ANTICIPATED ACQUISITION BY STRYKER CORPORATION OF WRIGHT MEDICAL GROUP N.V.

Decision on relevant merger situation and substantial lessening of competition

ME/6870/19

The CMA's decision on reference under section 33(1) of the Enterprise Act 2002 given on 30 June 2020. Full text of the decision published on 24 July 2020.

Please note that [✂] indicates figures or text which have been deleted or replaced in ranges at the request of the parties or third parties for reasons of commercial confidentiality.

SUMMARY

1. On 4 November 2019, Stryker Corporation (**Stryker**) agreed to acquire, through its wholly owned subsidiary, Stryker B.V., all of the outstanding ordinary shares of Wright Medical Group N.V. (**Wright**) (the **Merger**). Stryker and Wright are together referred to as the **Parties** and, for statements referring to the future, as the **Merged Entity**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that each of Stryker and Wright is an enterprise; that these enterprises will cease to be distinct as a result of the Merger; and that the share of supply test is met. Accordingly, arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

3. Stryker and Wright are both globally active suppliers of medical devices. The Parties overlap in the supply of several types of orthopaedic medical devices in the UK, including total ankle replacement prostheses products, which comprises the primary area of overlap between the Parties in the UK. Total ankle replacement prostheses refer to prosthetic components used in elective surgical procedures to treat arthritis by replacing the damaged articular surfaces of the human ankle joint. The CMA assessed the impact of the

Merger on the supply of total ankle replacement prostheses products in the UK.

4. On 12 June 2020, the Parties indicated that they believed that the test for reference was met on the basis that the Merger raises a realistic prospect of a substantial lessening of competition (**SLC**) arising from horizontal unilateral effects in the supply of total ankle replacement prostheses products in the UK. The Parties requested that the CMA accelerate the Phase 1 timetable and reach a decision on the SLC ahead of the CMA's statutory deadline for issuing its Phase 1 decision. As part of their request, the Parties waived their procedural rights at Phase 1 (including their right to an issues meeting and for the case to be discussed at a case review meeting).

5. The CMA has concluded that it has evidence objectively justifying its belief that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of total ankle replacement prostheses products in the UK, thereby justifying its acceleration of a Phase 1 decision. The Parties have an extremely high combined share of supply of [90-100]% by revenue in the supply of total ankle replacement prostheses products in the UK, with a significant increment of [10-20]% arising as a result of the Merger. Wright is by far the largest firm in the market having a share of supply of [70-80]%, and the Merger will remove its only sizeable competitor in the UK with a share of above 10%.

6. The CMA found there is a high degree of competitive interaction between the Parties, as evidenced by third party views, and that the Merger will remove the only sizeable constraint on Wright in an already highly concentrated market and eliminate a significant competitive force in Stryker. As noted above, the CMA found that the Merged Entity would face no other significant competitors post-Merger; its next largest competitor, Corin, would have a significantly smaller share of only [5-10]% and all remaining competitors would have shares of less than [0-5]%. This is consistent with the feedback received from third parties on the Merger. The CMA therefore found that other competitors posed only a weak competitive constraint, both individually and in aggregate. The CMA also found that entry and/or expansion would not be sufficiently timely, likely and sufficient to offset the effects of the Merger on competition.

7. The CMA also assessed whether the Merger may give rise to competition concerns as a result of horizontal unilateral effects arising from the supply in the UK of: (i) finger joints arthroplasty products; (ii) foot plating products; (iii) hammertoe arthrodesis products; and (iv) synthetic bone graft substitutes. In light of the Parties' moderate market position and the competitive constraint from other suppliers that the Merged Entity will continue to face in these

markets, the CMA does not believe that the Merger gives rise to a realistic prospect of an SLC in any of these markets.

8. The CMA also assessed whether the Merger leads to horizontal unilateral effects from a loss of potential competition in the supply of shoulder implants in the UK by reference to: (i) whether Stryker would be likely to enter the market in the absence of the Merger; and (ii) whether this would lead to greater competition. However, the CMA did not find a realistic prospect that the Merger would give rise to an SLC on this basis as even if Stryker did enter the market, the Merged Entity would continue to be constrained by several strong competitors.

9. The CMA therefore believes that it is or may be the case that (i) arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation; and (ii) the creation of that situation may be expected to result in an SLC as a result of horizontal unilateral effects in the supply of total ankle replacement prostheses products in the UK.

10. The CMA is therefore considering whether to accept undertakings under section 73 of the Enterprise Act 2002 (**the Act**). Stryker has until 7 July 2020 to offer an undertaking to the CMA that might be accepted by the CMA. If no such undertaking is offered, then the CMA will refer the Merger pursuant to sections 33(1) and 34ZA(2) of the Act.

ASSESSMENT

Parties

11. Stryker is a publicly listed medical technology company traded on the New York Stock Exchange. Stryker segments its activities in three business units: (i) Orthopaedics, (ii) MedSurg, and (iii) Neurotechnology & Spine. Stryker's UK turnover in the financial year 2019 was approximately £[✂] (USD[✂]).

12. Wright is a Dutch company listed on the NASDAQ Global Select Market. Wright is a global medical device company focused on extremities and biologics products. Wright's UK turnover in the financial year 2019 was approximately £[✂] (USD[✂]).[1]

[1] This does not include Wright's revenues for Northern Ireland, which Wright estimates to be [✂]. Wright's Irish revenues are approximately [✂].

Transaction

13. The Merger relates to the purchase by Stryker through its wholly owned subsidiary, Stryker B.V., of all outstanding ordinary shares of Wright for $30.75 per share, in cash (approximately £4.2[2] billion in total) pursuant to a share purchase agreement dated 4 November 2019.

14. The Merger is also the subject of review by the US Federal Trade Commission and by the competition authority of Saudi Arabia.

Procedure

15. On 12 June 2020, the Parties submitted that the test for reference under section 33 of the Act is met (ie that the CMA believes that there is a realistic prospect that the Merger will give rise to an SLC). The Parties requested that the CMA's review of the Merger be accelerated for a Phase 1 decision finding that the Merger raises a realistic prospect of an SLC arising from horizontal unilateral effects in the supply of total ankle replacement prostheses products in the UK.

16. As part of the request, the Parties waived their procedural rights during the Phase 1 investigation and agreed that the CMA would not be required to follow all of the procedural steps it normally follows in cases that raise more complex or material competition issues (including, the discussion of the case with the Parties at an issues meeting, and the case team conducting a case review meeting).

17. The CMA has considered the Parties' request and, for the reasons set out in in this decision, finds that the Merger gives rise to a realistic prospect of an SLC in one or more markets in the UK. The CMA has also had regard to its administrative resources and the efficient conduct of the case. In light of these considerations, the CMA decided that in this case it was appropriate to proceed with an accelerated Phase 1 timetable, reaching a decision ahead of its statutory 40 working day deadline.

[2] Stryker's press release dated 4 November 2019 in relation to the transaction refers to 'total equity value of approximately $4.0 billion and a total enterprise value of approximately $5.4 billion (including convertible notes)' (see https://investors.stryker.com/press-releases/news-details/2019/Stryker-announces-definitive-agreement-to-acquire-Wright-Medical/default.aspx). The CMA applied the USD/GBP exchange rate of the Bank of England for 4 November 2019 (0.7748) and the average rate for 2019 (0.7839) to the latter figure of $5.4 billion to calculate its rounded figure of £4.2 billion.

Jurisdiction

18. Each of the Parties is an enterprise. As a result of the Merger, Stryker will obtain sole control over Wright and, accordingly, Stryker and Wright will cease to be distinct.

19. The Parties overlap in the supply of, *inter alia*, total ankle replacement prostheses products in the UK, where they have a combined share of supply of [90-100]%, with an increment of [10-20]% brought about by the Merger.[3] The CMA therefore believes that the share of supply test in section 23 of the Act is met.

20. The CMA believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

21. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 20 May 2020 and the statutory 40 working day deadline for a decision is therefore 15 July 2020.

Counterfactual

22. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual). For anticipated mergers the CMA generally adopts the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. However, the CMA will assess the merger against an alternative counterfactual where, based on the evidence available to it, it believes that, in the absence of the merger, the prospect of these conditions continuing is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than these conditions.[4]

23. The Parties submitted that the Merger should be assessed against the prevailing conditions of competition. The available evidence indicates that the development and sale of orthopaedic medical devices is a relatively dynamic area in which all suppliers invest in R&D to improve or develop new or existing products to some extent (including, in the form of pre-operative technologies), though some product areas (such as shoulder implants) appear to more dynamic than others. Both Parties refer in their internal documents to

[3] See Table 1.
[4] *Merger Assessment Guidelines* (OFT1254/CC2), September 2010, from paragraph 4.3.5. The *Merger Assessment Guidelines* have been adopted by the CMA (see *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, Annex D).

various investment and R&D plans,[5] and third party feedback to the CMA's market investigation indicates several suppliers are developing robotics and other technologies in relation to various orthopaedics products. The CMA has not received any evidence to support an alternative counterfactual.

24. Therefore, the CMA believes the prevailing conditions of competition to be the relevant counterfactual. Given the relatively dynamic nature of various orthopaedic medical device markets, the CMA considers that the prevailing conditions includes an environment where the Parties (and other suppliers) would have continued with levels of investment and innovation commensurate with their pre-Merger business plans.

Frame of reference

25. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The boundaries of the market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merging parties from outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[6]

26. The Parties overlap in the supply of several orthopaedic medical device products in the UK. The CMA considered the impact of the Merger on the supply in the UK of: (i) total ankle replacement prostheses products (ii) finger joints arthroplasty products; (iii) foot plating products; (iv) hammertoe arthrodesis products; and (v) synthetic bone graft substitutes, and on whether the Merger would lead to a loss of actual potential competition in the supply of shoulder implants.[7]

27. The CMA has considered the appropriate frames of reference for each of these areas below.

Product scope

Total ankle replacement

28. Total ankle replacement (**TAR**) prostheses products consist of prosthetic components used in elective surgical procedures to replace the damaged

[5] Annex 035 to final merger notice submitted by the Parties on 18 May 2020 (**FMN**), '[✂]'; see also Annex 695 to FMN '[✂]' and Annex 006 to FMN '[✂]'.
[6] *Merger Assessment Guidelines*, paragraph 5.2.2.
[7] The Parties also overlap in a number of other types of orthopaedic medical devices. However, given the Parties' relatively small UK presence in these areas, the CMA does not consider these overlaps further in this decision.

articular surfaces of the human ankle joint. These can have a three-piece design with mobile bearing or a two-piece design with fixed bearing.

29. The Parties submitted that the market definition should be that of TAR prostheses,[8] given that both mobile and fixed bearing prostheses can be used for all applications and patients.[9] The Parties further submitted that this market definition is also in line with the European Commission's previous decisional practice which, despite not dealing with TAR specifically, considered separate markets for joint reconstructive implants per anatomic lid (knee, elbow, hip, etc).[10]

30. The evidence received by the CMA also indicates that there is demand-side substitutability between mobile and fixed bearing TAR prostheses:

    (a) Customer responses broadly indicated that, while some surgeons may have a specific preference for one type of bearing design over the other, both types can generally be used interchangeably.

    (b) Competitor responses all indicated that mobile and fixed bearing TAR prostheses are substitutable in terms of use applications. A few competitors noted that there may be some barriers for customers to switch, such as training and familiarity with the type of design. However, the CMA considers that while this indicates that customers' preferences for one type over the other may be 'sticky' to some extent, it does not rule out that customers might be willing to receive further training and switch between both types if the relative competitive offering changes.[11]

31. The CMA did not receive any evidence to suggest that that the frame of reference should be widened to include any other types of products. The CMA therefore considers that the appropriate product frame of reference is the supply of TAR prostheses products.

[8] FMN, paragraph 196.
[9] FMN, paragraph 198.
[10] Eg case No COMP/M.7265 *Zimmer Holdings/Biomet* (***Zimmer/Biomet***), paragraphs 254-257 *(*with reference to Case No COMP/M.3146 Smith & Nephew/Centerpulse, paragraph 10). Also see FMN, paragraph 195.
[11] This is also consistent with an external European market study submitted by Stryker, which indicates that surgeons in Europe have been changing their preferences between mobile bearing and fixed bearing TAR prostheses over time, suggesting that surgeons can switch between both types of product in line with the understanding that they can both be used for the same applications - see Annex 197 to FMN, 'Orthopaedic Extremity Devices Market Analysis', November 2017, page 47.

Finger joints arthroplasty

32. Finger joints arthroplasty products consist of implants and prostheses used to replace, remodel or realign musculoskeletal joints in the fingers (excluding the thumb) by orthopaedic surgery.

33. The Parties submitted that the appropriate frame of reference for finger joints included arthroplasty products for basal thumb and wrist joints (thereby defining a market for hand and wrist arthroplasty), on the basis that suppliers tend to offer arthroplasty products for all three types of hand and wrist joints, and hospitals tend to source all these products from the same supplier.[12]

34. However, the available evidence does not support the Parties' frame of reference. The CMA notes that there is no demand-side substitutability between joint arthroplasty products for the three different anatomies (fingers, basal thumb and wrist). With regards to supply-side substitutability, the CMA notes that in contrast with the Parties' submission, the vast majority of the Parties' competitors in the supply of finger joints arthroplasty products in the UK stated that they are not active in the supply of arthroplasty products for other types of hand and wrist joints. The CMA considers this to be indicative of the conditions of competition for each product type being different. Furthermore, competitor responses indicated that it would be difficult for a supplier of basal thumb or wrist joints arthroplasty products to start supplying finger joints arthroplasty products and gain a market share of 5% or more due to high regulatory, marketing and training costs. One competitor also indicated that it would be difficult to switch production capacity between different types of hand and wrist arthroplasty products due to differences in equipment and manufacturing processes, as well as required organisational changes and potential financial and commercial risks.

35. The CMA therefore considers that the evidence does not support widening the product frame of reference for finger joints arthroplasty products to include basal thumb and wrist joints arthroplasty products, and that the appropriate product frame of reference is the supply of finger joints arthroplasty products.

Foot plating

36. Plating systems are internal fixation devices used for surgical application of devices/implants that physically hold a broken bone together. Foot plating systems are used in the treatment of fractures in bones of the feet.[13]

[12] FMN, paragraphs 177-178.
[13] FMN, paragraph 187.

37. The Parties submitted that the narrowest product market defined by the European Commission is foot plating systems and that there are no elements justifying a further sub-segmentation within the market for foot plating systems.[14]

38. The evidence the CMA received is consistent with there being a distinct frame of reference for foot plating systems. There is no demand-side substitutability between plating systems for different anatomies, and feedback from competitors indicated that there is limited supply-side substitutability. Although competitors indicated that most suppliers of foot plating products (including the Parties) also supply ankle plating products, and that customers tend to buy ankle and foot plating products from the same supplier, most competitors indicated that switching production capacity from ankle to foot plating is difficult and costly. Additionally, several competitors indicated that foot plating is considered a more specialised market.

39. Therefore, the CMA considers that the appropriate product frame of reference is foot plating, and that this should not be widened to include ankle plating or plating products for other anatomies.

Hammertoe arthrodesis

40. The hammertoe arthrodesis segment consists of intramedullary implants used during corrective surgery of a hammertoe deformity to align the toe in the cardinal planes and relieve the patient's pain.

41. The Parties submitted that the narrowest possible market definition is that of hammertoe arthrodesis implants, and that further sub-segmentation is not warranted. The Parties noted that hammertoe arthrodesis implants vary by design but that all hammertoe arthrodesis implants have the same functionality and use.[15] The Parties also submitted that hammertoe arthrodesis implants are low-value products that are typically not separately sourced by contract and are often sold/purchased together with cannulated screws, as a hammertoe can also be operated on through fixation surgery using cannulated screws.[16]

42. The CMA believes that the available evidence indicates further segmentation of hammertoe arthrodesis implants (by design or otherwise) is not warranted. Some customer and competitor responses confirmed that hammertoe arthrodesis implants may vary by design but did not provide a consistent segmentation based on design. Furthermore, while customer responses

[14] FMN, paragraph 189.
[15] FMN, paragraph 210, 211.
[16] FMN, paragraph 209.

generally indicated that their choice of hammertoe arthrodesis products is based on surgeon's preferences and the specific needs of the patient, none of them indicated that there are any specific types that are not substitutable. Similarly, competitors largely indicated that hammertoe arthrodesis implants with different designs could be used for the same end-use.

43. The CMA also believes it is not appropriate to widen the product frame of reference for hammertoe arthrodesis products to include cannulated screws. Responses to the CMA's market investigation indicated that both customers and competitors consider hammertoe arthrodesis products and cannulated screws to be distinct and non-substitutable products.

44. The CMA therefore considers that the appropriate product frame of reference is the supply of hammertoe arthrodesis products.

Synthetic bone graft substitutes

45. Synthetic bone graft substitutes are laboratory-manufactured bone graft substitutes (**BGS**) that emulate the scaffolding function of the bone. They can be used for the treatment of a bone defect.

46. The Parties submitted that the product scope should be widened to also include other types of BGS (traditional allografts, de-mineralized bone matrix, cellular allografts and growth factors), on the basis that they can be used interchangeably with some minor deviations based on regulatory approval or combined with one another.[17]

47. The CMA received mixed views on the substitutability of other types of BGS with synthetic BGS. With regards to demand-side substitutability, feedback from competitors indicated that some types of non-synthetic BGS (mainly traditional allografts, de-mineralized bone matrix and cellular allografts) could be used in place of synthetic BGS. Similarly, a few customers mentioned traditional allografts and de-mineralized bone matrix (DBM) as alternatives (although not as close alternatives) to the Parties' products.

48. With regards to supply-side substitutability, competitors' responses indicated that it would be difficult for a supplier of non-synthetic BGS to start supplying synthetics and gain a market share of 5% or more, mainly due to regulatory, R&D, marketing and training costs. Similarly, most competitors noted that switching production capacity from non-synthetic to synthetic BGS may be difficult and costly.

[17] FMN, paragraph 254.

49. In light of the distinct features of synthetic BGS and the mixed evidence on substitutability, the CMA has assessed the impact of the Merger on the narrowest plausible market definition for the supply of synthetic BGS, while also taking into account out-of-market constraints from non-synthetic BGS in the competitive assessment, where relevant.

Shoulder implants

50. The shoulder is the most mobile joint in the body, and it is a complex ball-and-socket joint. In the shoulder, the rounded end of the upper arm bone (humerus) glides against a dish-like socket (glenoid) in the shoulder blade (capsula). A shoulder implant generally consists of three basic components: (i) a humeral stem that fits into the proximal intramedullary canal of the humerus, (ii) a humeral head that connects to the humeral stem, and (iii) a glenoid component, against which the humeral head articulates (or moves).

51. The Parties did not make any submissions regarding the appropriate product frame of reference for shoulder implants. The European Commission has considered (but not defined) a distinct product market for shoulder implants as well as narrower markets for each of the three pathologies: fracture, degenerative and reverse implants. The European Commission considered that further sub-segmentation based on the level of intervention (total, partial, stemless, resurfacing or revision) was not appropriate.[18]

52. The CMA received mixed views on the substitutability between different types of shoulder implants (whether based on pathology, or by level of intervention). The Parties each use different categorisations for their shoulder implant offerings.[19] Competitors' views on the segmentation of the shoulder implants market were also mixed and differed from those of both Parties. However, the CMA notes that, consistently with the European Commission's consideration of segmentation by pathology, competitors consistently identified fracture and reverse shoulder implants as distinct categories. Customers that responded to the CMA's market investigation did not, however, provide clear views on the extent to which different types of shoulder implants (whether by type of pathology or intervention-type) are substitutable for one another.

53. The evidence indicates that supply-side substitutability between different types of shoulder implant (whether based on pathology, or by level of intervention) is likely to be limited. Competitors' responses indicated that significant resource (including collection of clinical data, training (internal and

[18] Case No COMP/M.6266, *Johnson & Johnson/Synthes* (***Johnson & Johnson/ /Synthes***), paragraphs 94-95, and *Zimmer/Biomet*, paragraphs 254-257.
[19] Wright classifies its shoulder implants between [✂]. (Source: Wright's response to CMA's email of 23 April 2020, paragraphs 1.1 and 1.2). By contrast, Stryker mentioned the following types of shoulder implants in its submission: [✂]. (Source: Parties' submission: '[✂] ', 29 May 2020, paragraphs 4 and 32).

external), marketing and administrative resources) were required for a supplier of any one type of shoulder implant to start supplying another type, with challenges involved in switching production capacity even for those competitors that already supply different types of shoulder implants.

54. Given the lack of competition concerns in this case under any frame of reference, it was not necessary for the CMA to conclude on whether the frame of reference should be segmented by pathology and/or by intervention type.

Geographic scope

55. The Parties submitted that the markets for upper extremities (including finger joints arthroplasty)[20] and lower extremities (including foot plating, total ankle replacement and hammertoe arthrodesis)[21] are national in scope based, *inter alia,* on differing national reimbursement regimes, the national scale of purchasing patterns by hospitals, and national sales organisations of competitors and price level differences per country.[22] With regards to BGS, the Parties submitted that given the small market position of the Parties and the highly fragmented competitive landscape, the geographic scope of the market can be left open.[23]

56. The CMA notes that the Parties' arguments as to the national geographic frame of reference are consistent with the European Commission's decisional practice.[24] The CMA did not receive any evidence to suggest that the market might be narrower or wider than UK-wide in relation to any of the product frames of reference in which it has assessed the Merger.

57. Accordingly, the CMA has considered the impact of the Merger on a UK-wide basis for each product frame of reference considered.

Conclusion on frame of reference

58. The CMA has therefore considered the impact of the Merger in the following frames of reference:

    (a) The supply of TAR prostheses products in the UK;

    (b) The supply of finger joints arthroplasty products in the UK;

    (c) The supply of foot plating products in the UK;

[20] FMN, paragraphs 179-182.
[21] FMN, paragraphs 216-219.
[22] FMN, paragraphs 180, 217, 224, 233, 240, 281.
[23] FMN, paragraph 255.
[24] See for example *Zimmer/Biomet*, paragraphs 254-257.

(d) The supply of hammertoe arthrodesis products in the UK;

(e) The supply of synthetic BGS in the UK; and

(f) The supply of shoulder implants in the UK.

59. Given the lack of competition concerns in relation to shoulder implants under any frame of reference, it was not necessary for the CMA to conclude on whether the frame of reference should be segmented by pathology and/or by intervention type.

Competitive assessment

60. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged firm profitably to raise prices or to degrade quality on its own and without needing to coordinate with its rivals.[25] Horizontal unilateral effects are more likely when the merging parties are close competitors. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC in relation to horizontal unilateral effects in the frames of reference:

(a) The supply of TAR prostheses products in the UK;

(b) The supply of finger joints arthroplasty products in the UK;

(c) The supply of foot plating products in the UK;

(d) The supply of hammertoe arthrodesis products in the UK;

(e) The supply of synthetic BGS in the UK; and

(f) The supply of shoulder implants in the UK, as a result of a loss of actual potential competition.

Horizontal unilateral effects - TAR prostheses products

61. In order to assess the likelihood of the Merger resulting in horizontal unilateral effects with respect to the supply of TAR prostheses products in the UK, the CMA considered evidence on:

(a) Shares of supply;

[25] *Merger Assessment Guidelines*, from paragraph 5.4.1.

(b) Closeness of competition between the Parties;[26] and

(c) Competitive constraints from alternative suppliers.

Shares of supply

62. The Parties estimated that they had a combined share of supply of [90-100]% in 2019 in the supply of TAR prostheses in the UK, with an increment of [10-20]%.[27] These estimates were based on their actual sales and their best internal estimates of the market size, taking into account the UK National Joint Registry and iData report.[28] The CMA calculated its own estimates based on the Parties' and their competitors' reported sales (which, being based on actual sales, is more accurate than the Parties' estimates and which are therefore given them more weight in the CMA's assessment).

Table 1: CMA's estimates of shares of supply of TAR prostheses in the UK (2019)

Segment size (£)	£[✂]
Shares of supply:	
Stryker	[10-20]%
Wright	[70-80]%
Parties' combined	**[90-100]%**
Corin	[5-10]%
Integra	[0-5]%
MatOrtho	[0-5]% (*)
Exactech	[0-5]%
Zimmer	[0-5]%

Source: Annex 231 to FMN and competitors' responses.
Note: (*) indicates that a competitor identified by the Parties did not respond to the CMA's market investigation, and therefore the CMA used the Parties' estimates for that competitor. The CMA did not include any revenue estimates for unspecified competitors grouped by the Parties as 'others' given the uncertainty around the existence of any such competitors.

63. Based on these estimates, in 2019 Wright and Stryker had shares of supply of [70-80]% and [10-20]%, respectively, resulting in a very high combined share

[26] The CMA received and reviewed a significant volume of internal documents from the Parties but did not, in the round, find these to be informative of closeness of competition in relation to any of the UK markets assessed in this decision. Both Parties typically monitor medical devices (and other suppliers) at a global or pan-European (rather than national UK) level which, in light of the specific differences in competitive conditions between different national regions in the product markets assessed in this Merger, meant the documents were not, as a rule, very informative of competition within the UK. The Parties also typically provided documents according to wider categories than the specific markets considered in this decision. The combination of these factors in the specific circumstances of this case has meant the CMA has placed limited weight on internal documents in this decision and has generally not gone on to cite these as a source of evidence on closeness of competition in this decision.
[27] Annex 231 to FMN.
[28] FMN, footnote 74.

of supply of [90-100]%. The Merger removes in Stryker Wright's only sizeable competitor with a share of above 10%. The next largest supplier, Corin, has a significantly smaller share of supply than the Merged Entity at the lower end of the range of [5-10]% by value. The shares of supply of other competitors are minimal, at [0-5]% by value.

64. Accordingly, the CMA considers that the Parties' combined shares of supply are extremely high with a significant increment resulting from the Merger. As a result, the CMA believes that the Merger raises *prima facie* competition concerns.

Closeness of competition

65. The Parties submitted that they are not close competitors in the supply of TAR prostheses products as their products and product designs are different: Stryker's product has a mobile bearing design, while Wright's product has a fixed bearing design.[29] The Parties submitted that TAR prostheses products are chosen by surgeons who do not frequently switch between mobile and fixed bearing implants (their preference for one type over the other being mostly based on training and education, as well as their surgical 'philosophy' on what makes a good TAR prostheses product).[30]

66. The CMA notes that there is a degree of differentiation between the Parties' TAR prostheses product designs but that, as outlined above at paragraph 30, these differences do not prevent surgeons from using the two products interchangeably for the same end-use applications, and that any stickiness to one particular design type is likely to be overcome by a surgeon receiving the requisite training.[31]

67. Stryker's marketing materials indicate that differences in bearing design should not be overstated as a competitive parameter. Several Stryker marketing documents compare the competitive propositions of Stryker's own mobile bearing product and other fixed design products [✂].[32]

68. Customer responses similarly indicated that there are other factors beyond bearing design that influence customer choice (such as clinical evidence, ease of use, product quality, quality of technical support and price, among others).

[29] FMN, paragraph 361.
[30] FMN, paragraphs 362-365.
[31] The Parties noted that the launch of any new TAR prostheses product (or product extension) is typically accompanied by trainings that are offered by suppliers and discussions with influential and experienced peers (FMN, paragraph 366).
[32] In addition to the flexibility to combine components in different patient-specific configurations, regulatory approval for use without cement; see Annex 114 to FMN, '[✂]', pages 1-2 and Annex 115 to FMN, '[✂]', page 1.

69. With respect to these competitive parameters, feedback from third parties indicates that overall, the Parties supply similar offerings. The majority of Stryker's customers indicated that if Stryker's TAR prostheses products had not been available, they would have purchased at least some of those products from Wright. Similarly, a significant proportion of Wright's customers indicated that they would have purchased at least some products from Stryker if Wright's were unavailable. The majority of competitor responses also identified Wright as Stryker's closest competitor in TAR prostheses products and Stryker as Wright's closest or second closest competitor.

70. Several third parties also expressed concerns about the Merger on the basis that, *inter alia*, the Merger would lead to the Merged Entity having a very high share and could lead to price increases and reduced competition in the market.

71. Accordingly, on the basis of the above, the CMA believes that the Merger will remove the only sizeable constraint on Wright in an already highly concentrated market and eliminate a significant competitive force in Stryker.

Alternative suppliers

72. The Parties submitted that post-Merger they will each continue to face intense competition from a large number of sophisticated suppliers including Integra and Zimmer as Wright's established competitors in the supply of fixed bearing TAR prostheses products, and Corin and MatOrtho as Stryker's established competitors in the supply of mobile bearing TAR prostheses products.[33]

73. As set out in paragraph 63, the CMA notes that the evidence indicates that the Parties' competitors currently provide, both individually and in aggregate, only a very limited constraint on the Parties. In particular:

    (a) All of these competitors' (Integra, Zimmer, Corin and MatOrtho) shares of supply are minimal (and with the exception of Corin (which has a small share at the lower end of [5-10]%), all fall within a [0-5]% range).

    (b) Overall, these competitors were mentioned by customers and competitors as close competitors to each of the Parties significantly less frequently than the Parties themselves.

74. With regards to recent and potential entry and expansion, the Parties submitted that Exactech recently entered the UK TAR prostheses product market, and that Integra had recently launched a new product, Cadence, which is a hybrid of fixed and mobile bearings. The Parties further submitted

[33] FMN, paragraph 375.

that FH Ortho recently launched a TAR prostheses product in France and could easily expand in the UK, and that other potential entrants include Ortho Solutions and Paragon 28.[34] However, as discussed further below from paragraph 106, there are relatively high barriers to entry in this market and the CMA does not believe that entry of expansion by third parties is likely to be sufficiently timely, likely or sufficient to mitigate any SLC arising.

Conclusion on horizontal unilateral effects

75. For the reasons set out above, the CMA believes that the Parties have a very high combined share of supply and the Merger will remove Wright's only sizeable competitor in the UK with a share of above 10%; that there is a high degree of competitive interaction between the Parties; that the Merger will eliminate a significant competitive force in Stryker; and that other suppliers pose only a limited competitive constraint (both individually and in aggregate). Accordingly, the CMA found that the Merger raises significant competition concerns as a result of horizontal unilateral effects in relation to the supply of TAR prostheses products in the UK.

Horizontal unilateral effects – finger joints arthroplasty

76. The Parties estimated that they had a combined share of supply of [30-40]% in 2019 in the supply of finger arthroplasty products in the UK, with an increment of [5-10]%. These estimates were based on the Parties' own sales, publicly available information, general market knowledge and third-party market intelligence.[35] The CMA calculated its own share of supply estimates based on the Parties' and its competitors' reported sales (which, being based on actual sales, is more accurate than the Parties' estimates and which the CMA has therefore given more weight to in its assessment).

Table 2: CMA's estimates of shares of supply of finger arthroplasty products in the UK (2019)

Segment size (£)	£[✂]
Shares of supply:	
Stryker	[5-10]%
Wright	[30-40]%
Parties' combined	**[40-50]%**
Integra	[20-30]%
Osteotec	[10-20]%
MatOrtho	[10-20]% (*)

[34] FMN, paragraph 376.
[35] FMN, paragraph 343.

KLS Martin	[0-5%] (**)

Source: Annex 202 to FMN and competitors' responses.
Note: (*) indicates that a competitor identified by the Parties did not respond to the CMA's market investigation, and therefore the CMA used the Parties' estimates for that competitor. The CMA did not include any revenue estimates for unspecified competitors grouped by the Parties as 'others' given the uncertainty around the existence of any such competitors.
(**) [✂].

77. Based on these estimates, in 2019 Wright and Stryker had a share of supply of [30-40]% and [5-10]%, respectively, resulting in a combined share of supply of [40-50]% and a relatively moderate increment of [5-10]%. Post-Merger, the Merged Entity will face three competitors with shares above 10%, the largest of these being Integra with a share of [20-30]% in 2019, followed by Osteotec ([10-20]%) and MatOrtho ([10-20]%).

78. The CMA believes the evidence shows the Parties to be relatively close competitors. Customers generally considered the Parties' finger joints arthroplasty products to be one of each other's closest alternatives. However, customers also named other competitors (including Osteotec, Integra and MatOrtho) as being similarly close alternatives, with Osteotec in particular being named as often as each of the Parties as a close alternative to each Party's product. One customer noted that Osteotec does an 'almost identical' silicone finger implant to Stryker's and Wright's.

79. The existence of strong competitors to the Parties was also supported by feedback from competitor responses, which ranked Integra as being the closest competitor to each Party's products more frequently than the other Party. Competitors also frequently ranked Osteotec among the closest alternatives to each Party's product.

80. The CMA therefore believes that while the Parties have a strong share of supply (with a relatively moderate increment arising as a result of the Merger) and that they compete relatively closely post-Merger, they will face strong competition from several other competitors with sizeable shares of supply (in particular, from Osteotec and Integra). Given the strong constraint (both individually, from Osteotec and Integra in particular, and in aggregate) from rivals post-Merger, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of finger joints arthroplasty products in the UK.

Horizontal unilateral effects – foot plating

81. The Parties submitted that their combined share of supply in 2019 was [20-30]% with a [5-10]% increment.[36] Their estimates are based on their own

[36] Annex 231 to FMN.

sales, market knowledge and market intelligence.[37] The CMA calculated its own share of supply estimates based on the Parties' and competitors' reported sales (which, being based on actual sales, is more accurate than the Parties' estimates and which are therefore given them more weight in the CMA's assessment).

Table 3: CMA's estimates of shares of supply of foot plating products in the UK (2019)

Segment size (£)	£[✂]
Shares of supply:	
Stryker	[30-40]%
Wright	[10-20]%
Parties' combined	**[40-50]%**
Ortho Solutions	[20-30]%
Johnson & Johnson	[10-20]%
Zimmer	[5-10]%
Arthrex	[5-10]%
Paragon 28	[0-5]%
Integra	[0-5]%
Smith & Nephew	[0-5]%
Medartis	[0-5]%
Acumed	[0-5]%

Source: Annex 231 to the FMN and competitors' responses.

82. Based on the above estimates, Stryker and Wright's shares in 2019 are [30-40]% and [10-20]% respectively, bringing the combined share to [40-50]% post-Merger. The next largest competitor, Ortho Solutions, has a strong share of ([20-30]%), followed by Johnson & Johnson with ([10-20]%).There is a long tail of competitors with smaller shares such as Zimmer ([5-10]%), Arthrex ([5-10]%), Paragon 28 ([0-5]%), Integra ([0-5]%), Smith & Nephew ([0-5]%), Medartis ([0-5]%) and Acumed ([0-5]%).

83. The CMA believes the evidence shows that, although the Parties compete relatively closely, other competitors also offer a close or closer alternative offering. Customer responses indicate that the Parties' products are seen as close alternatives by a limited number of customers and that other competitors such as Ortho Solutions, Johnson & Johnson, Arthrex and Zimmer were mentioned more frequently as close alternatives to the Parties' products than the Parties themselves.

[37] FMN, paragraph 293.

84. Competitors' responses indicated that the Parties are close competitors and that the Parties' offerings are largely substitutable. However, competitors also confirmed that there exists a high number of alternative suppliers in foot plating and that their products are substitutable and strong competitors to the Parties' offerings. These competitors include Johnson & Johnson, Ortho Solutions, Zimmer, Arthrex and Smith & Nephew.

85. For the reasons set out above, the CMA believes that, while the Parties have material shares of supply, their products are seen as close alternatives by only a limited number of customers and there exists a number of viable competitors to the Parties, including closer alternatives than the Parties themselves. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of foot plating products in the UK.

Horizontal unilateral effects – hammertoe arthrodesis

86. The Parties estimated that their combined share of supply for hammertoe arthrodesis in the UK was [10-20]% in 2019, with an increment of [0-5]%, based on their own best estimates.[38] The Parties further submitted that the respective share estimates of Stryker, Wright and competitors are dynamic, with new and recent entrants expected to gain share.[39] The CMA calculated its own estimates based on the Parties' and its competitors' reported sales (which, being based on actual sales, is more accurate than the Parties' estimates and which are therefore given them more weight in the CMA's assessment).

[38] Annex 231 to FMN. The Parties stated that small markets, including hammertoe arthrodesis, are not covered by reports (FMN, paragraph 318).
[39] FMN, paragraph 388.

Table 4: CMA's estimates of shares of supply of hammertoe arthrodesis (2019)

Segment size (£)	£[✂]
Shares of supply:	
Stryker	[20-30]%
Wright	[5-10]%
Parties' combined	**[30-40]%**
Ortho Solutions	[10-20]%
Smith & Nephew	[10-20]%
Arthrex	[10-20]%
Acumed	[5-10]%
Novastep	[5-10]% (*)
Integra	[5-10]%
Paragon 28	[0-5]%
Zimmer	[0-5]%
Johnson & Johnson	[0-5]%

Source: Annex 231 to FMN and competitors' responses.
Note: (*) indicates that a competitor identified by the Parties did not respond to the CMA's market investigation, and therefore the CMA used the Parties' estimates for that competitor. The CMA did not include any revenue estimates for those unspecified competitors grouped by the Parties as 'others', given the uncertainty around the existence of any such competitors.

87. Based on these estimates, in 2019 Stryker and Wright had a share of supply of [20-30]% and [5-10]% respectively, resulting in a combined share of supply of [30-40]%, with a relatively moderate increment of [5-10]% arising as a result of the Merger. Post-Merger, there will remain three competitors other than the Merged Entity with shares above 10%: Ortho Solutions ([10-20]%), Smith & Nephew ([10-20]%) and Arthrex ([10-20]%). A number of competitors with a share of supply lower than 10% will also remain post-Merger.

88. The CMA believes that the Parties compete relatively closely. Customers generally considered each Party's hammertoe arthrodesis products to be a good alternative to that of the other, but also named other competitors (including Ortho Solutions, Arthrex, Zimmer, Johnson & Johnson and Smith & Nephew), as being equally or similarly close alternatives. Ortho Solutions in particular was named as often as each of the Parties as alternatives to each Party's product, with one customer stating that Ortho Solutions' product is better than Stryker's.

89. The existence of strong competitors to the Parties was also supported by competitor responses, which ranked Johnson & Johnson as being the closest competitor to each Party's products (in addition to naming the other Party). Competitors also frequently indicated Zimmer, Ortho Solutions and Smith &

Nephew as close alternatives to each of the Parties' hammertoe arthrodesis products.

90. For the reasons set out above, the CMA believes that, while the Parties' products are seen as close alternatives by some customers, there exists a number of strong competitors to the Parties, including closer alternatives than the Parties themselves, that will continue to exert competitive pressure post-Merger. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of hammertoe arthrodesis products in the UK.

Horizontal unilateral effects – synthetic BGS

91. The Parties estimated that they had a combined share of supply of [10-20]% in 2019 in the supply of synthetic BGS in the UK, with an increment of [0-5]%. These estimates were based on the Parties' own sales, publicly available information, general market knowledge and third-party market intelligence.[40] The CMA calculated its own share of supply estimates based on the Parties' and its competitors' reported sales (which, being based on actual sales, is more accurate than the Parties' estimates and which are therefore given more weight in the CMA's assessment).

Table 5: CMA's estimates of shares of supply of synthetic BGS in the UK (2019)

Segment size (£)	£[✂]
Shares of supply:	
Stryker	[20-30]%
Wright	[5-10]%
Parties' combined	**[20-30]%**
Biocomposites	[20-30]%
Baxter	[10-20]%
Cerapedics	[10-20]% (*)
Nuvasive	[5-10]%
Bone Support	[5-10]% (*)
Johnson & Johnson	[0-5]%
Arthrex	[0-5]%
Acumed	[0-5]%
Medtronic	[0-5]%
Zimmer	[0-5]%
Exactech	[0-5]%

Source: Annex 231 to FMN and competitors' responses.

[40] FMN, paragraph 343.

Note: (*) indicates that a competitor identified by the Parties did not respond to the CMA's market investigation, and therefore the CMA used the Parties' estimates for that competitor. The CMA did not include any revenue estimates for those unspecified competitors grouped by the Parties as 'others' given the higher uncertainty around the existence of any such competitors.

92. Based on these estimates, in 2019 Stryker and Wright had a share of supply of [20-30]% and [5-10]%, respectively, resulting in a moderate combined share of supply of [20-30]%. Post-Merger, the Merged Entity will face three competitors with shares above 10%, the largest of these being Biocomposites with a share of [20-30]% in 2019, followed by Baxter ([10-20]%), Cerapedics [10-20]%. The CMA notes that there is also a tail of other competitors holding a small share of supply of between [0-5]%.

93. With respect to closeness of competition between the Parties, the CMA believes the evidence shows the Parties to be relatively close competitors. Some customers considered the Parties' synthetic BGS to be close alternatives to each other. However, customers also named other competitors (including Zimmer, Bone Support, Biocomposites and Johnson & Johnson) as being similarly close alternatives to each of the Parties' own products.

94. The existence of strong competitors to the Parties was also supported by feedback from competitors, who ranked Zimmer and Johnson & Johnson as the closest competitor to each Party's products similarly frequently than the other Party. Some competitors also ranked Baxter as each Party's closest competitor.

95. With regards to potential out-of-market constraints, a few customers also mentioned traditional allografts and DBM products as alternatives (although not close alternatives) to the Parties' products.

96. For the reasons set out above, the CMA believes that while the Parties' products are seen as close alternatives by some customers, there exists a number of strong competitors to the Parties (in particular Biocomposites and Baxter) that will continue to exert competitive pressure post-Merger. While it is possible that the Parties will also face some out-of-market constraint from traditional allografts and DBM products, the CMA considers the in-market constraint posed by competitors will provide sufficient competitive constraints to the Merged Entity.

97. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of synthetic BGS products in the UK.

Horizontal unilateral effects from the loss of actual potential competition in the supply of shoulder implants in the UK

98. Stryker is active in the supply of shoulder implants in the US (specifically, of total, reverse, fracture and short stem shoulder implants), and [✂] shoulder implants in Europe.[41] Wright is active in the supply of shoulder implants in the UK, including the types supplied by Stryker in the US, among others.[42] The CMA assessed whether the Merger leads to horizontal unilateral effects from a loss of potential competition in the supply of shoulder implants (or in any segments therein) in the UK, by reference to: (i) whether Stryker would be likely to supply shoulder implants in the UK in the absence of the Merger; and (ii) whether this would lead to greater competition, taking into account other competitors as part of its assessment.

99. Stryker submitted that, although it had [✂] shoulder implants in Europe[✂], it had [✂] following [✂].[43,44] Stryker eventually [✂].[45] An internal document dated March 2019 suggests that [✂][46] – Stryker had planned to [✂].[47]

100. The CMA notes that [✂] Stryker's [✂] decision [✂] post-dates both the point at which the Parties began contemplating the Merger in March 2019[48] and also the signing of the Merger agreement on 4 November 2019. The CMA considers that Stryker's subsequent decision [✂] may, therefore, have been taken as a result of the Merger (rather than one taken independently of it). The CMA considers that, absent the Merger, it is possible that Stryker would have [✂], expanded its shoulder implant offering to the UK.[49] The CMA also notes that Stryker is [✂].[50]

101. However, the CMA does not believe that the loss of any constraint posed by the potential entry of Stryker would give rise to a realistic prospect of an SLC in the supply of shoulder implants in the UK. Based on the CMA's estimates, Wright had a moderate [20-30]% share in the supply of shoulder implants in

[41] FMN, paragraphs 534 and 535. Specifically,
[42] Wright's response to CMA's email of 23 April 2020, paragraphs 1.1 and 1.2.
[43] The commercialisation of orthopaedics products requires regulatory approval, such as the CE mark in Europe. The Parties submitted that the product development cycle for a medical device can range from 12 to 36 months depending on scope of the project, and the process for obtaining CE mark approval itself can range from 6 to 12 months (though the Parties note elsewhere in the FMN that the regulatory submissions can take '12 to 18' months (FMN, paragraph 604)). Product approval is dependent on many factors including satisfactory bench or laboratory testing, biocompatibility, cleaning and often sterilization validation data meeting or exceeding industry quality standards and often pre-market clinical trial results. All of the design history, testing and validation data is captured in product technical files audited for maintenance of the CE certification (FMN, paragraphs 604 and 608-609).
[44] FMN, paragraph 535.
[45] Parties' submission: '[✂]', 29 May 2020, paragraph 6.
[46] Parties' submission: '[✂]', 29 May 2020, paragraph 19.
[47] Annex 297 to FMN, '[✂]', March 2019, p. 12.
[48] FMN, paragraph 15.
[49] [✂] (Stryker's response to RFI of 15 May 2020, paragraph 1).
[50] Parties' submission: '[✂]', 29 May 2020, paragraph 19. The CMA's understanding is that [✂].

the UK in 2019.[51] The Merged Entity will continue to be constrained by several strong competitors supplying shoulder implants in the UK, namely Zimmer (which will have a share of [20-30]%), as well as Johnson & Johnson (which will have a share of [10-20]%), followed by Exactech ([5-10]%) Lima ([5-10]%), Mathys ([5-10]%) and a tail of several other suppliers with shares lower than 5%.[52] The CMA does not have any evidence to indicate that Stryker's shoulder implants would pose a particularly strong competitive constraint on Wright (for example, in the form of product features or technologies) vis-à-vis the products of Wright's existing or future competitors. The CMA also notes that any entry by Stryker is not expected to take place in the immediate future due at least in part to the length of time that would be required to obtain a CE mark for its fracture and short stem shoulder implant products.

102. The market positioning reflected in these shares of supply also does not materially differ when segmented by pathology (as between degenerative, fracture and reverse implants); Wright's 2019 share remains in the same range or lower ([10-20]% in degenerative and [20-30]% in fracture and reverse), with Zimmer also maintaining large or moderate shares in the range of [40-50]%, [10-20]% and [20-30]% for degenerative, fracture and reverse shoulder implants respectively. Similarly, Johnson & Johnson will have moderate shares in the range of [5-10]%, [20-30]% and [10-20]% for degenerative, fracture and reverse shoulder implants respectively. Within the degenerative segment, Zimmer, Johnson & Johnson, Exactech and Arthrex all supply total shoulder implants in the UK.[53]

103. The existence of strong competitors in shoulder implants and in segments therein was also supported by evidence from internal documents,[54] as well as customer and competitor responses.

104. Furthermore, four competitors indicated expansion plans in the UK at least within the next five years with the launch of new versions of existing products in their shoulder portfolio and/or new types of products to expand their portfolio. Two competitors also indicated they had plans to adapt robotic-arm technology for use with shoulder implants, suggesting this is relatively dynamic market where many suppliers, in addition to the Parties, are seeking to improve or develop products.

105. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to a

[51] The CMA calculated its own estimates based on Wright's and competitors' actual sales data.
[52] Lima and Mathys did not respond to the CMA's request for data; the CMA has therefore substituted the Parties' share of supply estimates for these competitors.
[53] The CMA was not able to get consistent data on sales for total shoulder implants only. However, it was able to confirm that several players will be active in this segment post-Merger.
[54] Annex 473 '[✂]', p. 36; Annex 586 '[✂]', p.21; Annex 654 '[✂]', p. 12

loss of potential competition in the supply of shoulder implants in the UK (or any plausible segments therein).

Barriers to entry and expansion

106. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[55]

107. The Parties submitted that there are relatively low barriers to entry in most of the product markets where the Parties overlap in the UK. The Parties further submitted that the main barrier to entry for medical devices in Europe is being CE mark-certified, a process the Parties estimated to take 6-18 months from application to approval.[56] The Parties further submitted that other than obtaining the CE mark, entry into the market is straightforward: third party manufacturing exists for the majority of products, independent sales agents are commonly used throughout Europe, switching is easy[57] and trainings are routinely offered by all suppliers.[58]

108. The evidence received by the CMA from third parties however suggests that barriers to entry and expansion are relatively high in orthopaedic device product markets, though the extent of this will differ across various product markets:

(a) The majority of competitors explained that the main barriers to entry for new products are the changing European Medical Device Regulations[59] (which entails increased requirements for clinical evidence, new risk classification criteria, new vigilance reporting timescales etc) and the required regulatory approvals/CE marking which are costly and time consuming to obtain.

(b) Some third party feedback also indicates that barriers to entry may be particularly high for smaller competitors in markets such as eg foot plating or hammertoe arthrodesis products, where customers are primarily won through NHS framework agreements that come up for tender relatively infrequently, ie every 4-5 years.

[55] *Merger Assessment Guidelines*, from paragraph 5.8.1.
[56] FMN, paragraph 604, 608 and 609.
[57] FMN, paragraphs 198-201, 338, 348, 355, 387, 394, 426, 433 and 442.
[58] FMN, paragraph 367.
[59] The Medical Device Regulations will fully apply in EU Member States from 26 May 2021 (see https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr).

109. With respect to the Parties' arguments outlined at paragraph 74 above regarding potential entrants in the TAR prostheses products in the UK, the CMA did not receive evidence to suggest that entry or expansion by suppliers would be timely, likely or sufficient to prevent a realistic prospect of an SLC in the TAR prostheses product market as a result of the Merger. Given the Parties' extremely high combined share of supply in this market, any new entrant would face particularly significant barriers in establishing a successful market presence. One competitor indicated that it did not plan to enter the UK market due to the cost and time associated with the new EU Medical Device Regulations. Another competitor indicated that it has submitted an application for regulatory clearance of a TAR prostheses product that it expects to launch in the UK in the next 12-24 months.

110. For the reasons set out above, in particular, the CMA believes that entry or expansion would not be timely, likely or sufficient to prevent a realistic prospect of an SLC as a result of the Merger.

Decision

111. Consequently, the CMA believes that it is or may be the case that (i) arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation; and (ii) the creation of that situation may be expected to result in an SLC within a market or markets in the United Kingdom.

112. The CMA therefore believes that it is under a duty to refer under section 33(1) of the Act. However, the duty to refer is not exercised whilst the CMA is considering whether to accept undertakings under section 73 of the Act instead of making such a reference.[60] The Parties have until **7 July 2020**[61] to offer an undertaking to the CMA.[62] The CMA will refer the Merger for a phase 2 investigation[63] if the Parties do not offer an undertaking by this date; if the Parties indicate before this date that they do not wish to offer an undertaking; or if the CMA decides[64] by **14 July 2020** that there are no reasonable grounds for believing that it might accept the undertaking offered by the Parties, or a modified version of it.

Joel Bamford
Senior Director, Mergers, Competition and Markets Authority
30 June 2020

[60] Section 33(3)(b) of the Act.
[61] Section 73A(1) of the Act.
[62] Section 73(2) of the Act.
[63] Sections 33(1) and 34ZA(2) of the Act.
[64] Section 73A(2) of the Act.