40 Third parties expressed mixed views on Demant's likely incentives and plans for the BCS business following a partial prohibition.

(a) One third party commented that it was surprised by the Merger announcement given the success of Oticon Medical and the BCS business as seen by key opinion leaders and healthcare professionals in the industry.[562]

(b) Another third party noted that there is significant desire within the hearing implants sector to avoid Cochlear creating a monopoly in BCS products. Therefore, this third party considered that there would be a willingness to support a competitor in BCS products, whether owned by Demant or an alternative purchaser, regardless of the business's presence in CI products.[563]

(c) A further third party, [564] commented (when discussing the BCS business's potential sales performance going forward absent the CI business) that the Merger process had taken longer than originally anticipated, and that this may have had an impact on the Oticon Medical brand, on customer confidence and on future confidence in the BCS business's products. Referencing Demant's public statements, this third party considered Demant was unlikely to be 'remotivated' to engage with the BCS business in the future.

Potential alternative purchasers of the BCS business

7.41 We received mixed evidence from third parties relating to potential interest in the BCS business, should it be sold to an alternative purchaser. However, the majority of the third parties considered the BCS business to be valuable and considered that it would generate interest from alternative purchasers.

(a) One third party considered that the transaction value paid, as it relates to the 'highly successful' BCS business, was perhaps significantly below market value.[565]

(b) Two third parties, expected that the BCS business, without the CI business, may be able to be acquired by an alternative purchaser who

[562] Note of call with third party [✂].
[563] Note of call with third party [✂].
[564] Note of call with third party [✂].
[565] Note of call with third party [✂].

would be able to reinvest in its development.[566] One of these third parties considered that a full prohibition would be preferable, and may increase a new acquirer's potential to compete effectively.[567] A further third party said that a sale to an alternative purchaser would likely be the best outcome for the competitive capability of the BCS business.[568]

(c) Another third party told us that in BCS it saw more limited structural growth drivers, as compared to the market for CI products, and – in this context – it expected that there would be limited interest from potential alternative acquirers. This party considered nonetheless that it would seem sensible for the BCS business to be sold to a player active in hearing implants.[569]

(d) A further third party considered that a 'generalist' acquirer (eg an acquirer active in hearing aids) may be able to successfully operate the BCS business, but this would require significant investment in developing the appropriate skills and infrastructure in Class III medical devices. This party said that there would likely be interest from players active in hearing implants, and that any such acquisition would be 'easier'.[570]

Clinicians' views relating to a partial prohibition

7.42 As noted, we received six submissions from clinicians (five questionnaire responses and one submission responding to the Remedies Notice). As noted above at paragraph 7.27, one response stated that 'any kind of merger would not be acceptable', implying a preference for a full prohibition.[571] Another submission gave support for both full and partial prohibition, without stating a preference for either.[572] The remaining responses demonstrated a slight preference for partial prohibition over full prohibition, with two clinics noting that Cochlear would continue to face competition from other incumbents in CI products, in the event that it acquired the CI business. Referencing considerations in relation to proportionality – two clinics stated that partial prohibition would be the 'fairer' and 'better' option.[573]

[566] Note of call with third party [✂]; Note of call with third party [✂].
[567] Note of call with third party [✂].
[568] Note of call with third party [✂].
[569] Note of call with third party [✂].
[570] Note of call with third party [✂].
[571] Response to the CMA questionnaire to clinics, May 2023 [✂].
[572] University Hospitals Plymouth NHS Trust response to Remedies Notice.
[573] Response to the CMA questionnaire to clinics, May 2023 [✂].

7.43 In general, the clinicians who responded to our questionnaires expressed strong views against the potential sale of the BCS business to Cochlear.[574]

Effectiveness of partial prohibition

7.44 The following section covers the effectiveness of a partial prohibition, including a summary of our assessment of factors which might limit or otherwise impact the effectiveness of such a remedy.

Financial performance of the BCS business following a partial prohibition

7.45 Following the Remedies Notice, and in contrast with what was submitted at an earlier stage of our investigation, Demant submitted analysis which it considered would demonstrate that 'the sale of the CI business would only serve to make the retained BCS business more financially robust'.[575] It explained that 'the loss of synergies the BCS business may have with the CI business can be readily overcome by the additional profitability generated by the disposal combined with the continued support of the Demant group'.[576]

7.46 Referring to the continued group-level support, Demant submitted that the BCS business would continue to benefit from:[577]

(a) group-level procurement and intra-group supply arrangements;

(b) group-level R&D as this relates to Demant's hearing aid business (particularly relevant to [✂] and [✂]);

(c) non-cash benefits, such as brand association; and

(d) shared intragroup services (eg legal, facilities management).

7.47 Demant submitted two new forecast scenarios to the CMA to demonstrate that the BCS business, following a partial prohibition, could be expected to remain profitable within the Demant group for the foreseeable future.

7.48 In the first forecast scenario shown at Table 7.1 Demant assumed:

(a) a higher revenue growth rate for the BCS business, compared to that submitted for the purposes of our provisional findings, for the years FY24 and FY25. This is achieved by Demant returning to the assumed growth rates (for these years) presented to potential acquirers during the

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[574] Response to the CMA questionnaire to clinics, May 2023 [✂].
[575] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.3.
[576] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.3.
[577] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.4.

transaction process, in March 2022. Demant told us that this aimed to respond to criticisms, raised in the CMA's provisional findings, that Demant had downgraded its forecasts for the purposes of its submissions, despite the BCS business [✂] exceeding revenue expectations set out at the time of the transaction process; and

(b) removing additional costs that Demant had expected the BCS business would incur if sold on a 'standalone basis' to a 'hypothetical private investor', as submitted for the purposes of our provisional findings.

7.49 In the second forecast scenario shown at Table 7.2 Demant assumed:[578]

(a) revenue performance to be in line with that presented to potential purchasers at the time of the transaction process, in March 2022; and

(b) some additional cost that the BCS business would face should the CI business be sold to Cochlear.

Table 7.1: Demant's 'scenario 1' forecast of its expectations for the BCS business

		2022	*2023*	*2024*	*2025*
	Unit	*Actual*	*Budget*	*Forecast*	*Forecast*
Revenue	DKKm	[✂]	[✂]	[✂]	[✂]
Year on year growth	*%*	[✂]	[✂]	[✂]	[✂]
Cost of Sales	DKKm	[✂]	[✂]	[✂]	[✂]
Gross profit	DKKm	[✂]	[✂]	[✂]	[✂]
Gross profit margin	*%*	[✂]	[✂]	[✂]	[✂]
Operating costs		[✂]	[✂]	[✂]	[✂]
R&D	DKKm	[✂]	[✂]	[✂]	[✂]
Distribution	DKKm	[✂]	[✂]	[✂]	[✂]
Admin	DKKm	[✂]	[✂]	[✂]	[✂]
EBIT *(upper bound)*	DKKm	[✂]	[✂]	[✂]	[✂]
EBIT margin	%	[✂]	[✂]	[✂]	[✂]
Depreciation and amortisation of Class 3 facility and equipment	DKKm	[✂]	[✂]	[✂]	[✂]
Cost of additional employees needed for Class 3 facility	DKKm	[✂]	[✂]	[✂]	[✂]
Total yearly costs of a Class 3 facility	DKKm	[✂]	[✂]	[✂]	[✂]
EBIT (lower bound)	DKKm	[✂]	[✂]	[✂]	[✂]

Source: Annex 1 to Demant response to the Remedies Notice, 4 May 2023.

[578] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.5(b).

Table 7.2: Demant's 'scenario 2' forecast of its expectations for the BCS business

		2022	*2023*	*2024*	*2025*
	Unit	*Actual*	*Budget*	*Forecast*	*Forecast*
Revenue	DKKm	[✂]	[✂]	[✂]	[✂]
Year on year growth	*%*	[✂]	[✂]	[✂]	[✂]
Cost of Sales	DKKm	[✂]	[✂]	[✂]	[✂]
Gross profit	DKKm	[✂]	[✂]	[✂]	[✂]
Gross profit margin	*%*	[✂]	[✂]	[✂]	[✂]
Operating costs		[✂]	[✂]	[✂]	[✂]
R&D	DKKm	[✂]	[✂]	[✂]	[✂]
Distribution	DKKm	[✂]	[✂]	[✂]	[✂]
Admin	DKKm	[✂]	[✂]	[✂]	[✂]
EBIT *(upper bound)*	DKKm	[✂]	[✂]	[✂]	[✂]
EBIT margin	%	[✂]	[✂]	[✂]	[✂]
Depreciation and amortisation of Class 3 facility and equipment	DKKm	[✂]	[✂]	[✂]	[✂]
Cost of additional employees needed for Class 3 facility	DKKm	[✂]	[✂]	[✂]	[✂]
Total yearly costs of a Class 3 facility	DKKm	[✂]	[✂]	[✂]	[✂]
EBIT (lower bound)	DKKm	[✂]	[✂]	[✂]	[✂]

Source: Annex 1 to Demant response to the Remedies Notice, 4 May 2023.

7.50 Demant submitted that this analysis showed the BCS business would remain profitable 'even under very conservative assumptions' relating to cost and revenue growth, and submitted that it expected the future profits of the BCS business to likely be somewhere between the two scenarios shown.

7.51 We questioned Demant on the changes to Demant's projections for the BCS business, as reflected in these submissions. In response to the Remedies Working Paper, Demant told us that the two financial models are attempting to illustrate two different scenarios. Demant stated that:

(a) the first financial model forecasted the profitability of the BCS business on a standalone basis, separate from the CI business but also the Demant group; whereas

(b) the second financial model forecasted the profitability of the BCS business separate from the CI business but retained by the Demant group.[579]

7.52 We have not independently verified these assumptions since any attempt to predict future financial performance is an inherently uncertain exercise.

[579] Demant response to Remedies Working Paper, 6 June 2023, paragraph 2.2.

However, as referenced in our discussions relating to the counterfactual (as set out in Chapter 4), we note that:

(a) Demant presented the BCS business to alternative purchasers, at the time of the transaction process, as a growing, profitable and sustainable business. This picture was reflected in Demant's internal management accounts before, around the time of, and subsequent to the announcement of the Merger. Demant was unable to submit any pre-Merger, or internally generated, evidence to demonstrate that it ordinarily considered the BCS's financial profile to be unrepresentative of its true performance, or to show that it might be [✂].

(b) This performance profile was also reflected in independent financial due diligence (**FDD**) undertaken by EY on behalf of Cochlear in August 2022.[580] As noted in our analysis of the counterfactual, this report [✂], and does not appear to consider its presentation of the BCS business to be unrepresentative when taking account of the CI business.[581]

(c) Even under the assumptions submitted by Demant at an earlier stage of our investigation (which attempted to demonstrate that the BCS business's performance would be [✂]), we assessed that the BCS business would likely have remained profitable in FY22 when accounting for additional costs presented, achieving an EBIT margin of around [✂]% (above Demant's FY22 group level performance);[582] and

(d) Management accounts submitted to the CMA for the purposes of our remedies assessment demonstrate that the BCS business continues to perform well, exceeding revenue expectations in the first quarter of FY23 (**Q1 '23**) and improving its performance by [✂]% as compared to Q1 '22.[583,584]

7.53 We therefore conclude, on the basis of the evidence provided to us in relation to operational structures and financial performance, that the BCS business (as it exists today) would likely remain financially viable in the event of a partial prohibition, absent the CI business, under the continued ownership of Demant.

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[580] Annex 435 to Cochlear's response to P2 s109 notice of 8 February 2023 – [✂].
[581] See discussion in Chapter 4, including at paragraph 4.100.
[582] See paragraph 4.79.
[583] Demant response to P2 s109 notice of 16 May 2023 – annex 12 – Oticon Medical 2023 Financials.
[584] 'Q1 '22' refers to the first quarter of the financial year ending in 2022.

Separability of the BCS business

7.54 As noted at paragraph 7.38 and 7.39, some third parties expressed concerns that there could be ongoing links between Cochlear and Demant, or the BCS business of Oticon Medical, following the transfer of the CI business to Cochlear in the event of a partial prohibition.

7.55 With regards to the feasibility of separating the two businesses, we note that the CI business and the BCS business are largely operated separately, with few tangible assets currently shared between the two businesses.[585] Some limited IT systems will transfer to Cochlear.[586] The Nice facility is primarily used by the CI business, but is also a sub-supplier to the BCS business for the development of Sentio.[587] However, Demant told us that there are a number of readily available manufacturing alternatives that it could use instead of the Nice facility, including:[588]

(a) upgrading one of Demant's existing facilities to comply with the requirements for a Class III device;

(b) outsourcing to a third-party manufacturer that could produce the Sentio implant; or

(c) establishing or acquiring a new facility for this purpose at an estimated cost of approximately EUR [✂].

7.56 We also understand that there are no shared customer or supplier contracts.[589] Therefore, other than the IP and transitional arrangements described below, we expect any carve out risks to be manageable and not to give rise to material asset or composition risks (especially as both Cochlear and Demant have incentives to preserve the value in the CI and BCS businesses respectively).

7.57 Demant has submitted that, in the event of a partial prohibition, the Oticon Medical employee base can be readily split, with approximately [✂] employees transferring to Cochlear as part of the CI business, including [✂] Oticon Medical employees that are currently shared between the CI and BCS businesses. These [✂] employees are CI sales staff working in France and Morocco.[590]

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[585] Demant response to the Remedies Notice, 4 May 2023, paragraph 3.3.
[586] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.9.
[587] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.15.
[588] Demant response to the Remedies Notice, 4 May 2023, paragraph 4.15.
[589] Demant response to P2 s109 notice of 16 May 2023, paragraph 2.8.
[590] Note of call with Demant, 12 June 2023, paragraph 20.

7.58 As part of our assessment of potential remedies, we asked Demant detailed questions around potential links between the BCS business and the CI business following its potential acquisition by Cochlear. Demant told us there would continue to be some ongoing links relating to the provision of products and services from Demant to Cochlear, comprising: [591]

(a) a transitional agreement in relation to Demant's [✂]; and

(b) a licensing agreement granting the CI business a right to benefit from those intellectual property rights (**IPR**) which are currently used by both the CI and BCS businesses. All IPR related exclusively to the CI business would transfer with that business and all IPR related exclusively to the BCS business would remain with Demant.

7.59 We recognise that a purchaser may require access to certain key inputs or services from the seller in order to enable the acquired business to operate effectively, and that such arrangements may be permitted for a limited period.[592] However, these agreements may present a risk that [✂] or IP rights which are important for the BCS business and its competitive position are shared with Cochlear, which may be able to exploit this proprietary technology and confidential information at the expense of the BCS business, or result in a reduction of the Parties' incentives to compete.

7.60 Demant confirmed that it would not transfer to Cochlear any of the IPR relating to the BCS business (whether shared with the CI business or not)[593] and there would be [✂] on the ability of the BCS business to use those or license them to other competitors if it chose to do so. [594]

7.61 Demant also submitted that the shared IPR which it proposes to license to Cochlear is not competitively sensitive or otherwise significant in a way that could be used to undermine the future competitive position of Demant's BCS business or the effectiveness of the remedy. To address our concerns that Cochlear's access to the licensed IPR might harm the competitive position of the BCS business, we sought further detail on all of the IPR that might be licensed. Demant explained that the licences relate to technology that is already in use in the Demant CI product. Demant said that it is already possible for the IPR to be downloaded and understood by third parties. In addition, obtaining the IPR without the design document behind it, does not

[591] Demant response to P2 s109 notice of 16 May 2023 – paragraph 1.2.
[592] Merger remedies guidance (CMA87), paragraph 5.25.
[593] Note of call with Demant, 12 June 2023, paragraph 11.
[594] Note of call with Demant, 12 June 2023, paragraph 12.

allow one to 'learn the recipe'. This is particularly so in the case of the shared IPR, which we discussed in detail with Demant, which is generic in nature.

7.62 In addition, the shared IPR would be licensed to Cochlear solely for use in the CI business being transferred and so could not be used by Cochlear, for example, in its BCS business.[595]

7.63 Having given detailed consideration to these links, we are satisfied that the proposed arrangements would not affect the ability of the BCS business to compete effectively following the separation of the two businesses for the following reasons:

(a) the provision of [✂] under the transitional agreement would be provided solely for use in the CI business transferring to Cochlear (and would not be available for use by Cochlear more widely).[596] There would not be any provision of technology or know-how to Cochlear – Demant explained that the agreement would be effectively contract manufacturing and would not provide Cochlear with any insight into the design.[597] As a transitional arrangement, we expect the scope of the supply agreement to be limited to the legacy CI customers transferring to Cochlear and would not, therefore, be likely to undermine the effectiveness of a partial prohibition remedy.

(b) The licensing of IPR would be provided solely for use in the CI business (and not be available for use by Cochlear more widely).[598] Although the licence would not be time-limited, the IPR would continue to be owned by Demant, with Cochlear only benefiting from a licence to exploit them solely in relation to the CI business (and not be available for use by Cochlear more widely). In addition, as discussed above, the IPR is generic in nature and would not provide Cochlear with any information it could use to undermine the competitive position of Demant's BCS business. The limited scope of these licensing arrangements, would not, therefore, be likely to undermine the effectiveness of a partial prohibition remedy.

7.64 During the separation process we note that Demant would have a strong incentive to protect the BCS business which it is retaining and not to agree to terms that undermined that business in any way.

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[595] Note of call with Demant, 12 June 2023, paragraph 10.
[596] Demant response to P2 s109 notice of 16 May 2023 – paragraphs 1.2 and 3.3.
[597] Note of call with Demant, 12 June 2023, paragraph 10.
[598] Demant response to P2 s109 notice of 16 May 2023 – paragraphs 1.2 and 3.3.

7.65 Nevertheless, we recognise that there is a risk that the separation could be done in a way that would undermine the competitiveness of the retained BCS business, whether intentionally or unintentionally, or result in a softening of competition between Demant and Cochlear in relation to BCS. For this reason we will oversee the agreed terms and final forms of the transitional and licensing agreements in order to ensure that the terms of these agreements are consistent with the principles set out above and do not risk undermining the effectiveness of a partial prohibition remedy. In doing so we will ensure that nothing transfers to Cochlear that is needed by the BCS business and that in separating any assets or staff currently shared between the two businesses, the competitive position of BCS business is not weakened.

7.66 We would also require that a monitoring trustee or equivalent independent expert is appointed to assist our assessment of the separation.

7.67 The Parties would only be able to complete the transfer of the CI business to Cochlear subject to our approval of the terms of all agreements related to the separation. In the event that we do not approve the terms of the transaction, the transfer of the CI business would not be permitted, and in that case the entire Merger would be prohibited.

The capabilities and incentives of a standalone BCS business to compete

7.68 As noted at paragraph 7.40, some third parties expressed concern in relation to Demant's continued motivation to compete in the market for BCS products given its reiteration of its public commitment to exit hearing implants, since the announcement of the Merger.

7.69 As part of our remedies assessment, we sought evidence from Demant in relation to its future plans and motivations for the BCS business as a strong competitive force.

7.70 Demant provided product roadmaps, developed by the BCS business's leadership team (operating below the Demant board level), which included plans for the BCS business over the coming years. These were consistent with documents provided during the course of our investigation, showing that the BCS business is planning for the future and incentivised to ensure strong financial performance. A document produced in August 2022, following the announcement of the Merger, demonstrates the BCS business's leadership team has ambitious product development strategies, and is planning for a range of future scenarios.[599] We note that the leadership of the BCS business

[599] Demant's response to P2 s109 notice of 10 January 2023, Q 11, [✂].

has delivered strong results since the announcement of the Merger, including sales performance for Q1 2023 being up [✂]% as compared to Q1 2022, noted to be partially as a result of [✂].[600]

7.71 Demant also submitted plans for [✂].[601]

7.72 As noted at paragraph 7.41, several third parties said to us that there would likely be interest in the BCS business from alternative purchasers, and some third parties indicated that this would likely be a beneficial market outcome.[602] With regard to potential plans to sell the BCS business, Demant submitted that it does not have any concrete plans on a potential sale of the business to a third party.

7.73 Against the backdrop of strong financial performance and motivation within the BCS business itself (translating into successful product releases and strong sales performance), we consider that Demant has the incentive, in principle, to continue to support the BCS business in the medium term. If Demant were to pursue a sale to a third party at some point in the longer-term future, we would expect that in the interim it would operate the BCS business to maintain this performance and, therefore, that the business would continue to operate as a significant competitive force in the market for BCS products.

Conclusion on the effectiveness of partial prohibition

7.74 We have assessed the evidence provided to us relating to:

(a) The financial performance of the BCS business;

(b) Expectations and perceptions of market participants in relation to the perceived quality and brand value of Oticon Medical's products (including when discussed with reference to Oticon Medical potentially being absent from the market for CI products), ie 'revenue synergies';

(c) The potential reliance of the BCS business on the CI business as it exists today, and the impact a separation (by way of the CI business being acquired by Cochlear) might have on the BCS business going forward, ie 'cost synergies'; and

[600] Demant response to P2 s109 notice of 16 May 2023 – paragraph 8.2,
[601] Demant response to P2 s109 notice of 16 May 2023 – paragraph 8.7.
[602] Note of call with third party [✂]; Note of call with third party [✂].

(d) The potential for ongoing links between Cochlear and Demant that may impair the independence or competitive capabilities of the BCS business, following the CI business's transfer to Cochlear.

7.75 As set out above, there are possible risks in relation to these issues which could impact the effectiveness of a partial prohibition remedy (in particular, by compromising the capabilities and/or incentives of the BCS business to compete). However, we conclude:

(a) The BCS business is likely to remain financially viable, including on the basis of its most recently available financial management accounts, following a partial prohibition.

(b) Market participants with the greatest professional exposure to BCS products have told us that Oticon Medical's brand and product quality is perceived favourably and would continue to be so following a divestment of the CI business. This is borne out in its sales performance and in data we have collected in the course of our investigation, which demonstrate that many clinicians favour Oticon Medical's BCS products over those of Cochlear.[603] Submissions from Demant show that the BCS business has [✂]. During this time, the BCS business has shown strong revenue growth which has contributed to consistently profitable financial performance. We therefore consider that the BCS business, absent the CI business, is likely to have the ability to overcome any market perception barriers which may result from the lack of an offering in CI products.

(c) Based on the evidence provided to us, the current financial reliance by the BCS business on the CI business is [✂]. Even taking account of Demant's submissions from an earlier stage of our investigation in relation to additional costs which would be incurred by the BCS business following a divestment, the BCS business would have remained profitable in FY22, achieving higher profit margins than those of the Demant group.[604]

(d) There would be a transitional agreement and a longer-term licensing agreement in place between Demant and Cochlear following an acquisition of the CI business. However, provided that:

(i) the transitional arrangements are of sufficiently limited duration;

(ii) both the transitional and licensing arrangements are sufficiently limited in scope (in particular, the provision of technology and the

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[603] See paragraph 5.55.
[604] See paragraph 4.79.

licensing of IPR currently used by the CI business are solely licensed for use by the CI business (and are not available for use by Cochlear more widely), and no restrictions are placed on the BCS business or Demant); and

(iii) we can verify that the IPR being licensed is generic in nature, and sharing it with Cochlear would not provide Cochlear with competitively sensitive information that may harm the competitive position of the BCS business, we would not anticipate that the transitional and licensing arrangements would be likely to undermine the effectiveness of a partial prohibition remedy.

7.76 In addition, during the separation process Demant would have a strong incentive to preserve the competitiveness of the BCS business and so we would expect Demant not to agree to any terms that had that effect.

7.77 We therefore conclude that, subject to our assessment and approval of the terms of the separation to address the risks set out above, a partial prohibition would be an effective remedy. This partial prohibition remedy would consist of prohibiting the sale to Cochlear of the BCS business, including any of its customers, contracts, staff, IPR or assets needed by the business. This would therefore comprehensively address the SLC that we have found, by preventing the SLC from arising and, consequently, preventing any of its adverse effects from arising.

Effectiveness of the SP Remedy

Description of remedy

7.78 Shortly prior to the publication of our provisional findings, the Parties proposed a behavioural remedy, the SP Remedy, which would allow Cochlear to acquire the entirety of Oticon Medical while making certain commitments with respect to quality and price over a five-year period. As part of this, the Parties referenced a behavioural remedy accepted by the Competition Commission in 2004 (Dräger Medical AG and Hillenbrand Industries, Inc), which they considered to be appropriate by analogy.

7.79 Under the SP Remedy:[605]

(a) Cochlear would commit to providing all of Oticon Medical's existing passive bone conduction sound processors and accessories for Oticon

[605] Parties' joint submission in relation to the SP Remedy, 12 April 2023.

Medical's current and legacy passive BCS products (Cochlear would no longer provide Oticon Medical's BCS implants);

(b) Demant would commit to provide these sound processors, accessories and spare parts to Cochlear to allow Cochlear to provide Oticon Medical's BCS products to customers;

(c) Cochlear would commit to provide servicing and spare parts to recipients of Oticon Medical's BCS products;

(d) Cochlear would commit not to unilaterally increase the price of the relevant products and accessories during the term of existing framework agreements with NHS procurement bodies and not to increase the price of the relevant products or accessories for any future framework agreements that arise within the five year term (apart from an allowance for inflation);

(e) Cochlear would appoint an external 'monitoring trustee' to review these commitments and ensure compliance with these obligations; and

(f) Cochlear would write to clinics annually to remind them of the commitments (which will also be available on the CMA's website).

Views of the Parties and third parties

Views of the Parties

7.80 Cochlear expressed a preference for partial prohibition, and urged the CMA to approve this as quickly as possible.[606] Cochlear submitted that the SP Remedy was a 'valid fall-back' in the eventuality of Demant exiting the BCS business, referencing Demant's continued public commitments to this effect since the publication of the Remedies Notice.[607] Cochlear did not provide views in relation to this remedy in any detail. Demant stated that this remedy [✂].[608]

Views of third parties

7.81 We received mixed responses from third parties relating to the SP Remedy, with the majority expressing some concerns.

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[606] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 4.
[607] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 4.
[608] Transcript of Demant response hearing, 10 May 2023, page 35, lines 1-3.

(a) Three third parties raised concerns that this remedy would enable Cochlear to take advantage of a monopolistic position and concluded that it would be ineffective.[609]

(b) One third party concluded that the remedy would likely be effective if the CMA ensured there were robust safeguards relating to pricing and other factors. This third party expressed concern that prices may 'hike significantly' after the five year period, and speculated that Cochlear may be able to divert users to Cochlear brands as opposed to investing in developing the Oticon Medical BCS technology. [610]

(c) Another third party said it was satisfied that the remedy would likely be effective.[611]

(d) A further third party submitted that any behavioural remedy should be adapted to (i) facilitate future competitors' entry into the field for BCS products, and (ii) ensure compatibility, so that future entrants and existing market players are able to provide current BCS patients with sound processors which are compatible with competitors' implants (thereby incentivising innovation in sound processors). This third party ultimately concluded, however, that allowing the transaction to proceed (especially without measures to facilitate entry) would be a 'sad story' for patients and clinicians.[612]

(e) Five out of six submissions from NHS clinicians expressed concern in relation to the SP Remedy. One respondent referenced their experience of the BCS market prior to Oticon Medical's entry, stating that it was 'very restricted', and that Cochlear were able to 'control' 'how and what' the NHS could do.[613] Another respondent said that the SP Remedy may be able to be effective (giving it a score of 3/5), but noted that the negative market impacts could be 'significant and drastic' if Cochlear were to face no competition going forward.[614] A further respondent described the proposed remedy as 'very ineffective', saying that Cochlear may be able to 'baby sit' the Oticon Medical range and stop production after the five year period, removing Oticon Medical's products from the market in the long term.[615] Another respondent did not support the 'remedy compromise' and said that companies competing in a market better

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[609] Note of call with third party [✂]. Note of call with third party [✂]. Note of call with third party [✂].
[610] Note of call with third party [✂].
[611] Note of call with third party [✂].
[612] Note of call with third party [✂].
[613] Response to the CMA questionnaire to clinics, May 2023, [✂].
[614] Response to the CMA questionnaire to clinics, May 2023 [✂].
[615] Response to the CMA questionnaire to clinics, May 2023 [✂].

incentivises innovation, competitive pricing and choice for patients.[616] A further respondent to the Remedies Notice said it believed that any behavioural remedy would not be in the best interests of patients or the NHS, and – in particular – this remedy was not suitable for the market for BCS products, which develops rapidly.[617]

Effectiveness of the SP Remedy

7.82 As noted at paragraph 1.16, the CMA will generally only select behavioural remedies as the primary source of remedial action where one or more of the following apply: [618]

(a) divestiture and/or prohibition is not feasible, or the relevant costs of any feasible structural remedy far exceed the scale of the adverse effects of the SLC;

(b) the SLC is expected to have a relatively short duration; or

(c) behavioural measures will preserve substantial RCBs that would be largely removed by structural remedies.

7.83 We do not consider any of these factors to be present in this case. We further consider that the process of rivalry between separate competitors is a more effective driver of innovation, quality improvements, and competitive pricing (the latter of which may increase in a dynamic and innovative market).

7.84 In addition, any behavioural remedy, including the SP Remedy, would require a material degree of oversight and enforcement by the CMA, and potentially other regulators, and/or could give rise to dispute resolution proceedings between the Parties, increasing the costs of the remedy and reducing its likely effectiveness.

7.85 We therefore conclude that the SP Remedy would not be effective in addressing the SLC that we have found, by remedying, mitigating or preventing the SLC and/or any of its resulting adverse effects.

Conclusion on remedy effectiveness

7.86 Based on the evidence provided to us and assessed above, we have concluded that either a full prohibition or a partial prohibition remedy would be

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[616] Response to the CMA questionnaire to clinics, May 2023 [✂].
[617] University Hospitals Plymouth NHS Trust response to Remedies Notice.
[618] Merger remedies guidance (CMA87), paragraphs 3.48 and 7.2.

effective to comprehensively address the SLC and any of its resulting adverse effects that we have found.

7.87 We have found that the SP Remedy would not be effective in addressing the SLC and/or any of its resulting adverse effects that we have found.

Proportionality

7.88 In order to be reasonable and proportionate, the CMA will seek to select the least costly remedy, or package of remedies, of those remedy options that it considers will be effective. If the CMA is choosing between two remedies which it considers will be equally effective, it will select the remedy that imposes the least cost or that is least restrictive. In addition, the CMA will seek to ensure that no remedy is disproportionate in relation to the SLC and its adverse effects.[619]

RCBs

7.89 In conducting this proportionality assessment, we would first consider whether there are any RCBs which would be preserved or foregone under each of the remedies that we have found would be effective, before considering the other factors relevant to proportionality. RCBs that will be foregone due to the implementation of a remedy may be considered as costs of that remedy.[620]

7.90 In the course of our remedies consultation process, the Parties and third parties have not made any submissions to us which describe RCBs within the meaning of the Act,[621] namely benefits to customers in the form of lower prices, higher quality or greater choice of goods or services in any UK market, or greater innovation in relation to such goods or services, which:

(a) may be expected to accrue within a reasonable period as a result of the creation of the relevant merger situation (in this case, the Merger); and

(b) are unlikely to accrue without the creation of that situation or a similar lessening of competition.[622]

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[619] Merger remedies guidance (CMA87), paragraph 3.6.
[620] Merger remedies guidance (CMA87), paragraphs 3.10 and 3.16.
[621] The merger parties will be expected to provide 'convincing evidence' regarding the nature and scale of RCBs that they claim to result from a merger and to demonstrate that these fall within the Act's definition of RCBs (Merger remedies guidance (CMA87), paragraph 3.20).
[622] Section 30(3) of the Act.

Proportionality assessment

7.91 In paragraphs 7.78 and 7.79 we summarised our conclusion that both full and partial prohibition would be effective in comprehensively addressing the SLC and any of its resulting adverse effects that we have found.

7.92 We set out below our assessment of, and conclusions on the proportionality of both full and partial prohibition as effective remedies.

Framework for the assessment of proportionality of merger remedies

7.93 As part of the assessment of the proportionality of remedies, we consider whether there are any relevant costs associated with the effective remedy options identified. When considering relevant costs, the CMA's considerations may include (but are not limited to):[623]

(a) distortions in market outcomes;

(b) compliance and monitoring costs incurred by the Parties, third parties, or the CMA; and

(c) the loss of any RCBs which are foregone as a result of the remedy.

7.94 The CMA will generally attribute less significance to the costs of a remedy that will be incurred by the merger parties than the costs that will be imposed by a remedy on third parties, the CMA or other monitoring agencies.[624]

Views of the Parties

7.95 Demant submitted that a partial prohibition would be more reasonable and proportionate, and less costly, than full prohibition.[625] Demant noted that the SLC provisional finding related only to the supply of BCS products in the UK, and as such a partial prohibition would remove the concern identified.[626]

7.96 Cochlear expressed a preference for partial prohibition and urged the CMA to approve this as quickly as possible.[627] Cochlear told us that Oticon Medical's CI patients 'urgently need reassurance that their interests will be protected'.[628]

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[623] CMA87, paragraph 3.10.
[624] CMA87, paragraph 3.8.
[625] Demant response to the Remedies Notice, 4 May 2023, paragraph 1.4.
[626] Demant response to the Remedies Notice, 4 May 2023, paragraphs 1.4(a), 1.4(d).
[627] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 4.
[628] Cochlear response to the Remedies Notice, 4 May 2023, paragraph 6.

Costs of the remedy and specificity to the SLC

7.97 For the reasons discussed in our assessment of effectiveness, we consider that both a full and a partial prohibition would largely preserve the structure of the market for BCS products and the competitive dynamics within it. Further, neither a full nor partial prohibition would (i) create significant risk of distortion in market outcomes, nor (ii) involve substantial compliance or monitoring costs. However, as the SLC is limited to the market for BCS products, preventing the transfer of the CI business may impose a disproportionate cost on the Parties, to the extent that a partial prohibition would be equally effective as a full prohibition. As we have concluded that the BCS and CI businesses can be separated without materially harming the competitive capabilities of the BCS business, we consider that a full prohibition would impose unnecessary costs on the Parties and, therefore, a partial prohibition would be more proportionate.

7.98 We acknowledge that there are likely to be some costs associated with a partial prohibition, such as the need (in a transitional period) for an ongoing relationship between the two key competitors in the market for BCS products, while Demant supports the CI business's transfer to Cochlear. As outlined below, in order to ensure that the effectiveness of a partial prohibition remedy is not undermined, we would therefore maintain oversight of any transfer of the CI business to Cochlear in the event of a partial prohibition.

Conclusion on choice of remedy

7.99 On the basis of the above assessment, we conclude that a partial prohibition of the Merger is the least costly or restrictive remedy out of the remedies that we consider to be effective in addressing the SLC that we have found.

Remedy implementation

7.100 Having identified our preferred remedy, we now consider how it should be implemented.

7.101 The CMA has the choice of implementing any final remedy decision either by accepting final undertakings from the Parties, or by making a final order.[629] The CMA will consult the Parties and other parties affected by the remedy in determining the required final undertakings or final order, including a period of formal public consultation, as specified in schedule 10 of the Act.

[629] Sections 82 and 84 of the Act.

7.102 The CMA is subject to a statutory deadline of 12 weeks following its final report to accept final undertakings or to make a final order. This period may be extended once by up to six weeks if the CMA considers there are special reasons for doing so.[630]

7.103 In line with the CMA's Remedies Guidance, Cochlear would be prohibited from subsequently acquiring the assets of the BCS business or acquiring any material influence over them. The CMA will normally limit this prohibition to a period of ten years[631] and we have found no compelling reason to depart from the Remedies Guidance in this case by seeking a shorter or longer prohibition period.

7.104 In order to ensure that the effectiveness of the remedy is not undermined, we will need to have oversight of relevant aspects of the sale of the CI business to Cochlear (for example, reviewing transaction documents and transitional arrangements before execution). We will also require that the Parties appoint a monitoring trustee or equivalent independent expert, approved by us, to oversee the separation process.

Conclusion on remedies

7.105 We conclude that a partial prohibition of the Merger, preventing the sale of the BCS business to Cochlear, with the separation overseen by us to address the risks we have identified, is the least costly or restrictive remedy out of the remedies that we consider to be effective to comprehensively address the SLC and any of its resulting adverse effects that we have found.

7.106 As noted above, the terms of the separation process and sale of the CI business will require our approval before the transaction may complete.

[630] Section 41A(2) of the Act.
[631] Merger remedies guidance (CMA87), paragraph 5.10.