



EUROPEAN COMMISSION
DG Competition

CASE M.7265 – ZIMMER/BIOMET

(Only the English text is authentic)

MERGER PROCEDURE REGULATION (EC) 139/2004

Article 8(2) Regulation (EC) 139/2004

Date: 30/3/2015

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Brussels, 30.3.2015
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COMMISSION DECISION

of 30.3.2015

**declaring a concentration to be compatible with the internal market and the EEA
agreement**

M.7265 - ZIMMER/BIOMET

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TABLE OF CONTENTS

1.	Introduction	2
2.	The Parties.....	3
3.	The Operation and the Concentration	3
4.	Union Dimension	3
5.	The procedure.....	4
6.	The in-depth investigation.....	5
7.	Market Definition.....	5
7.1.	Relevant Product Market.....	6
7.1.1.	Knee Implants	7
7.1.2.	Elbow Implants	28
7.1.3.	Hip Implants.....	30
7.1.4.	Shoulder Implants	35
7.1.5.	Other Products.....	37
7.2.	Relevant Geographic Market	45
7.2.1.	The views of the Notifying Party	45
7.2.2.	The Commission's Assessment	45
7.2.3.	Conclusion.....	46
8.	Competitive Assessment	47
8.1.	Legal framework	47
8.2.	Market share estimates provided by the Notifying Party.....	48
8.3.	Targeted market reconstruction during the in-depth investigation	50
8.4.	Relevance of market shares, joint reconstructive implants and other products	51
8.4.1.	Adoption of a filtering system.....	52
8.5.	General characteristics of the markets	52
8.5.1.	Role of regulatory approvals and track records	53
8.5.2.	Importance of training and local presence	54
8.5.3.	Limited role of Intellectual Property Rights	55
8.5.4.	Purchasing patterns of hospitals and pricing trends.....	55
8.6.	Knee Implants	59
8.6.1.	Overview of the market for knee implants.....	59
8.6.2.	Primary Knee Implants	60
8.6.3.	Revision Knee Implants	100
8.6.4.	Total Knee Implants.....	112
8.6.5.	Extreme Orthopaedics.....	115
8.6.6.	Hinged Knee Implants Segment.....	122

8.6.7.	Limb Salvage Segment	127
8.6.8.	Unicondylar Knee Implants	131
8.6.9.	Patello-femoral Implants	184
8.6.10.	Conclusion – Knee implants	192
8.7.	Elbow Implants	192
8.7.1.	Overview of the market for elbow implants	192
8.7.2.	Structure of the elbow implants market	192
8.7.3.	The Parties' and their competitors' products	193
8.7.4.	General Competitive Assessment	193
8.7.5.	Country-specific Competitive Assessment	208
8.7.6.	Conclusion – Elbow implants	243
8.8.	Hip Implants.....	243
8.8.1.	Overview of the market for hip implants	243
8.8.2.	The Parties' and their competitors' products	244
8.8.3.	Structure of the hip implants market.....	246
8.8.4.	General Competitive Assessment	248
8.8.5.	Country-specific Competitive Assessment	255
8.8.6.	Conclusion – Hip implants.....	267
8.9.	Shoulder Implants	267
8.9.1.	Overview of the market for shoulder implants	267
8.9.2.	The Parties' and their competitors' products	268
8.9.3.	General Competitive Assessment	269
8.9.4.	Overall Shoulder Implants	270
8.9.5.	Degenerative Shoulder Implants	273
8.9.6.	Fracture Implants	279
8.9.7.	Reverse Implants.....	280
8.9.8.	Conclusion – Shoulder implants	283
8.10.	Other Products.....	283
8.10.1.	Bone Cement.....	283
8.10.2.	Bone Cement Accessories.....	289
8.10.3.	Surgical Tools (Pulsed Lavage)	295
8.10.4.	Spine Devices.....	303
8.10.5.	Trauma Devices	306
9.	Commitments	308
9.1.	Remedies principles	309
9.2.	Description of the proposed commitments	310
9.2.1.	The Commitments of 3 December 2014	310

9.2.2.	The Final Commitments of 9 February 2015	322
9.3.	The Commission's overall assessment of the Final Commitments	330
9.3.1.	The Final Commitments are suitable to remove the significant impediment to effective competition.....	330
9.3.2.	The Final Commitments are viable, comprehensive and effective	331
9.3.3.	The Final Commitments are capable of being implemented effectively within a short period of time	333
9.3.4.	The need to include additional purchaser criteria	334
9.3.5.	The need for the upfront buyer clause.....	334
9.4.	Conclusion.....	335
9.5.	Conditions and Obligations.....	335

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Agreement on the European Economic Area, and in particular Article 57 thereof,

Having regard to Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings,¹ and in particular Article 8(2) thereof,

Having regard to the Commission's Decision of 3 October 2014 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission,

Having regard to the opinion of the Advisory Committee on Concentrations,²

Having regard to the final report of the Hearing Officer in this case,³

Whereas:

1. INTRODUCTION

- (1) On 3 June 2014 the Commission received a notification of a proposed concentration pursuant to Article 4 of Regulation (EC) No 139/2004 (the "Merger Regulation") by which the undertaking Zimmer Holdings, Inc. ("Zimmer" or the "Notifying Party"), established in the United States, acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of the whole of Biomet, Inc. ("Biomet"), established in the United States, by way of purchase of shares. Zimmer and Biomet are hereinafter referred to as the "Parties".
- (2) On 11 June 2014, the Commission declared the notification of 3 June 2014 incomplete by means of a Decision taken pursuant to Article 5(2) of Regulation (EC) No 802/2004 (the "Implementing Regulation") (the "Article 5(2) Decision"). The Notifying Party submitted a revised draft notification on 4 July

¹ OJ L 24, 29.1.2004, page 1 ("the Merger Regulation"). With effect from 01.12.2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this Decision.

² OJ C ..,200 p.

³ OJ C ..,200 p.

2014. On 15 August, 18 August and 29 August 2014, the Notifying Party submitted complementary information, following a request for information dated 14 July 2014. The notification was deemed effective as of 29 August 2014.

2. THE PARTIES

- (3) Zimmer is a US publicly traded company with a dispersed stockholders' base. It is neither solely nor jointly controlled by any other undertaking. Its common stock is traded on the New York Stock Exchange and the SIX Swiss Exchange. Zimmer is active in the design, development, manufacture and marketing of orthopaedics, reconstructive, spinal and trauma devices, biologics, dental implants and related surgical products.
- (4) Biomet is a wholly owned subsidiary of LVB, a holding company whose shares are not publicly traded. The controlling stockholder of LVB is LVB Acquisition Holding LLC ("LVB Holding") through which Biomet was acquired in 2007 by investment funds affiliated with the Blackstone Group L.P., Goldman Sachs & Co, Kohlberg Kravis Roberts & Co L.P., and TPG Capital, L.P. (the "Sponsors"). LVB Holding is neither solely nor jointly controlled by these four funds. No Sponsor alone has the ability to veto strategic decisions. In addition, there are no strong common interests and the various Sponsors may shift their alliances. On this basis, the Sponsors do not exercise joint control.⁴ Biomet is active in orthopaedic and other medical devices and related products.

3. THE OPERATION AND THE CONCENTRATION

- (5) On 24 April 2014, Zimmer, Owl Merger Sub, Inc., a newly formed, indirect wholly owned subsidiary of Zimmer and LVB Holding executed the Agreement and Plan of Merger (the "Merger Agreement") which involves the acquisition by Zimmer of LVB Holding and, therefore, Biomet as a wholly owned direct subsidiary of LVB Holding, through the merger of Owl Merger Sub, Inc., with LVB Holding. LVB Holding will be the surviving corporation of this merger. At the time of the merger, the separate corporate existence of Owl Merger Sub, Inc. will cease, while the separate corporate existence of LVB Holding with all its properties, rights, powers, privileges, immunities and franchises will be unaffected. Each issued and outstanding share of common stock of Owl Merger Sub, Inc. will be converted into one share of common stock of LVB Holding. With this, Zimmer will become the parent company of LVB Holding, the surviving corporation in the merger.
- (6) The proposed operation therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

4. UNION DIMENSION

- (7) The undertakings concerned have a combined aggregate worldwide turnover of more than EUR 5 000 million (Zimmer: EUR 3 481 million, Biomet: EUR 2

⁴ Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (2008/C 95/01) (the "Consolidated Jurisdictional Notice"), paragraph 80.

298 million). Each of them has an EU-wide turnover in excess of EUR 250 million (Zimmer: EUR [...]*, Biomet: EUR [...]*) and none of them achieves more than two-thirds of their aggregate Union-wide turnover within one and the same Member State. The merger therefore has a Union dimension.

5. THE PROCEDURE

- (8) Having examined the notification and following a market investigation, the Commission concluded that the operation falls within the scope of the Merger Regulation and raised serious doubts as to its compatibility with the internal market and the EEA Agreement. During a state of play meeting held on 19 September 2014, the Notifying Party was informed of the substance of the serious doubts raised by the proposed merger. The Notifying Party did not submit commitments during the first phase investigation. The Commission adopted a Decision to initiate proceedings pursuant to Article 6(1)(c) of the Merger Regulation on 3 October 2014 (the "Article 6(1)(c) Decision").
- (9) On 9 October 2014, the in-depth investigation period was extended by 15 working days at the request of the Notifying Party pursuant to Article 10(3), second subparagraph, first sentence, of the Merger Regulation.
- (10) On 22 October 2014, the Notifying Party submitted its written comments to the Article 6(1)(c) Decision (the "Response to the Article 6(1)(c) Decision").
- (11) On 17 November 2014, the Commission adopted a Decision to further extend the deadline by 5 working days, pursuant to Article 10(3), second subparagraph, third sentence of the Merger Regulation.
- (12) On 18 November 2014, the Commission sent a request for information ("RFI") to the Notifying Party pursuant to Article 11(2) of the Merger Regulation. The deadline fixed by the Commission to supply the information was 24 November 2014. This deadline was extended by the Commission upon request of the Notifying Party till 1 December 2014. On 3 December the Commission adopted a Decision pursuant to Article 11(3), suspending the in-depth investigation as from 2 December 2014. Proceedings resumed on 10 February 2015 following the submission by the Notifying Party of the requested information.
- (13) The Notifying Party submitted a first set of commitments on 3 December 2014. The Commission carried out a market test of these commitments on 5 December. The results of the market test were discussed with the Parties in a State of Play meeting held on 18 December 2014. The Notifying Party submitted an informal revised version of a second commitments package on 24 January 2015, which was subjected to a targeted market test. On this basis, the Notifying Party submitted formally revised remedies on 9 February 2015.
- (14) In the present Decision, the Commission first defines the relevant markets (section 7). Next, the Commission provides an overview of the orthopaedic implants sector (section 8.5) and sets out its competitive assessment (section 8), reaching the conclusion that the merger is likely to significantly impede effective competition in a number of national elbow, and knee implants markets in the EEA. Finally, the Commission analyses the remedies submitted by the Notifying Party and reaches the conclusion that the remedies submitted on 9 February 2015 eliminate entirely the competition concerns identified by the Commission (section 9).

6. THE IN-DEPTH INVESTIGATION

- (15) During the in-depth investigation, the Commission:
- (a) reviewed the submissions of the Parties, sent several requests for information to the Parties and reviewed responses, visited Zimmer's production site in Motebelliard, attended product presentations organised by the Parties, held several meetings and telephone interviews with the Parties;
 - (b) sent several requests for information to third parties (such as competitors, customers, key opinion leaders, purchasing groups and national health authorities), reviewed responses, conducted meetings and telephone interviews;
 - (c) reviewed the internal documents submitted by the Parties;
 - (d) conducted a targeted market reconstruction analysis by requesting data from major market participants; and
 - (e) reviewed bidding data, including data gathered by the Parties' themselves as well as tender data registered in TED,⁵ Parties' merger data, Parties' Customer Relation Management ("CRM") data, and data from the United Kingdom Orthopaedic Data Evaluation Panel ("ODEP"), from the United Kingdom National Joint Registry ("NJR") and from the Dutch orthopaedic implants registry⁶.

7. MARKET DEFINITION

- (16) The proposed merger has an impact on a number of markets of the orthopaedic devices industry and more precisely on (a) joint reconstructive implants: *knee, elbow, hip and shoulder implants*, which are used to replace damaged joints with prosthetic components, and (b) other products: *bone cement*, which is used to aid the fixation of reconstructive implants, *bone cement accessories*, used as an aid in the application of bone cement, *pulsed lavage*, which is a high-pressure wound irrigation system used in orthopaedic surgery, *spinal devices*, which are used to correct various conditions of the spine, *trauma devices*, which are used to treat bone fractures, and *dental implants*, which are a form of dental prosthetics.
- (17) This section defines the relevant markets which are affected by the merger. The Commission Notice on the definition of relevant market for the purposes of Community competition law (the "Market Definition Notice") sets out the guiding principles,⁷ which the Commission uses in this respect.
- (18) According to the Market Definition Notice, "*[m]arket definition is a tool to identify and define the boundaries of competition between firms*".⁸ The main purpose of market definition is "*to identify in a systematic way the competitive*

⁵ According to Union law on public procurements all contracts valued above EUR 200,000 are mandated to be published as a public procurement contest. TED (Tenders Electronic Data) gathers this information and is publicly available (see <http://ted.europa.eu/TED/main/HomePage.do>).

⁶ The merger data and most of the bidding data proved unsuitable to conduct a meaningful analysis. The Commission did analyse the CRM and registry data to evaluate the competitive constraints prevailing in the market.

⁷ Commission Notice on the definition of relevant market for the purposes of Community competition law, Official Journal C 372, 09.12.1997.

⁸ Commission Notice on the definition of relevant market for the purposes of Community competition law, paragraph 2.

constraints that the undertakings involved face", and "to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure".⁹

7.1. Relevant Product Market

- (19) The Market Definition Notice defines a relevant product market as a market comprising all those products and/or services which are regarded as interchangeable or substitutable by the consumers, by reason of the products' characteristics, their prices and their intended use.¹⁰ In determining the relevant market, the Commission assesses demand substitution by the range of products which are viewed as substitutes by the consumers.¹¹ The Commission may also take into account supply-side substitutability, namely when its effect is equivalent to those of demand substitution in terms of effectiveness and immediacy.¹² This is the case where suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices.¹³
- (20) The Market Definition Notice suggests that supply-side substitutability may typically play a role in a scenario where companies market a wide range of qualities or grades of one product; even if, for a given final customer or group of consumers, the different qualities are not substitutable, the different qualities will be grouped into one product market, provided that most of the suppliers are able to offer and sell the various qualities immediately and without the significant increases in costs.¹⁴
- (21) In past decisions, the Commission rejected a single market encompassing all joint reconstructive implants based on the absence of substitutability from both demand and supply-side. In *Smith&Nephew/Centerpulse*,¹⁵ the Commission stated that despite the fact that all main competitors produce a full range of implants, a change in the type of replacement joint entails substantial modifications of the manufacturing process. Moreover, the need of clinical evidence supporting implants' reliability is the key to penetrate the market and may constitute a factor capable of delaying a rapid and timing entry by newcomers, even in case they are already active players in neighbouring segments. This conclusion is also supported by the Notifying Party in the proposed merger which does not claim the existence of an overall market encompassing all joint reconstructive implants (knee, elbow, hip and elbow implants).
- (22) In sections 7.1.1 to 7.1.4 below the Commission analyses the relevant product market definition for joint reconstructive implants (knee, elbow, hip and

⁹ Commission Notice on the definition of relevant market for the purposes of Community competition law, paragraph 2. See also Horizontal Merger Guidelines, paragraph 10 ("The main purpose of market definition is to identify in a systematic way the immediate competitive constraints facing the merged entity").

¹⁰ Market Definition Notice, paragraph 7.

¹¹ Market Definition Notice, paragraph 15.

¹² Market Definition Notice, paragraph 20.

¹³ Market Definition Notice, paragraph 20.

¹⁴ Market Definition Notice, paragraph 21.

¹⁵ Commission decision of 27.05.2003 in Case M.3146 – *Smith&Nephew/Centerpulse*, paragraph 10.

shoulder implants), and in section 7.1.5 below the relevant product market definition for bone cement, bone cement accessories, pulsed lavage, spine devices, trauma devices, and dental implants.

7.1.1. Knee Implants

- (23) The knee is the largest hinge joint in the human body. It is formed by the articulation of the distal end of the femur, the proximal end of the tibia and the patella, which floats in the patellar tendon over the femur and the tibia.
- (24) Knee replacement is a surgical procedure by which the knee joint is replaced (in whole or in part) by a prosthetic implant to treat a given pathology (for example a fracture, arthritis or a previous knee replacement procedure which has failed).
- (25) Based on its in-depth market investigation, the Commission understands that there are different types of surgery - involving different kinds of knee implants - depending on the severity of the injury suffered by a patient.
- (26) If the damage suffered by a patient is limited to a section of the knee, and is unlikely to spread to other healthy areas, surgeons will generally strive to be as non-intrusive as possible by performing a partial knee arthroplasty. There are two main types of partial knee arthroplasty: unicondylar knee arthroplasty and patello-femoral replacement.
- (27) **Patello-femoral replacement.** This is a mildly intrusive surgery aimed to replace the back of the patella. The implant for such surgery consists of a metal groove to fit on the end of the femur, and a plastic disc that attaches to the underside of the kneecap. Figure 1 below shows a design of such implant.

Figure 1: Design of a PATELLO-FEMORAL knee implant



Source: Zimmer's website

- (28) **Unicondylar Knee Arthroplasty ("UKA").** This is a relatively non-intrusive surgery that replaces only a part of the joint, namely a femoral condyle. This surgery can be performed only when all ligaments are functioning and only when one femoral condyle is damaged. By its very nature, the UKA targets a limited set of patients.
- (29) When performing a UKA, surgeons use the so-called unicondylar knee implants. These implants replace only one side of the joint. They consist of three components, the femoral component, the meniscal bearing and the tibial component. Sometimes, these types of surgery are also associated with the addition of patello-femoral components to replace the articular surface/cartilage underneath the knee cap. Figure 2 below shows a design of such implant.

Figure 2: Design of a UNICONDYLAR knee implant



Source: Zimmer's product presentation of 22 October 2014

- (30) **Total Knee Arthroplasty ("TKA").** This surgery affects the entire joint, and therefore is an intrusive surgery. In essence, the surfaces of the joint are "crowned" with a surface replacement, and additional elements are used to reproduce – to the extent possible – the natural biomechanics of the joint.
- (31) There are two types of TKA interventions. Primary TKA interventions are carried out to replace the joint for the first time. Revision TKA interventions are carried out when a primary TKA fails, for example, due to infection or dislocation. Accordingly, there are various types of implants for TKAs.
- (32) **Primary implants.** These implants generally have four components: (i) a femoral component to replace the femoral condyles; (ii) a tibial component; (iii) a polyethylene insert that replaces the meniscus and acts as the articulating and bearing surface between the femoral and tibial components; (iv) and, frequently, a patello-femoral component. They are by far the most common type of knee implants. Figure 3 below shows a design of such implant.

Figure 3: Design of a PRIMARY knee implant



Source: Zimmer's product presentation of 22 October 2014

- (33) **Revision implants.** These implants are to some extent composed of the same basic components as primary implants. However, they display a much greater degree of modularity to allow surgeons to place additional accessories and augments to suit the specific needs of a given patient. For example, surgeons may use longer stems to provide better fixation and compensate for bone loss that may have occurred during the removal of the original primary implant. Figure 4 below shows a design of such implant.

Figure 4: Design of a REVISION knee implant



Source: Zimmer's product presentation of 22 October 2014

- (34) When the stability of the joint is compromised, surgeons will have to make up for that loss. For this purpose, they will use more "constrained" solutions. For the purpose of this Decision, the solutions used in such cases will be referred to as hinged knee implants.¹⁶ Also, in some extreme situations, surgeons resort to limb salvage implants, which replace most of the patient's limb. Hinged implants and limb salvage implants are described in more detail in recitals (35) onwards.
- (35) **Hinged implants.** These implants replace the whole surface of the joint parts as well, but they are fixed with an extended shaft. They also display some additional elements such as supplementary metal plates to replace defective bone and prostheses axles to direct movements. Among hinged implants, surgeons also distinguish between rotating hinged implants, if the muscle apparatus and joint capsule are still intact, and axially supported implants, which are much less flexible than rotating hinged implants but provide the necessary support required. Hinged knee implants also appear to be much more expensive than unicondylar and other total implants.¹⁷ Figure 5 below shows a design of such implant:

¹⁶ There are also rather rare situations, where surgeons also use these solutions as a first line treatment in primary interventions. For example, according to the 2014 Annual Report of the Swedish Knee Arthroplasty Register, over 2003-2012, 535 hinged knee implants were used in primary interventions. This would make be less 1% of the total number implants used for primary interventions.

¹⁷ According to the written submission of Aesculap, in Germany for example, an unconstrained implant costs below EUR 1 000, while the costs for a modern hinged implant range between EUR 3 700 and EUR 7 000, depending on the severity of the injury. BBraun/Aesculap AG ("Aesculap"), Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08.2014, page 9.

Figure 5: Design of a HINGED knee implant



Source: Zimmer's website

- (36) **Limb Salvage implants.** In some extreme cases, surgeons undertake very intrusive procedures. Through these procedures, surgeons literally replace most of the limb of a patient to avoid dramatic outcomes such as amputation. In essence, these procedures target two areas: (i) very complex revision surgery, which occur when prior arthroplasty surgery fails; and (ii) bone and tissue cancer, which in the past would simply lead to the amputation of the limb. These procedures require very specific implants, which may often border custom-made solutions in terms of components personalisation due to the advanced and often peculiar conditions of the patient being treated. Figure 6 below shows a design of such an implant.

Figure 6: Design of a LIMB SALVAGE knee implant



Source: Form CO

- (37) Additionally, knee implants can be subject to other possible segmentations. For example, they can be segmented by design, fixation and stabilisation method.
- (a) Knee implants may have different designs, depending on whether they retain or remove the posterior cruciate ligament (namely, cruciate retaining, cruciate sacrificing and posterior stabilized).
 - (b) Knee implants may also be distinguished by fixation method, namely implants fixed with bone cement (cemented implants) or without cement (cementless implants).
 - (c) Knee implants may follow a fixed or mobile bearing philosophy, depending on whether only one or both of the two main components of the implant (namely, the femoral and tibial components) can move across the polyethylene insert, thereby creating single- or dual-surface articulation.
- (38) The following section 7.1.1.1 onwards analyses the relevance of all the above segmentations in recital (37) for the purpose of carrying out the competition assessment in this case.

7.1.1.1. Past Commission decisions

- (39) In past decisions,¹⁸ the Commission considered three possible ways to segment the market for knee implants: (i) by type of intervention for which they are used (primary versus revision interventions); (ii) by fixation method (cemented versus cementless implants); and (iii) by bearing type (fixed versus mobile bearings). Ultimately, in the *Smith&Nephew/Centerpulse* decision, the Commission carried out its assessment based on a single product market for knee implants.¹⁹

7.1.1.2. The views of the Notifying Party

- (40) The Notifying Party argues that the relevant product market is an overall market for all knee implants because the market features both demand-side and supply-side substitution.
- (41) First, the Notifying Party argues that demand-side substitution links implants of different types and features.²⁰ For many patients, more than one option would be a viable solution. For example, for patients with medial compartment arthritis, either a total or a partial procedure could be considered.
- (42) Second, from a supply-side perspective, all suppliers active in the knee market generally offer solutions for all different pathologies, and can easily start producing another type of implant or expand production for a specific type of implant, should the price of that type of implant increase by a small but significant amount.²¹
- (43) For these reasons, the Notifying Party submits that any further segmentation of the overall knee market would not be appropriate.
- (44) On 19 November 2014,²² the Notifying Party submitted a White Paper on Total Knees Market Definition (the "White Paper on Total Knees") to substantiate its argument that, at least, primary and revision implants belong to the same product market. The White Paper on Total Knees in essence reiterates some of the arguments already put forward in the Form CO of Annex I of the Implementing Regulation (the "Form CO"), and stresses some additional aspects relating to demand- and supply-side substitutability, which are addressed in section 7.1.1.3.
- (45) On 7 January 2015, the Notifying Party also submitted a note explaining the relationship between the patello-femoral knee replacement and, one of Zimmer's unicondylar knee implants, that is to say ZUK (the "PFJ/ZUK Note")²³ which was being offered to remedy the competition concerns the Commission identified at the material time. The PFJ/ZUK Note provided useful information regarding the use of patello-femoral and unicondylar knee implants, and will therefore be considered in the context of market definition.

¹⁸ Commission decision of 28.10.1998 in Case M.1286 – *Johnson&Johnson/DePuy*, paragraphs 10 and following; and Commission decision of 27.05.2003 in Case M.3146 – *Smith&Nephew/Centerpulse*, paragraphs 13-14.

¹⁹ Commission decision of 27.05.2003 in Case M.3146 – *Smith&Nephew/Centerpulse*, paragraphs 13-14.

²⁰ Form CO, paragraph 1324(a).

²¹ Form CO, paragraph 1324(b).

²² Notifying Party, White Paper on Total Knees Market Definition of 19.11.2014.

²³ Notifying Party, White Paper, Patello-Femoral Joint Replacement and ZUK, 7.01.2015.

7.1.1.3. The Commission's Assessment

- (46) The in-depth market investigation provided evidence that separate markets exist for patello-femoral and unicondylar knee implants, distinct from implants designed for TKAs. With respect to these latter, the market investigation has provided strong indications supporting the existence of separate markets for primary and revision knee implants. Additionally, the Commission's investigation indicated that a potential market for extreme orthopaedics implants should be distinguished from the market for revision knee implants. This market for extreme orthopaedic implants may encompass hinged knee and limb salvage implants, but the precise market definition in this regard is left open for the purposes of this Decision.
- (47) Overall, the in-depth market investigation did not indicate that further segmentations by design, fixation method and type of bearing are appropriate. Market participants explained that these segmentations are less commonly used in the industry compared to those retained in this section, and not necessarily commercially meaningful from the suppliers' point of view.²⁴ Finally, segmentation by pathology was not considered meaningful by market participants, mainly due to the fact that various types of implants can be used to treat the same pathologies.²⁵
- (48) The Commission articulates its reasoning as regards the market definitions that it has retained as plausible in recital (49) onwards.

Patello-femoral implants

- (49) During the in-depth market investigation, the Commission found strong indications that the patello-femoral implants represent a separate market from unicondylar knee implants and primary total knee implants.
- (50) From a demand-side perspective, unicondylar knee implants and patello-femoral implants are used to treat different indications: as shown in recital (27) surgeons perform a partial surgery by placing patello-femoral implants that replace the articular surface/cartilage underneath the knee cap. Such surgery is very rare. According to one major supplier "[...] *In some rather isolated cases, only the patella is affected, and therefore surgeons will only use a femoro-patellar²⁶ component*".²⁷
- (51) According to a key opinion leader, these cases are uncommon in Europe.²⁸ For instance, according to the Swedish Knee Arthroplasty Register, between 2003 and 2012, only 247 patello-femoral implants were used in Sweden (representing 0.2% of all the primary arthroplasty surgery).²⁹ In England and Wales, according to the National Joint Registry report for 2014, patello-

²⁴ Responses to Questionnaire Q1 to competitors, questions 19-31 and responses to Questionnaire Q2 to customers, questions 6 and 7.

²⁵ Responses to Questionnaire Q1 to competitors, question 7.

²⁶ Sometimes the term "femoro-patellar implant" is used by certain suppliers to designate the same type of implant.

²⁷ Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraph 16, letter c.

²⁸ Non-confidential minutes of the conference call with Dr Robertsson, 22.12.2014, paragraph 4.

²⁹ The 2014 Annual report of the Swedish Knee Arthroplasty Register, page 30.

femoral implants were used in approximately 1% of primary arthroplasty surgery.³⁰

- (52) On the other hand, unicondylar knee implants treat patients with pain in the medial and lateral compartments of the knee. Hence, a surgeon cannot make an intraoperative switch from one implant to another.
- (53) If a condylar is affected, as well as the patella cap, the surgeon theoretically has a choice between using a total knee implant or a unicondylar and a patello-femoral implant. However, according to the Australian registry (a highly regarded orthopaedic implants registry), such bi-compartmental surgical procedure takes place in approximately 0.4% of the partial knee procedures.³¹ In most cases, the surgeon will choose to use a primary total knee implant, and not a unicondylar and patello-femoral implant together, as this is a very complicated intervention.³²
- (54) Therefore, it can be concluded that from a demand-side perspective, the patello-femoral implants are a separate product.
- (55) From a supply-side perspective, there are also indications that patello-femoral and unicondylar knee implants are different. One important difference lies in the instrumentation used for surgery which is specific to each type of implant. For instance Zimmer's partial knee implant, ZUK involves a pure resection procedure, while the patello-femoral implant (the PFJ) involves a resurfacing procedure. Thus, the different surgical procedures require different instrumentation for these two types of implants.
- (56) In the light of the arguments set out in this section, the Commission takes the view that the patello-femoral implants represent a separate product from unicondylar knee implants and primary total knee implants.

Unicondylar knee implants³³ versus Total knee implants

- (57) The Commission analysed in particular whether total and unicondylar knee implants formed part of a single market or whether they constituted separate markets. Based on the results of the in-depth market investigation, the Commission concludes that unicondylar knee implants constitute a distinct product market.

Demand-side substitution

- (58) From a demand-side perspective, unicondylar implants address specific clinical conditions. Unicondylar knee implants are used when all ligaments are functioning and only one femoral condyle is damaged. Such damage must be unlikely to spread to other sections of the knee. Thus, in principle, unicondylar knee implants are suited to the needs of a very specific set of patients.
- (59) During its in-depth investigation, the Commission addressed a number of questionnaires³⁴ and held several conference calls with the Notifying Party's

³⁰ The 2014 Annual Report of the National Joint Registry, page 18.

³¹ <https://aoanjrr.dmac.adelaide.edu.au/documents/10180/172286/Annual%20Report%202014>, page 128.

³² Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraph 16, letter b; Non-confidential minutes of the conference call with Lima, of 10.11.2014, paragraph 13.

³³ Unicondylar knee implants are often referred to by competitors and customers as 'partial' or 'uni' knees.

³⁴ Responses to Questionnaire Q1 to competitors, question 15; responses to Questionnaire Q1 to competitors, question 18.

competitors, customers and with key opinion leaders (such as university professors) to better understand the competitive interaction between total and unicondylar knee implants. A close review of the evidence in the Commission's file shows that this segmentation is indeed appropriate.

- (60) The Notifying Party's competitors have made several submissions indicating that unicondylar and total knee implants are distinct not only in terms of their characteristics, but notably in terms of their intended use, with surgeons being unable to substitute the two products for the majority of knee surgery. These submissions are corroborated by the views of surgeons/key opinion leaders themselves.
- (a) DePuy Synthes (a Johnson & Johnson company) ("J&J/DePuy") explained that total and partial implants *"have separate indications. Partial knee implants are as yet used in a more limited number of countries/cases, notably when surgeons use this technique and there is therefore demand for it. Not all cases allow for the use of a partial knee implant instead of a total knee implant"*.³⁵
 - (b) Smith and Nephew plc ("S&N") stated: *"Surgeons choose the most appropriate implant intervention based on patient pathology. Total and partial knee segmentation is an appropriate broad first level segmentation for helping design implants and market knee implants efficiently"*.³⁶
 - (c) Stryker Corporation ("Stryker") considered that *"Unicompartmental knees and Tricompartmental (total) knee replacement might be considered as two different segments as they simply aren't the same procedures. However, in some cases the intent is to put in a uni knee but during the surgery the surgeon may decide to do a total knee procedure. A company could play a significant role in the knee market without having any Unicompartmental knee implants or a company might decide to only participate in the Uni segment, which is far smaller, but be a niche player"*.³⁷
- (61) The in-depth market investigation has provided indications that sometimes surgeons may still use a total - most likely a primary - knee implant, despite a patient's condition being in principle suitable for the less intrusive unicondylar knee implant. For example, according to J&J/DePuy the proportion of cases that could be treated with either of the two type of implants could go up to approximately 10% of all primary surgery.³⁸
- (62) Such an overlap does not however call into question the clear existence of market delineation between unicondylar knee implants as opposed to total knee implants. J&J/DePuy clearly stated that *"A market for unicondylar knee implants is warranted by the existence of very different clinical indications"*.³⁹ Stryker went even further listing some of the reasons as to why unicondylar knee implants constitute a separate market: *"First, it is only used for very specific clinical indications. Second, only a limited number of surgeons are able to perform such a difficult surgery, perform it enough to achieve a certain*

³⁵ Response to Questionnaire Q1 to competitors, question 15.

³⁶ Response to Questionnaire Q1 to competitors, question 15.

³⁷ Response to Questionnaire Q1 to competitors, question 15.

³⁸ Non-confidential minutes of the conference call with J&J/DePuy of 07.11.2014, paragraph 15.

³⁹ Non-confidential minutes of the conference call with J&J/DePuy of 07.11.2014, paragraph 14.

degree of success. [...] Third, the instrumentation is different than primary knee [implants]".⁴⁰

- (63) Aesculap summarised the matter as follows *"when the damage caused to the knee is partial, with very limited risks to spread, the surgeon will tend to choose a unicondylar knee implant. However, when the damage is partial, but the risk of spread high, the surgeon will follow a cautious approach by choosing a total knee replacement. When the patient suffers from a severe injury of the whole knee (with, however, the ligaments being still mostly intact), then a total knee replacement is compulsory"*.⁴¹
- (64) Surgeons have a certain margin of manoeuvre to decide which implant would be the most appropriate in a given case. According to a key opinion leader, when choosing between a unicondylar or total knee implant, their decision will eventually depend on various factors, including the age of a given patient, the likelihood of a damage spreading and the evaluation of pre-existing conditions.⁴² One key opinion leader explained that *"when the damage is partial, and the patient is young, the surgeon will, most of the time, choose a partial implant"*.⁴³ The opposite is however not true, in that a surgeon would not choose a partial knee implant for a condition affecting the whole knee.⁴⁴
- (65) Therefore, there is in principle a potential unilateral demand-side substitutability, in that patients suitable for UKAs are sometimes treated with a total - most likely a primary - knee implant. However, the in-depth market investigation has demonstrated that even within this area of overlap substitutability is limited for a number of non-price considerations.
- (66) Firstly, surgeons unfamiliar with UKAs encounter significant barriers, when trying to learn this procedure, which is generally perceived as more demanding than TKAs.⁴⁵ In this regard, Stryker explained that *"when surgeons without enough practice or experience perform such surgeries, this negatively impact the overall success rate of this type of surgeries the increased number of complications lead to a contraction in the number of unicondylar knee surgeries. At that point in time, only experienced surgeons will continue to perform unicondylar surgeries"*.⁴⁶
- (67) Furthermore, according to S&N one of Biomet's greatest achievements over the last 10 years has been to educate and draw towards its flagship product, the Oxford Knee, surgeons who were either unfamiliar, untrained or even opposed to UKAs.⁴⁷ In spite of that, UKAs still remain a niche market compared to mainstream TKAs.

⁴⁰ Non-confidential minutes of the conference call with Stryker of 11.11.014, paragraph 8.

⁴¹ Non-confidential minutes of the conference call with Aesculap of 14.08 2014, paragraph 6.

⁴² Non-confidential minutes of the conference call with Professor Marcacci of Istituto Ortopedico Rizzoli of 09.07 2014, paragraph 8; and Non-confidential minutes of the conference call with Professor Robertsson of Lund University Hospital of 25.06.2014, paragraph 7.

⁴³ Non-confidential minutes of the conference call with Professor Marcacci of Istituto Ortopedico Rizzoli of 09.07. 2014, paragraph 8.

⁴⁴ Non-confidential minutes of the conference call with Professor Robertsson of Lund University Hospital of 25.06. 2014, paragraph 7.

⁴⁵ Responses to Questionnaire Q2 to customers, question 8. Non-confidential minutes of the conference call with Dr Marcacci from Istituto Ortopedico Rizzoli of 9.7.2014, paragraph 11.

⁴⁶ Non-confidential minutes of the conference call with Stryker of 11.11.2014, paragraph 9.

⁴⁷ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 12.

- (68) In the light of the arguments set out in this section, the Commission concludes that unicondylar knee implants are designed to treat a limited set of cases, where ligaments and soft tissues are in good condition, only one condyle is damaged, and such damage is unlikely to spread. Injuries affecting more sections of the knee, the entire knee or severe injuries will not be treated with unicondylar knee implants. Conversely, there are cases where total - most likely primary - knee implants could be used instead of unicondylar ones, despite a patient's condition being in principle suitable for the less intrusive UKA.
- (69) Based on the evidence in the file, the Commission concludes that this potential unilateral demand-side substitutability does not justify the finding of a single market encompassing total and unicondylar knee implants. Quite to the contrary, the results of the in-depth market investigation overwhelmingly suggest the existence of a distinct market for unicondylar knee implants. Therefore, the Commission takes the view that, from a demand-side perspective, unicondylar knee implants constitute a distinct product market.

Supply-side substitution

- (70) Some suppliers of total knee implants do not offer unicondylar implants (for instance, Limacorporate spa ("Lima"), Medacta International ("Medacta") and Sanatmetal Ltd. ("Sanatmetal")). Yet, the market investigation has indicated that a competitor active in total knee implants - but not in unicondylar knee implants - will not be able to *"switch production to the relevant products [unicondylar segment] and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices"*.⁴⁸
- (71) For instance as explained by J&J/DePuy:
"Developing a new total or partial knee implant, that is not just a "me too" product, would take between 3-5 years to accomplish and would require significant investment. In terms of production, some equipment may be used to produce different implants, but there is typically also dedicated equipment for some components or implants and components. It may well be necessary to develop and/or acquire such dedicated equipment to make a switch".⁴⁹
- (72) J&J/DePuy's explanation continues by elaborating on the difficulties that a firm seeking to switch to unicondylar implants would face. For example, this firm would need to build up product track records, establish relationships with hospitals and surgeons, and retrain medical and non-medical staff. This view has been largely corroborated by several other players in the industry. For example, S&N explains that:
"Orthopaedic implants are highly specialised products. Their manufacturing process requires complex machinery operated by highly trained employees. This process has to comply with regulatory authorisation requirements, including GMP. Switching production from one type of implant to another would require significant investment and a considerable time commitment".⁵⁰

⁴⁸ Market Definition Notice, paragraph 20.

⁴⁹ Response to Questionnaire Q1 to competitors, question 16.

⁵⁰ Response to Questionnaire Q1 to competitors, question 16.

- (73) Another total knee supplier, Lima, which is not currently active in unicondylar knee implants provided further elements in this regard. In particular, Lima stated that *"Total knee are different from partial knee in design and also in all the other related costs"*.⁵¹ Importantly, Lima indicated that it has considered entering the unicondylar segment, and concluded that this would be a major undertaking requiring approximately two years, even if Lima were to produce a copycat or me-too product of an existing implant. This is so because such a project would entail risks, complexities and uncertainties:
- "Even reverse engineering an existing implant, which is not part of Lima's philosophy and strategy, would not be a shortcut. This is because Lima would need to make sure that all components, separately and together, would deliver the same degree of reliability as the original implant"*.⁵²
- (74) The Commission understands that entry into a new segment of the overall knee arena generally entails long pathways, which may even go beyond two years. Those pathways include, among other things, R&D, production and testing, regulatory approvals, sales force training and recruitment, project launch, up until achieving meaningful sales. According to S&N, *"[...] even when a company is active in the total knee segment, it still needs an R&D period which can last several years"*.⁵³
- (75) Even if one were to focus on a supply-side switch/expansion by players which are already active in both total and unicondylar knee implants, the in-depth market investigation indicated that there are factors limiting the ability and/or diminishing the incentives of such suppliers to switch production from one implant to the other.
- (76) When asked whether they would switch production between total and unicondylar knee implants in response to a small but significant and non-transitory increase in price ("SSNIP"), the majority of suppliers replied negatively.⁵⁴
- (77) During the in-depth market investigation, the Commission investigated whether, in the past, suppliers switched capacity between total and unicondylar knee implants, following past price increases. However, due to the specific clinical indications of each of these implants and surgeons' inertia, along with the particular structure of this market, where hospitals purchase implants in response to surgeons' requests and based on previous years' volumes, there seems to be little or no incentive for suppliers to engage in such switches.
- (78) In this regard, Stryker confirmed: *"We are not aware of any such switch in the past. The surgeon decides on the appropriate implant for the patient; the supplier doesn't make that decision"*.⁵⁵
- (79) J&J/DePuy also agreed that *"A decision to produce more of a given product would primarily be driven by increased customer demand. A price increase may indicate that a market potentially is more profitable, and if so represents a*

⁵¹ Response to Questionnaire Q1 to competitors, question 16.

⁵² Non-confidential minutes of the conference call with Lima of 10.11.2014, paragraphs 16-18.

⁵³ Non-confidential minutes of the conference call with S&N of 10.10.2015, paragraph 16.

⁵⁴ Response to Questionnaire Q1 to competitors, question 17.

⁵⁵ Response to Questionnaire Q1 to competitors, question 17.

*business opportunity; but does not mean that there would be more relevant cases or increased demand for a particular supplier's products".*⁵⁶

- (80) Moreover, the evidence on file shows that the segment for unicondylar implants is characterised by different dynamics than those which affect competition in total knee implants.
- (81) First, even those players (including the three majors S&N, Stryker and J&J/DePuy) that entered the segment are experiencing significant difficulties in marketing their products effectively and achieving meaningful market positions. This is evidenced by the market share information provided further under section 8.6.8.
- (82) Second, Biomet and Zimmer are offering the two leading, legacy unicondylar products, and their market shares largely exceed those of the remaining three majors. In particular, Biomet's OXFORD knee is the most renowned unicondylar knee. This significantly alters market dynamics as opposed to the total knee segment.
- (83) Third, nowadays the number of surgeons performing unicondylar surgery is much lower when compared to surgeons performing total knee surgery. This creates additional hurdles in terms of marketing, which are not present or at least present to a much lesser extent in total implants.
- (84) Finally, the segment for unicondylar knee implants is different as compared to the one for total knee implants in terms of overall size and expected growth. For example, S&N explained that "*The unicondylar knee market is growing at a greater rate, i.e. 3% CAGR,*⁵⁷ *than the total knee one, which is flat or growing at 1-2% CAGR, but remains larger overall*".⁵⁸
- (85) In light of the arguments set out in this section, supply-side dynamics do not appear to justify the finding of a single product market encompassing total and unicondylar knee implants.
- (86) Based on the evidence in the file, the Commission concludes that unicondylar knee implants constitute a market distinct from total knee implants.

Total Primary versus Revision Implants

- (87) The in-depth market investigation has indicated that primary knee implants belong to a product market distinct from the one for revision knee implants.
- (88) It is important to note that even though revision implants are mostly used in revision surgery and primary implants are mostly used in primary surgery, in rare cases revision implants may be used in primary surgery instead of primary implants. By the same token, primary knee implants may be used in revision surgery, if the specific condition of the patient does not warrant more advanced treatment. Moreover, even in the context of revision surgery, there are different levels of intervention because only one or some components could be replaced rather than the entire implant.

Demand-side substitution

⁵⁶ Response to Questionnaire Q1 to competitors, question 17.

⁵⁷ Compound annual growth rate. The year-over-year growth rate of an investment over a specified period of time.

⁵⁸ Non-confidential minutes of the conference call with Smith & Nephew of 10.11.2014, paragraph 14.

- (89) From a demand-side perspective, primary and revision implants address different clinical indications. Primary knee implants may be regarded as constituting a "first line" treatment of degenerative conditions, mainly arthritis and more rarely, fractures. Revision knee implants respond to more serious joint damage, following removal of a primary knee implant due to, among other things, dislocation or infection.
- (90) In revision surgery, the extent of the damage suffered by the joint forces surgeons to achieve greater stability and fill bone voids. To do so, revision knee implants offer a greater degree of modularity than primary knee implants do. For instance, surgeons will need to add a number of extra options to respond the specific needs of a given patient, such as longer stems, wedges of different thickness and even bone grafts. Primary knee implants do not generally offer - and do not generally need to offer - such a degree of modularity.
- (91) During its in-depth market investigation, the Commission addressed a number of questionnaires to the Notifying Party's competitors and held several conference calls to understand better the competitive interaction between primary and revision knee implants. The majority of competitors agreed that segmentation between primary and revision knee implants is appropriate.⁵⁹
- (92) Customers identified the distinction between primary and revision knee implants as the most common product segmentation used by surgeons to classify products in their daily practice.⁶⁰ Customers stressed that revision knee implants generally entail more demanding, often complex surgery, and therefore a different degree of skill and training of surgeons as opposed to simpler primary knee implants.⁶¹ They also stressed that revision surgery is also far less common than primary surgery.
- (93) The Notifying Party's competitors have made several submissions indicating that primary and revision knee implants are distinct not only in terms of their characteristics but notably in terms of their intended use, with surgeons being unable to substitute the two products for the majority of knee surgery. These submissions are corroborated by the views of surgeons/key opinion leaders themselves.
- (94) Some competitors explained that there appears to be surgeons' demand for fully modular implants capable of addressing all patients' needs and which would make a distinction between primary and revision knee implants obsolete. However, those competitors also confirmed that such a high degree of modularity within a single system has not been achieved to date and it is difficult to predict when that will materialise, if ever.⁶² In this regard, S&N opined that "*Moreover, an implant with enough modularity to match both types of surgeries, i.e. primary and revision surgeries would likely be too expensive*

⁵⁹ Responses to Questionnaire Q1 to competitors, question 11. Stryker however had a number of reservations as regards this segmentation for the reasons set out in recital (88).

⁶⁰ Responses to Questionnaire Q2 to customers, question 6.

⁶¹ Responses to Questionnaire Q2 to customers, question 8.

⁶² Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 4; Non-confidential minutes of the conference call with J&J/DePuy of 7.11.14, paragraph 3; and Non-confidential minutes of the conference calls with Link of 26.9.14 and 28.10.14, paragraphs 10-11.

for customers. Primary surgeries do not require all accessories and instruments needed in the context of revision surgeries".⁶³

- (95) S&N explained that segmentation between primary and revision "provides a first broad division of the market that is useful. Primary implants and revision implants are different clinical situations, involving different procedures. Revisions are more complex procedures, presenting technological challenges to the implant system and impacting the provider situation in terms of operating time, staff training and post-operative care required".⁶⁴
- (96) J&J/DePuy further explained that "[p]rimary and revision implants are generally made of the same base materials, however revision products contain items (e.g. stems & augments) required to provide additional fixation and fill large bone voids when replacing a primary implant. Hospitals also frequently tender revision products separately (through separate tenders or separate lots in tenders)".⁶⁵
- (97) A majority of competitors also confirmed that customers would not switch between these two implants in response to a SSNIP.⁶⁶ As S&N explained: "An implant indicated for a Primary surgery would be unlikely to be indicated for a Revision surgery (and vice-versa). It is not a clinically viable option".⁶⁷
- (98) Several players also indicated that hospital's procurement practices with respect to primary and revision implants vary from tender to tender. Sometimes, both implants are tendered within the same tender or lot, some other times that is not the case.⁶⁸
- (99) To better understand the dynamics between primary and revision knee implants, the Commission has also analysed the 2014 Annual Report of the Swedish Knee Arthroplasty Register ("2014 SKAR"), which was put forward by the Parties in their White Paper on Total Knees. The 2014 SKAR is fundamentally focused on analysing the survival rates of primary implants and the ensuing revision surgery. This is because the historical purpose of the SKAR was - and still is - to warn surgeons against techniques and implants leading to sub-optimal results.
- (100) The 2014 SKAR states that "TKA-revision models are TKA that are mainly used for revisions or difficult primary cases [...] Many have proper names that make them easy to distinguish from common TKA's".⁶⁹ It further adds that "[i]mplants that are specifically made for use in revision surgery or standard

⁶³ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 4.

⁶⁴ Response to Questionnaire Q1 to competitors, question 11.

⁶⁵ Response to Questionnaire Q1 to competitors, question 11.

⁶⁶ Responses to Questionnaire Q1 to competitors, question 14. It is worth nothing that actually no competitor replied positively to this question.

⁶⁷ Response to Questionnaire Q1 to competitors, question 14.

⁶⁸ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 9; Non-confidential minutes of the conference call with Stryker of 11.11. 2014, paragraph 7; Non-confidential minutes of the conference call with J&J/DePuy of 07.11.2014, paragraph 6. See also response to Questionnaire Q1 to competitors, question 14 ("*Customers source products on the basis of patient needs, rather than price differentials between devices that are designed to meet different patient needs*").

⁶⁹ 2014 SKAR, page 4.

*models with extra-long stems (5cm or longer) are classified as revision models".*⁷⁰

- (101) As already noted in recital (88), there may be cases where a primary knee implant is used in a revision surgery, and a revision knee implant in a primary surgery. That said, the Commission understands that such an overlap between cases is quite limited.
- (102) The great majority of patients undergoing a primary surgery are treated with a primary knee implant. For instance, the 2014 SKAR explains that, over 2003-2012, the number of implants used for primary TKAs was in total 102 953.⁷¹ Only a small sub-segment of this total amount, that is to say 1 269 - or 1.2% - of all primary TKAs were performed using revision models. The proportion remains identical when compared to the previous 2013 Annual Report covering 2002-2011, that is to say 1 119 - or 1.2% - of all primary TKAs performed using revision models.⁷²
- (103) Whilst the 2014 SKAR states that, over 2003-2012, out of 3 313 revision surgery procedures caused by osteoarthritis, surgeons replaced a primary knee implant with another total implant in 867 cases (26.2% of the cases),⁷³ the percentage of those revision surgery procedures which utilised primary knee implants is unclear. In the words of Dr Robertsson, one of the authors of the 2014 and 2013 SKAR, "*the data do not explain whether the new implant was a revision or primary TKA*".⁷⁴
- (104) In this regard, the Commission interviewed several suppliers of primary and revision knee implants. Lima, for example, explained that the use of primary knee implants in revision surgery would materialise in approximately 1-2% of revision surgery procedures.⁷⁵
- (105) S&N explained that "*[...] a primary implant could be used in a revision surgery, provided that there is enough bone stock and good quality tissue [...] this overlap would not exceed 5% of all revision cases. In this light, S&N believes that, there is very limited substitutability between primary and revision implants*".⁷⁶
- (106) According to J&J/DePuy, "*Today, in a minority of cases, a primary implant can be used in a revision surgery. Nonetheless, the larger majority of revision cases are treated with a revision implant*".⁷⁷
- (107) Another supplier even stated that "*[...] in more than 90% of the cases a revision implant is used for revision surgery. Therefore, the cases where a revision implant is used for a primary surgery and where a primary total implant is used for a revision surgeries remain rather limited*".⁷⁸

⁷⁰ 2014 SKAR, page 30.

⁷¹ 2014 SKAR, page 30.

⁷² 2013 SKAR, page 30.

⁷³ 2014 SKAR, page 31.

⁷⁴ Non-confidential minutes of the conference call with Dr Robertsson of 5.12.2014, paragraph 13.

⁷⁵ Non-confidential minutes of the conference call with Lima of 10.10.2014, paragraph 4.

⁷⁶ Non-confidential minutes of the conference call with S&N of 10.10.2014, paragraph 5.

⁷⁷ Non-confidential minutes of the conference call with J&J/DePuy, 7.11.2014, paragraph 4.

⁷⁸ Non-confidential minutes of the conference call with Link, 26.9.2014, paragraph 9.

- (108) Based on the arguments set out in this section, the Commission concludes that this potential demand-side substitutability between primary and revision knee implants, within revision surgery, remains very limited. Suppliers' statements also confirm that revision surgery is a second-line intervention, and therefore the likelihood of finding enough bone stock and good quality tissue for a primary knee implant to be used is inherently low.
- (109) Moreover, the Commission also understands that surgeons may decide to replace a single component of a primary implant, instead of the entire knee implant. In such cases, they will usually stick to the same supplier or even the same product family for compatibility reasons.⁷⁹
- (110) Conversely, when a surgeon decides that it is in the patient's best interest to remove an entire primary implant, s/he may decide to use a revision knee implant from the same supplier that sold that primary knee implant or to use a revision knee implant from a completely different supplier.⁸⁰ This was confirmed by J&J/DePuy, which explained that revision knee implants can be used to enter and win new accounts, which in turn also reinforces the view that the procurement of primary knee implants is different from that of revision knee implants.⁸¹
- (111) In the light of the arguments set out in this section, the Commission considers that primary knee implants are designed as a first line of treatment for the most common degenerative conditions. It is noted that cases where a revision knee implant is used - instead of a primary knee implant - in a primary surgery are extremely rare. Cases where primary knee implants are used - instead of revision knee implants - in revision surgery largely depend on the specific conditions of a given patient and also appear to be limited.
- (112) Based on the evidence in the file, the Commission considers that the limited, potential overlap between primary and revision knee implants does not justify the finding of a single product market. Quite to the contrary, the results of the in-depth market investigation strongly suggest the existence of distinct markets for primary and revision knee implants. The Commission takes the view that, from a demand-side perspective, primary and revision knee implants constitute distinct product markets.

Supply-side substitution

- (113) Generally, the main suppliers of primary knee implants also supply revision knee implants, with few exceptions. For example, Corin Group plc ("Corin") is active in primary knee implants, but not in revision knee implants.
- (114) The Commission's market investigation has indicated that a competitor active in primary implants - but not in revision implants - will not be able to "*switch production to the relevant products [revision segment] and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices*".⁸²
- (115) This is for instance explained by J&J/DePuy:

⁷⁹ Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraph 5.

⁸⁰ Non-confidential minutes of the conference call with Stryker of 11.11.2014, paragraph 6.

⁸¹ Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraph 6.

⁸² Commission Notice on the definition of relevant market for the purposes of Community competition law, paragraph 20.

"Developing a new primary or revision knee implant, that is not just a "me too" product, would take between 3-5 years to accomplish and would require significant investment. In terms of production, some equipment may be used to produce different implants, but there is typically also dedicated equipment for some components or implants and components. It may well be necessary to develop and/or acquire such dedicated equipment to make a switch [...]"⁸³

- (116) J&J/DePuy's explanation continues by elaborating on the difficulties that a firm seeking to switch to revision implants would encounter. For example, this firm would need to build up product track records, establish relationships with hospitals and surgeons, and retrain medical and non-medical staff. This view has been largely corroborated by several other players in the industry. For example, S&N explained that:

"Orthopaedic implants are highly specialised products. Their manufacturing process requires complex machinery operated by highly trained employees. This process has to comply with regulatory authorisation requirements, including GMP. Switching production from one type of implant to another would require significant investment and a considerable time commitment. It should be noted that it is significantly more expensive to manufacture revision implants. Sales force training is more complex, surgeon training is more complex. Distribution channels are the same. Generation of clinical evidence is much more complex with revision".⁸⁴

- (117) One of the more recent entrants to the European market (both primary and revision, but not unicondylar), Lima, also confirmed that, based on their experience, a project to enter the revision segment would take longer than two years.⁸⁵ Corin, another supplier active in primary implants, but not in revision, explained that:

"From a manufacturing standpoint, although the equipment is the same, producing components for revision implants is slightly different and significantly more expensive. A supplier has to deal with a much larger number of items in terms of components and accessories. By the same token, a supplier has to invest significant time and resources in additional instruments. [...] There is also substantial research and development activity to be undertaken to enter the revision market. It is just not possible to copy another revision implant or to simply extend an existing line of primary products".⁸⁶

- (118) Even players which are already producing primary and revision knee implants appear to face factors which limit their ability or diminish their incentives to switch production from one set of implants to the other.

- (119) When asked whether they would switch production between primary and revision knee implants in response to a SSNIP, the majority of suppliers replied negatively.⁸⁷

⁸³ Response to Questionnaire Q1 to competitors, question 12. See also Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraphs 7-9.

⁸⁴ Response to Questionnaire Q1 to competitors, question 12.1.

⁸⁵ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 6; and Non-confidential minutes with of the call with Lima of 10.11.2014, paragraph 10.

⁸⁶ Non-confidential minutes of the conference call with Corin of 12.11.2014, paragraphs 11 and 12.

⁸⁷ Response to Questionnaire Q1 to competitors, questions 13 and 14.

- (120) The Commission further assessed supply-side substitutability during several conference calls with the Notifying Parties' competitors.
- (a) J&J/DePuy explained that *"From a production standpoint[...] there is a clear difference between primary and revision implants [...]. Switching production from one component to another may be cumbersome because manufacturing processes are not necessarily the same [...]. This has direct repercussions on the production process in terms of time and costs and ability to switch ...the machine capacity that can be allocated to producing revision implants and their components is not totally unconstrained. The scale of such production is much reduced compared to the mass market, i.e. the market for primary knee implants. Some accessories designed for revision implants are even outsourced to external companies"*.⁸⁸
 - (b) S&N stated that *"[...] because revision knees are lower volume (around 10% of the knee market) this kind of switching [between primary and revision implants] would be difficult to do in a meaningful way. An orthopaedic company is accordingly unlikely to want to sacrifice part of its primary production for the revision one [...] switching production also requires switching production of instrument sets as revision implants also have many more instruments than primary implants, in the range of eight to 10 additional trays of instruments on top of the standard trays for primary surgeries"*.⁸⁹
 - (c) Lima considered that their manufacturing process varies significantly when it comes to femoral components for primary knee implants, as opposed to femoral components for revision implants. More in detail, Lima explained that *"Although femoral components share the same material and equipment with all others, they have more surfaces to machine and are more complex to produce. Overall, they are more costly to produce and target a market that is smaller than the mainstream primary market"*.⁹⁰
- (121) Moreover, the evidence in the file shows that the segment for revision knee implants is also characterised by different dynamics than those which affect competition in primary knee implants. The market for revision knee implants is smaller in size as confirmed by the arguments set out in this section. The number of surgeons performing revision surgery is also smaller than those performing mainstream primary surgery due to their level of complexity. Consequently, suppliers compete on a partially different target audience between these two segments.
- (122) In light of the arguments set out in this section, it appears that supply-side dynamics do not support a single product market encompassing primary and revision knee implants.
- (123) Based on the evidence in the file, the Commission concludes that primary and revision knee implants constitute distinct product markets.
- (124) Finally, for the sake of completeness, the Commission also considered whether its competitive assessment would materially have changed by retaining a single product market encompassing both primary and revision knee implants. The result of this exercise showed that in any event - as explained in section 8.6.4 -

⁸⁸ Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraphs 7-10.

⁸⁹ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 8.

⁹⁰ Non-confidential minutes of the conference call with Lima of 10.11.2014, paragraph 9.

the merger would significantly impede effective competition in Denmark and Sweden, even under this hypothetical product market definition.

Extreme Orthopaedics

- (125) During the in-depth market investigation, the Commission also found strong indications that hinged and limb salvage implants do not form part of the revision implant market.
- (126) From a demand-side perspective, two different situations can in principle be distinguished. First, as noted in recital (35), when the ligaments responsible for guiding the axle are not intact, and the stability of the joint is compromised, surgeons will have to use hinged implants. Second, in a number of extreme cases such as very complex revision surgery or tumorous conditions, surgeons will replace almost the entirety of the limb, often to avoid dramatic outcomes such as amputation.
- (127) Overall, as pointed out by Dr Robertsson, one of the authors of the 2014 and 2013 SKAR, "*There is a gradual transition from [hinged] implants into limb-saving implants and custom made implants*".⁹¹
- (128) The Commission notes that hinged implants are frequently used in revision surgery, but sometimes patients' conditions require this type of implants to be used already at the stage of primary surgery. Limb salvage implants can be used in the context of primary surgery in response to often dramatic patient conditions, and sometimes also in the context of revision surgery.
- (129) With respect to hinged implants, Aesculap lodged a complaint providing a number of arguments in support of a stand-alone market for hinged implants.⁹²
- (130) In its submission, Aesculap stated that hinged implants are primarily used as revision implants, though use in primary surgery is not excluded. However, it explains that those implants respond to specific clinical indications in case of severe injuries such as accidents. Hinged knee implants substitute the function of the collateral ligaments if they are deficient and not functioning, are connected by an axle and mostly lack flexibility.⁹³
- (131) According to the complainant, even if hinged implants can in principle be used for less severe injuries, substitutability is limited due to high costs and higher risks, as well as the surgical skill required to place this type of implants and the complex post-operation for patients.⁹⁴
- (132) The limited demand-side substitutability between hinged implants and other revision knee implants also appears to be supported by an article submitted by the Notifying Party in its White Paper on Total Knees. This article explains that hinged knee implants aim at very serious patient conditions, when the use of other designs is questionable.⁹⁵ More precisely, the article indicates that "A

⁹¹ Non-confidential minutes of the conference call with Dr Robertsson of 5.12.2014, paragraph 16.

⁹² Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08.2014, pages 9 and ff.

⁹³ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08.2014, page 9.

⁹⁴ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08.2014, page 10.

⁹⁵ The Journal of Bone and Joint Surgery (Br.) 2004 Aug; 86(6):813-7, available at <http://www.ncbi.nlm.nih.gov/pubmed/15330020>, retrieved on 17.12.2014.

*rotating-hinge total knee replacement (TKR) attempts to deal with deformed and destroyed knees with serious bony and ligamentous defects [...]. If unconstrained prostheses are used in such cases, a number of problems may occur. These include inadequate alignment, poor soft-tissue balance, post-operative instability and other longer term complications".*⁹⁶

- (133) From a supply-side perspective, the complainant argues that suppliers face difficulties when switching between hinged implants and other implants. In particular:

*"The production of hinge knees requires special instruments, different components as well as customized software. Hinge knees are more complex than other knee implants and the necessary developments efforts as well as investments are considerably higher".*⁹⁷

- (134) Moreover, Aesculap indicates that this segment is characterised by the increasing role of patent barriers, which hinder entry and even production of hinged knee implants. In particular, this would apply to modern hinged implants of third generation, which address some of the most common complications in the segment. Those implants try to avoid distraction and drilling, and improve security against dislocation.⁹⁸ Indeed, the segment for hinged knee implants is the only one that featured patent litigation.⁹⁹
- (135) The Commission also takes note of additional factors that could distinguish hinged knee implants from the other knee segments. For example, hinged knee implants are accounted for in separate tables and rows in the 2014 and 2013 SKAR,¹⁰⁰ which suggests that those knee implants constitute a different segment from a demand-side perspective. During a conference call, Dr Robertsson explained that, in case the ligaments of a given patient are no longer functional, surgeons will have to use a hinged knee implant, and in this segment there is much more inclination to switch to different suppliers compared to other knee segments, that is to say much less loyalty to brands.¹⁰¹
- (136) With respect to limb salvage implants, several suppliers, including major competitors, referred to these implants as extremely complex devices, often bordering custom-made solutions.
- (137) From a demand-side perspective, there is no doubt that these implants require intrusive and complex surgery on patients who are often in difficult clinical conditions. Switching to more standard revision implants is not an option for such patients.
- (138) These implants also entail significant challenges from a manufacturing point of view. As pointed out by J&J/DePuy:

⁹⁶ The Journal of Bone and Joint Surgery (Br.) 2004 Aug; 86(6):813-7, available at <http://www.ncbi.nlm.nih.gov/pubmed/15330020>, retrieved on 17.12. 2014.

⁹⁷ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08.2014, page 10.

⁹⁸ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08.2014, page 11.

⁹⁹ The litigation took place between Aesculap and Zimmer, and stemmed from a patent claim from Zimmer regarding patent EP 2 272 468 B1, which deals with the security against dislocation.

¹⁰⁰ 2014 SKAR, pages 30-31, and 2013 SKAR, page 30-31.

¹⁰¹ Non-confidential minutes of the conference call with Dr Robertsson of 5.12.2014, paragraphs 16-19.

"Suppliers active in this segment must offer comprehensive solutions, which border custom-made implants. Intuitively, production costs are very different than the ones for mass markets such as primary knee implants or even smaller segments such as revision and unicondylar knee implants".¹⁰²

- (139) S&N also indicated that limb salvage implants constitute a segment distinct from the revision one because products are very specific and usually even custom-made for patients.¹⁰³ Lima explained that resorting to limb salvage implants is in essence the next step following hinged knees, which could even be considered, in its view, as constituting a market in its own right.¹⁰⁴ Stryker also took the view that due to some specific features such as the level of surgeon skill required by these types of surgery; the overall low volume of such surgery and the need to produce almost custom-made solutions, limb salvage implants could be considered as constituting a stand-alone market.¹⁰⁵
- (140) In conclusion, it is worth noting that not all suppliers active in revision implants are also active in hinged knee and limb salvage implants. The Commission's market reconstruction indicates that suppliers such as Aesculap and Waldemar LINK GmbH & Co. KG ("Link") seem to be highly specialised in some types of extreme orthopaedics implants whilst only fringe players in primary and revision knee implants.
- (141) The in-depth market investigation has however been inconclusive as to whether hinged knee and limb salvage implants constitute distinct product markets or whether they constitute a single product market. In any event, the exact scope of the product market definition in this regard can be left open for the purposes of this Decision because the merger will not significantly impede effective competition under the narrowest market definition.

7.1.1.4. Conclusion

- (142) In light of the arguments set out in this section, for the purposes of this Decision, the Commission concludes that patello-femoral knee implants and unicondylar knee implants constitute two separate product markets, distinct from total knee implants.
- (143) As regards total implants, the Commission also concludes that demand and supply-side considerations do not support the finding of a single overall market for total knee implants encompassing primary and revision implants. Therefore, the competitive assessment will assess the merger in relation to separate product markets for primary knee implants and revision knee implants.
- (144) As regards extreme orthopaedic implants, the Commission concludes that these implants do not form part of the market for revision knee implants. The exact scope of this product market may however be left open for the purposes of this Decision because the merger will not significantly impede competition under the narrowest market definition, that is to say two separate markets for hinged knee implants and limb salvage implants.

¹⁰² Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraph 28.

¹⁰³ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 21.

¹⁰⁴ Non-confidential minutes of the conference call with Lima of 10.11.2014, paragraph 21.

¹⁰⁵ Non-confidential minutes of the conference call with Stryker of 11.11.2014, paragraph 20.

7.1.2. Elbow Implants

- (145) The elbow is a joint formed by the combination of the upper arm bone (the humerus) and the two lower arm bones (the radius and the ulna). The medial and lateral collateral ligaments along the inner aspect of the elbow support the elbow joint and limit the amount of rotation the joint experiences while the elbow is flexed. Although the elbow is capable of some rotation, the action of the hinge joint is largely uniaxial.
- (146) Total elbow replacement is a surgical procedure by which the elbow joint is replaced by a prosthetic implant. Total elbow prostheses are implants that resurface the two lower arm bones of the elbow joint and the distal humerus. A total elbow implant is made of two basic components: a humeral stem and an ulnar stem. The two stems are usually connected in a hinge-like fashion. All elbow implants are suitable both for fractures and degenerative pathologies.¹⁰⁶
- (147) There are two types of elbow implants: unconstrained and semi-constrained implants. With unconstrained implants there is no physical connection holding the parts of the implant together. The joint capsule, ligaments, muscles, and other structures of the joint maintain the contact between the moving surfaces of the implant. Unconstrained implants reproduce the natural anatomy of the joint as much as possible but rely on intact bone stock and ligaments for implant stability. Semi-constrained implants have a more limited range of motion, however, require less resection of bone stock for implantation and as a result are indicated for a wide variety of patients. The design of unconstrained and semi-constrained elbow implants is exhibited in Figure 7 below.

Figure 7: Design of unconstrained and semi-constrained elbow implants



Source: Form CO

- (148) In historic terms, the first elbow implant was completely constrained. Due to clinical problems related to the forces generated by the constrained hinge, new developments were made, resulting in semi-constrained elbows. Finally, the unconstrained types were developed. Currently semi-constrained elbow implants represent the bulk of the market as unconstrained elbow implants have had a limited adoption due to their more limitative conditions.

¹⁰⁶ The information submitted by the Notifying Party indicates that there are no differences in the elbow replacement implant used for primary and revision elbow procedures (Form CO, footnote 179).

- (149) The activities of the Parties only overlap in semi-constrained elbow implants. Zimmer does not manufacture unconstrained elbow implants. No market players are active in constrained elbow implants anymore.¹⁰⁷
- (150) The following section 7.1.2.2 onwards analyses the relevance of all the above segmentations in recital (149) for the purpose of carrying out the competition assessment in this case.

7.1.2.1. Past Commission decisions

- (151) The Commission has not analysed a market for elbow implants in the past.

7.1.2.2. The views of the Notifying Party

- (152) The Notifying Party submits that there is a single relevant product market for all total elbow implants and that further segmentation based on pathology or fixation method (unconstrained and semi-constrained) is not relevant. Distinction by pathology is not appropriate as total elbow replacement implants do not target specific pathologies (total elbows are used for both degenerative conditions and fractures). Further segmentation by type of implant (unconstrained versus semi-constrained) is not appropriate either, as both types of implants can be used to treat the same pathology and most major suppliers manufacture both unconstrained and semi-constrained elbow implants.
- (153) The Notifying Party submits that most second generation designs today incorporate some sort of stability or modular stability. Most companies today market their products in both, a semi- and un-constrained capacity. Moreover, Tornier Inc. ("Tornier") manufactures a total elbow replacement implant, Latitude, which is convertible and can be used either as a semi-constrained or as a constrained prosthesis. In addition, Link introduced the Endo-Model, which integrates a fully constrained hinge for the insertion of the humeroulnar joint with an unconstrained replacement of the humeroradial joint.
- (154) Based on the arguments set out in this section, the Notifying Party submits that the correct market definition should include both semi-constrained and unconstrained elbows.

7.1.2.3. The Commission's Assessment

- (155) All total elbow implants are used to treat both degenerative pathologies and fractures. Suppliers cannot discriminate between the different uses of their product. This is because hospitals negotiate a purchase price for elbow replacements independently from pathology. The market investigation did not indicate that segmentation by pathology would be appropriate.¹⁰⁸
- (156) Whilst there were some limited indications in the market investigation that segmentation by type of implant might not be appropriate, the market investigation was inconclusive on this point.¹⁰⁹ This segmentation is commonly

¹⁰⁷ Biomet also supplies "radial head replacements", which are used for certain degenerative and fracture pathologies of the radius only. Zimmer indicated that it does not supply radial heads [...]*. In the EEA sales for these devices amounted to EUR [1-50] million in 2013. Biomet's sales of these devices (constituting approximately [5-10]% of the total sales of these devices in the EEA) are not included in the market share figures submitted by the Notifying Party regarding elbow implants. These radial head replacements are therefore not referred to further for the purposes of this Decision.

¹⁰⁸ Responses to Questionnaire Q1 to competitors, question 75; Responses to Questionnaire Q2 to customers, question 15.

¹⁰⁹ Responses to Questionnaire Q1 to competitors, questions 70-74.

used by surgeons when deciding which type of elbow implant to use relates to the relevant characteristics of each elbow implant product.

- (157) Despite the physical differences between semi-constrained and unconstrained implants, both are used to treat the same pathologies and used both for degenerative conditions and fractures.
- (158) With a semi-constrained implant, the elbow has a more limited range of motion, but all patients may use this type of implant. In contrast, unconstrained implants rely on intact bone stock and ligaments for implant stability and will have a greater range of motion as a result.
- (159) Therefore, from a demand-side, an unconstrained elbow implant is a substitute for a semi-constrained implant if the patient has sufficiently strong soft tissues. On the other hand, unconstrained implants are always substitutable by semi-constrained implants. A semi-constrained elbow constitutes an option that suits all types of patients because it provides the highest stability to the joint.
- (160) In addition, some implants are convertible, and as such capable of being used both as semi-constrained or unconstrained elbow implants. To adapt the product to be semi-constrained in convertible implants, only an additional pin is inserted, connecting the two components together.

7.1.2.4. Conclusion

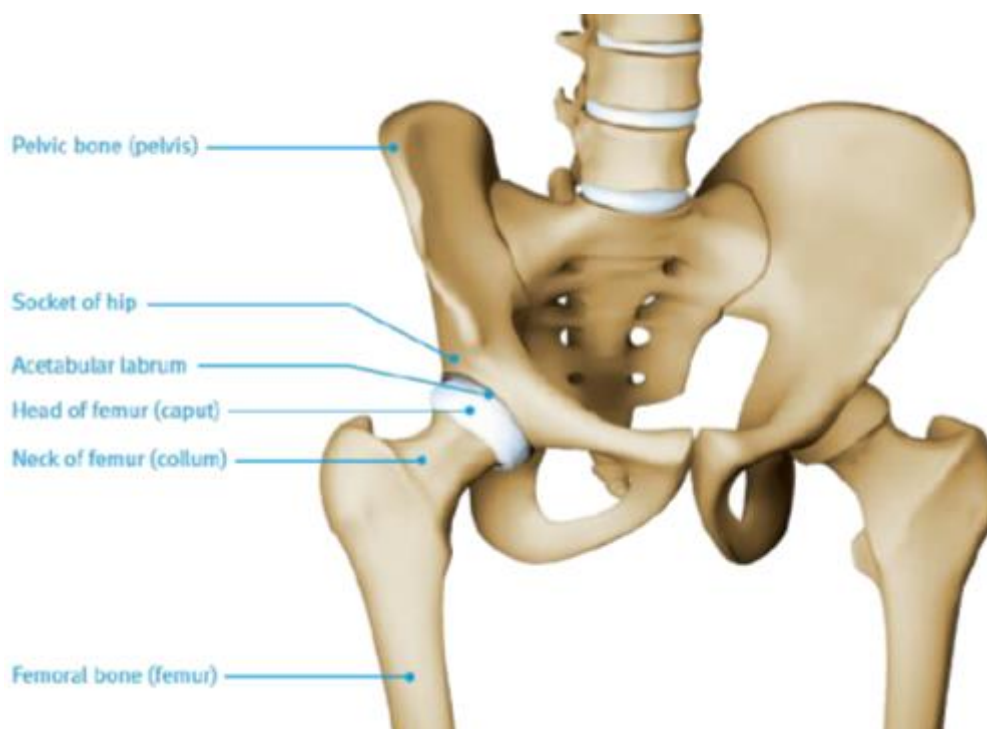
- (161) In light of the arguments set out in this section, for the purposes of this Decision, the exact product market definition can be left open since the proposed merger does not significantly impede effective competition under any of the plausible alternative product market definitions relevant to this case (that is, in relation to (i) an overall market comprising semi-constrained and unconstrained elbow implants; and (ii) a market comprising semi-constrained elbow implants only). In any event, the commitments submitted by the Notifying Party remedy the concerns both in the overall elbow market and in a potential narrower market for semi-constrained implants. Therefore, it is not necessary to reach a definitive conclusion in this regard.

7.1.3. *Hip Implants*

- (162) The hip is a ball-and-socket joint through which the dome-shaped head of the femur (thighbone) articulates within the pelvis.¹¹⁰

¹¹⁰ Form CO, paragraph 854.

Figure 8: Anatomy of the hip joint



Source: Notifying Party's Product Overview Hips-14.10.2014

- (163) Hip replacement is a surgical procedure where the damaged bone and cartilage are removed and replaced with prosthetic components.¹¹¹ There are three main types of hip replacement interventions: (i) primary hip replacement (surgery takes place for a first time), (ii) revision hip replacement (when a previous total or partial hip implant has worn out or failed),¹¹² and (iii) resurfacing hip replacement (the femoral head is trimmed and capped with a smooth metal covering).¹¹³
- (164) Hip replacement may be indicated to treat several pathologies, including complex hip fractures which cannot heal naturally (fracture hip replacement) and degenerative hip conditions, such as osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis and childhood hip disease (degenerative hip replacement).¹¹⁴
- (165) A total hip implant consists of four basic components: an acetabular cup, a femoral stem, an acetabular insert and a modular head. The damaged femoral head is removed and replaced with a metal stem that is placed into the hollow centre of the femur. The femoral stem may be either cemented or "press fit" into the bone. A metal or ceramic ball is placed on the upper part of the stem. This ball replaces the damaged femoral head that was removed. The damaged cartilage surface of the socket (acetabulum) is removed and replaced with a metal socket.¹¹⁵ Screws or cement are sometimes used to hold the socket in

¹¹¹ Form CO, paragraph 857.

¹¹² Form CO, paragraph 858.

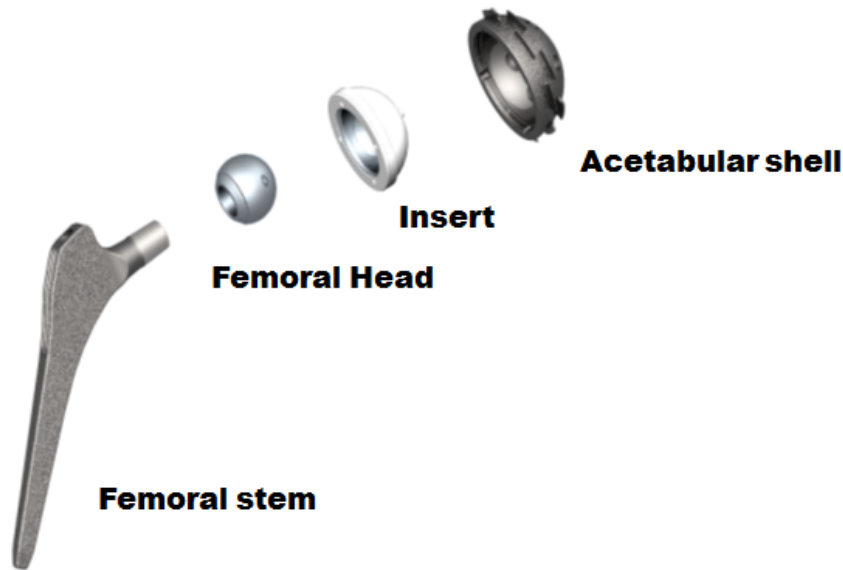
¹¹³ Form CO, paragraph 858.

¹¹⁴ Form CO, paragraph 852.

¹¹⁵ In case of a cemented acetabular component, the plastic part can be directly cemented into the acetabulum, without the need of a metal socket.

place. A plastic, ceramic or metal spacer is inserted between the new ball and the socket to allow for a smooth gliding surface.¹¹⁶

Figure 9: Components of a full hip system



Source: Notifying Party's Product Overview Hips-14.10.2014

- (166) In revision interventions longer and larger stems than in primary interventions are usually used to accommodate the extra bone loss that results from the removal of the initial implant.¹¹⁷ Resurfacing hip implants (the most recent hip implants to come to market) have a larger head, or "ball" portion resulting in an increased contact area between the acetabular and femoral components, reducing the chance of implant dislocation and a shorter stem attached to the one-piece femoral head.¹¹⁸
- (167) When a femoral stem, a femoral head and an acetabular cup are used during surgery, the procedure is called total hip replacement. When only the femoral or acetabular side of the joint is replaced, the procedure is called partial hip replacement. Indeed, partial implants are often modular components of total implant systems.¹¹⁹
- (168) A further differentiating factor is the surgical design philosophy on which the different implants are based. Surgical design philosophies for hip implants include the Charnley, Müller, Exeter and Stanmore traditions.
- (169) Hip implants vary by fixation method and bearing type. Depending on the fixation method used between the bone and the implant in order for the latter to be kept in place, hip implants can be (i) cemented, (ii) cementless, or (iii) hybrid.¹²⁰ Hybrid implants typically refer to implants in which a cementless acetabular cup is placed on a cemented stem to create a complete system; however, the opposite can also occur (a cemented cup is placed with a cementless stem).¹²¹

¹¹⁶ Form CO, paragraph 857.
¹¹⁷ Form CO, paragraph 860.
¹¹⁸ Form CO, paragraph 865.
¹¹⁹ Form CO, paragraph 861.
¹²⁰ Form CO, paragraph 872.
¹²¹ Form CO, paragraph 873.

- (170) The articulation whereby the acetabular cup itself is lined with a friction-reducing lining that articulates with the head of the femoral side of the implant is known as the bearing. Hip implants may be of (i) polyethylene bearing, (ii) metal bearings, and (iii) ceramic bearings. Acetabular insert liners and modular heads may be made of different materials.¹²²

7.1.3.1. Past Commission decisions

- (171) In past decisions,¹²³ the Commission considered the following segmentations of the market for hip implants: (i) by surgical design philosophy; (ii) by pathology (fractures and degenerative conditions); (iii) by fixation method (cemented and cementless); and (iii) by type of intervention (primary, revision, partial, total and resurfacing). However, the Commission ultimately defined a single product market for hip implants.

7.1.3.2. The views of the Notifying Party

- (172) The Notifying Party believes there are no grounds for departing from the approach followed by the Commission in past decisions, namely, that there is a single relevant product market encompassing all hip implants. This contention is made on the basis that on the demand-side, various implants of different intervention types, as well as implants for different pathologies and implants with different features are used interchangeably. On the supply-side, the Notifying Party claims that all manufacturers active in the hip market offer solutions with different features for all pathologies and types of intervention and that they can easily start producing another type of implant or expand production.¹²⁴
- (173) More precisely, the Notifying Party claims that a market segmentation by pathology is not appropriate given that all implants can be used interchangeably to treat all pathologies and, therefore, it is not possible to raise the price of implants treating either fracture or arthritis pathologies.
- (174) As regards a possible segmentation by type of intervention the Notifying Party explains that it is possible to mix and match hip components of the same supplier ("intra-brand mix and matching") that can be used indistinctly for different types of intervention.
- (175) Finally, the Notifying Party also claims that a market definition by feature (material, fixation mode) is neither appropriate because different types of fixation and materials are fairly substitutable. Moreover implants with different features are often priced the same when suppliers respond to tenders. Each of them has its advantages and disadvantages and therefore surgeons switch between all products available depending on the specific needs of each patient.

7.1.3.3. The Commission's Assessment

- (176) The market investigation provided evidence the Notifying Party's claim that segmentation of the hip implants market by pathology, into fracture, degenerative and failure hip implants, is not appropriate. Indeed, the majority

¹²² Form CO, paragraph 874.

¹²³ Commission decision of 28.10.1998 in case M.1286 – *Johnson & Johnson / DePuy*, paragraphs 12-13 and Commission decision of 27.05.2003 in case M.3146 – *Smith&Nephew / Centerpulse*, paragraphs 11-12.

¹²⁴ Form CO, paragraph 886; Response to the Article 6(1)(c) Decision, paragraph 144.

of competitors and customers indicated that most implants can be used interchangeably, without specifying the pathology of a patient as a differentiating factor. Respondents to the market investigation were divided as regards a possible segmentation by type (into primary, revision and resurfacing hip implants) and level of intervention (total, partial).¹²⁵

- (177) From the demand-side, although numerous respondents to the market investigation indicated that segmentation of hip implants according to the type of intervention may be appropriate, they pointed out that choosing an implant over another depends mostly on the age and morphology of the patient, and that most implants can be used interchangeably.¹²⁶
- (178) At the same time, revision interventions are usually more complex than primary interventions, femoral implant stability being of critical importance, thus requiring significant experience and expertise on the part of the surgeon and the training force of the suppliers. The case is the same for hip resurfacing interventions.¹²⁷
- (179) However, the market investigation provided evidence that segmentation of the market by type/level of intervention is not justified in the market for hip implants. Indeed, the Commission notes that the different modular components of a total hip system can be used for primary and revision surgery, as well as for total and partial revision surgery indistinctly.¹²⁸ Intra- brand mix and matching is common practice and generally encouraged by the suppliers, including by Zimmer.¹²⁹ In order to ensure functional compatibility of different components and the quality of performance, Zimmer performs tests and engineering evaluations on each product's combination. As way of example, a typical Zimmer hip stem has been tested and approved for use with 5-10 CoCr femoral heads, 5-10 ceramic heads, approximately 5 unipolar or bipolar heads and a couple of stainless steel titanium femoral heads. Zimmer publishes precise tables showing the compatibility of different pairs of products, that is, separate tables for a) different head and stem combinations, b) articulating combinations and c) other combinations.¹³⁰ Other competitors also test their products for compatibility purposes.¹³¹
- (180) The common mix and matching between components of the same supplier depending on the type (primary, revision) and level (total, partial) of intervention suggests demand and also supply-side substitutability, insofar as all players have hip implants systems allowing such modularity. Tenders are also organised by components rather than by type/level of intervention.¹³²

¹²⁵ Responses to Questionnaire Q1 to competitors question 38, Responses to Questionnaire Q2 to customers, question 9.

¹²⁶ Responses to Questionnaire Q2 to customers, questions 9-10.

¹²⁷ Responses to Questionnaire Q2 to customers, question 11.1.

¹²⁸ Response to the Article 6(1)(c) Decision, paragraph 154.

¹²⁹ Response to the Article 6(1)(c) Decision, paragraph 155.

¹³⁰ This information publicly available at <http://www.zimmer.com/en-SE/hcp/hip-product-compatibility.aspx>, accessed on 23.02.2015.

¹³¹ See for example for Medacta <https://www.medacta.com/en/europe/medical-professionals/products/hip/hip-compatibility>, accessed on 23.02.2015 and for Stryker [http://www.rpa.spot.pt/getdoc/f9b4d81d-6b34-4d22-a374-d90299143771/RESTORATION-MODULAR-Surgical-Technique-\(Stryker\).aspx](http://www.rpa.spot.pt/getdoc/f9b4d81d-6b34-4d22-a374-d90299143771/RESTORATION-MODULAR-Surgical-Technique-(Stryker).aspx), accessed on 23.02. 2015.

¹³² See for example Responses to Questionnaires 21 on tenders in Denmark of 22.10. 2014.

- (181) Similarly, the market investigation did not suggest segmentation of an overall hip implants market by fixation method. The investigation indicated that surgeons appear to have different approaches concerning the fixation method of hip implants, driven by their surgical philosophy, clinical evidence, geographical tendency and peers opinion. Also, some categories of patients might need cemented hip implants, such as elderly patients.¹³³ Yet, the choice between a cemented and a cementless hip implant may depend as well on other factors such as the requirements of the patient's disease state, and mobility. In certain countries a mix of cemented and cementless (known as hybrid implants) is used.¹³⁴
- (182) As regards a possible segmentation of the overall hip market by bearing type and surgical design philosophy respondents pointed out that these segmentations are less commonly used and not necessarily commercially meaningful from the suppliers' point of view.¹³⁵

7.1.3.4. Conclusion

- (183) In light of the arguments set out in this section and on the basis of the above demand and supply-side considerations, the Commission concludes that the relevant product market is the overall market for hip implants.

7.1.4. *Shoulder Implants*

- (184) 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 glides against a dish-like socket (glenoid) in the shoulder blade (capsula). It is a multiaxial joint, permitting a wide range of movement. The shoulder can move up and down, forward and backward, as well as laterally.
- (185) A shoulder implant 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). When both the humeral and glenoid components are used during surgery, the procedure is called total shoulder replacement; when only the humeral head and the stem, but not the glenoid, are used in the surgery, the procedure is called partial shoulder replacement; when the socket and the metal ball are switched (reversed) compared to the standard shoulder prosthesis, the procedure is called reverse shoulder replacement.

7.1.4.1. Past Commission decisions

- (186) In the past,¹³⁶ the Commission has left open the question of whether the relevant product market should be considered as an overall shoulder implants market or whether that market should be spilt into three categories on the basis of three corresponding pathologies. The Commission carried out its assessment on the basis of an overall market for shoulder implants as well as on the basis of narrower markets for each of the three pathologies: (i) fracture shoulder

¹³³ Non-confidential minutes of the conference call with Dr Marcacci from the Istituto Ortopedico Rizzoli of 09.07.2014; and Non-confidential minutes of the conference call with Johnson&Johnson/DePuy Synthes (competitor) of 04.07. 2014.

¹³⁴ Responses to Questionnaire Q1 to competitors, questions 46-49.

¹³⁵ Responses to Questionnaire Q1 to competitors, questions 34-37.

¹³⁶ Commission decision of 18.04.2012 in Case M.6266 – *Johnson&Johnson/Synthes*, paragraphs 89 - 96.

replacement, (ii) degenerative shoulder replacement, and (iii) reverse shoulder replacement. The Commission, however, concluded that further sub-segmentation according to the level of intervention (total, partial, stemless, resurfacing or revision) inside each of the three pathology categories was not plausible.

7.1.4.2. The views of the Notifying Party

- (187) According to the Notifying Party, there are two main types of implants that can be used for shoulder replacements (i) total/primary shoulder replacement and (ii) reverse shoulder replacement implants. Both of them can be used to treat either (i) degenerative diseases such as osteoarthritis or rheumatoid arthritis, or (ii) severe fractures. In addition, reverse implants are recommended when a total/primary shoulder replacement has failed. In shoulder revision surgery, the operation would most likely be performed using a reverse shoulder implant since the muscles and the tendons will already have suffered from the first surgery.
- (188) The Notifying Party submits that there is a single relevant product market for all shoulder implants. On the demand-side, surgeons can use interchangeably various implants to treat both fracture and degenerative conditions. On the supply-side, the manufacturing process and the technology are very similar, with only minor differences. In fact, many suppliers have a complete portfolio of shoulder implants that can treat all pathologies.

7.1.4.3. The Commission's Assessment

- (189) The market investigation¹³⁷ provided indications supporting the recent findings in the *Johnson&Johnson/Synthes* Decision that segmentation of the overall market for shoulder implants on the basis of the pathology to be treated, as well as the definition of a separate market for reverse shoulders is appropriate. In this regard it is to be noted that hospitals frequently tender fracture, degenerative and reverse implants separately (through separate tenders or separate lots in a given tender).¹³⁸
- (190) On the contrary, there are no valid reasons justifying a further segmentation of the market based on the level of intervention (total, partial, stemless, resurfacing, revision). Indeed, total implants,¹³⁹ resurfacing implants and stemless implants are all used to treat degenerative conditions, whilst partial implants are mainly used to treat fractures since they are intended to replace only the humeral stem, and not the glenoid.¹⁴⁰ In revision procedures, any of the following implants can be used: reverse implants, total implants (anatomic) or partial implants.¹⁴¹

7.1.4.4. Conclusion

- (191) The Commission considers that for the purposes of the present Decision the exact product market definition can be left open since the proposed merger does not significantly impede competition under any of the plausible

¹³⁷ Responses to Questionnaire Q1 to competitors, questions 53, 57 and 65. Responses to Questionnaire Q2 to customers, question 12.

¹³⁸ Responses to Questionnaire Q1 to competitors, questions 53, 57 and 65.

¹³⁹ In 98% of the cases total implants are used to treat degenerative conditions.

¹⁴⁰ Non-confidential minutes of the conference call with Lima of 25.09.2014, paragraph 5.

¹⁴¹ Non-confidential minutes of the conference call with Lima of 25.09.2014, paragraph 5.

alternative product market definitions, namely i) the overall market for shoulder replacement, ii) the market for fracture shoulder replacement; iii) the market for degenerative shoulder replacement and iv) the market for reverse shoulder replacement.

7.1.5. *Other Products*

7.1.5.1. Bone Cement

- (192) Bone cement is used to aid the fixation of large joint (hip and knee) and small joint (shoulder, elbow and ankle) reconstructive implants. The cement fills the space between the bone and the implant and provides an important elastic zone to absorb the force that is exerted on the joints and implant, as well as anchoring the implant to the bone. Bone cement is prepared by mixing separate liquid and powder components on site during the procedure.
- (193) The characteristics of bone cement may vary according to the following factors:
- (a) Antibiotic mix. Bone cement may or may not be mixed with antibiotics. Antibiotic cement provides the added benefit of reducing the risk of infection.
 - (b) Viscosity. Cement may be of a higher or lower viscosity. Low viscosity cement has a longer waiting phase than high viscosity cement. The viscosity rapidly increases during the working phase. Conversely, high viscosity cement has a relatively shorter waiting phase and a relatively longer working phase, as the viscosity remains constant until the end of the working phase. The hardening phase may also vary as a function of the viscosity of the bone cement.
- (194) Low viscosity bone cement is used for small joints, such as shoulders and elbows, because it is easier to flow inside and get a better seat on such bones, which are more difficult to access and which cannot be otherwise prepared by pulsed lavage due to their small size. High viscosity bone cement has a better clinical outcome and is used for large joints, such as hips and knees. It should be noted that there is no strict definition, nor regulation, regarding viscosity and each supplier specifies its own criteria to define its products as high and low viscosity.¹⁴²

Past Commission decisions

- (195) The Commission has not previously examined the market for bone cement.

The views of the Notifying Party

- (196) The Notifying Party submits that there is a single relevant product market for all bone cements since (i) customers are expected to switch to alternative types of cement in the event of a price increase, and (ii) the products and the manufacturing process are similar and relatively uncomplicated and chemical specifications have been in the public domain for many years.
- (197) From a supply-side perspective, all bone cement is produced in the same way. Antibiotic cement is produced by taking standard bone cement and adding one or two different antibiotics through an industrial mixing process. Antibiotics typically added to bone cement, such as gentamicin, are no longer patent-

¹⁴² Non-confidential minutes of the conference call with Heraeus of 22.09.2014.

protected and are offered by numerous generic manufactures. Accordingly, there are no restrictions preventing access to the antibiotics.¹⁴³

- (198) From a demand-side perspective, both formulations (antibiotic and non-antibiotic) can be used across different types of joint reconstruction interventions. The Parties are not aware of any particular intervention which could be performed with only bone cement with or without antibiotics. Importantly, the frequency of use of each formulation is the same regardless of the intervention.¹⁴⁴
- (199) Similarly for the level of viscosity, from a supply-side perspective, suppliers can easily move from the production of a higher to lower formulation (and the other way around). While individual surgeons may find it more convenient to use a specific formulation of bone cement for certain types of interventions, from a clinical point of view, bone cements with lower or higher viscosity are substitutable and can be used across all different joint arthroplasty procedures.¹⁴⁵

The Commission's Assessment

- (200) According to the market investigation antibiotic bone cement represents 95% of the overall bone cement market in the EEA. The non-antibiotic bone cement covers only the remaining 5% of the market. Similarly, high viscosity bone cement represents 91% of the market, whereas the remaining 9% of the market is split between medium and low viscosity bone cement.¹⁴⁶

Conclusion

- (201) For the purpose of the present Decision, the Commission carried out its competitive assessment based on an overall market for bone cement. The assessment would not significantly differ if the market was further segmented taking into account whether the bone cement is or not mixed with antibiotics and whether the bone cement is high, medium or low viscosity given that high viscosity bone cement with antibiotics represents more than 90% of the market.

7.1.5.2. Bone Cement Accessories

- (202) Bone cement accessories are used as an aid in the application of bone cement in cemented joint replacement and other procedures such as vertebroplasty. They fall into five broad categories, associated with mixing and delivery ("Cement Delivery and Mixing Systems"), moulding cement, cleaning the area where cement is to be inserted, and pressurisation accessories used to pressurise the cement. The cement mixing and delivery systems include: gun cartridges, enclosed vacuum mixers and manual mixing bowls.

Past Commission decisions

- (203) The Commission has not previously examined the market for bone cement accessories.

¹⁴³ Reply to the Article 6(1)(c) Decision, paragraph 1013.

¹⁴⁴ Reply to the Article 6(1)(c) Decision, paragraphs 1009 and 1010.

¹⁴⁵ Reply to the Article 6(1)(c) Decision, paragraphs 1017 and 1023.

¹⁴⁶ Non-confidential minutes of the conference call with Heraeus of 22.09.2014.

The views of the Notifying Party

- (204) According to the Notifying Party there is a single relevant product market for all bone cements accessories since (i) different bone cement accessories are all used in conjunction with each other when applying bone cement during surgery and (ii) all bone cement accessories are available from third-party manufacturers.
- (205) In terms of manufacturing, all bone cement accessories are produced using the same basic materials such as plastic and metal and their production does not require the use of very advanced technologies. Furthermore, there are third-party manufacturers offering complete sets of bone cement accessories. [...]*

The Commission's Assessment

- (206) The market investigation indicated that bone cement accessories are procured together,¹⁴⁷ meaning customers see mixing and delivery systems as an assortment market and procure both types of accessories together. The procurement of all bone cement accessories is standard practice at European level as noted by one competitor: "*Bone cement accessories are tendered all together and not in separate lots. This trend is the standard all over Europe*".¹⁴⁸
- (207) Switching between the production of different bone cement accessories is possible as evidenced by the market investigation: "*switching [...] is relatively inexpensive in terms of production costs – provided that the supplier either manufactures their own accessories or can find another provider. Finding distribution channels is generally not difficult*".¹⁴⁹
- (208) Furthermore, open and vacuum mixing systems are used interchangeably. Differentiation between gun cartridges and mixing systems also is not plausible as typically the same device has a role of a mixing container and a gun cartridge.

Conclusion

- (209) On this basis, for the purposes of the present Decision, the Commission concludes that the relevant product market is the overall market for bone cement accessories.

7.1.5.3. Surgical Tools (Pulsed Lavage)

- (210) Pulsed lavage, or pulsatile jet lavage, is a high-pressure wound irrigation system commonly used in orthopaedic surgery and in wound treatment. The pulsed lavage system consists of an electrically powered device which delivers a pressurised and irrigating solution to the wound. The device administers a fluid stream to the target area and has a built-in suction tube that concurrently removes the fluid as it is dispensed. A small circular shield is attached to the nozzle of the device, which serves to decrease gross splash when placed in contact with the wound. Tubing connects the device to a sterile irrigation fluid bag and a suction pump with a collection canister. A pulsed lavage device is depicted in Figure 10 below.

¹⁴⁷ Non-confidential minutes of the conference call with Heraeus of 22.09.2014.

¹⁴⁸ Non-confidential minutes of the conference call with KMT of 30.09.2014.

¹⁴⁹ Replies to question 83 of the Commission's request for information pursuant to Article 11 Council Regulation (EC) No 139/2004 addressed to competitors Q1-Questionnaire to Competitors.

Figure 10: Pulsed Lavage Device



Source: Form CO

- (211) In wound cleansing, pulsed lavage is used to remove necrotic tissue, bacteria and foreign material from the wound. In orthopaedic surgery, the pulsed lavage uses pulsed jets of irrigated solution to penetrate into the cancellous bone, removing blood and debris, increasing cement penetration, and likewise cement-bone interface strength.
- (212) Pulsed lavage devices can be distinguished based on the power of pressure administered to target tissue and type of tissue which they are supposed to irrigate to: (a) high-pressure devices offering high pressure cleansing action for bone and (b) low-pressure devices for soft tissue debridement. Further, pulsed lavage devices can be disposable, semi-disposable and non-disposable.¹⁵⁰

Past Commission decisions

- (213) The Commission has not previously defined a market for surgical power accessories, and particularly for pulsed lavage.

The views of the Notifying Party

- (214) The Notifying Party claims that the relevant product market is at least as broad as pulsed lavage, or even broader, meaning that pulsed lavage belongs to a market for surgical accessories or wound cleaning systems.
- (215) The Notifying Party claims that despite the well-recognised therapeutic benefits of pulse lavage, surgeons often use cheaper, less effective wound cleaning methods, such as bulb syringes or whirlpool therapy. In some markets, pulsed lavage is considered a mandatory element of cemented arthroplasty procedures (for example in the Nordic countries), whereas in other markets, it is used in less than [50-60]% of cemented interventions (for example in Poland). Similarly, while the high-pressure pulsed lavage devices are best suited for the bone preparation in cemented arthroplasty procedures, low-pressure pulsed lavage systems can be used for the same indication.

¹⁵⁰ Form CO, paragraph 2527.

The Commission's Assessment

- (216) Based on conference calls and feedback collected from competitors, customers of the Notifying Party and key opinion leaders, the Commission considers that there is a high degree of substitutability between high/low pressure pulsed lavage, as well as between disposable/non-disposable and semi-disposable devices.

Conclusion

- (217) The Commission considers that for the purposes of the present Decision the exact product market definition and in particular the question whether pulsed lavage belongs to a broader market encompassing surgical accessories or other wound cleaning system can be left open since the proposed merger does not significantly impede competition under any of the plausible alternative product market definitions.
- (218) Based on the arguments set out in this section, in this Decision the Commission will assess the market for pulsed lavage which is considered the narrowest possible plausible segmentation.

7.1.5.4. Spine Devices

- (219) Spine devices are used in surgical procedures to repair vertebrae and intervertebral discs in the spinal column.
- (220) The spine is a complex structure. It is a column consisting of twenty four separate vertebrae interspaced with cartilage and nine fused vertebrae forming the sacrum and the coccyx. The vertebrae of the spine align so that their vertebral canals form a hollow, bony tube to protect the spinal cord from external damage and infection. There are five major regions of the spine, differing in terms of the function, as well as the structure: cervical, thoracic, lumbar sacral and coccygeal.

Past Commission decisions

- (221) In *J&J/Synthes*,¹⁵¹ the Commission left the market definition for spine devices open. The Commission identified three broad segments of spine implant products (i) fusion devices, (ii) non-fusion (or motion) devices and (iii) Vertebral Compression Fractures ("VCF") systems.
- (222) In *J&J/Synthes*, the Commission identified further segmentations within these three broad product categories but left open whether the markets should be further sub-segmented.
- (223) Fusion devices are implants used to permanently fuse together two or more vertebrae to immobilise and stabilise the spine in the affected area. Fusion devices can be segmented into several broad categories: (i) pedicle screw / rod based fixation devices, (ii) plating systems, (iii) inter-body cages and (iv) corpectomy cages. Some of these segments are further divided between cervical and thoracolumbar devices.
- (224) Non-fusion devices are generally used to treat similar pathologies to fusion devices, but they seek to preserve the natural motion of the spine. They may be segmented into (i) dynamic stabilisation devices and (ii) artificial disks. In

¹⁵¹ Commission decision of 18.04.2012 in Case M.6266 – *Johnson&Johnson/Synthes*.

addition, there are a number of other non-fusion implants and technologies, most of which are still in development.

- (225) VCF devices are used in the minimally invasive ("MIS") non-surgical treatment of vertebral compression fractures. Such fractures are caused by a sudden collapse of vertebrae which are significantly weakened (most commonly by osteoporosis, but also by tumours) causing significant pain to the patient. The two main types of VCF procedure are (i) vertebroplasty and (ii) vertebral augmentation.

The views of the Notifying Party

- (226) The Notifying Party argues that the relevant product market could be defined as the overall spine market, based on demand and supply-side substitution considerations.
- (227) The Notifying Party notes that spine products target in general the same set of pathologies. Similarly, surgeons are trained to treat the same set of pathologies using different techniques.
- (228) The surgeon's decision on which product to use will be based on a set of different parameters, such as age, area of pathology, expertise / education of the surgeon, clinical outcome and local / regional habits. Importantly, different techniques could be used to treat the same pathology. In this sense, fusion, non-fusion and VCF target similar pathologies and share the same patient base.
- (229) The Notifying Party also notes that there is substitution between fusion and non-fusion products. In particular, in pathologies that require an intervention in the posterior part of the spine, fusion and non-fusion products may be used interchangeably.
- (230) In addition, major suppliers tend to have a complete portfolio that can treat all pathologies.
- (231) Finally, most suppliers outsource parts of their production process. This makes it easier for suppliers to react to changes in relative prices by adjusting their outsourced production.

The Commission's Assessment

- (232) The market investigation has not provided indications leading to consider that there are valid reasons to depart from the market definition retained by the Commission in *J&J/Synthes*.

Conclusion

- (233) The Commission considers that for the purposes of the present Decision the exact product market definition can be left open since the proposed merger does not significantly impede competition under any of the plausible alternative product market definitions.
- (234) Based on the arguments set out in this section, in this Decision the Commission will assess the markets for spine implants based on the following plausible segmentations: (i) overall spine implants; and (ii) fusion devices; (iii) non-fusion devices; and (iv) VCF devices. The Commission will also consider possible further sub-segmentations: Within fusion devices: (v) pedicle screw / rod based fixation devices, (vi) plating systems, (vii) inter-body cages and (viii) corpectomy cages. Some of these segments are further divided between cervical and thoracolumbar devices. Within non-fusion devices: (ix) dynamic

stabilisation devices and (x) artificial disks. Within VCF devices: (xi) vertebroplasty and (xii) vertebral augmentation.

7.1.5.5. Trauma Devices

- (235) Trauma devices are used to treat bone fractures throughout the appendicular skeleton, that is, the upper extremities (including hand and wrist), the lower extremities (including foot and ankle), the shoulder girdle and the pelvic girdle. Their main purpose is to keep the bone in place and support it during the healing process. The treatment method for bone fractures depends primarily on the nature and severity of the fracture. Surgeons can apply internal and external fixation devices.

Past Commission decisions

- (236) In the past,¹⁵² the Commission analysed the trauma market devices identifying two main potential product markets, namely internal fixation devices and external fixation devices, that can be further segmented. As regards internal fixation devices the Commission carried out its assessment on the basis of the following narrower sub-segments: (i) plating systems (plates and screws), (ii) intramedullary ("IM") nails, (iii) cannulated screws, (iv) compression hip screws, (v) IM hip screws, and (vi) ancillary devices (such as pins, wires and cables). Among the plating systems, a distinction was made between non-anatomic and the anatomically shaped plates. External fixation devices were assessed taking into consideration the following sub-segments: (i) universal external fixation, and (ii) specialised external fixation.

The views of the Notifying Party

- (237) The Notifying Party broadly endorses the above market segmentation in recital (236). However it submits that IM nails and IM hips screws belong to a single product market as they are complementary products used together and typically purchased in a bundle. The Notifying Party sells these two products together at a single price.

The Commission's Assessment

- (238) The market investigation has not provided indications leading to consider that there are valid reasons to depart from the market definition retained by the Commission in *J&J/Synthes* or to further subdivide the segments mentioned above in recital (237). As regards a possible segment encompassing both IM nails and IM hips screws, the market investigation has shown that, as the parties claim, these two products are frequently used, purchased and sold together and that therefore there are no reasons in this case to assess them separately.

Conclusion

- (239) The Commission considers that for the purposes of the present Decision the exact product market definition can be left open since the proposed merger does not significantly impede competition under any of the plausible alternative product market definitions.
- (240) Based on the arguments set out in this section, in this Decision the Commission will assess the trauma markets based on the following plausible segmentations:

¹⁵² Commission decision of 18.04.2012 in Case M.6266 – *Johnson&Johnson/Synthes*, paragraphs 17-43.

(i) internal fixation devices and its sub-segments, namely plating systems (non-anatomic and anatomically shaped plates and screws), intramedullary ("IM") nails and IM hip screws, cannulated screws, compression hip screws, and ancillary devices; and (ii) external fixation devices and its sub-segments, namely universal external fixation and specialised external fixation.

7.1.5.6. Dental Implants

- (241) Dental implants are a form of prosthetic (artificial replacement) dentistry. Dental prosthetics is used to restore intraoral defects such as missing teeth, or missing parts of teeth, and missing soft or hard structures of the jaw and palate. Such prostheses are used to rehabilitate mastication (chewing), improve aesthetics, and aid speech. Dental prostheses include products such as: dentures (and partial dentures), palatal obturators, orthodontic appliance, dental implants, crowns and bridges, inlays, copings and bars.
- (242) Dental implants encompass implant fixtures, which are artificial tooth-like roots that are affixed to the bone of the jaw or skull, and restorative products used to restore the patient's functional and aesthetic dental requirements. Dental implants also make use of regenerative products. These are biological materials used to rehabilitate both hard and soft oral tissues.
- (243) Dental implants are only a small part of a broader market for dental prosthetics. Dental implants compete with substitute products and technologies including traditional crowns and bridges as well as dentures which are not supported by implants.

Past Commission decisions

- (244) The Commission has not previously analysed the market for dental implants.

The views of the Notifying Party

- (245) The Notifying Party submits that dental implants belong to a single product market encompassing all the three main segments: implant fixtures, restoratives and regenerative products. In this regard, Zimmer argues that the approach adopted in the *J&J/Synthes* Decision would support such a conclusion because, in practice, customers purchase bundles of these products, even if products are not mutually substitutable. In any event, the Parties also provided distinct competitive assessments for each of the potential three narrower product market definitions.

The Commission's Assessment

- (246) The market investigation has provided indications in support of retaining a product market segmentation between implant fixtures, restoratives and regenerative products, as those products are not necessarily always purchased in bundles by all customers or across all EEA countries, as claimed by the Notifying Party.
- (247) In a market for all dental implants, the merger would give rise to no affected market, and therefore no Group 1 national markets. Even considering narrower market definitions, that is to say implant fixtures, restoratives and regeneratives, the merger would not give rise any Group 1 national markets.
- (248) For completeness, the Commission notes that, based on the Notifying Party's data, the merger would only give rise to two affected markets in France and Spain in the potential market for implant fixtures, where however the merged entity's market share would be [20-30]*% and [20-30]*%, respectively.

- (249) In relation to the two non-Group 1 affected markets, the Commission examined the potential effects of the merger in relation to Group 2 and Group 3 markets in section 8.4.1 and concluded that that the proposed merger would not significantly impede effective competition on the market for the provision of dental implants (and sub-segments thereof) in the EEA.

Conclusion

- (250) The Commission considers that for the purposes of the present Decision the exact product market definition can be left open since the proposed merger does not significantly impede competition under any of the plausible alternative product market definitions.
- (251) Based on the arguments set out in this section, in this Decision the Commission will assess the markets for dental implants based on the following plausible segmentations: (i) all dental implants; (ii) implant fixtures; (iii) restoratives; and (iv) regeneratives.

7.2. Relevant Geographic Market

- (252) The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas.¹⁵³

7.2.1. *The views of the Notifying Party*

- (253) The Notifying Party agrees with the approach adopted in the *Johnson&Johnson/Synthes* case. However, the Notifying Party also submits that a number of developments in the market point to an EEA dimension. In particular: (i) national public bodies which negotiate the reimbursement amount follow prices in neighbouring countries as benchmarks in their own pricing decisions; (ii) variations in market shares reflect historical preferences and are being eroded; and (iii) many suppliers are present globally.

7.2.2. *The Commission's Assessment*

- (254) In previous cases concerning orthopaedic medical devices the Commission has considered the markets for orthopaedic medical devices as national.¹⁵⁴ In the *Johnson&Johnson/Synthes* case, the Commission reached this conclusion particularly in light of: (i) market structures which vary from country to country; (ii) existence of different public reimbursement systems in a large number of EEA countries, which has served to partition the markets at national level and resulted in significant price differences across EEA countries; (iii) hospital purchasing behaviour, which differs from one country to another (individual customer versus purchasing groups; tender procedures versus bilateral negotiations); and (iv) the importance of local/national sales force, training and assistance in the operating theatre ("OR"), and quick delivery. All

¹⁵³ Commission Notice on the definition of relevant market for the purposes of Community competition law, paragraph 7.

¹⁵⁴ Commission decision of 18.04.2012 in Case M.6266 - *Johnson&Johnson/Synthes*, paragraph 118; Commission decision of 28.10.1998 in Case M.1286 - *Johnson & Johnson/DePuy*, paragraphs 16-20 and Commission decision of 27.05.2003 in Case M.3146 - *Smith&Nephew/Centerpulse*, paragraph 16.

those parameters are regarded as essential by hospitals when selecting suppliers.¹⁵⁵

- (255) The Notifying Party submits that in ten EEA countries (Bulgaria, Estonia, Finland, Hungary, Italy, Latvia, Norway, Poland, Romania, Sweden, Slovenia and the UK), approximately 90% of implants nationwide are sourced through tender procedures, while in another seven countries (Croatia, Greece, Cyprus, Denmark, Lithuania, Portugal and Slovakia), sales via tenders amount to approximately 80% of the market. In the Czech Republic, Ireland, Spain and France, tenders account for approximately 40% of implants total market sales. In other countries (Austria, Belgium (including Luxembourg) and Ireland) tenders have traditionally been rare.¹⁵⁶
- (256) The market investigation provided evidence that the markets for medical devices are national in scope, notably due to different market structures (for example, public reimbursement systems, hospitals' purchasing behaviour) from country to country and to the importance of a local/national sales force.¹⁵⁷ More specifically, a competitor stated that "*different market structures, acceptance criteria for medical devices, as well as language barriers still require local sales force and local training possibilities*"¹⁵⁸ This is consistent with the fact that in a number of EEA countries, many local competitors are present. For instance, Metrimed and Sanametal are only active in Hungary; Biotech is active in Hungary and Croatia; Dediene is active in France and Spain; Summit is only active in Germany; Stanmore Implants Worldwide Ltd ("Stanmore") is only active in the UK; Beznoska is only active in the Czech Republic; Aston, ATF, Biotecni, C2F, Euros, Evolutis are only active in France etc.¹⁵⁹
- (257) Furthermore, similar to other medical sectors, the presence of public reimbursement systems in a large number of EEA countries has partitioned the markets at national level. Reimbursement schemes vary from country to country resulting to diverging competitive conditions as well as significant price differences across EEA countries.¹⁶⁰ Finally, hospitals' purchasing behaviour differs from one country to another (direct negotiations versus purchasing groups; winner takes all versus shortlist of tender winners; different duration of tender contracts; volume commitment etc.).

7.2.3. Conclusion

- (258) In view of the arguments set out in this section, the product markets considered in this Decision are analysed on a national level.

¹⁵⁵ Commission decision of 18.04.2012 in Case M.6266 - *Johnson&Johnson/Synthes*, paragraph 120.

¹⁵⁶ Form CO, paragraph 116.

¹⁵⁷ Responses to Questionnaire Q1 to competitors, question 91, and Responses to Questionnaire Q2 to customers, question 21.

¹⁵⁸ Responses to Questionnaire Q1 to competitors, question 91 and Responses to Questionnaire Q2 to customers, question 21.

¹⁵⁹ Form CO, paragraph 1092, Annex 6.2(a) to the Form CO.

¹⁶⁰ For instance, the same Next Gen Rotating Hinge is sold by Zimmer at very different prices across Europe. If we look at specific SKUs, we observe that for the last quarter of 2013 the NexGen Rotating Hinge right femoral component of size D was sold in Denmark on average for EUR [4,000-5,000]*, in France for EUR [1,000-2,000]* and in Spain for EUR [2,000-3,000]* (SKU "NG Rot.hinge knee fem sz D right"). Likewise the NexGen Rotating hinge tibia plate of size 3 was sold in Denmark for EUR [1,000-2,000]*, in France for EUR [1,000-2,000]* and in Spain for EUR [0-1,000]* (Source: Zimmer's merger data).

8. COMPETITIVE ASSESSMENT

8.1. Legal framework

- (259) Under Article 2(2) and (3) of the Merger Regulation, the Commission must assess whether a proposed concentration would significantly impede effective competition in the internal market or in a substantial part of it, in particular through the creation or strengthening of a dominant position.
- (260) A merger may significantly impede effective competition in a market by removing important competitive constraints on one or more sellers, who consequently have increased market power. The most direct effect of the merger will be the loss of competition between the merging firms. For example, if prior to the merger one of the merging firms had raised its price, it would have lost some sales to the other merging firm. The merger removes this particular constraint. The reduction in these competitive constraints could lead to significant price increases in the relevant market.¹⁶¹
- (261) Generally, a merger giving rise to such non-coordinated effects would significantly impede effective competition by creating or strengthening the dominant position of a single firm, one which, typically, would have an appreciably larger market share than the next competitor post-merger.¹⁶²
- (262) The Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (the "Horizontal Merger Guidelines")¹⁶³ list a number of factors which may influence whether or not significant non-coordinated effects are likely to result from a merger, such as the large market shares of the merging firms, the fact that the merging firms are close competitors, the limited possibilities for customers to switch suppliers, or the fact that the merger would eliminate an important competitive force. These factors apply equally when determining whether a merger would create or strengthen a dominant position, or would otherwise significantly impede effective competition due to non-coordinated effects. Furthermore, not all of these factors need to be present to make significant non-coordinated effects likely and this is not an exhaustive list.¹⁶⁴
- (263) In evaluating the likelihood of non-coordinated effects potentially caused by a merger, it is important to assess to which extent the products of one merging party are close substitutes to the products sold by the other merging party. The merging firms' incentive to raise prices is more likely to be constrained when rival firms produce close substitutes to the products of the merging firms than when they offer less close substitutes.¹⁶⁵
- (264) The Commission is unlikely to find that the merger will create or strengthen a dominant position or otherwise significantly impede effective competition when rival firms have available capacity and find it profitable to expand output sufficiently. In other words, the extent to which competitors to the merged entity constrain the merged entity from raising prices not only depends on the

¹⁶¹ Guidelines on the Assessment of horizontal mergers under the Council regulation on the control of concentrations between undertakings, paragraph 24.

¹⁶² Horizontal Merger Guidelines, paragraph 25.

¹⁶³ OJ C 31, 5.2.2004.

¹⁶⁴ Horizontal Merger Guidelines, paragraph 26.

¹⁶⁵ Horizontal Merger Guidelines, paragraph 28.

level of their spare capacity but also on whether these firms have the incentive to react aggressively to a post-merger price increase.¹⁶⁶

- (265) The merging firms' incentive to raise prices is more likely to be constrained when rival firms produce close substitutes to the products of the merging firms than when they offer less close substitutes. It is therefore less likely that a merger will significantly impede effective competition, in particular through the creation or strengthening of a dominant position, when there is a high degree of substitutability between the products of the merging firms and those supplied by rival producers.
- (266) Furthermore, non-merging firms in a given market can benefit from the reduction of competitive pressure that can result from a merger, since any price increase by merging firms may switch some demand to rival firms, which, in turn, may find it profitable to increase their prices.¹⁶⁷
- (267) Finally, in line with the Horizontal Merger Guidelines, "*countervailing buyer power cannot be found to sufficiently off-set potential adverse effects of a merger if it only ensures that a particular segment of customers, with particular bargaining strength, is shielded from significantly higher prices or deteriorated conditions after the merger*".¹⁶⁸

8.2. Market share estimates provided by the Notifying Party

- (268) To provide reliable market data, the Notifying Party used the data sets provided by Eucomed as a starting point. The latter provides its members with, among other things, turnover data for the total market, units sold in each covered market and average sale price for each product. In the orthopaedic market, the Eucomed data cover the largest segments of the implant market, including knee, elbow, hip, shoulder, radial head (including elbow applications) and bone cement. The Eucomed data are further subdivided into components constituting an implant.¹⁶⁹ For the market reconstruction exercise the Parties used the total market sizes as reported by Eucomed and their own revenues and volumes. As the Parties do not have access to data provided by other companies to Eucomed, they relied on internal market intelligence to provide information for their competitors who report to Eucomed, as well as for those companies not covered by Eucomed.
- (269) The Notifying Party explained that, despite Eucomed being the most comprehensive source in the market, the dataset suffers from a number of weaknesses. First, Eucomed does not cover the sales of all medical devices companies (for example Arthrex, Lima and Mathys Ltd ("Mathys") do not participate in Eucomed's annual surveys). Second, Eucomed does not cover all the product markets that are relevant for the competitive assessment of this merger. Third, Eucomed does not cover 11 EEA countries.¹⁷⁰ Fourth, Eucomed does not provide information on competitors' sales to its members.

¹⁶⁶ Horizontal Merger Guidelines, paragraph 33.

¹⁶⁷ Horizontal Merger Guidelines, paragraph 24.

¹⁶⁸ Horizontal Merger Guidelines, paragraph 24.

¹⁶⁹ There are separate Eucomed data sets for trauma and spine.

¹⁷⁰ Eucomed data cover 22 countries, including 19 EEA, that is to say Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. Eucomed

- (270) The Notifying Party submits that the Eucomed data cover approximately between 37% - 100% of the total market value, depending on product and country (fractions hereafter referred to as "Eucomed coverage ratios"). In order to address the market value not covered by the Eucomed data, the Notifying Party used certain assumptions to refine and complete the data set. Moreover, as regards products and countries that are not covered by Eucomed data, the Commission has relied on the estimates provided by the Parties and in the qualitative evidence gathered throughout the investigation for its assessment given the difficulty to produce more precise figures. Eventually, the Notifying Party provided estimates of its competitors' sales value, even for those who report to Eucomed, using internal market intelligence. Nevertheless, both exercises resulted in a number of discrepancies.
- (271) Firstly, with respect to the countries covered by Eucomed (the "Eucomed countries"), the Notifying Party, which had access to its own sales and the total market sales as reported by Eucomed, provided estimates of the size of the total market as against the market that is covered by Eucomed (the coverage ratio). The Notifying Party adjusted the total market size reported by Eucomed for each country and each implant employing this coverage ratio, to account for the share of total market which they deemed not to be covered. This adjustment mechanically increased the total market size reported by Eucomed. The Commission requested the complete raw dataset from Eucomed and conducted a preliminary analysis on the accuracy of the coverage ratios assumed by the Notifying Party by contrasting them with information gathered during the market investigation.
- (272) Based on this preliminary analysis, the Commission considered that the Notifying Party's assumptions concerning the coverage ratio were difficult to justify and might have assumed excessive share of sales not reported to Eucomed, resulting in overly low coverage ratios. Consequently, a downward adjustment of total market sizes may be appropriate in certain market segments. Such adjustment may lead to higher market shares of all players reporting to Eucomed in a given segment, including Zimmer and Biomet.
- (273) Secondly, the Notifying Party used internal market intelligence to estimate its competitors' sales figure or market shares, on the basis of Eucomed's market size and the Notifying Party's estimates of the coverage ratio. As described in section 8.3, the Commission requested Eucomed's raw data. Using Eucomed members' own sales figures, the Commission concluded that, in some instances, the estimations of the Notifying Party were not correct.
- (274) Thirdly, with respect to the countries not covered by Eucomed (the "non-Eucomed countries"), the Notifying Party complemented the computation with its internal estimates. Those estimates underestimate the size of several markets, where Biomet's sales are even greater than the market itself. For this reason, the market data, contained in the Form CO and used for the purpose of the competitive assessment, sometimes exceeded 100%. In those instances, the merged entity's actual market shares should, at least in principle, be lower.

data do not cover Bulgaria, Cyprus, Croatia, Estonia, Iceland, Latvia, Lithuania, Malta, Romania, Slovakia and Slovenia.

8.3. Targeted market reconstruction during the in-depth investigation

- (275) As a result of the above discrepancies in section 8.2, the Commission decided to undertake a targeted market reconstruction, focusing on suppliers active in product markets for which it identified serious concerns and in geographic markets for which market shares were likely to be informative.¹⁷¹
- (276) By Decision of 6 August 2014, the Commission first requested Eucomed to provide all sales information supplied by its members between 2008 and 2013 for the purpose of producing Eucomed's "Reconstructive Bi-annual survey". This enabled the Commission to gather individual sales volumes and revenues for Eucomed members.
- (277) Furthermore, the Commission sent requests for information to several implant suppliers so as to complement Eucomed's coverage,¹⁷² on the basis of the Notifying Party's list of alleged active suppliers in each product and geographic market.¹⁷³ The suppliers were requested to provide similar information as Eucomed gathers from its members, using Eucomed's templates and instructions, covering their sales in all EEA countries during 2008-2013.¹⁷⁴ The following suppliers responded and are therefore included in the targeted market reconstruction conducted by the Commission: AdlerOrtho srl ("AdlerOrtho"), Arthrex Inc. ("Arthrex"), Peter Brehm GmbH ("Brehm"), Société Ceraver ("Ceraver"), Exactech Inc. ("Exatech"), Heraeus Holding GmbH ("Heraeus"), Implantcast GmbH ("Implantcast"), Groupe Lepine ("Lepine"), Lima, Link, Mathys, Medacta, Mediform Group ("Mediform"), and Tecres spa ("Tecres").
- (278) Finally, the Commission used the information provided by these suppliers in combination with the information gathered from Eucomed in order to compute market shares for those countries covered by Eucomed¹⁷⁵ and for a limited subset of product markets, notably primary knee, revision knee, partial knee, elbow, hip, shoulder, and bone cement. Despite the fact that the Commission's targeted market reconstruction does not cover all suppliers active in the EEA, the Commission believes, based on the information provided by the Parties, that the resulting market shares are more accurate than those provided by the Notifying Party and that the inclusion of the missing suppliers would not materially affect the magnitude of these market shares.
- (279) In its competitive assessment, the Commission relies on the Notifying Party's market share estimates where those are in line with those of the Commission's targeted market reconstruction. Otherwise, the Commission uses its target market reconstruction, whose market share data are displayed in ranges for reasons of confidentiality.

¹⁷¹ Section 0 is devoted to discussing markets in which market shares are more prone to be informative.

¹⁷² Commission' Request for Information pursuant to Article 11 Council Regulation (EC) No 139/2004 Q09.

¹⁷³ Commission' Request for Information pursuant to Article 11 Council Regulation (EC) No 139/2004 Q06 sent on 15.09.2014.

¹⁷⁴ Adjustments have been made regarding the scope of implants and years for some suppliers.

¹⁷⁵ Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom

8.4. Relevance of market shares, joint reconstructive implants and other products

- (280) The Notifying Party argues that market shares are not indicative of market power. In particular, the Notifying Party argues that these are bidding markets and therefore the Commission should not rely on market shares in its assessment.¹⁷⁶
- (281) The Commission disagrees with this argument. It is clear from section 8.5.4 that different procurement and tendering processes are present across the EEA. Some countries are just starting to launch tenders and non-tender based procedures still represent a significant share of the transactions. Moreover, the tenders that do take place are not often "winner-takes-all". For instance, the outcome of the tender process may be structured as a "winner-takes-all" situation or simply as a shortlist of suppliers whereby there is the possibility to purchase from several suppliers.
- (282) The Commission recognises that, for some EEA countries, the low volume of implants bought on a yearly basis and the limited numbers of procurement processes and/or hospital are such that each procurement process might significantly change the market shares. In these instances, market shares are usually not the best available information in order to assess whether the merging parties exert significant competitive constraint on one another.
- (283) Nevertheless, in most EEA countries, the number and diversity of hospitals and procurement processes, as well as the volume of implants sold on a yearly basis throughout a multiplicity of tender and non-tender based transactions are of such a magnitude that the aggregated view gathered by market shares provides valuable insights.
- (284) Furthermore, the market investigation has shown that market entry is not easy and that there is a certain degree of "stickiness" in the surgeons preferences for the orthopaedic implants they have so far been using.¹⁷⁷
- (285) In this light, the Commission concludes that while tenders do play a role to a smaller or larger extent in some of the product and geographic markets covered in this Decision,¹⁷⁸ market shares provide useful indications of market power for the assessment of the markets for orthopaedic products, and uses the filtering system advocated by the Notifying Party for the purpose of the competitive assessment in this case.

¹⁷⁶ The Notifying Party in paragraph 117 of the Form CO states *"In these bidding markets, supply is contestable on an ongoing basis. In these conditions, market shares do not accurately reflect the strength of competitors present on the market who exert competitive constraint on the (current) suppliers by participating in the bidding contest. Any market player can typically take part in tenders and, because there are (and, post-merger, will continue to be) a number of suppliers in the EEA with a wide range of similar products, tenders are mostly won on price. In such an environment, it is not possible for suppliers to impose prices above the competitive level"*.

¹⁷⁷ See below in recital (321) onwards and more generally on the characteristics of bidding markets see for example, Paul Klempere, Competition Commission, "Bidding Markets", June 2005 .

¹⁷⁸ See section 0 for a description of purchasing patterns of hospitals.

8.4.1. Adoption of a filtering system

- (286) As proposed by the Notifying Party, and in line with recent medical and orthopaedic medical devices cases, the affected markets were grouped in three categories:¹⁷⁹
- **Group 1 national markets:** the Parties' combined market share exceeds 35% and the increment exceeds 1%;
 - **Group 2 national markets:** the Parties' combined market share exceeds 35% but the increment is less than 1%; and
 - **Group 3 national markets:** the Parties' combined market share is between 20% and 35%.
- (287) In relation to Group 2 and Group 3 national markets, the Commission considers that the merger does not give rise to serious doubts as to the compatibility of the merger with the common market and the EEA Agreement. This is due, among other things, to insignificant increments and the presence of significant competitors. Also, the market investigation has not revealed any indications pointing at possible competition concerns in Group 2 or 3 national markets.
- (288) Therefore, for the purposes of this Decision, the competitive assessment focuses on the Group 1 national markets for joint reconstructive implants (hip, knee, elbow and shoulder implants) as well as for bone cement, bone cement accessories, pulsed lavage, spine devices and trauma devices.

8.5. General characteristics of the markets

- (289) The products concerned by this Decision are orthopaedic implants and medical devices intended to treat fractures or degenerative conditions.
- (290) The in-depth investigation focused on the joint implants markets and the markets for bone cement, bone cement accessories and pulsed lavage. The Commission concluded that these markets have different characteristics and that the parties' and their competitors' positions in each of these markets also differ.
- (291) More precisely, in terms of size, the overall hip and knee implants markets are large with total sales exceeding one billion euros. This compares with the remaining joint implants markets which are much smaller in size: the total value of the overall shoulder implants market in the EEA is approximately EUR [100-200]* million whilst the total value of the elbow implants market in the EEA is approximately EUR [1-50]* million. As regards bone cement and bone cement accessories their total sales in the EEA are in the range of EUR [50-100]* million.
- (292) In terms of market maturity, the market for hip implants is the most mature, followed by the knee implants market (with the exception of some segments thereof) and by shoulder and elbows implants. The markets for shoulder and

¹⁷⁹ This approach has also been applied in other cases in the area of orthopaedic medical devices and pharmaceutical products. See Commission decision of 22.07.2013 in Case M.6851 – *Baxter International/Gambro*, paragraph 117; Commission decision of 18.08.2011 in Case M.6293 – *Thermo Fisher/Phadia*, paragraphs 26-27; and Commission decision of 18.04.2012 in Case M.6266 – *Johnson&Johnson/Synthes*, paragraphs 139-140.

elbow implants are newer, faster growing markets. Bone cement and bone cement accessories are also considered mature markets. The hip implants market is the most populated one with a large number of competitors present. Indeed, its size and level of maturity result in lower entry barriers than in the remaining markets for joint implants. Barriers to entry are higher in the remaining joint implants market which are less mature and more innovative, particularly in those markets which are smaller in size, as evidenced by the limited number of competitors present, namely the elbow and unicondylar knee implant markets.

- (293) As regards the Parties' position in the different joint implants markets, the market investigation provided indications that Zimmer and Biomet are not particularly close competitors in the hip and shoulder implants markets. However Zimmer and Biomet are close competitors in the knees and elbow implants markets, particularly in some segments of the overall knee implants market and in some geographic markets. The specific characteristics of each market are discussed in detail in the implant-specific competitive assessment, in sections 8.6 to 8.9 below.
- (294) There are however features which are common to all the markets concerned by this Decision. These are discussed in the present section.

8.5.1. *Role of regulatory approvals and track records*

- (295) Unlike medicinal products, there is no marketing authorisation granted by public authorities before medical devices are placed on the market in the EU. The European regulatory system provides for a so-called conformity assessment procedure whereby compliance with the essential requirements is certified by the manufacturer or by a notified body, depending on the risk class of the device.
- (296) Devices that meet the essential requirements and have undergone the appropriate conformity assessment can be CE-marked and can circulate freely in the European Union's internal market.
- (297) The timeline for market access depends on several factors, including the characteristics of the medical device. The in-depth market investigation suggests that, suppliers face a pathway of 6-12 months for a new product. Such pathway can be much longer for truly innovative or complex medical devices. In *Johson&Johnson/Synthes*, the Commission found that it could take up to 30 months before obtaining the CE marking so that a new medical device can be sold in the EEA.
- (298) Another barrier to entry is the need to develop long-term track records for each product. This is a particular difficult hurdle that applies to large and small players alike as regards joint reconstructive implants. There appears to be a strong trend, particularly in Scandinavia, towards the so-called evidence-based medicine, whereby suppliers cannot even compete in the market, unless they reach very high clinical and historical requirements.
- (299) In this light, the Commission concludes that suppliers face pre-market hurdles to place new medical devices in the EEA market, particularly in those countries where, in addition to the CE marking, extensive clinical data and long track records are required.

8.5.2. Importance of training and local presence

- (300) Training and education play a critical role in the orthopaedic implants industry, particularly as regards joint implants. Suppliers strive to approach surgeons to influence their training at the early stages of their careers, which translates into a long term competitive advantage. Suppliers generally operate training centres and make non-negligible investments in education and training of surgeons. A new player must convince a surgeon to "switch" from a product he is familiar with to a new product. That entails that surgeons, medical and other medical staff in the OR (for example, scrub nurses) will have to undergo the re-training, which may take a short or long period of time depending on a number of circumstances such as the surgical philosophies used by a surgeon, her/his level of skill, the resources of a given hospital, etc.
- (301) Scientific evidence also shows that a switch from one implant to another increases the risk of post-op complications, making surgeons averse to changing brand and supplier, and more in general surgery technique. This is because the first number of surgery following a switch can give rise to poor outcomes, increasing the risk of future revision surgery. This may also have implications for surgeons and hospitals in terms of reputation and liabilities.
- (302) Similarly, new players not only need to enter a market (product or geographic), but they must establish a local network in close contact with surgeons, and convince them to give up the guarantees and certainties offered by a major established firm with whom they have established relationships. This is a difficult undertaking, even if some countries such as France show a higher degree of penetration of these smaller players.
- (303) For example, dedicated sales representatives play a crucial role in the competitive dynamics of some national markets. Sales representatives generally encompass three categories of actors: direct sales force, distributors and agents. These actors run the day-to-day business by, for example, taking care of restocking supplies and accessories, promoting new products and assisting surgeons in the OR. Sales representatives visit the hospitals frequently (sometimes on a weekly basis) and maintain a very close relationship with the staff. They train - and re-train - surgeons in case of switches to new or more innovative products, and advise surgeons on the choice of the devices to be used and provide assistance during surgery. In particular, Aesculap explains that sales representatives, distributors or agents, where appropriate, contribute significantly to building up a solid, longstanding relationship with hospitals and surgeons - sometimes over long or very long periods. Such relationship/loyalty is developed: "*[...] as early as the surgeons-to-be receive their training in university. These so-called "PPI's" (for Physician Preferred Item) play an important role especially in the sector of reconstructive implants*".¹⁸⁰
- (304) The choice between direct sales force and distributors or agents is essentially an economic one. Direct sales force is preferred in large countries that guarantee a certain level of turnover and justifies the addition of new employees, while in smaller countries manufacturers tend to rely on distributors or agents. However, the level of specialisation of the sales

¹⁸⁰ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08. 2014, page 26.

representatives, their relationship with surgeons and their degree of participation in the operation room, which varies even within the same country, has a bearing on this type of organisational decisions.

- (305) Therefore, even moving from one country to another with an existing product remains a major undertaking, particularly for smaller players due to the need to overcome surgeons' reluctance to switch. This entails the need to have training capabilities and local presence.

8.5.3. *Limited role of Intellectual Property Rights*

- (306) In general, there are indications that Intellectual Property Rights ("IPRs") do not play a major role in the industry at this point in time. However, in relation to some technologies, such as polyethylene materials and coatings, patents and IPRs are still important. In addition, the industry has recently seen some IPR litigation in the segment for hinge knee implants.
- (307) It is also possible to reverse engineer bestselling products in the market, once their IPR protection has expired. Some players (large and small) strive to win sales from their competitors by copying existing products and introducing some added value (for example, a different coating or set of instruments).

8.5.4. *Purchasing patterns of hospitals and pricing trends*

- (308) In the EEA, there is a trend towards purchasing through tenders and other auctioning systems, when sourcing orthopaedic devices. Recitals (309)-(330) below describe the most common features of tender procedures across the EEA:
- (309) The main principles and requirements applicable to tender procedures in which public contracts are awarded are set out in the European Procurement Directive 2004/18/EC (the "Public Procurement Directive"). Subject to stricter national rules, the Public Procurement Directive applies to the award of contracts exceeding EUR 207 000. Both public and private hospitals are required to follow the Union - and potentially national - public procurement rules if they perform medical procedures financed from the public budget.
- (310) Tenders are typically divided into multiple lots which may be defined broadly (for example all types of total knee replacements) or very narrowly (for example at the level of specific type of implant or even implant component). Usually, interested suppliers may bid for one or several lots; very rarely they must be able to supply all products covered by a specific tender procedure.
- (311) As a general rule, the criteria on which the contracting authorities award contracts are either: (a) the lowest price or (b) a combination of various criteria linked to the contract in question, such as quality, price or technical expertise. In the latter case, the contracting authority chooses the most economically advantageous tender (the "MEAT criterion"), which matches the relevant specification criteria. The relative weight of each MEAT criterion is individually determined by the contracting authority and set forth in the tender documentation. In tenders for orthopaedic implants, these criteria typically include price, implant longevity and services provided by the suppliers.
- (312) Contracts for the supply of goods and services exceeding the Union and national thresholds are typically awarded via five tender procedures:
- (a) **Open procedure.** This is the most common procedure and consists of a one-stage process, where the invitation to tender is advertised and all interested suppliers can submit their bids.

- (b) **Restricted procedure.** This is a two-stage process where only shortlisted providers are invited to submit bids after they have been approved by responding to a pre-qualification questionnaire ("PQQ"). Under this procedure, at least five companies should participate in the tender.
 - (c) **Competitive dialogue procedure.** This procedure is used for technically complex contracts, when the contracting authority is unclear as to the most suitable technical, legal or financial solution required to meet its needs. Following a dialogue with various participants, the contracting authority identifies a solution and invites those bidders which remain at the end of the dialogue. Under this procedure, the public contract is awarded on the sole basis of the MEAT criteria. At least three companies need to participate in the competitive dialogue procedure.
 - (d) **Negotiated procedure.** This procedure involves a direct negotiation with a single provider or a few selected providers and may include a call for bids. Under this procedure, there are a minimum of three tenderers. However, in certain circumstances the contract notice does not have to be advertised and there is no minimum number of tenderers. The selection criteria vary across countries and purchasers and may be either the lowest price only or a combination of several criteria determined by the purchaser.
 - (e) **Electronic tender processes.** Tender procedures can be organised also via electronic means such as the dynamic purchasing system and the electronic auction system.
- (313) The awards resulting from these tender procedures can be roughly divided into two contract categories: public contracts and framework agreements. Public contracts are concluded for a specified period of time in which all contractual terms, including price, are set. Such contracts typically include volume commitments. Framework agreements establish the terms governing contracts to be awarded during a given period (which cannot exceed four years) in particular with regard to price and, where appropriate, volume. Under framework agreements, the Parties to the agreement may be again in competition for specific supply orders on the basis of the same or more precisely formulated terms, and, where appropriate, other terms referred to in the specifications of the framework agreement.
- (314) The Notifying Party submits that a number of factors are contributing to more competitive orthopaedic markets and a significant downward pressure on prices. It is argued that this is a reflection of the general economic scenario in the EEA, which is forcing EEA countries to cut health budgets and reallocate resources. This has in turn triggered higher cost-awareness in traditional customers of medical devices, when sourcing their needs.
- (315) The Notifying Party argues that countries across the EEA are increasingly adopting the tender procedures described above in recital (312). According to the Notifying Party, these procedures are fundamentally based on price-criteria and favour the most economically attractive offer. According to the Notifying Party this spurs fierce price-competition and would constrain the merged entity post-merger.
- (316) The Notifying Party argues that another consequence of the recent cost-awareness of customers is the consolidation of buyer power, that is to say the trend to aggregate purchases within Group Purchasing Organisations ("GPOs"). According to the Notifying Party, hospitals are increasingly striking alliances

to bundle together their purchases of medical devices. This reduces administrative costs and allows them to obtain larger discounts on volumes.

- (317) According to the Notifying Party, the shifts toward tender-based procurement systems and GPOs have moved the decisional power from surgeons to hospital administrations. The Notifying Party states that hospitals would be able to impose a switch of orthopaedic implant on the surgeon if this was warranted by better economic terms.
- (318) The Commission agrees that the impact of the current pressure on healthcare budgets, as well as the means that customers are adopting to cope with such changes, must be taken into account in the context of the competitive assessment. However, based on the results of the in-depth market investigation, the actual market situation appears to be more complex than claimed by the Notifying Party.
- (319) First, the in-depth market investigation provided evidence that, across the EEA and even within the same country or regions thereof, the procurement of orthopaedic products may differ substantially in structure.¹⁸¹ The investigation has also indicated that winning a tender does not necessarily imply winning an exclusive contract. Indeed, a significant number of customers during the market investigation indicated that the outcome of tenders is the selection of a handful of suppliers, from which products will be purchased later on.¹⁸² In these instances, competition between the shortlisted suppliers therefore takes place beyond the tender award date.
- (320) Moreover, tenders do not often cover the entirety of customer needs. They tend to cover only between 70-80% of the requirements of a customer in a given year, while the remaining 20-30% is reserved for off-tender purchases (for example very innovative implants or special implants tailored for exceptional circumstances). This 20-30% appears to be materially different from standard tender procedures, as it entails different types of bilateral negotiations.
- (321) This much diversified picture suggests that, contrary to the Notifying Party's argument, the markets for orthopaedic devices do not present all the main characteristics of traditional bidding markets.¹⁸³ In particular, sales are made through a multiplicity of tender types, but also through direct negotiations off-tender. Based on the market investigation, the Commission notes that each individual tender does not represent a sizeable part of the market. Moreover, tenders are not infrequent and renewal of contracts and agreements is relatively common. Therefore, there is no clear sign of a "winner-take-all"-type of competition. Finally, there are also strong indications that entry of new suppliers is complex, which is also partly due to incumbency effects, namely the preferential position of the incumbent supplier(s).
- (322) Second, as noted in section 8.5.1, long-lasting track records constitute an important factor through which competition takes place in the orthopaedic markets, and sometimes even become a critical barrier to entry. Track records can effectively steer customers' purchasing decisions. One of the Parties'

¹⁸¹ Responses to Questionnaire Q2 to customers, questions 26 to 31.

¹⁸² Responses to Questionnaire Q2 to customers, question 35.

¹⁸³ See, for example, Paul Klemperer, Competition Commission, "Bidding Markets", June 2005. See also Commission decision of 23.11.2011 in Case M.6203 – *Western Digital Ireland / Viviti Technologies*, paragraph 524 and footnote 441.

competitors explained that "2 years of clinical evidence are the minimum to enter a market with a new product, 5 years to become credible, 10 years to have consolidated clinical evidence, over 15 years to be considered reliable".¹⁸⁴ Another major competitor stated: "The longer a device has been on the market, the stronger the business case for its manufacturer will be".¹⁸⁵

- (323) In some geographic areas such as Scandinavia, track records tend to become eligibility criteria rather than award criteria. This means that participation in competitive dynamics is made depending on already existing track records. In practice, tenders target only those suppliers whose implants carry long performance history, and significantly narrow down the number of credible competitors. This barrier cannot be overcome in the short term, as track records must by their very nature be built over time.
- (324) Another aspect of these industry-wide trends is highlighted by a study sponsored by "Eucomed" which indicates that "*Procurement centralization disfavours SMEs by means of non-product-specific requirements such as large volumes, broad portfolio and administrative requests. In the areas affected, competition will be reduced*".¹⁸⁶ One competitor confirmed this view, by stating "*It's about being able to offer a full-scale pallet of products, not just the implant. [major companies] are able to bundle implants with for example power tools, cement, etc. The other implant manufacturers typically only offer the implant and therefore lack the power to bundle*".¹⁸⁷ The result is that this trend further contributes to reducing the number of competitors that can credibly compete - or even participate - in tenders.
- (325) As regards the consolidation of buyer power, it should be noted that this trend varies greatly across the EEA. While large procurement alliances are being set up in some countries such as Germany, the same does not hold true for others. In addition, GPOs are not nation-wide associations and many hospitals still purchase medical devices on a stand-alone basis. In line with the Horizontal Merger Guidelines, "*Countervailing buyer power cannot be found to sufficiently off-set potential adverse effects of a merger if it only ensures that a particular segment of customers, with particular bargaining strength, is shielded from significantly higher prices or deteriorated conditions after the merger*".¹⁸⁸
- (326) The in-depth market investigation also provided indications that price considerations are not always crucial for purchasing decisions and surgeons' preferences still rank high in this regard.¹⁸⁹ This is partly because customers tend to base their decision on the so-called total cost of ownership, that is to say all the factors impacting on the cost of a given procedure, in lieu of a simple product-price approach.
- (327) In addition, surgeons are often consulted in the drafting of tender eligibility and award criteria, which further strengthens their role in the purchasing process.

¹⁸⁴ Responses to Questionnaire Q1 to competitors, question 111.

¹⁸⁵ Responses to Questionnaire Q1 to competitors, question 111.

¹⁸⁶ Simon Kucher & Partners, "Procurement of Medtech Innovations in the EU", slide 67.

¹⁸⁷ Responses to Questionnaire Q1 to competitors, question 103.

¹⁸⁸ Horizontal Merger Guidelines, paragraph 67.

¹⁸⁹ Responses to Questionnaire Q2 to customers, question 39. Customers generally referred to a price difference of above 10% to trigger any such switching, up to even 30-40% for some customers.

More specifically, surgeons are fully involved in the drafting and selection of candidates and winners. Usually, surgeons communicate to hospital administrations their needs, draft the eligibility and award criteria for bidding processes, and eventually score the bidders. Of course, their degree of involvement will differ depending on the type of implant and the specific purchase environment set by a hospital (for example, from bilateral negotiations for patient-specific or less common implants to larger volume tenders).

- (328) With regard to multi-sourcing, the Commission notes that this type of customer behaviour may not necessarily lead to enhanced price competition, as claimed by the Notifying Party. In this regard, the market investigation provided indications that customers often multi-source for reasons other than price competition. For example, they may want to provide their surgeons with their preferred implants or need to maintain alternative supply channels for reasons related to security of supply.¹⁹⁰ Moreover, in some segments and geographies of the knee market, for example, multi-sourcing may render the effects of merger even more anticompetitive because it deprives customers of a crucial supply option or endangers the pursuit of this strategy.
- (329) Finally, even if prices are decreasing, as the Notifying Party argues, the merger will halt this decrease. The Commission notes that the merger is capable of slowing down the pace of the downward price pressure or of otherwise negatively affecting other parameters of competition (for example, innovation).
- (330) In light of the arguments set out in this section, the Commission concludes that the industry-wide trends described by the Notifying Party are not such as to allow the Commission to exclude the likelihood of anti-competitive effects resulting from the merger in the Group 1 national markets identified in sections 8.6 onwards.

8.6. Knee Implants

8.6.1. Overview of the market for knee implants

- (331) According to the data submitted by the Notifying Party, the EEA market for overall knee implants is a large market by sales, amounting to approximately EUR [over 1,000]* million in 2013. The largest knee market is the one for primary knee implants, with sales amounting to approximately EUR [900-1,000]* million in 2013. This is followed by (i) the overall market for revision implants (including extreme orthopaedics)¹⁹¹, with sales amounting to approximately EUR [100-200]* million in 2013; (ii) the market for unicondylar knee implants, with sales amounting to EUR [50-100]* million in 2013; and (iii) the market for patello-femoral implants, with sales amounting to approximately EUR [1-50]* million in 2013.
- (332) The primary knee implants market is a relatively mature market, although not as commoditised as the one for hip implants. Five global American suppliers play a major role in this market: Zimmer, Biomet, J&J/DePuy, Stryker and S&N.

¹⁹⁰ Responses to Questionnaire Q2 to customers, question 25.

¹⁹¹ The Notifying Party submits that the extreme orthopaedics market if taken separately would account for approximately EUR [50-100 million]* in 2013.

- (333) Based on the Notifying Party's submissions, most suppliers of knee implants are active in primary and revision knee implants alike.¹⁹² A number of these suppliers also offer unicondylar knee implants.
- (334) Over the years, a number of small- to medium-sized suppliers have been able to enter some EEA countries to varying extents, generally with their own versions of existing successful implants. Most of these players have first entered the market with a primary total implant, at a later stage developing revision and/or partial knee implants. However, the importance of those players by sales - taken either individually or jointly - appears limited, especially in Denmark and Sweden, countries where the rating of implants in the national orthopaedic registries plays a vital role in the choice of the customers.
- (335) As regards the extreme orthopaedics market (comprising hinged and limb salvage products), not all the main manufacturers have developed such specialised implants; however a number of other players are present (and sometimes more successful) in this niche market, such as: Stanmore, Implantcast or Link.¹⁹³ The Commission received a formal complaint in relation to this market, and in particular to hinged knee implants and has investigated its plausibility (see recitals (129) and (694)).

8.6.2. Primary Knee Implants

8.6.2.1. The Parties' and their competitors' products

- (336) With respect to primary knee implants, Zimmer essentially competes with its most successful product line, the NexGen Knee. However, it has recently produced and is currently deploying a new primary knee implant, the Persona Knee.
- (337) As for Biomet, it supplies two main lines of products: the Vanguard Complete Knee system, as well as the AGC Total Knee system, [...]*
- (338) As shown in Table 1 below, virtually all suppliers of knee implants compete in the market for primary knee implants, with at least some models. However, with the exception of the five majors of the industry, namely Zimmer, Biomet, Stryker, J&J/DePuy and S&N, the presence of the remaining players is far from being significant throughout the EEA.

Table 1: Overview of the Parties' and competitors' primary knee implant products

Competitor	Primary knee implant products
Zimmer	Persona Knee; Gender Solutions Natural-Knee Flex; Gender Solutions NexGen High-Flex Knee; NexGen LPS-Flex Mobile and LPS Mobile Bearing Knee; NexGen Complete Knee Solution Legacy Knee Posterior Stabilized (LPS) LPS-Flex Fixed Bearing Knee;
Biomet	Vanguard Complete Knee System; AGC Total Knee System;
Stryker	Triathlon, Scorpio NRG and Scorpio Single Axis;
J&J/DePuy	ATTUNE Primary Total Knee System; LCS Complete Knee System; Sigma CR150 High flex Knee System; Sigma Fixed Bearing Knee System

¹⁹² Form CO, paragraph 1321, table 55.

¹⁹³ Non-confidential minutes of the conference call with Lima, of 10.11.2014, paragraph 21.

Competitor	Primary knee implant products
S&N	Journey knee, Genesis II CR; Genesis II PS; Legion CR; Legion PS; Legion CK
Aesculap	VEGA System; Columbus Knee System;
Wright / Microport	Evolution Medial Pivot Knee; Advance Medial Pivot Knee;
Tornier	HLS KneeTec, HLS Noetos;
Corin	Rotaglide+TM, Unity knee
Link	Endo; Sled; MITUS; MIT-K; Extrabone, Gemini;
Lima	Multigen Plus total knee system Aequos Knee; 3D Knee;
Mathys	Balansys Knee System;
Medacta	GMK Sphere Knee, GMK Primary Knee; Evolis Knee.

Source: Form CO, pages 352-354

8.6.2.2. Structure of the EEA markets for primary knee implants

- (339) Based on the Notifying Party's submissions, the market for primary knee implants accounted for approximately two thirds of all knee implants, approximately EUR [900-1,000]* million in 2013 at EEA level. In the same year, the Parties' sales amounted to approximately EUR [...] for Zimmer and EUR [...] for Biomet. On the basis of the information provided by the Notifying Party, the merged entity would have a market share of approximately [30-40]*% by value at EEA level in this market, with an increment of [10-20]*%.
- (340) Table 2 shows the position of the Parties at EEA level over the last three years, and their relative importance against the other three major suppliers in the market: J&J/DePuy, S&N and Stryker. All the other remaining players appear to each have a very limited presence in the market, with market shares below [5-10]*%.

**Table 2: Market Shares for primary knee implants by value
at EEA-level over the last three years**

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[20-30]*%	[20-30]*%
Biomet	[10-20]*%	[10-20]*%	[10-20]*%
<i>Merged Entity</i>	[30-40]*%	[30-40]*%	[30-40]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
S&N	[10-20]*%	[10-20]*%	[10-20]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Other players	[10-20]*%	[10-20]*%	[10-20]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (341) At national level, according to the data provided by the Notifying Party, the merger would give rise to 15 Group 1 national markets, namely Austria, Belgium (including Luxembourg), Cyprus, Denmark, Greece, Iceland, Italy, Lithuania, Malta, the Netherlands, Norway, Romania, Slovenia, Spain and Sweden.
- (342) In the absence of reliable data, the Commission carried out a targeted market reconstruction to validate, to the extent possible, the Notifying Party's estimates in the Form CO. However, this exercise does not cover a number of EEA countries as explained in section 8.3. For these countries, the best estimates available remain those provided by the Notifying Party.
- (343) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group 1 national markets in: Austria, Belgium (including Luxembourg), Denmark, Italy, the Netherlands, Norway, Spain and Sweden. In addition, the Commission found that also the Czech Republic and France would qualify as Group 1 national markets. Conversely, Greece would not qualify as a Group 1 national market. In the majority of those countries, the merged entity's market share would be between [30-50%], with at least two other competitors capable of exercising a strong competitive constraint over the merged entity. The Commission's targeted market investigation did not include Cyprus, Malta, Iceland, Lithuania, Romania and Slovenia, and for these countries, the market shares provided by the Notifying Party represent the basis for the analysis of the Commission in the country-by-country section.
- (344) However, the in-depth investigation has indicated that the merger would raise competition concerns in relation to each of Denmark and Sweden, where the merged entity's market share exceeds [50-60]*%, there are high barriers to entry and remaining competitors are unlikely to exert credible competitive pressure on the merged entity.

8.6.2.3. General Competitive Assessment

8.6.2.4. Closeness of competition

The views of the Notifying Party

- (345) The Notifying Party submits that Zimmer and Biomet do not perceive each other as the closest competitors in the market for primary knee implants. In fact, this market has undergone a significant amount of commoditisation, with a number of players offering products viewed as similar by customers. As such, the Notifying Party submits that it does not perceive any specific competitors as being closer than others. Rather, in broad terms, all major competitors are equally close. For this reason, the Notifying Party reaches the conclusion that, due to the relatively large number of "close competitors", the notion of "closeness" bears little relevance in this case, and is in any event not appropriate to assess the effects of the merger.
- (346) The Notifying Party tries to corroborate this argument by submitting a CRM analysis focused on Germany and the United Kingdom¹⁹⁴, as well as a review of its own internal documents, which would illustrate that several players can be seen as close. In essence, the Notifying Party submits that while Biomet is sometimes mentioned in Zimmer's internal documents, such references are no more frequent than references to various other market players, and do not identify Biomet as an especially close competitor.

The Commission's Assessment

- (347) The Commission considers that the Parties are two leading players in the market for primary knee implants, and certainly close competitors. For the sake of clarity, there is no need for the Commission to reach the conclusion that the Parties are each other's *closest* competitors. Paragraph 28 of the Horizontal Merger Guidelines clearly focuses on the concept of "*merging firms [being] close competitors*".¹⁹⁵ The market for primary knee implants is characterised by the presence of major suppliers which are seen as closely competing against each other as suggested by the Notifying Party. As will be explained in further detail, the elimination of a close competitor, Biomet, as a result of the merger, lowers the competitive pressure currently in force in the market.
- (348) In particular, the information gathered during the in-depth market investigation, as well as the Parties' internal documents, show that there are only three other major suppliers in the EEA, that is to say S&N, J&J/DePuy and Stryker.
- (349) Moreover, the Notifying Party does not - and cannot - deny the existing competitive relationship between itself and Biomet. As pointed out by the Horizontal Merger Guidelines, "[...] *the fact that rivalry between the parties has been an important source of competition on the market may be a central factor in the analysis [...]*". Therefore, the Commission concludes that the concept of closeness does bear relevance to the analysis in this case.
- (350) In its Response to the Article 6(1)(c) Decision the Notifying Party submitted an analysis of its CRM database. The Notifying Party claims that this analysis is

¹⁹⁴ "Zimmer's CRM database: Salesforce.com", RBB Economics. Annex 3 to the Reply to the 6.1.c decision, 21.10.2014.

¹⁹⁵ Horizontal Merger Guidelines, paragraph 38.

indicative of the fact that the Parties are not closest competitors in knee, hip and shoulder implants.¹⁹⁶ However, the Notifying Party admits that "considerable caution must be exercised in attributing too much significance to the results obtained from the Salesforce.com database", which the Commission agrees with.¹⁹⁷ Furthermore, the Commission notes that the CRM data as presented by the Parties is not disaggregated at the relevant product market level. For instance, in the case of knee implants,¹⁹⁸ the Parties report results without segmenting for unicondylar knee implants, primary or revision knee implants. Without a proper disaggregation of the data this data is not able to provide any insight. The Commission acknowledges that there are limitations as to how much this data can be disaggregated in a meaningful way. However, the Commission has conducted this analysis where possible, and in particular for unicondylar knee implants and shown that the Parties are closest competitors.¹⁹⁹ This data is also useful to provide additional insight on relevant product markets where the data matches the definition adopted by the Commission. This is the case for hip implants where the both the Commission's and the Parties' analysis coincide in the fact that Zimmer does not perceive Biomet as being the closest competitor.²⁰⁰

- (351) In one of its internal documents,²⁰¹ Zimmer builds a matrix that identifies the competitors' product that best match its own primary knee implants. The matrix, presented in Figure 11 essentially focuses on the primary knee implants produced by Biomet,[...]* The only non-major supplier in the matrix is [...]*. Figure 11 also shows that Biomet's Vanguard and AGC are among the best matches for Zimmer's NexGen. Conversely, [...]* is identified as a best match for one of Zimmer's [...]*.

Figure 11: Zimmer's Comparison Matrix

[...]*

Source: Zimmer's internal documents

- (352) Another internal document of Zimmer contains instructions to its salesforce on how to sell the NexGen against the Vanguard Complete knee system.²⁰²
- (353) In turn,²⁰³ Biomet confirms in one of its internal documents that it perceives Zimmer as a close competitor or even very close competitor for some products. For example, Figure 12 shows that Zimmer is the market leader for uncemented knee implants, while [...]* are perceived as ranging from moderate to non-competitive threats. In cemented implants, Biomet considers Zimmer less strong than [...]*, as strong as [...]*, but definitely less strong than [...]*. Figure 12 does mention other competitors such as [...]*, but Biomet generally perceives them as weak or no competitive threat at all.

¹⁹⁶ See paragraph 63 of the Reply to the 6.1.c decision

¹⁹⁷ See page 17 of "Zimmer's CRM database: Salesforce.com", RBB Economics. Annex 3 to the Reply to the 6 (1)(c) Decision, 21.10.2014.

¹⁹⁸ A similar issue occurs in the analysis presented for elbow.

¹⁹⁹ See below in recitals (777) onwards.

²⁰⁰ See below in recital (1464).

²⁰¹ Zimmer's internal documents, "Knee Profiler" of 2012-2009, page 364, ID278.

²⁰² Zimmer's internal documents, "NexGen complete knee solution, Vanguard complete knee system"; ID 360.

²⁰³ Biomet's internal documents, "Building our future: United Kingdom FY15 Marketing strategy", page 15, ID BIO-0556.

Figure 12: Knee Landscape according to Biomet

[...]*

Source: Biomet's internal documents

- (354) In this light, the Commission concludes that Zimmer and Biomet are close competitors in the market for primary knee implants. Their closeness will be further analysed, where appropriate, in the country-by-country analysis contained in section 8.6.2.9 onwards because the Parties can even be considered as each other's closest competitors in certain national markets.

8.6.2.5. Customer Switching - difficulties to switch and limited possibilities of switching suppliers

The views of the Notifying Party

- (355) The Notifying Party submits that, in the majority of cases, surgeon preferences in relation to orthopaedic implants do not appear to influence the decision making process of hospitals when purchasing knee implants. In particular, the role of surgeons' preference in purchasing decisions is in constant decline in the EEA due to the increasing commoditisation of the market and the downward pricing pressure from customers and health authorities.
- (356) Against this background, the Notifying Party argues that the majority of suppliers meet standard technical requirements, which makes price considerations the most important criterion for competition in the market. In this regard, the Notifying Party stresses that the merged entity will not be able to raise prices as a hospital would immediately consider switching part of its purchases to rival suppliers.
- (357) Finally, the Notifying Party also provided a set of examples, at country level, to prove that hospitals did switch away from the Parties, and in only [20-30]*% of the cases those hospitals switched from Zimmer to Biomet or the other way around.²⁰⁴

The Commission's Assessment

- (358) According to paragraph 31 of the Horizontal Merger Guidelines:
- "Customers of the merging parties may have difficulties switching to other suppliers because there are few alternative suppliers or because they face substantial switching costs. Such customers are particularly vulnerable to price increases. The merger may affect these customers' ability to protect themselves against price increases".*²⁰⁵
- (359) The Commission's in-depth market investigation provided evidence that customers generally face significant difficulties to switch to other suppliers. The intensity of those difficulties may, of course, vary depending on a number of factors such as the nature of the institution (public or private), the type of products previously used by a surgeon in comparison to the other ones, the number of resources available to a given hospital and the number of surgery performed. Moreover, switching appears to be more difficult in certain countries such as Denmark and Sweden where the trend towards evidence-based medicine and the role of the national registries are stronger.

²⁰⁴ Response to the Article 6(1)(c) Decision, paragraph 491.
²⁰⁵ Horizontal Merger Guidelines, paragraph 31.

(360) The following reasons make it difficult to switch:

- (a) **Risks associated to a switch of supplier/brand.** The Commission observes that, from a medical point of view, scientific literature indicates that switches to new suppliers and brands may increase the risk of revision surgery in the future.²⁰⁶ This explains both surgeons' inertia when considering a switch to a new implant and hospitals' reluctance due to increased costs, risks and even liabilities. Based on the discussions with market participants, the Commission became aware of public studies on the subject matter. An article authored by MSc. M. Peltola and others queried whether the first patients operated on with a new endoprosthesis type in a hospital have a higher revision rate than patients whose implants are conventional in that hospital.²⁰⁷ The researchers concluded that:

"Our data show there is an increased risk of early revision surgery for the first patients obtaining a knee endoprosthesis model previously unused in a hospital. Patients should be informed if there is a plan to introduce a new model and offered the possibility to choose a conventional endoprosthesis instead. Surgeons should be aware of the risks and preferably practice beforehand with the new model using, eg, cadavers or plastic bone models. Units performing arthroplasties might consider introducing endoprosthesis models. Although introducing potentially better endoprosthesis models is important, there is a need for managed uptake of new technology".²⁰⁸

Therefore, switching in the market for primary knee implants entails major consequences, not only for hospitals, and surgeons, but also for patients. In this regard, Aesculap explains *"Another relevant factor [to assess the possibility of switching] are the negative consequences after the change of supplier, such as the affected procedures in the operating theatres, the inferior results of the operations shortly after the change and a decrease in the income of the hospitals due to these difficulties".²⁰⁹*

- (b) **Surgeon's preferences/loyalty do influence the choice of hospitals and limit the ability to switch supplier.** Contrary to the Notifying Party's submission, the in-depth market investigation indicates that in the majority of the cases surgeons' preference does influence the decision making process of hospitals.

In this respect, Aesculap explains that sales representatives, distributors or agents, contribute significantly to building up a solid, longstanding relationship

²⁰⁶ M. Peltola and others, Clin Orthop Relat Res. Jun 2012; 470(6): 1711–1717, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348304/>, retrieved on 12.12.2014; and M. Peltola and others, Acta Orthop. February 2013;84(1) pages 25-31, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3584598/>, retrieved on 10.12.2014.

²⁰⁷ M. Peltola and others, Clin Orthop Relat Res. Jun 2012; 470(6): 1711–1717, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348304/>, retrieved on 12.12.2014.

²⁰⁸ M. Peltola and others, Clin Orthop Relat Res. Jun 2012; 470(6): 1711–1717, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3348304/>, retrieved on 12.12.2014. This conclusion is reiterated in a subsequent article enquiring on the effects of switches on total hip arthroplasty procedures. M. Peltola and others, Acta Orthop. February 2013;84(1) pages 25-31, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3584598/>, retrieved on 10.12.2014.

²⁰⁹ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08. 2014, page 27. See Bernhard Fleischner, Beschaffungsprozesse ausgewählter Produktgruppen in Krankenanstalten, Orthopädische und kardiologische Implantate, HTA Projektbericht 2009, Nr. 38, Ene. GMW 1, page 39.

with hospitals and surgeons - sometimes over long or very long periods.²¹⁰ Such relationship/loyalty is developed:

"[...] as early as the surgeons-to-be receive their training in university. These so-called "PPI's" (for Physician Preferred Item) play an important role especially in the sector of reconstructive implants and prevent the hospitals from switching suppliers easily".²¹¹

As anticipated in recital (327), the Commission notes that, even in the context of bidding processes, surgeons are fully involved in the drafting and selection of candidates and winners. This happens in several different ways and at different points in time. For example, surgeons communicate to hospital administrations their needs, draft the eligibility and award criteria for bidding processes, and eventually score the different offers.²¹²

- (c) **Price is not the main driver of competition.** During the in-depth market investigation, customers stressed that price is just one of the various criteria used to award contracts in their bidding processes. Quality of products, appropriate track records and aftersales support, all play an important role in those bidding processes. In this regard, one customer pointed out that *"Support is very important for the hospital. Small companies might not be able to provide such support, whereas larger companies are more likely to do so because they cover more territories".²¹³* Another customer added: *"[...] it is difficult for the small players to be part of the rationalisation process because they are not price competitive and they are not willing to invest in the characteristics mentioned above (i.e. enlarging their portfolio, distribution network or presence of salesforce across the territory)".²¹⁴* One customer even stated: *"Even though price is important, the hospital will never buy a product just because it is cheaper".²¹⁵*

Moreover, in certain EEA countries, namely in Scandinavian countries, only knee implants meeting very high standards and having a certain rating in national registries, can effectively compete. In Sweden, one hospital explained the role of the registry in choosing an implant as follows: *"The Swedish registry is important in the process of choosing implants suppliers. It limits the number of suppliers a hospital can buy from as the product must be good enough to be considered by the hospital, meaning top three in the Swedish registry".²¹⁶*

- (d) **Switching is in practice possible, although relatively infrequent.** Out of 34 customers responding to the Questionnaire to hospitals on switching, only nine customers have actually changed supplier since 2012, usually following a

²¹⁰ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08. 2014, page 27.

²¹¹ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.08. 2014, page 26. Bernhard Fleischner, Beschaffungsprozesse ausgewählter Produktgruppen in Krankenanstalten, Orthopädische und kardiologische Implantate, HTA Projektbericht 2009, Nr. 38, Ene. GMW 1, page 31.

²¹² Responses to Questionnaire Q31 to hospitals, question 4.

²¹³ Non-confidential minutes of the conference call with Blekinge Hospital, of 24.10.2014, paragraph 9.

²¹⁴ Non-confidential minutes of the conference call with Peninsula Purchasing and Supply Alliance NHS ("PPSA"), of 11.11.2014, paragraph 25.

²¹⁵ Non-confidential minutes of the conference call with Blekinge Hospital, of 24.10.2014, paragraph 3.

²¹⁶ Non-confidential minutes of the conference call with Blekinge Hospital, of 24.10.2014, paragraph 20.

tender.²¹⁷ In other words, about a quarter of the sample changed supplier in the last three years. It is worth noting that in most cases, tenders are organised every two or three years, therefore customers had the opportunity to change supplier if they chose to.²¹⁸ Moreover, some of these customers (in particular smaller or private hospitals) rely on bilateral negotiations, rather than on tendering. Some customers indicated that it was difficult to convince surgeons to change implants for several reasons such as quality and quantity of clinical data, steep learning curves, etc.²¹⁹ Moreover, no customer within the sample expects to shift a portion of its purchases of knee implants to alternative suppliers post-merger.²²⁰ The large majority did not in fact shift their purchases to other suppliers in response to mergers in the past.²²¹

With respect to switches to "me-too" or "copy-cat" implants, customers in countries in which the trend towards evidence-based medicine is strong such as Denmark and Sweden declared that they would not purchase such products.²²² However, in other countries such as France, Portugal, Poland or the Czech Republic, customers explained that they either already acquired these products or would be inclined to. Moreover, these customers would also take into account the clinical results of the respective original implants, when assessing a copy-cat or me-too product.²²³ Overall, the number of customers purchasing such products seems to remain limited.

Finally, the Commission conducted additional conference calls to better understand under which circumstances switching occurs. During those interviews, one customer pointed out that - unless confronted with a significant price increase (over 15-20%) by the merged entity - they would not switch to another supplier of knee implants.²²⁴ Another customer said: *"For the procurement department, since a switch is very costly, the benefit of the new deal must always be huge in comparison with the cost, especially the costs of revision surgeries which might appear following the use of a new implant"*.²²⁵

- (361) In the light of the arguments set out in this section, the Commission concludes that customers generally face significant difficulties to switch. Those difficulties reach their apex in certain EEA countries, particularly Denmark and Sweden, where only knee implants meeting very high standards and having a certain rating in national registries can effectively compete. In those countries, it appears highly unlikely that customers might switch a significant portion of their purchases to other suppliers in a timely manner to constrain the merged entity's behaviour, in the event of a price increase by the merged entity post-merger.

8.6.2.6. Elimination of an important competitive force

The views of the Notifying Party

²¹⁷ Responses to Questionnaire Q31 to hospitals, question 24.

²¹⁸ Responses to Questionnaire Q31 to hospitals, question 5.

²¹⁹ Responses to Questionnaire Q31 to hospitals, question 28.

²²⁰ Responses to Questionnaire Q31 to hospitals, question 31.5.

²²¹ Responses to Questionnaire Q31 to hospitals, question 33.

²²² See country sections Denmark and Sweden.

²²³ Responses to Questionnaire Q31 to hospitals, question 26.

²²⁴ Non-confidential minutes of the conference call with Bleckinge Hospital, of 24.10.2014 paragraph 29.

²²⁵ Non-confidential minutes of the conference call with Santa Anna Hospital, of 6.11.2014, paragraph 6.

- (362) The Notifying Party submits that the orthopaedic industry is in general mature, with only incremental innovation taking place. As such, innovation is not an important competitive parameter for assessing competitive dynamics in the market for knee implants. In fact, the majority of new implants introduced in the market constitute "me-too" or "copy-cat" products, and entirely new knee designs are not expected on the market.
- (363) The Notifying Party further argues that the Parties are not particularly important innovators. Zimmer only expects to achieve a negligible market share increase from the development of pipeline products, and stresses that some smaller, niche players such as OrthoAlign may even be more innovative than larger players. The Notifying Party mentions other smaller firms which are bringing to the market incremental innovations such as Lima with its ceramic knee implants, Medacta with its disposable instruments and ConforMis with its customised knee implants and robot-based technologies.

The Commission's Assessment

- (364) The Commission considers that both Parties, each in its own right, constitute key competitive forces in the market, and important innovators. For example, Zimmer recently launched its newest primary knee implant, the Persona. Biomet also has launched a very innovative product, the Vanguard XP, which preserves the anterior cruciate ligament ("ACL").
- (365) More in detail, Zimmer's pipeline up to 2018 includes a variety of products as shown in Figure 13. Among those pipeline products, Zimmer appears to distinguish between "*Top Priority Projects*" and projects granting a "*Market Parity*", "*Moderate Advantage*" or "*Significant Advantage*".

Figure 13: [...]*

- (366) [...]*.
- (367) [...]*.
- (368) Based on the information provided in its submissions, Biomet appears to be working on a large number of projects.²²⁶ [...].²²⁷[...].

Figure 14: [...]*

- (369) Contrary to the Notifying Party's argument, the above description in recital (364) onwards shows that the Parties are very active in terms of R&D, and do constitute important innovators in the knee market. While the in-depth market investigation suggests that entirely new knee implants are indeed rarely launched in the market (approximately every ten years),²²⁸ Zimmer and Biomet just engaged in major projects by deploying new, very ambitious projects and implant strategies, such as the Persona and Vanguard XP implants.
- (370) Indeed, Zimmer's internal documents report a statement from Biomet's CEO according to whom "[...] about [70-80]*% of patients who go in for knee replacement surgery have an intact ACL".²²⁹ In its internal documents, Zimmer appears to be already concerned about the deployment of Biomet's Vanguard

²²⁶ Form CO, Annex 8.3(d).

²²⁷ Form CO, paragraphs 1719.

²²⁸ Responses to Questionnaire Q30 to competitors, question 36.

²²⁹ Zimmer's internal document, "Persona Competitive Selling Guide" of 28.04.2014, page 4, ID011.

XP, and about how it compares with its own latest innovation, the Persona. For this purpose, Zimmer prepared a fully-fledged "*Competitive Selling Guide*".²³⁰

Figure 15 : Zimmer's Competitive Selling Guide - Persona versus Vanguard XP

[...]*

Source: Zimmer's internal documents

- (371) With respect to the Notifying Party's argument that innovation is usually brought by new entrants such as ConforMis, the following can be noted. The vast majority of the respondents to the Commission's questionnaires identified Zimmer and Biomet as major innovators in the market, particularly Zimmer. Biomet was also very often singled out as an outstanding innovator in relation to the market for unicondylar knee implants, see section 8.6.8.2.²³¹ This is because the market expects players of the magnitude of Zimmer, Biomet, as well as the other three majors, to have the necessary "deep pockets" to invest in R&D and develop new products, materials or even constantly improve their existing portfolio.
- (372) In this regard, one competitor stated: "*The larger orthopaedic suppliers (Zimmer, J&J/DePuy etc) spend in our experience significantly more money for the market entries of new products, resulting in faster penetration, market access and at the end success and faster ROI*".²³² These views also seem to be shared by the medical community. For example, a key opinion leader explained that: "*[...] only the largest manufacturers are the drivers of innovation, and innovative products are essential in the orthopaedic sector*".²³³
- (373) Finally, the Commission notes that those new entrants, who according to the Notifying Party would bring innovation to the market, play a marginal role at EEA level. Based on the Notifying Party's estimates, none of them exceeds 5%, which was also confirmed by the Commission's market reconstruction. Even assuming they had been able to introduce a ground-breaking concept over the last three to five years, the uptake of any such innovation appears limited. Moreover, the Commission considers that the role of small firms in bringing innovative concepts to the market, like in any other industry, does not diminish the clout of larger firms such as Zimmer and Biomet.
- (374) In light of the arguments set out in this section, it is likely that the merger would eliminate one of the major innovators in the primary knee implants market.

8.6.2.7. Countervailing buyer power

The views of the Notifying Party

- (375) The Notifying Party submits that customers in this market are large and sophisticated, and have the power to play suppliers against each other to obtain the lowest possible price. Additionally, in a large number of countries, purchases and tenders are not even done at hospital level, but rather at a more aggregate level, for example at regional or GPO-level. In those countries, buyer

²³⁰ Zimmer's internal document, "Persona Competitive Selling Guide" of 28.04.2014, page 3, ID011.

²³¹ Responses to Questionnaire Q30 to competitors, question 37.

²³² Responses to Questionnaire Q30 to competitors, question 29.3.

²³³ Non-confidential minutes of the conference call with Dr Vaquero Martin, Gregorio Maranon General University Hospital, of 22.10.2014, paragraph 10.

power would be further enhanced because the sophistication of tender structures also increases. Furthermore, the Notifying Party submits that, due to the large volumes purchased, hospitals could sponsor entry of new suppliers.

The Commission's Assessment

(376) As explained in section 8.5 onwards, there are a number of industry-wide trends that are affecting the way competition takes place in orthopaedic markets. In line with the Horizontal Merger Guidelines, "*Countervailing buyer power cannot be found to sufficiently off-set potential adverse effects of a merger if it only ensures that a particular segment of customers, with particular bargaining strength, is shielded from significantly higher prices or deteriorated conditions after the merger*".²³⁴ The Horizontal Merger Guidelines further explain that:

"One source of countervailing buyer power would be if a customer could credibly threaten to resort, within a reasonable timeframe, to alternative sources of supply should the supplier decide to increase prices or to otherwise deteriorate quality or the conditions of delivery. This would be the case if the buyer could immediately switch to other suppliers, credibly threaten to vertically integrate into the upstream market or to sponsor upstream expansion or entry [...]". (emphasis added)²³⁵

(377) The in-depth market investigation provided evidence that many customers purchase at least a significant part of their orthopaedic implants via tenders and other auctioning systems.²³⁶ As regards buyer consolidation, while this phenomenon has reached significant levels in certain countries such as the United Kingdom and Germany, that is not yet true for all of the EEA.²³⁷ In other words, the trend towards tender-based procurement systems and GPOs is not as generalised as to shield all customers from higher prices or deteriorated competitive terms post-merger. For example, private hospitals rely on individual negotiations with suppliers and are not obliged by law to tender out their needs for orthopaedic products.

(378) First, as described in the precedent section on customer switching, apart from being an infrequent phenomenon, switching in this market is difficult. Therefore, the hypothetical exercise of buyer power already fails the "immediacy" condition set by the Horizontal Merger Guidelines.

(379) Second, with respect to the ability and incentives of customers to sponsor entry, the Commission considers that this strategy would require a level of sophistication that only few players could realistically exercise in this type of market, for example a large purchasing group. However, in reality the vast majority of customers in this market still remain stand-alone public hospitals.

(380) Even assuming the potential exercise of buyer power by a large customer like a purchasing group, mainly stemming from larger volumes, there are a number of other non-price considerations that limit the real extent of any such buyer power in this market.

²³⁴ Horizontal Merger Guidelines, paragraph 67.

²³⁵ Horizontal Merger Guidelines, paragraph 65.

²³⁶ Responses to Questionnaire Q31 to hospitals, question 4.

²³⁷ Responses to Questionnaire Q31 to hospitals, question 3.

- (381) During the in-depth market investigation, very few customers confirmed that, during commercial negotiations with their suppliers, they would threaten to switch to other suppliers or engage in other strategies to obtain a better price.²³⁸ All customers interviewed by the Commission during the in-depth market investigation explained that, in tenders, suppliers are not only evaluated on the basis of price criteria, but also of clinical evidence.²³⁹ As noted in section 8.5.4, surgeons are involved in the drafting of tender requirements, and participate in the process in different ways and points in time. In some countries, such as Denmark and Sweden, surgeons are particularly demanding, and consequently the number of available suppliers for tenders is extremely limited.²⁴⁰
- (382) Additionally, the entry of copycat or me-too products or, in any event, smaller firms has not significantly influenced purchasing patterns at EEA level. Depending on the country, some smaller players have fared better than others. However, even in those countries, market structures still show a quite clear "Tier-1" player versus "Tier-2" player dynamics. This means that purchasers' choices still remain largely bound to few major suppliers. This would hold even truer, in the event of further consolidation on the buyer side because larger customers would intuitively require larger volumes and larger sellers with larger portfolios.²⁴¹
- (383) In addition, the in-depth market investigation provided evidence that many hospitals prefer to multi-source their requirements of knee implants, the principal reason for this being security of supply.²⁴² Multi-sourcing implies that there are, at the very least, two alternative suppliers in the market. Some respondents indicated that the absolute minimum number to ensure an effective multi-sourcing policy is three.²⁴³ The Commission notes that in some countries such as Denmark, this minimum number of suppliers will not even be ensured post-merger.
- (384) In light of the arguments set out in this section, the Commission concludes that buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.

8.6.2.8. Barriers to entry and expansion

The views of the Notifying Party

- (385) The Notifying Party submits that the market dynamics are such that new entry opportunities in the knee market arise frequently. The Notifying Party also argues that CE certification enables a product to be supplied freely across the EEA, and the respective process is a simple auditing one.²⁴⁴ Indeed, Zimmer

²³⁸ Responses to Questionnaire Q31 to hospitals, question 6.

²³⁹ See Non-confidential minutes of conference calls with customers quoted in the country-by-country specific analysis.

²⁴⁰ Non-confidential minutes of the conference calls with customers in Denmark and Sweden.

²⁴¹ For instance one purchasing group in the United Kingdom indicated that it has started a "rationalisation project" due to the significant discounts which are granted when the implants are acquired from few suppliers. Non-confidential minutes of the conference call with PPSA NHS, of 11.11.2014, paragraph 23.

²⁴² Responses to Questionnaire Q31 to hospitals, question 30 and 31.1.

²⁴³ Responses to Questionnaire Q31 to hospitals, question 31.4.

²⁴⁴ In the Notifying Party's experience, it takes approximately two months to receive a certification for Class III products such as knee implants. Source: Response to the Article 6(1)(c) Decision, paragraph 498.

submits that a new player that has developed a new product will not face burdensome regulatory barriers and claims that there have been numerous examples of entry in the past years.

- (386) The Notifying Party also argues that, for international players, it is easy to expand to a new geographic area. This is so because (i) large hospitals and GPOs are able to sponsor new entrants; (ii) entry in a new market requires only small upfront fixed costs; and (iii) the industry is not subject to capacity constraints or IPRs barriers. Moreover, any potential reputational concerns may be resolved through engaging local sales representatives (distributors or agents).
- (387) To substantiate this line of arguments, the Notifying Party submits examples of recent entry in a number of countries.²⁴⁵

The Commission's Assessment

- (388) According to paragraph 68 of the Horizontal Merger Guidelines, "*When entering a market is sufficiently easy, a merger is unlikely to pose any significant anti-competitive risk. Therefore, entry analysis constitutes an important element of the overall competitive assessment. For entry to be considered a sufficient competitive constraint on the merging parties, it must be shown to be likely, timely and sufficient to deter or defeat any potential anti-competitive effects of the merger*".
- (389) The Commission's in-depth market investigation provided evidence that barriers to entry and expansion in the market for primary knee implants are high, and even very high for some EEA countries such as Denmark and Sweden.
- (390) As regards entry with an entirely new product, the results of the in-depth market investigation suggest that already the first step to enter orthopaedic markets, that is to say the CE marking, can turn into a lengthy procedure. Competitors indicated a time window span from six months to two years for obtaining the CE marking.²⁴⁶
- (391) In this regard, Stryker stated that: "*Regulatory authorities have raised their thresholds following the "hip metal-on-metal" disaster, which caused a great deal of discussions in the industry. Therefore, Stryker expects that the intensification of the scrutiny will slow down the entry of new products*".²⁴⁷ S&N added: "*[...] it is very difficult to predict how long it takes to obtain the CE mark because this will largely depend on the type of product at hand. In the last two-three years, the landscape has changed dramatically. This shift was triggered by the infamous recent recalls of certain products (for instance, PIP breast implants). Regulatory bodies have reconsidered what should be their approach toward regulatory approvals, and have become more cautious when examining a product. In S&N's view, in theory, it should take 6-18 months for a CE mark to be obtained, depending on the class of the device, but it can now*

²⁴⁵ For instance, Allomedica, Tornier and Medacta in Austria, Corin in Belgium, Symbios in Bulgaria, Mathys and Implantcast in the Czech Republic, Implantcast Hellas in Greece and Medcomtech, Corin, Integra and Exactech in Spain. See FORM CO paragraphs 131, 142, 161, 228 and 340.

²⁴⁶ Responses to Questionnaire Q30 to competitors on entry and innovation, question 15.

²⁴⁷ Non-confidential minutes of the conference call with Stryker, of 11.11.2014, paragraph 17.

take years. A lot more questions are asked during the regulatory approval process".²⁴⁸

- (392) Market participants also pointed out that it is extremely difficult for a new or unknown supplier to convince hospitals and, in particular, surgeons to try a new product. According to these sources, it can take between two and four years to achieve meaningful sales after a product is launched.²⁴⁹ The innovativeness of a product, its quality and added value compared to existing products, and the reputation of the supplier, as well as of the distributor, are all key factors to shorten the pathway to market and help attract customers. According to Aesculap *"Several obstacles like patent protection, relevance of track records and the strong faith of customers in existing products make a market entry into a new product market quite difficult and constitute a significant entry barrier"*.²⁵⁰
- (393) This holds particularly true for Denmark and Sweden, where entry with a new product appears to be extremely difficult due to a market trend towards evidence-based medicine and the role played by national registries.²⁵¹ Other EEA countries such as the United Kingdom are also currently adopting a tougher stance towards knee implants.
- (394) One market participant explained that: *"ODEP for the United Kingdom is clearly limiting new product entry. Also the "Beyond Compliance" campaign raises the requirements for new products, will delay market entries and make it more difficult for smaller companies to enter into the UK. Registers typically favour "old and established" products that have been implanted often"*.²⁵²
- (395) Another market participant pointed out that: *"The tradition is the strongest in these countries [in the Nordic countries], and they have the highest requirements"*.²⁵³
- (396) The in-depth market investigation showed that some competitors have developed me-too or copycat versions of existing primary knee implants. However, the acceptance of those products by customers remained limited. One competitor, Mathys, explained: *"[...] it is difficult in reality. One might enter a market segment (such as the Zwymueller stem) offering a similar product. Sometime this is possible, even necessary, but additional options are required (training options, surgical options)"*.²⁵⁴
- (397) While the Notifying Party claims that copycat products can profit from the original implant's clinical data, and therefore market entry with such products does not imply significant difficulties, the in-depth market investigation did not support this view. First, as explained in recital (382), the entry of copycat products has not been particularly successful because surgeons are reluctant to

²⁴⁸ Non-confidential minutes of the conference call with S&N, of 10.11.2014, paragraph 17.

²⁴⁹ Responses to Questionnaire Q30 to competitors on entry and innovation, question 18.

²⁵⁰ Aesculap, further discussion of competitive concerns and assessment of the commitments proposed by Zimmer/Biomet, of 11.12.2014, page 8.

²⁵¹ Responses to Questionnaire Q30 to competitors on entry and innovation, question 25.

²⁵² Responses to Questionnaire Q30 to competitors on entry and innovation, question 25. See Aesculap's response.

²⁵³ Responses to Questionnaire Q30 to competitors on entry and innovation, question 25. See Sanatmetal's response.

²⁵⁴ Responses to Questionnaire Q30 to competitors on entry and innovation, question 20.2. See Mathys' response.

use these types of implants. In certain countries, such as Denmark and Sweden, surgeons do not even consider using such products.²⁵⁵ Second, only in some countries customers indicated that they have purchased copycat or me-too products,²⁵⁶ and that they evaluate these products based on track records of the respective original products.

- (398) As regards geographic expansion with existing products, all respondents to the in-depth market investigation indicated that this is difficult, regardless of whether this is carried out through setting up a direct sales force or hiring a distributor.²⁵⁷ The evidence on file indicates that the conditions for such entry/expansion to be considered a sufficient competitive constraint on the merging parties are not met. For example, one of the Notifying Party's competitors, Exactech, explained the following:

*"[...] the time horizon to enter and expand in a new EEA country will depend on a variety of factors. In the company's experience, it can take anywhere from one to five years. In particular, building the necessary awareness for a product to be known in the market and well respected from a medical point of view takes a long time. In absence of regulatory approval, an additional 18 to 24 months should be added to the three-to-five period above".*²⁵⁸

- (399) In its submissions, Aesculap also commented on geographic expansion as follows:

*"Notably, it is a considerable challenge to find sales representatives that have the necessary knowledge, skills and contacts to effectively support the sales force in the area of orthopaedic implants. This lack of qualified personnel significantly limits the expansion of the undertakings. Also, the costs for sales staff are significantly lower per unit sold if the sales personnel represent a large portfolio of products".*²⁵⁹

- (400) The need for a suitable distributorship becomes stronger for certain countries due to their large and widely spread customer base. Relying on a reputed distributor is necessary to provide rapid and continuous logistic services.²⁶⁰ However, finding a local distributor, with the required reputation, experience and knowledge, can be challenging due to the existence of exclusivity regimes.²⁶¹ Finally, respondents indicated that it takes at least two years to achieve meaningful sales for a profitable business in a new country.²⁶²

- (401) While geographic expansion is certainly a more realistic option than a greenfield entry, the number of challenges associated with this undertaking still

²⁵⁵ See for instance Non-confidential minutes of the conference call with Blekinge Hospital, of 24.10.2014, paragraph 8.

²⁵⁶ Responses to Questionnaire Q31 to hospitals, question 26. Very few customers (hospitals in Austria, the Czech Republic, Poland and Portugal) indicated that they would consider copycat products based on the results of the original products.

²⁵⁷ Responses to Questionnaire Q30 to competitors on entry and innovation, questions 2.3 and 10.

²⁵⁸ Non-confidential minutes of the conference call with Exactech of 10.10.2014, paragraph 14.

²⁵⁹ Aesculap, Further discussion of competitive concerns and assessment of the commitments proposed by Zimmer/Biomet, of 11.12.2014, page 6.

²⁶⁰ Responses to Questionnaire Q30 to competitors on entry and innovation, question 2. See Aesculap's response.

²⁶¹ Responses to Questionnaire Q30 to competitors on entry and innovation, question 9.

²⁶² Responses to Questionnaire Q30 to competitors on entry and innovation, question 3.

appears to be high.²⁶³ This holds particularly true for smaller firms, which follow more cautious growth strategies. For example, Lima's expansion in the knee market throughout Europe was to some extent based on a planning, which took into account the size of a given market, the price of the implants, the concentration of the supply-side, the characteristics of the demand-side, etc. However, one of the main factors supporting Lima's expansion was its success in the shoulder segment, which then fostered entry in hip and knee implants.²⁶⁴ Despite the Notifying Party's depiction of Lima's as a success story in the knee segment, the Commission's market reconstruction shows that at EEA level this player has remained a fringe player, particularly when compared to the major suppliers in the industry.

- (402) Conversely, geographic expansion may be a more credible threat when posed by the other three majors of the industry (namely, J&J/DePuy, S&N and Stryker). However, those three players are already broadly present across the EEA, and their limited presence in certain countries is related to structural barriers that are not easy to overcome such as the trend for evidence-based medicine and the need to be present for a number of years in the national registry in Denmark and Sweden.
- (403) In order to be considered a sufficient competitive constraint on the merged entity, the Horizontal Merger Guidelines would require both entry and geographic expansion to be likely and timely. These two conditions are not satisfied.
- (404) Finally, in accordance with the Horizontal Merger Guidelines, entry or expansion should also be sufficient to constrain the behaviour of the merged entity post-merger. In certain EEA countries such as Denmark and Sweden, the merger gives rise to particularly sensitive competitive scenarios such as 3-to-2 and 4-to-3. To be able to exclude competition concerns, the Commission should find that entry would be particularly effective in disciplining the behaviour of the merged entity. However, based on the results of the market investigation, the specific setting of these two countries make such a finding very unlikely.
- (405) In light of the arguments set out in this section, the Commission concludes that barriers to entry and expansion in the market for primary knee implants are high, and even very high in certain EEA countries, particularly in Denmark and Sweden, where national registries play a key role.

8.6.2.9. Country-specific Competitive Assessment

- (406) Based on the Notifying Party's estimates, the merger would give rise to 15 Group 1 national markets, namely Austria, Belgium (including Luxembourg), Cyprus, Denmark, Greece, Iceland, Italy, Lithuania, Malta, the Netherlands, Norway, Romania, Slovenia, Spain and Sweden.

²⁶³ Non-confidential minutes of the conference call with Aesculap of 14.8.2014, paragraph 16. This supplier indicated that it would probably take even for an experienced manufacturer three to five years to launch a product on the market and start achieving sales (provided that the manufacturer has access to necessary patents).

²⁶⁴ Non-confidential minutes of the conference call with Lima of 10.10.2014, paragraphs 22 and ff. In certain EEA countries, Lima entered primarily via hips and subsequently sold shoulders and knees.

Table 3: Primary knee implants – Group 1 national markets – Market shares by value, 2013²⁶⁵

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>DK</i>	[30-40]*%	[20-30]*%	[60-70]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([5-10]*%), others ([0-5]*%)
<i>SE</i>	[40-50]*%	[10-20]*%	[60-70]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([5-10]*%), S&N ([0-5]*%), others ([0-5]*%)
<i>AT</i>	[20-30]*%	[10-20]*%	[30-40]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([5-10]*%), S&N ([5-10]*%), Medacta ([5-10]*%), others ([10-20]*%)
<i>BE</i>	[20-30]*%	[10-20]*%	[30-40]*%	[50-100]*	S&N ([20-30]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), others ([10-20]*%)
<i>GR</i>	[10-20]*%	[30-40]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), Medacta ([5-10]*%), Stryker ([5-10]*%), Wright/Microport ([5-10]*%), others ([5-10]*%)
<i>IC</i>	[40-50]*%	[40-50]*%	[90-100]*%	[less than 1]*	Others ([5-10]*%)
<i>IT</i>	[30-40]*%	[10-20]*%	[40-50]*%	[100-200]*	J&J/DePuy ([10-20]*%), S&N ([10-20]*%), Stryker ([5-10]*%), others ([10-20]*%)
<i>LT</i>	[20-30]*%	[10-20]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([20-30]*%), Stryker ([10-20]*%), others ([0-5]*%)
<i>NL</i>	[20-30]*%	[20-30]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([20-30]*%), Stryker ([5-10]*%)
<i>NO</i>	[30-40]*%	[0-5]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([10-20]*%), Stryker ([5-10]*%), others ([10-20]*%)
<i>RO</i>	[60-70]*%	[10-20]*%	[70-80]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([5-10]*%), Stryker ([5-10]*%)
<i>SL</i>	[20-30]*%	[10-20]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([20-30]*%), Stryker ([10-20]*%), others ([0-5]*%)
<i>ES</i>	[30-40]*%	[10-20]*%	[50-60]*%	[50-100]*	Stryker ([10-20]*%), J&J/DePuy ([10-20]*%), S&N ([10-20]*%), others ([10-20]*%)

265

The Notifying Party was not able to provide reliable market shares for Cyprus and Malta.

<i>EEA</i>	[20-30]*%	[10-20]*%	[30-40]*%	[900-1,000]*	J&J/DePuy ([20-30]*%), S&N ([10-20]*%), Stryker ([5-10]*%), others ([10-20]*%)
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Source: Form CO, Annex 6.2(a)

- (407) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group 1 national markets in Austria, Belgium (including Luxembourg), Denmark, Italy, the Netherlands, Norway, Spain and Sweden. In addition, the Commission found that also the Czech Republic and France would qualify as Group 1 national markets. As regards Cyprus, Lithuania, Malta, Iceland, Romania and Slovenia, which were not covered by the Commission's targeted market reconstruction, they will be analysed based on the data provided by the Notifying Party.
- (408) The in-depth market investigation has shown that the merger significantly impedes effective competition in only two Group 1 national markets, namely, Denmark and Sweden.
- (409) Furthermore, the Commission asked the Parties for tender data for 11 countries (Austria, the Czech Republic, Denmark, Finland, Italy, the Netherlands, Norway, Poland, Spain, Sweden and the United Kingdom). The main data sources supplied by the Parties are tenders for hip, knee, shoulder and elbow implants in which Zimmer and Biomet took part in recent years, and the TED database which gathers information on significant public procurement processes in Europe. The Parties have consolidated the information coming from these two sources into a unique dataset per country.
- (410) The Commission's main purpose with this request was to ensure an accurate assessment of competition conditions across several geographic markets in the EEA. The bidding data analysis has actually been performed to shed light on those countries where the market reconstruction and the qualitative assessment have raised competition concerns. In particular, tender data have been used to check the degree of market contestability, the number of active bidders and the identity of successful companies and to assess entry. The Commission also attempted to do a runner-up analysis to quantitatively assess the closeness of competition between the merging parties. However, important data limitations have jeopardised the validity of such an analysis.
- (411) The tender data analysis suffered from two important limitations: (1) the unavailability of reliable information on the volumes tendered in each tender and lot which implied that big and small tenders/lots would be given the same weight and, (2) the tender information recurrently referred to very broad categories, which at times could even relate jointly to two or more different joint reconstructive implants, and therefore the Commission was often not able to associate the data to each of the relevant product market identified in the decision.
- (412) Finally, the representativeness of these tender data is not fully clear to the Commission since the Parties were not able to clarify what percentage of the actual national markets were covered by the tender data. In particular, the tender data received by the Commission for most of the countries was anecdotal and included a limited set of observations which only was relevant for a number of markets. In particular, the Commission has only employed this data to extract some information on Italy where the sample covered was the

largest of all and where relevant information for the purposes of assessing the merger was available.²⁶⁶

Denmark

Structure of the market

- (413) According to the Notifying Party, in Denmark, the value of the market for primary knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [60-70]*% in this market, with Biomet contributing an increment of approximately [20-30]*%.

Table 4: Shares of value for primary knee implants in Denmark

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[30-40]*%	[30-40]*%
Biomet	[20-30]*%	[20-30]*%	[20-30]*%
Merged Entity	[50-60]*%	[60-70]*%	[60-70]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Other players	[5-10]*%	-	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (414) Market shares provide a useful first indication of the market structure and of the competitive importance of both the merging parties and their competitors.²⁶⁷ According to well-established case law, very large market shares - 50% or more - may be evidence of the existence of a dominant market position.²⁶⁸
- (415) Through the merger, the merged entity would come to hold a share of over [50-60]*% of the market in Denmark. Indeed, based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating the market leader with a very large gap of approximately [30-40]*% between the merged entity and J&J/DePuy. Post-merger, besides J&J/DePuy there would be only one other competitor left with a market share above 5% (Stryker, with a market share of only 6% according to the Notifying Party's data). Finally, over the last three years, Zimmer has gained non-negligible market share (+[5-10]*%), while Biomet only lost a [0-5]*% market share.

Views of the Notifying Party

²⁶⁶ See recital (503) onwards.

²⁶⁷ Horizontal Merger Guidelines, paragraph 14.

²⁶⁸ Horizontal Merger Guidelines, paragraph 17.

- (416) The Notifying Party explains that, over 2011-2013, Zimmer's market share increase is due to the introduction of its cemented knees in the market. This would show that the Danish market can feature notable shifts, which in turn illustrate the contestability of market shares in a competitive tender-based market, where a very high proportion of demand is allocated via tenders.²⁶⁹
- (417) Zimmer further submits that entry is relatively easy because of open tender procedures. In particular, Corin and Lima could be potential entrants.²⁷⁰

Commission's assessment

- (418) Based on the Commission's market reconstruction, the merged entity's market share would be slightly lower than estimated by the Notifying Party in this country, but still over [50-60]*%. The merger would effectively lead to a quasi 3-to-2 scenario because the Notifying Party seems to have overestimated the market shares of some of its remaining competitors. On the other hand, in the Commission's market reconstruction, one competitor would have a market share much higher than estimated by the Notifying Party. That said, the results of the Commission's market reconstruction do not materially differ from the market structure scenario presented by the Notifying Party, which gives rise to a presumption of dominance.²⁷¹

Table 5: Parties' shares of value for primary knee implants in Denmark

Suppliers	2009	2010	2011	2012	2013
Zimmer	[20-30%]	[20-30%]	[20-30%]	[30-40%]	[30-40%]
Biomet	[20-30%]	[20-30%]	[20-30%]	[20-30%]	[20-30%]
Merged Entity	[50-60%]	[40-50%]	[50-60%]	[50-60%]	[50-60%]

Source: Commission's targeted market reconstruction

- (419) As shown in section 8.6.2.4, Zimmer and Biomet are close competitors as regards primary knee implants.
- (420) In Denmark, the large majority of joint replacement procedures are performed in public hospitals. Public hospitals are required to purchase orthopaedic implants through tenders, except where the value of the purchase is very low. Tenders are usually organised by regions, and take place every four years. Surgeons are fully involved in the bidding process. Usually, tender criteria include clinical data and price, which are the main aspects under scrutiny, but also after-sales services such as support in the OR and logistics.
- (421) The in-depth market investigation provided evidence of the importance of clinical data in the choice of orthopaedic implants in Denmark. The Danish Knee Arthroplasty Register ("DKR") was initiated by the Danish Orthopaedic Society and the Danish Society for Hip and Knee Arthroplasty Surgery. Data collection began on 1 January 1997.²⁷² Similarly to the SKAR for Sweden, the

²⁶⁹ Response to the Article 6(1)(c) Decision, paragraph 578.

²⁷⁰ Form CO, paragraph 181.

²⁷¹ Horizontal Merger Guidelines, paragraph 17.

²⁷² Alma B. Pedersen, Frank Mehnert, Henrik M Schrøder "Existing data sources for clinical epidemiology: The Danish Knee Arthroplasty Register", 5.05.2012, pages 25-26.

aim of the DKR is to examine the epidemiology of knee replacement procedures in Denmark, and to facilitate continuous improvement of surgery outcomes. The DKR contains information on all primary and revision knee arthroplasty procedures performed in Denmark.²⁷³ The in-depth market investigation provided evidence that the DKR is a very important tool for surgeons to choose implants.

- (422) Against this background, one customer explained that Biomet, Zimmer and J&J/DePuy are the only suppliers that fully comply with its clinical requirements. It also indicated that S&N and Stryker were the last companies to enter the market in Scandinavia, and that their products have not been on the Danish market for as long as the ones of their competitors.²⁷⁴
- (423) Furthermore, according to another customer: "*J&J/DePuy, Zimmer, Biomet, Stryker, and Smith&Nephew are in principle viable options. However, Stryker is only marginally present in Denmark, while Smith&Nephew is scaling back its activities in this country, shown by the distributor not investing very many forces in marketing*".²⁷⁵ This customer also indicated that there are fewer and fewer viable alternatives on the market in light of the Scandinavian strict approach towards evidence-based medicine, and that the trend towards consolidation may pose problems in the future.²⁷⁶
- (424) Another customer stated "*Denmark is a small country, with 20 centres which tend to stick to few suppliers, typically Zimmer, Biomet and Johnson & Johnson. Stryker has a significant presence in hip implants but not in knee implants, as they are not present in key places forming knee surgeons. Despite the fact that their implants are of good quality, it is difficult for them to enter. The same applies to S&N*".²⁷⁷
- (425) In short, customers in Denmark indicated that Zimmer, Biomet, and J&J/DePuy are the only three credible players in the Danish market. One of them indicated: "*AHP is concerned about possible price increases post-merger scenario. Post-merger, there will be only two credible competitors for AHP. This is all the more worrying because Denmark has historically been a difficult market for the other two majors (Smith&Nephew and Stryker)*".²⁷⁸
- (426) Another customer added: "*Because Hvidovre Hospital is currently supplied by two companies for knee implants, Zimmer and Biomet, Professor Gebuhr believes that the transaction will have a significant impact for the hospital. First, some of the hip implants and knee implants currently available will disappear as the merged entity will likely rationalize its products portfolio. Second, as a result of the disappearance of Biomet as an independent*

²⁷³ Alma B. Pedersen, Frank Mehnert, Henrik M Schröder "Existing data sources for clinical epidemiology: The Danish Knee Arthroplasty Register", 5.05.2012, pages 25-26.

²⁷⁴ Non-confidential minutes of the conference call with Aleris Hamlet private hospital, of 4.11.2014, paragraph 8.

²⁷⁵ Non-confidential minutes of the conference call with Bispebjerg hospital, of 31.10.2014, paragraph 6.

²⁷⁶ Non-confidential minutes of the conference call with Bispebjerg hospital, of 31.10.2014, paragraph 18.

²⁷⁷ Non-confidential minutes of the conference call with Vejle Sygehus hospital, of 29.01.2015, paragraph 11.

²⁷⁸ Non-confidential minutes of the conference call with Aleris Hamlet private hospital, of 4.11.2014, paragraph 10.

*competitor, the competition will significantly decrease and that will have detrimental effects on the hospital".*²⁷⁹

- (427) Besides indicating the barriers to switching faced by customers in Denmark (please see also section 8.6.2.5), this further corroborates the existence of very high barriers to entry in Denmark. As indicated in section 8.6.2.8, barriers to entry/expansion are high due to a number of different factors. Those barriers reach their apex in Denmark and Sweden, where the role of evidence-based medicine, the importance of long standing clinical data and the presence of a national registry greatly heightens the difficulties to penetrate the market. As one customer explained:

*"In Denmark, a supplier has to show scientific evidence in order to enter the market. Therefore, on top of all the R&D activities to create an implant, a company should also wait 5-10 years to gather all the necessary scientific data on its product's life cycle. This is because a product must be monitored throughout its life cycle to assess whether it breaks or has other technical defects. This is a competitive feature common in the Nordic countries, which put a strong emphasis on evidence-based medicine".*²⁸⁰

- (428) Indeed, Danish surgeons rely heavily on the clinical data and the survival rates described in the DKR. Therefore, even assuming a firm were to offer a lower price, that would not suffice. It would take years before this firm could actually participate in a tender and compete on an equal footing with the three main suppliers. A customer explained: *"In Denmark and Sweden, hospitals are demanding with respect to clinical data. The quality of the products available is similar and, at the end of the day, the differentiating factor is often price. However, no hospital would compromise quality for the purpose of obtaining a lower price".*²⁸¹ As regards smaller companies, a customer said: *"In Denmark and Sweden, [...] smaller companies usually cannot compete on price in tenders, as they do not have the necessary scale, and they rather compete on implant quality and associated services, which they can, overall, provide".*²⁸²
- (429) Entry with a copycat product would also be difficult because customers would consider such products only based on their own merits and clinical results.
- (430) Moreover, a review of the Parties' internal documents further suggests that the rivalry between Zimmer and Biomet has been an important source of competition on the Danish market.
- (431) According to a Biomet internal document entitled "Marketing Plan FY 2007 Denmark", Biomet estimated its market share to be approximately [30-40]*%, and complains about losing market positions and fierce competition. The document shows a very concentrated market only with four additional players, J&J/DePuy with [40-50]*%, Zimmer with [10-20]*%, Stryker with [5-10]*% and Wright/Microport with [5-10]*%. Based on a number of observations, Biomet concludes that *"Through an aggressive market effort we intend to*

²⁷⁹ Non-confidential minutes of the conference call with Hvidovre Hospital, of 30.01.2015, paragraph 8.

²⁸⁰ Non-confidential minutes of the conference call with Bispebjerg hospital, of 31.11.2014, paragraph 12.

²⁸¹ Non-confidential minutes of the conference call with Vejle Sygehus hospital, of 29.01.2015, paragraph 12.

²⁸² Non-confidential minutes of the conference call with Vejle Sygehus hospital, of 29.01.2015, paragraph 12.

regain market leadership and market share".²⁸³ The document remains an illustrative example of the type of rivalry that would be removed post-merger.

- (432) On the basis of the arguments set out in this section, the Commission considers that the merging firms are close competitors, customers have limited possibilities of switching suppliers and barriers to entry/expansion are high. Also, as described in section 8.6.2.7 above, countervailing buyer power does not appear sufficient to constrain the merged entity's behaviour post-merger.

Conclusion

- (433) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for primary knee implants in Denmark through the creation or strengthening of a dominant position.

Sweden

Structure of the market

- (434) According to the Notifying Party, in Sweden, the total value of the market for primary knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [60-70]*%, with Biomet contributing an increment of around [10-20]*%.

Table 6: Shares of value for primary knee implants in Sweden

Suppliers	2011	2012	2013
Zimmer	[40-50]*%	[50-60]*%	[40-50]*%
Biomet	[10-20]*%	[10-20]*%	[10-20]*%
Merged Entity	[50-60]*%	[60-70]*%	[60-70]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Other players	[5-10]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (435) Market shares provide a useful first indication of the market structure and of the competitive importance of both the merging parties and their competitors. According to well-established case law, very large market shares – 50% or more – may be evidence of the existence of a dominant market position.
- (436) Through the merger, the merged entity would come to hold a share of over [50-60]*% of the market in Sweden. Based on the data provided by the Notifying Party, the merger would combine the number one and number three players,

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Biomet's internal documents, "Marketing Plan FY 2007 Denmark", page 12, BIO-10011877.

creating an undisputed market leader with a very large gap of approximately [30-40]*% between the merged entity and J&J/DePuy. Post-merger, there would be only two other competitors left with a market share above 5%, that is, J&J/DePuy ([20-30]*%) and Stryker ([5-10]*%). Finally, over the last three years, while Zimmer has overall gained a [0-5]*% market share, Biomet's position has remained roughly stable.

The views of the Notifying Party

- (437) The Notifying Party submits that Sweden is a bidding market where price is playing an essential role in the choice of the product. Tendering has pushed down price over the years in Sweden.
- (438) According to the Notifying Party, the fluctuations of market shares over 2011-2013 illustrate the ease of switching in this largely tender-based market.
- (439) Zimmer also identified examples of customers, who recently switched suppliers in Sweden such as [...]*.
- (440) Finally, the Notifying Party submits that there are no significant entry barriers, and gives as a recent example of entry Arthrex.

The Commission's Assessment

- (441) Based on the Commission's market reconstruction, the merged entity's market share would be slightly higher than that estimated by the Notifying Party in this country. The merger would result in a quasi 4-to-3 scenario, where three players would account for most of the market, the merged entity being the market leader. Indeed, post-merger only two other competitors would remain with market shares above 5%.

Table 7: Parties' shares of value for primary knee implants in Sweden

Suppliers	2009	2010	2011	2012	2013
Zimmer	[40-50%]	[40-50%]	[40-50%]	[50-60%]	[40-50%]
Biomet	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
<i>Merged Entity</i>	<i>[50-60%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[50-60%]</i>

Source: Commission's targeted market reconstruction

- (442) As shown in section 8.6.2.4, Zimmer and Biomet are close competitors as regards primary knee implants. One of the key opinion leaders in Sweden also confirmed that Zimmer and Biomet are each other's closest competitor in the market.²⁸⁴
- (443) Moreover, in its internal documents regarding the Scandinavian region, Zimmer identifies J&J/DePuy, Stryker and Biomet as its main competitive threats in Sweden. In its internal document titled "2014 Operating Plan Nordics",²⁸⁵ Zimmer states "*In regards to direct target of the competition, we will have to stay alert and be present in order to defend out [40-50]*% market*

²⁸⁴ Non-confidential minutes of the conference call with Prof. Dr. Kärrholm of University of Gothenburg, paragraph 16.

²⁸⁵ Zimmer's internal documents, 2014 Operating Plan Nordics, Executive review, slide 15.

share position in the knee segment, mainly against J&J/DePuy, Stryker and Biomet".

- (444) The in-depth market investigation provided evidence that Zimmer and Biomet are two major suppliers for the Swedish hospitals, and are two of the few suppliers with high level clinical data according to the Swedish registry. As in Denmark, the role of the national registry is extremely important. The SKAR as referred to in paragraph (99) is the essential instrument for assessing clinical evidence in Sweden, on which hospitals rely when selecting an implant and suppliers.
- (445) As one customer explained: "*The Swedish registry is important in the process of choosing implants supplier. It limits the number of suppliers a hospital can buy from as the product must be good enough to be considered by the hospital, meaning in the top 3 of the Swedish registry. The most important feature of the registry is "time to revision" (after 2-20 years); another outcome is "patient measurements" (i.e. PROM = patient related outcome measurements)*".²⁸⁶
- (446) While the Notifying Party submits that price would account for 40-80% in the criteria for purchasing an implant, customers indicated that even though price is important, they would not buy a product just because it is cheaper. Hospitals are very conservative in Sweden, which turns into high levels of surgeons' inertia. As pointed out by a customer: "*As you only find out that the product is not working well after 5-10 years (when revisions are needed), the product will be used in many surgeries by that time and therefore many patients will suffer from the bad implant and need revisions. That explains the ultra-conservatism of the surgeons/hospital who will always buy products with a good reputation*".²⁸⁷
- (447) The in-depth market investigation indicated that Zimmer and Biomet are among the main players in terms of reputation among Swedish surgeons and ranking in the Swedish national registry.²⁸⁸ Other players, such as Stryker or S&N are well-known, but not as well-established as the Parties.
- (448) As shown in section 8.6.2.5 switching from one orthopaedic implant to another is infrequent, necessarily takes time, as convincing surgeons to change product is not easy and moreover, a learning curve for the surgeons follows as a result of the switch. For example, in Sweden, during the in-depth market investigation, only one of the hospitals responding to the Commission's questionnaire on switching indicated that it had switched supplier since 2012.²⁸⁹ One key opinion leader explained: "*Hospitals tend to stick to a few types of implants. The choice of those implants is very much based on the surgeons' preferences. As a consequence, hospitals do not switch between suppliers of implants very often. This can happen when a new implant performs*

²⁸⁶ Non-confidential minutes of the conference call with Bleckinge Hospital, paragraph 20.

²⁸⁷ Non-confidential minutes of the conference call with Bleckinge Hospital, paragraph 3.

²⁸⁸ Non-confidential minutes of the conference call with Bleckinge Hospital, paragraphs 21 and 27; and Non-confidential minutes of the conference call with Västra Götalandsregionen Regionservice, of 28.10.2014, paragraphs 6 and 7.

²⁸⁹ Responses to Questionnaire Q31-to hospitals, question 24.

*better and this success is very well documented. In this regard, a track record covering the last 10-15 years is a "must" to be considered reliable".*²⁹⁰

- (449) Furthermore, all customers indicated that they would not purchase a copycat or me-too product.²⁹¹ Such products would need to start their own registry track records from scratch because they cannot use the clinical data of their respective original products.
- (450) Finally, the in-depth market investigation provided evidence that barriers to entry are particularly high in Sweden, higher than in the rest of the EEA. As shown in section 8.6.2.8, barriers to entry in the market for primary knee implants are already high due to different factors such as obtaining the necessary regulatory approvals, the need to persuade surgeons to try new products, etc.
- (451) In Sweden, market entry is rendered even more difficult by the fact that surgeons rely heavily on the clinical data and the survival rates analysed in the SKAR, when deciding which products to purchase. One customer explained that *"major suppliers from France or from the United Kingdom are not present in the Swedish registry despite having products of good quality".*²⁹²
- (452) Entry with a new product is extremely difficult, as explained by a key opinion leader, co-author of the SKAR: *"Even if knee implants are to some extent commoditized products, a new supplier - even with a perfect replica of Zimmer's or Biomet's implants - will need to show that the new product has good long term results. Obviously, it is very time consuming for a supplier to develop a track record. The results of a new implant have to be observed over a rather long time period. While pharmaceutical substances most of the time trigger an immediate reaction in the patient, the performance of a knee implant is assessed over its life span. Even if a company were to offer a lower price, it would take years before it can actually participate in a tender and compete on an equal footing with the main suppliers. The hospital putting out the tender could give up or lower significantly its requirements to let such a new company compete in the short term. But this has never happened in the Scandinavian region and is unlikely to happen [...]"*.²⁹³ Another key opinion leader in Sweden considers that *"entry of new players [in Sweden] is extremely difficult due to its conservative nature".*²⁹⁴
- (453) One customer expressed its concerns as regards the merger as follows: *"If the merged entity were to increase its prices, the hospital would make a trade-off between quality and price, especially in the context of the financial crisis which made price elements more important than before. For example, a product that would be twice as expensive would only be bought if it would be twice as good. Faced with a price increase of 15-20% (compared to the price levels achieved at the last round of tenders), the hospital would probably not switch to an inferior quality product. However, when there are good alternatives that are*

²⁹⁰ Non-confidential minutes of the conference call with Prof. Dr. Kärrholm, University of Gothenburg of 2.07.2014, paragraph 4.

²⁹¹ Responses to Questionnaire Q31-to hospitals, questions 25-26.

²⁹² Non-confidential minutes of the conference call with Bleckinge Hospital, paragraph 24.

²⁹³ Non-confidential minutes of the conference call with Prof. Dr. Robertsson of Lund University Hospital of 25.06.2014, paragraphs 27-28.

²⁹⁴ Non-confidential minutes of the conference call with Prof. Dr. Kärrholm, University of Gothenburg of 2.07.2014, paragraph 16.

cheaper they are inclined to switch. What is meant by "good alternatives" are products that should be present in the Swedish registry that can demonstrate similar "time to revision" (after 20 years, 10 years and 5 years) than the products currently selected". Specifically as regards knee implants, "in the current market conditions, the hospital would probably not switch in case of a price increase of 15-20% by the merged entity". The same customer pointed out that "In knees, Zimmer, Biomet and Stryker have 80% of the market in Sweden, which means competition would go from 3 to 2 after the merger".²⁹⁵

- (454) A purchasing group also shared its concerns about the merger: *"There is a risk that Zimmer and Biomet become dominant in the knee implants sector, and some concerns also arise in other sectors. Both companies offer good quality products, but their prices might go up".²⁹⁶*
- (455) In light of the arguments set out in this section, the Commission takes the view that merging firms are close competitors, customers have limited possibilities of switching suppliers and barriers to entry/expansion in the Swedish knee market are high, and possibly higher than in the rest of the EEA. Also, as described in section 8.6.2.7 above, countervailing buyer power does not appear sufficient to constrain the merged entity's behaviour post-merger.

Conclusion

- (456) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for primary knee implants in Sweden through the creation or strengthening of a dominant position.

Austria

- (457) According to the Notifying Party, in Austria, the total value of the market for primary knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [10-20]*%.
- (458) Over 2011-2013, Zimmer's position slightly decreased by less than [0-5%]*, while Biomet's position increased from approximately [10-20]*% to [10-20]*%.
- (459) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least four of those competitors would have non-negligible market shares: J&J/DePuy ([20-30]*%), Stryker ([5-10]*%) S&N ([5-10]*%) and Medacta ([5-10]*%).
- (460) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party slightly overestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [30-40%]*, with Biomet contributing an increment of approximately [10-20%]*. The market reconstruction confirmed the presence of another nine

²⁹⁵ Non-confidential minutes of the conference call with Bleckinge Hospital of 24.10.2014, paragraphs 27 and 28.

²⁹⁶ Non-confidential minutes of the conference call with Västra Götalandsregionen Regionservice of 28.10.2014, paragraph 11.

competitors in the market, with one competitor having a market share above 10% and six others having market shares above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (461) The Notifying Party also pointed towards market entry by Brehm and Ceraver in 2011 and Corin in 2012 in the Austrian market as indicating an absence of significant barriers to entry.²⁹⁷ The Commission's market reconstruction partially confirmed this claim. Indeed, two suppliers succeeded in entering the Austrian market and achieving meaningful market shares over the last five years.
- (462) Finally, no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (463) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Austria.

Belgium (including Luxembourg)

- (464) According to the Notifying Party, in Belgium (including Luxembourg), the total value of the primary total knee implant market was EUR [50-100]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [10-20]*%.
- (465) Over 2011-2013, Zimmer's position increased from [10-20]*% to [20-30]*%, while Biomet's position also increased from [10-20]*% to [10-20]*%.
- (466) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have non-negligible market shares: S&N ([20-30]*%), J&J/DePuy ([10-20]*%) and Stryker ([10-20]*%).
- (467) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party slightly overestimated the Parties' market shares. The Parties appear to have a combined market share of approximately [30-40%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction confirmed the presence of another ten competitors in the market, with three other players having market shares above 10%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (468) The Notifying Party pointed towards entry by Adler in 2009, C2F Implants in 2012, and Arthrex and Lima in 2013 in the Belgian market as indicating an absence of significant barriers to entry.²⁹⁸ The Commission's targeted market reconstruction partially confirmed this claim. Indeed, one supplier succeeded in

²⁹⁷ Response to the Article 6(1)(c) Decision, paragraph 568.

²⁹⁸ Response to the Article 6(1)(c) Decision, paragraph 568.

entering the Belgian market and achieving meaningful market shares over the last five years.

- (469) Finally, no concerns were raised by participants to the market investigation in relation to Belgium (including Luxembourg).

Conclusion

- (470) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Belgium (including Luxembourg).

Cyprus

- (471) According to the Notifying Party, in Cyprus, the total value of the market for primary knee implants amounted to EUR [less than 1]* million in 2013. However, the Notifying Party was not able to provide reliable market shares for this country. Cyprus was also not one of the countries included in the Commission's market reconstruction. That said, on the basis of the Notifying Party's estimates, the merged entity's market share would potentially be over [50-60]*%, with Zimmer contributing an increment of approximately [20-30]*%.

- (472) However, due to the low volumes purchased in this market, market shares may not be representative of real market power. In Cyprus, one contract can drastically change the competitive landscape.

- (473) Post-merger, on the basis of the information submitted by the Notifying Party it appears that the merged entity would continue to face competition from a number of players. At least three other competitors would have significant market presence: J&J/DePuy, S&N and Stryker, that is to say the other three majors in the industry. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (474) Market participants also indicated that implants are purchased centrally by the Ministry of Health's supply directorate through tenders for all hospitals. In essence, the directorate aggregates the needs of all hospitals, and publishes open tenders for two-year contracts. Quantities are only indicative, and contracts are assigned to the lowest price within the technical specifications and terms set therein. The specific set of circumstances of this country, combined with its volumes, provides a certain degree of buyer power capable of promoting competition.²⁹⁹

- (475) Finally, no concerns were raised by participants to the market investigation in relation in Cyprus.

Conclusion

- (476) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Cyprus.

Czech Republic

- (477) According to Notifying Party, in the Czech Republic, the total value of the market for primary knee implants amounted to EUR [1-50]* million in 2013.

²⁹⁹ Responses to Questionnaire Q31-to hospitals, questions 5.1 and 5.2.

In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Zimmer contributing an increment of around [10-20]*%.

- (478) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least five of those competitors would have non-negligible market shares: Aesculap ([20-30]*%), Wright/Microport ([5-10]*%), Beznoska ([5-10]*%), S&N ([5-10]*%) and J&J/DePuy ([5-10]*%). Over 2011-2013, Zimmer's position decreased from [10-20]*% to [10-20]*%, while Biomet's position decreased from [10-20]*% to [10-20]*%.
- (479) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party slightly underestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction confirmed the presence of another seven competitors in the market, one of which with a market share even higher than the merged entity, and one with a market share above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (480) One hospital in the Czech Republic indicated that it had recently switched from Aesculap to Zimmer for primary knee implants, and that the switch had not been difficult.³⁰⁰ Hospitals in this country also indicated that they take into consideration copycat or me-too products.³⁰¹
- (481) Furthermore, the Parties' internal documents indicate that competition in the Czech Republic is quite intense. One of Zimmer's internal documents notes that *"our strongest competitors remain in Czech B Braun, Biomet, S&N – and yes – somewhere below also Mathys, Beznoska, Lima, Wright, Link, J+J [...]. We have to fight with everybody for every single knee, hip – a lot of companies fight for a piece of Czech 22.000 hip and knee surgeries [...]"*.³⁰² The competition brought in the market by these latter players is emphasized in another internal document, an email in which Zimmer is seeking *"information about competitive products, especially from European Hip & Knee products from small players – which [are] starting to be more and more aggressive on the Czech market (Mathys, Aesculap, Implantcast, Lima)"*.³⁰³
- (482) Finally, no concerns were raised by participants to the market investigation in relation to the Czech Republic.

Conclusion

- (483) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in the Czech Republic.

³⁰⁰ Responses to Questionnaire Q31-to hospitals, questions 24 and 28.

³⁰¹ Responses to Questionnaire Q31-to hospitals, question 11 and 12.

³⁰² Zimmer's internal documents, ID ZM 161899.

³⁰³ Zimmer's internal documents, ID: ZM 162116.

France

- (484) According to the Notifying Party, in France, the total value of the market for primary knee implants amounted to EUR [100-200]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [5-10]*%.
- (485) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least seven of those competitors would have non-negligible market shares: Amplitude SAS ("Amplitude") ([10-20]*%), J&J/DePuy ([10-20]*%), Tornier ([5-10]*%), S&N ([5-10]*%), Stryker ([5-10]*%), Mathys ([5-10]*%) and Medacta ([5-10]*%). Over 2011-2013, Zimmer's position significantly decreased from [20-30]*% to [20-30]*%, while Biomet's position slightly increased from [5-10]*% to [5-10]*%.
- (486) Eucomed's data and the Commission's targeted market reconstruction confirmed that Notifying Party slightly underestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of another twelve competitors in the market, with at least two having market shares of above 10% and a number of competitors having a market share above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (487) In terms of market entry, the Commission's in-depth market investigation provided evidence the presence of new entries in France.³⁰⁴ Indeed, one supplier succeeded in entering the French market and achieving a meaningful a market share over the last few years.

Conclusion

- (488) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in France.

Iceland

- (489) According to the Notifying Party, in Iceland, the total value of the market for primary knee implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. On the basis of the information submitted by the Notifying Party, the merged entity would have market share of approximately [90-100]*%, with Biomet contributing an increment of approximately [40-50]*%. Iceland was not one of the countries covered by the Commission's targeted market reconstruction.
- (490) Due to the low volumes purchased in this market, market shares may not however be representative of actual market power. In Iceland, one contract can drastically change the competitive landscape. In Iceland, the buyer side in Iceland is very concentrated, consisting of essentially two public hospitals,

³⁰⁴ Responses to Questionnaire Q30 to competitors, on entry and innovation.

accounting for approximately 300 knee arthroplasty surgery procedures per year.

- (491) Post-merger, the competitors left in the market would have a combined market share of less than 5%. Nevertheless, on the basis of the information provided by the Notifying Party, many suppliers - including Zimmer - do not have a direct presence in Iceland, and cover Iceland from other EEA countries. This also includes S&N, which covers Iceland from Denmark, and Medtronic, which supplies from the United Kingdom. Moreover, contracts are awarded following direct negotiations between suppliers and the hospitals' purchasing departments, instead of tenders due to the low volumes. Typically contracts are signed for one year and can be extended.
- (492) One customer pointed out that it has already indicated - during commercial negotiations - its readiness to switch supplier to obtain a better price. It also explained that it would consider J&J/DePuy as a suitable alternative source of supply.³⁰⁵ The specific set of circumstances of this country, combined with its volumes, provides a certain degree of buyer power capable of promoting competition
- (493) Finally, respondents to the market investigation did not raise any concern in relation to the primary knee market in Iceland.

Conclusion

- (494) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Iceland.

Italy

- (495) According to the Notifying Party, in Italy, the total value of the market for primary knee implants amounted to EUR [100-200]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have combined market share of approximately [40-50]*%, with Biomet contributing an increment of approximately [10-20]*%.
- (496) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have non-negligible market shares: J&J/DePuy ([10-20]*%), S&N ([10-20]*%) and Stryker ([5-10]*%). Over 2011-2013, Zimmer's and Biomet's positions remained relatively stable.
- (497) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party slightly underestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction confirmed the presence of another eleven competitors, with one competitor having a market share above 10% and at least three others having market shares above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

³⁰⁵

Responses to Questionnaire Q31-to hospitals, questions 6 and 32.

- (498) The results of the market investigation also provided indications of the absence of competitive concerns as regards the Italian market for primary knee implants.
- (499) First, during the in-depth market investigation, customers pointed out that their main suppliers were Zimmer, J&J/DePuy and S&N.³⁰⁶
- (500) Second, the Notifying Party's internal documents confirm that the Italian market is indeed characterised by tough competition: "*Situation in Italy stays challenging with several account losses to key competitors on knee side (competitive pricing by DePuy and change of chief surgeon using Stryker)*".³⁰⁷
- (501) In terms of market entry, the Notifying Party claimed that a large number of new entrants had entered the Italian market in recent years, including Adler (2011), Aesculap (2009), Ceraver (2009), Corin (2009), Exactech (2012), Gruppo Bioimpianti (2012), Implantcast (2011), Groupe Lepine (2009) and Micro Port (2013), which would prove the absence of significant barriers to entry.³⁰⁸ The market investigation partially confirmed this claim. Indeed, three suppliers succeeded in entering and achieving a meaningful market share over the last years.
- (502) The Commission considers that entry in the Italian market may be facilitated by a number of factors, such as the less important role played by orthopaedic registries,³⁰⁹ as well as the fact that, at national level, there seem to be more openness towards accepting copycat or me-too products.³¹⁰
- (503) The Italian tender dataset included the largest sample, with 306 knee implants bidding contests corresponding to the period 2008-2014 of which over 70% are "Winner-takes-all" competitions while the remaining 30% concerned short-list type of tenders.³¹¹
- (504) As shown in Table 8 below and recitals (409)-(412) above, the tender information available mainly referred to the broad knee category. Only in a limited number of observations it is specified whether the bidding contest referred to primary and revision knee implants, respectively 13.7% and 15% of the times. It is therefore very complex to draw conclusions in matters such as closeness of competition given that more than 50% of the observations were classified under the broad knee category.

Table 8: Frequency of tender lots for Italy by segment (2008-2014)

Eucomed Segments	Knee bidding contests
Knee	179
Knee (partial)	39
Knee (primary)	42
Knee (revision)	46

³⁰⁶ Responses to Questionnaire Q31-to hospitals, question 30.

³⁰⁷ Zimmer's internal document: "internal correspondence"; ID 3010.

³⁰⁸ Response to the Article 6(1)(c) Decision, paragraph 590.

³⁰⁹ Italy does not yet have a national orthopaedic registry.

³¹⁰ Non-confidential minutes of the conference call with Medi Tecnica, of 23.10.2014, paragraph 11.

³¹¹ See recitals (409)-(412) above for a description of the bidding analysis.

Number of bidding contests	306
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Source: Parties' data

- (505) With all these limitations in mind the tender data shows that at least 25 suppliers took part in the bidding competitions for primary knee implants. 13 companies out of these 25 producers proved to be successful and won at least one lot. In general, about 10.8% of all knee bidding contests were won by 7 small competitors (Tier 3 players) who have not been targeted by the Commission market reconstruction.
- (506) Since the tender data did not allow controlling for the volume awarded, the Commission was unable to infer how these figures are representative of the market. However, they do suggest that the Italian competitive landscape is characterised by a larger number of suppliers and that a fringe of successful small players is present. However, besides this, due to the data limitations the Commission has not been able to disentangle which suppliers were awarded big and important tenders and which among them won small and not very important tenders and therefore, the Commission analysis in this regard is not suitable to understand fully the competitive constraints imposed by each of the suppliers.
- (507) Finally, no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (508) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Italy.

Lithuania

- (509) According to the Notifying Party, in Lithuania, the total value of the market for primary knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Biomet contributing an increment of approximately [10-20]*%. Lithuania was not one of the countries covered by the Commission's targeted market reconstruction.
- (510) This market presents various differences in comparison to the ones in Denmark and Sweden. On the basis of the information submitted by the Notifying Parties, post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have significant market shares: J&J/DePuy ([20-30]*%), S&N ([20-30]*%) and Stryker ([10-20]*%). Over 2011-2013, Zimmer's position increased from [20-30]*% to [20-30]*%, while Biomet's position significantly decreased from [20-30]*% to [10-20]*%. The Commission considers that, due to the significant presence of the three other majors of the industry, the merged entity would continue to face competition from a number of players.
- (511) Finally, no concerns were raised by participants to the market investigation in relation to Lithuania.

Conclusion

- (512) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Lithuania.

Malta

- (513) According to the Notifying Party, in Malta, the total value of the market for primary knee implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. However, the Notifying Party was not able to provide reliable market shares for this country. Malta was also not one of the countries included in the Commission's targeted market reconstruction. That said, the merged entity's market share would potentially be [50-60]*%, with Zimmer contributing an increment of around [20-30]*%.
- (514) Due to the low volumes purchased in this market, market shares may not be representative of real market power. In Malta, one contract can drastically change the competitive landscape.
- (515) On the basis of the information submitted by the Notifying Party, it appears that post-merger, the merged entity would continue to face competitive pressure from a number of suppliers. The Notifying Party has submitted that three of competitors have significant market presence: J&J/DePuy, S&N and Stryker. The Notifying Party has also submitted that other smaller firms are present in this country, such as Tornier and Corin.
- (516) Therefore, on the basis of the arguments set out in this section, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (517) Finally, no concerns were raised by participants to the market investigation in relation to Malta.

Conclusion

- (518) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Malta.

Netherlands

- (519) According the Notifying Party, in the Netherlands, the total value of the market for primary knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Zimmer contributing an increment of approximately [20-30]*%.
- (520) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least, three of those competitors would have significant market shares: J&J/DePuy ([20-30]*%), S&N ([20-30]*%) and Stryker ([5-10]*%). Over 2011-2013, Zimmer's position slightly increased from [20-30]*% to [20-30]*%, while Biomet's position remained essentially the same, moving from [20-30]*% to [20-30]*%.
- (521) Eucomed's data and the Commission's targeted market reconstruction showed that the Notifying Party slightly overestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [40-50%],

with Biomet contributing an increment of approximately [10-20%]. The market reconstruction confirmed the presence of another five competitors in the market, with two competitors having a market share over 10%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (522) Based on the results of the in-depth market investigation, in the Netherlands Zimmer and Biomet are regarded as rather distant competitors, despite being amongst the majors in the industry. One large customer explained: "*Biomet and Zimmer are marginally competing though they can be leaders in some segments. In the Netherlands, Zimmer is big in knees whereas Biomet has significant market shares in hip implants. After the merger, the market will be more consolidated, but the surgeons' opinions are still important. Besides, small companies are competitive and adapt very easily to innovative products and better instrumentation*".³¹²
- (523) In terms of market entry, the Commission's targeted market reconstruction identified a number of entries. Indeed, four suppliers recently entered this market, even if only one of them was capable of achieving meaningful market share over the last five years.
- (524) Finally, no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (525) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in the Netherlands.

Norway

- (526) According to the Notifying Party, in Norway, the total value of the market of the primary knee implant market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Biomet contributing an increment of only approximately [0-5]*%.
- (527) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have significant market shares: J&J/DePuy ([20-30]*%), S&N ([10-20]*%) and Stryker ([5-10]*%). Over 2011-2013, Zimmer's position significantly increased from [5-10]*% to [30-40]*%, while Biomet's position significantly decreased from [10-20]*% to [0-5]*%.
- (528) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party significantly overstated the Parties' market shares. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an insignificant increment of approximately [0-5%]. The market reconstruction confirmed the presence of another four competitors, with two strong competitors having market shares of

³¹² Non-confidential minutes of the conference call with Dr Rob G.H.H. Nelissen (Orthopaedic Surgeon, Leiden University), of 11.11.2014, paragraphs 14 and 15.

above 10%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (529) Finally no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (530) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Norway.

Romania

- (531) According the Notifying Party, in Romania, the total value of the market of primary knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [70-80]*%, with Biomet contributing an increment of around [10-20]*% Romania was not one of the countries included in the Commission's targeted market reconstruction.
- (532) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least, three of those competitors would have non-negligible market: J&J/DePuy ([20-30]*%), S&N ([5-10]*%) and Stryker ([5-10]*%). Over 2011-2013, Zimmer's position also increased substantially by approximately the same percentage, while Biomet's position remained stable.
- (533) Based on the in-depth market investigation, the Commission understands that the market for primary knee implants in Romania (as well as the overall knee segment) is still a small market compared to other Eastern countries such as Poland.³¹³ In Romania knee arthroplasty is quite rare. Only around 20 hospitals in Romania are purchasing significant volumes of these implants.³¹⁴ Such implants are acquired via individual public tenders. The Commission also notes that, recently, there have been discussions about organising tenders at national level for the purchase of medical products to achieve economies of scale, but no decision has been taken yet.³¹⁵
- (534) In Romania, there exists a National Registry of Orthopaedic Implants, but its role is to monitor products, and inclusion of one product in the registry is not a requirement to participate in tenders, nor does it add any value in tender scores.³¹⁶
- (535) Market participants indicated that the Romanian market is dynamic, and mentioned several players such as Zimmer, J&J/DePuy, Biomet, Link, S&N

³¹³ Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 3.

³¹⁴ Non-confidential minutes of the conference call with Bio-Technic of 24.10.2014, paragraphs 9 and 10.

³¹⁵ Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 14.

³¹⁶ Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 16.

and Stryker.³¹⁷ They also perceived Biomet as being quite a small player in the market,³¹⁸ which is not currently very active, its market position becoming more and more marginal nowadays in knees implants.³¹⁹

- (536) Moreover, in Romania, the relationship between customers and distributors appears to be extremely important, and can potentially matter more than the relationship between customers and suppliers. This is so because distributors' reputation and strategy - rather than intrinsic product characteristics - seem to be key competitive assets and drive surgeons' choices.³²⁰ On this basis, the Parties' market share may not necessarily be indicative of market power in Romania. In addition, mergers in the industry lead to some rationalisation in terms of distributorships, making one of the Parties' distributors available to new or existing suppliers for entry or expansion.
- (537) In terms of market entry, market participants explained that it is relatively easy for non-Romanian suppliers to find local players and distribute implants in Romania. This is so because not all distributors are bound by exclusivity terms. For example, there are distributors such as Bio-technic which represent several suppliers.³²¹
- (538) Based on the in-depth market investigation, the Commission identified a number of recent entries in the Romanian market such as Link and Sanatmetal.³²² The Notifying Party's internal documents also show the entry of newcomers such as AAP, Wright, Implantcast, Medacta and Intraplant, which offer low-price implants.³²³
- (539) Finally, no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (540) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Romania.

Slovenia

- (541) According to the Notifying Party, in Slovenia, the total value of the market for primary knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Biomet contributing an increment of approximately [10-20]*%.

³¹⁷ Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 4.

³¹⁸ Non-confidential minutes of the conference call with Bio-Technic of 24.10.2014, paragraph 5.

³¹⁹ Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 7.

³²⁰ One distributor explained that Stryker used to be the number 1 supplier of orthopaedic implants in Romania; however when its distributor started to distribute Zimmer's products instead, its customers also switched to Zimmer products. Non-confidential minutes of the conference call with Bio-Technic of 24.10.2014, paragraph 8.

³²¹ Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 10.

³²² Responses to Questionnaire Q30 to competitors, on entry and innovation; and Non-confidential minutes of the conference call with SC Medical Technologies of 28.10.2014, paragraph 8.

³²³ Zimmer's internal documents, ID 6073, slide 12.

Slovenia was not one of the countries covered by the Commission's targeted market reconstruction.

- (542) This market presents various differences in comparison to the ones in Denmark and Sweden. On the basis of the information submitted by the Notifying Party, it appears that post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have significant market shares: J&J/DePuy ([20-30]*%), S&N ([20-30]*%) and Stryker ([10-20]*%), that is to say the three majors of the industry. Over 2011-2013, Zimmer's position significantly decreased from [40-50]*% to [20-30]*%, while Biomet's position significantly increased from [5-10]*% to [10-20]*%. The Commission considers that, due to the significant presence of the three other majors of the industry, as well as of other players such as Tornier and Corin, the merged entity would continue to face competition from a number of players.
- (543) Finally, no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (544) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Slovenia.

Spain

- (545) According to the Notifying Party, in Spain, the total value of the market for primary knee implants amounted to EUR [50-100]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of around [10-20]*%.
- (546) This market presents various differences in comparison to the ones in Denmark and Sweden. Post-merger, the merged entity would continue to face competition from a number of players. At least, three of those competitors would have non-negligible market shares: Stryker ([10-20]*%), J&J/DePuy ([10-20]*%) and S&N ([10-20]*%). Over 2011-2013, Zimmer's position remained stable, while Biomet's position decreased by approximately [0-5]*%.
- (547) Eucomed's data and the Commission's targeted market reconstruction confirmed the Parties' market shares. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction also confirmed the presence of another seven competitors in the market, with two competitors having market shares above 10% and two others having market share above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (548) During the in-depth market investigation, customers stated that they can choose among several suppliers of primary knee implants, and mentioned Zimmer, Biomet, Orthomedical, Exactech, S&N, J&J/DePuy, as well as some other local suppliers.³²⁴

³²⁴ Responses to Questionnaire Q31-to hospitals, question 22.

- (549) In terms of entry, the Notifying Party claimed that a large number of new entrants entered the Spanish market in recent years, including Aesculap (2006), Amplitude (2006), Ceraver (20005), Corin (2010), Exactech (2010), Lafitt (2009), MBA (2010), Mathys (2011), Medacta (2005), Samo (2011), Surgival (2006) and Tornier, which proved the absence of significant entry barriers.³²⁵ The in-depth market investigation identified at least three suppliers, which succeeded in entering and achieving meaningful market shares over the last few years.
- (550) Finally, no concerns were raised by participants to the market investigation in relation to this market.

Conclusion

- (551) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of primary knee implants in Spain.

8.6.3. Revision Knee Implants

8.6.3.1. The Parties' and their competitors' products

- (552) With respect revision knee implants, Zimmer mainly competes with the NexGen Legacy System and Biomet with its Vanguard 360 Revision System.
- (553) As it can be noted from Table 9 below, there are a number of competitors on the revision knee implants market. Nevertheless, not all competitors active in primary knee implants are active in revision implants (for example, Corin). Moreover, the presence of some of these competitors is far from being significant throughout the EEA.

Table 9: Overview of the Main Offerings for Revision Knee Implants

Competitor	Revision knee implant products
Zimmer	NextGen Legacy Constrained Condylar Knee (LCCK)
Biomet	Vanguard 360 Revision System, Vanguard SSK and AGC Dual Articular 2000
Stryker	Scorpio TS, Duracon TS and Triathlon TS Knee System
J&J/DePuy	LCS Complete Revision Knee System; PFC Sigma Revision Knee System;
S&N	Legion Revision Knee System
Aesculap	Columbus Revision Total Knee System
Wright / Microport	Advance Stemmed Medial-Pivot and Revision Knee System
Tornier	HLS Noetos Revision
Lima	Multigen Plus Condylar Constrained Revision (CCK) Knee System
Mathys	balanSys Knee REV System

³²⁵ Response to the Article 6(1)(c) Decision, paragraph 614.

Competitor	Revision knee implant products
Medacta	GMK Revision Knee System

Source: Form CO, pages 352-354 and Commission's market investigation

8.6.3.2. Structure of the revision knee implants market

- (554) Based on the Notifying Party's submissions, the market for revision knee implants accounts for approximately EUR [100-200]* million in 2013 at EEA level. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. On the basis of the information provided by the Notifying Party, the merged entity would have a market share of approximately [30-40]*% by value at EEA level in this market, with an increment of approximately [5-10]*%.
- (555) However, the Commission notes that the Notifying Party's data include sales relating to the extreme orthopaedics market³²⁶. Therefore, the market share data provided by the Notifying Party does not fully reflect the Commission's market definition. In any event, even on the basis of such data, Table 10 shows the relative importance of the merged entity at the EEA level over the last three years in comparison to the other three major suppliers in the market, that is to say J&J/DePuy, S&N and Stryker.

Table 10: Market Shares for revision knee implants by value at EEA-level over the last three years

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[20-30]*%	[20-30]*%
Biomet	[5-10]*%	[5-10]*%	[5-10]*%
Merged Entity	[30-40]*%	[30-40]*%	[30-40]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
S&N	[10-20]*%	[10-20]*%	[10-20]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Link	[0-5]*%	[0-5]*%	[0-5]*%
Other players	[10-20]*%	[10-20]*%	[10-20]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (556) At national level, according to the data provided by the Notifying Party, the merger would give rise to 8 Group 1 national markets, namely Belgium (including Luxembourg), Cyprus, Denmark, Finland, Iceland, Italy, Spain and Sweden.
- (557) As noted in section 8.3, the Commission carried out a market reconstruction to validate the Notifying Parties' estimates. However, this exercise could not cover a number of EEA countries.

³²⁶ As indicated in recital (125), the Commission considers that extreme orthopaedics products do not form part of the revision knee implant product market.

- (558) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group 1 national markets in Denmark, Finland, Italy and Sweden. In addition, the Commission found that also the Czech Republic, France and Greece would qualify as Group 1 national markets. In the majority of those countries, the merged entity's market shares would be between [30-40%], with at least two other competitors which would continue to exert strong competitive pressure on the merged entity.
- (559) However, the in-depth investigation has provided strong evidence that the merger would raise competition concerns only in relation to Denmark, where the merged entity's market share is close to [50-60]*%, the Parties are close competitors, there are high barriers to entry, there is limited buyer power, customers have limited possibilities of switching supplier and remaining competitors are unlikely to exert credible competitive pressure on the merged entity.

8.6.3.3. General Competitive Assessment

Closeness of competition

The views of the Notifying Party

- (560) The Notifying Party submits that Zimmer and Biomet do not perceive each other as the closest competitor in revision knees. The Notifying Party reiterates the same line of arguments put forward with respect to the market for primary knee implants, and concludes that the notion of "closeness" bears little relevance to assess the effects of the merger in this case (see section 8.6.2.4).

The Commission's Assessment

- (561) The Commission considers that the Parties are two leading players in the market for revision knee implants, and certainly close competitors. In this regard, the Commission makes reference to the reasoning contained in section 8.6.2.4. The market for revision knee implants is characterised by the presence of major suppliers which are seen as closely competing against each other. The elimination of a close competitor, Biomet, as a result of the merger lowers the competitive pressure currently in force in the market.
- (562) In particular, the information gathered during the in-depth market investigation, as well as the Parties' internal documents, show that there are only three other major suppliers in the EEA, that is to say S&N, J&J/DePuy and Stryker. Besides the fact that only these three players have comparable product portfolios to that of Zimmer and Biomet and are present in a consistent way throughout the EEA, these players are also the only ones whose products have enough clinical data to meet the high standard set by certain EEA countries (such as Denmark), where orthopaedic registries play an important role in directing customer choice.
- (563) Moreover, the Notifying Party does not and cannot deny the existing competitive relationship between itself and Biomet. As pointed out by the Horizontal Merger Guidelines, "[...] *the fact that rivalry between the parties has been an important source of competition on the market may be a central factor in the analysis [...]*". Therefore, the Commission concludes that the concept of closeness does bear relevance to the analysis in this case.

- (564) In one of its internal documents,³²⁷ Biomet singles out the main threats to its own Vanguard 360 Revision System. Figure 16 shows that[...]*.

Figure 16: [...]*

- (565) In another internal document,³²⁸ as shown in Figure 17, Biomet makes a detailed comparative matrix between its own product and Zimmer's NexGen LCKK Revision knee system. The same document contains the very same type of matrix for the four main competitors, namely [...] and Zimmer. This indicates that Biomet perceives Zimmer as a close competitor in this market.

Figure 17: [...]*

- (566) In a further internal document,³²⁹ Biomet identifies its competitive threats in revision knee implants, and refers to Zimmer launching new components regarding its revision system such as[...]*.
- (567) In this light, the Commission concludes that Zimmer and Biomet are close competitors in the market for revision knee implants. Their closeness will be further analysed, where appropriate, in the country-by-country analysis contained in section 8.6.3.4 onwards because the Parties can even be considered as each other's closest competitors in certain national markets.

Customer Switching

- (568) The findings set out in section 8.6.2.5 regarding customer switching (difficulties to switch and limited possibilities of switching suppliers) in the market also apply to revision knee implants. In particular, customer switching may be even more difficult in relation to revision knee implants, as the choice of suppliers is more limited than in the case of primary implants.

Elimination of an important competitive force

- (569) The findings set out in section 8.6.2.6 regarding the elimination of an important competitive force in the market also apply to revision knee implants. In particular, Biomet is considered one of the main innovators in the knee implants market, including revision implants.

Countervailing buyer power

- (570) The findings set out in section 8.6.2.7 regarding countervailing buyer power also apply to revision knee implants. In particular, the trend towards tender-based procurement systems and GPOs is not as generalised as to shield all customers from higher prices or deteriorated competitive terms post-merger in the market for revision implants.

Barriers to entry and expansion

- (571) The findings set out in section 8.6.2.8 regarding entry and expansion also apply to revision knee implants. Entry and expansion in this market is at least as difficult as entry in the market for primary knee implants, especially in countries where the trend for clinical evidence is strong, such as Denmark,

³²⁷ Biomet's internal documents, "Principal competencia de Vanguard 360", slide 2, ID: BIO-0762.

³²⁸ Biomet's internal documents, "Vanguard 360, Revision Knee System, Incorporating SSK and DA, Competitive Matrix", slide 11, ID, BIO-0591.

³²⁹ Biomet's internal documents. "SWOT analysis, Revision knee business". ID: BIO-0770.

8.6.3.4. Country-specific Competitive Assessment

(572) Based on the Notifying Party's estimates, the merger would give rise to 8 Group 1 national markets, namely Belgium (including Luxembourg), Cyprus, Denmark, Finland, Iceland, Italy, Spain and Sweden. However, the Commission notes that the Notifying Party's data include sales relating to the extreme orthopaedics market³³⁰. Therefore, the market share data provided by the Notifying Party does not fully reflect the Commission's market definition.

Table 11: Revision knee implants – Group 1 national markets – Market shares by value, 2013³³¹

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>DK</i>	[40-50]*%	[0-5]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([5-10]*%), others ([20-30]*%)
<i>BE</i>	[20-30]*%	[10-20]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([10-20]*%), Stryker ([10-20]*%), others ([10-20]*%)
<i>FI</i>	[40-50]*%	[0-5]*%	[40-50]*%	[1-50]*	Stryker ([20-30]*%), J&J/DePuy ([20-30]*%), others ([5-10]*%)
<i>IC</i>	[30-40]*%	[20-30]*%	[50-60]*%	[less than 1]*	Others ([40-50]*%)
<i>IT</i>	[30-40]*%	[5-10]*%	[30-40]*	[1-50]*	J&J/DePuy ([10-20]*%), S&N ([5-10]*%), Stryker ([5-10]*%), others ([20-30]*%)
<i>ES</i>	[20-30]*%	[10-20]*%	[30-40]*%	[1-50]*	S&N ([10-20]*%), Stryker ([10-20]*%), J&J/DePuy ([10-20]*%), Link ([10-20]*%), others ([0-5]*%)
<i>SE</i>	[40-50]*%	[5-10]*%	[50-60]*%	[1-50]*	J&J/DePuy ([20-30]*%), Link ([10-20]*%), Stryker ([5-10]*%), others ([5-10]*%)
<i>EEA</i>	[20-30]*%	[5-10]*%	[30-40]*%	[100-200]*	J&J/DePuy ([20-30]*%), S&N ([10-20]*%), Stryker ([5-10]*%), Link ([0-5]*%), others ([10-20]*%)

Source: Form CO, Annex 6.2(a)

(573) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group 1 national markets in Denmark, Finland, Italy and Sweden. In addition, the Commission found that also the Czech Republic, France and Greece would qualify as Group 1 national markets. In the majority of those countries, the merged entity's market shares would be between [30-40%]*, with at least two other competitors which would continue to exert strong competitive pressure on the merged entity. However,

³³⁰ As indicated in recital (125), the Commission considers that extreme orthopaedics products do not form part of the revision knee implant product market.

³³¹ The Notifying Party was not able to provide reliable market shares for Cyprus.

the in-depth investigation has provided strong evidence that the merger would raise competition concerns only in relation to Denmark.

Denmark

- (574) According to the Notifying Party, in Denmark, the total value of the market for revision knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Biomet contributing an increment of around [5-10]*%.

Table 12: Shares of value for revision knee implants in Denmark

Suppliers	2011	2012	2013
Zimmer	[30-40]*%	[30-40]*%	[40-50]*%
Biomet	[5-10]*%	[0-5]*%	[0-5]*%
Merged Entity	[30-40]*%	[30-40]*%	[40-50]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Other players	[30-40]*%	[30-40]*%	[20-30]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (575) Based on the data provided by the Notifying Party, the merger would combine the number one and number four players, reinforcing Zimmer's position as market leader with a large gap of approximately [20-30]*% between the merged entity and J&J/DePuy. Post-merger, there would be two other competitors left with market shares over [5-10]*%, J&J/DePuy ([20-30]*%) and Stryker ([5-10]*%). Finally, over 2011-2013, Zimmer's position increased from [30-40]*% to [40-50]*%, while Biomet's position essentially remained stable at approximately [5-10]*%.

Views of the Notifying Party

- (576) The Notifying Party explains that, over 2011-2013, Zimmer's market share increase was due to the introduction of a new system in the market, which illustrates the dynamic nature of competition in the Danish market for revision knees, as well as the contestability of market shares in what is largely a bidding market.³³²

Commission's assessment

- (577) Based on the Commission's market reconstruction, the Notifying Party slightly overestimated both the Parties' market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. Although the market reconstruction confirmed the presence of another two competitors in the market, the Notifying

³³² Response to the Article 6(1)(c) Decision, paragraph 629.

Party's representation of the market is not accurate. Indeed, only one of the remaining competitors has a meaningful market share with the other player holding a share below 5%, which appears to have remained stable over time. The merger would thus effectively lead to a quasi 3-to-2 scenario.

Table 13: Parties' shares of value for revision knee implants in Denmark

Suppliers	2009	2010	2011	2012	2013
Zimmer	[20-30%]	[30-40%]	[20-30%]	[20-30%]	[20-30%]
Biomet	[5-10%]	[5-10%]	[10-20%]	[10-20%]	[10-20%]
<i>Merged Entity</i>	<i>[30-40%]</i>	<i>[40-50%]</i>	<i>[30-40%]</i>	<i>[30-40%]</i>	<i>[40-50%]</i>

Source: Commission's targeted market reconstruction

- (578) The additional findings set out in section 8.6.2.9 (Denmark) also apply to this market.
- (579) Thus, the merger involves close competitors and leads to a high market share in a market which is characterised by very high barriers to entry, limited buyer power and where remaining competitors are unlikely to exert sufficient competitive pressure on the merged entity and customers have limited possibilities of switching supplier.

Conclusion

- (580) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for revision knee implants in Denmark through the creation or strengthening of a dominant position.

Cyprus

- (581) According to the Notifying Party, in Cyprus, the total value of the market for revision knee implants amounted to EUR [less than 1]* million in 2013. However, the Notifying Party was not able to provide reliable market shares for this country. Cyprus was also not one of the countries included in the Commission's targeted market reconstruction. That said, the merged entity's market share would potentially be over [50-60]*%, with Zimmer contributing an increment of approximately [20-30]*%.
- (582) Due to the low volumes purchased in this market, market shares may not be representative of real market power. In Cyprus, one contract can drastically change the competitive landscape.
- (583) Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have significant market presence: J&J/DePuy, S&N and Stryker, that is the other three majors of the industry. Moreover, according to the Notifying Party, other smaller firms are present in Cyprus such as Tornier and Corin. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (584) The additional findings set out in section 8.6.2.9 (Cyprus) also apply to this market.

- (585) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for revision knee implants in Cyprus.

Conclusion

- (586) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in Cyprus.

Czech Republic

- (587) According to the Notifying Party, in the Czech Republic, the total value of the market for revision knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [10-20]*%, with Biomet contributing an increment of around [5-10]*%.

- (588) Post-merger, the merged entity would continue to face competition from a number of players. At least four of those competitors would have non-negligible market shares: Aesculap ([20-30]*%), S&N ([10-20]*%), J&J/DePuy ([5-10]*%) and Wright ([5-10]*%). Over 2011-2013, Zimmer's position decreased from [10-20]*% to [10-20]*%, while Biomet's position also decreased from [5-10]*% to [5-10]*%.

- (589) Eucomed's data and the Commission's targeted market reconstruction indicated that the Notifying Party's significantly underestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [40-50]*, with Zimmer contributing an increment of approximately [20-30]*. However, the market reconstruction also confirmed the presence of other seven competitors in the market, one of them with a market share significantly above 10% and four others with market share above or equal to 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (590) The additional findings set out in section 8.6.2.9 (Czech Republic) also apply to this market.

- (591) In terms of market entry, the targeted market reconstruction identified at least three suppliers, which succeeded in entering and achieving meaningful market shares over the last few years.

- (592) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for the provision of revision knee implants in the Czech Republic.

Conclusion

- (593) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in the Czech Republic.

Finland

- (594) According to the Notifying Party, in Finland, the total value of the market for revision knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Biomet contributing an increment of around [0-5]*%.

- (595) Post-merger, the merged entity would continue to face competition from a number of players. At least two of those competitors would have significant market shares: Stryker ([20-30]*%) and J&J/DePuy ([20-30]*%). According to the Notifying Party, S&N is also marginally present in Finland, along with other smaller firms. Over 2011-2013, Zimmer's position increased from [30-40]*% to [40-50]*%, while Biomet's position decreased from [5-10]*% to [0-5]*%.
- (596) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party overestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an insignificant increment of approximately [0-5%]. The actual market increment brought about by the merger is small. The market reconstruction confirmed the presence of the other major players in the market, one of them with market share higher than the one of the merged entity, and another one with a market share above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (597) Biomet's internal documents also confirm [...] is perceived as a strong competitor in the Finnish market.³³³
- (598) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for revision knee implants in Finland.

Conclusion

- (599) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in Finland.

France

- (600) According to the Notifying Party, in France, the total value of the market for revision knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of around [5-10]*%.
- (601) Post-merger, the merged entity would continue to face competition from a number of players. At least five of those competitors would have non-negligible market shares: J&J/DePuy ([10-20]*%), Tornier ([10-20]*%), S&N ([10-20]*%), Amplitude ([10-20]*%) and Stryker ([5-10]*%). The market would also be populated by a wide array of smaller firms such as Ceraver, FH, Corin, Aesculap, etc. Over 2011-2013, Zimmer's position remained relatively stable, while Biomet's position increased from [5-10]*% to [5-10]*%.
- (602) Eucomed's data and the Commission's targeted market reconstruction showed that the Notifying Party slightly underestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an increment of approximately [10-20%]. However, the market reconstruction confirmed the presence of other eleven competitors in the market, two of them with market shares above 10% and three of them

³³³ Biomet's internal documents. ID: BIO-0685.

with market shares above or equal to 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (603) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for revision knee implants in France.

Conclusion

- (604) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in France.

Greece

- (605) According to the Notifying Party, in Greece, the total value of the market for revision knee implants amounted to EUR [less than 1]* million in 2012.³³⁴ However, the Notifying Party was not able to provide reliable market shares for this country.

- (606) According to Eucomed's data and the Commission's targeted market reconstruction the merged entity appear to have a market share of approximately [30-40%]*, with Biomet contributing an small increment of approximately [0-5%]*. The market reconstruction confirmed the presence of other four competitors in the market, two of them with market share above 10%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (607) In terms of market entry, the Notifying Party claimed several players entered this market such as Implantcast in 2011, Medacta in 2006 and Lima in 2009 - which according to the Notifying Party - proves the absence of significant barriers to entry. The Commission's targeted market reconstruction partially confirmed this claim. Indeed, a few suppliers entered the Greek market for revision knee implants, even if only one of them seem to have succeeded in entering and achieving meaningful market share over the last years.

- (608) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for revision knee implants in Greece.

Conclusion

- (609) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in Greece.

Iceland

- (610) According to the Notifying Party, in Iceland, the total value of the market for revision knee implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of

³³⁴ The Notifying Party was unable to provide market share data for the year 2013.

approximately [20-30]*%. Iceland was not one of the countries covered by the Commission's targeted market reconstruction.

- (611) Due to the low volumes purchased in this market, market shares may not however be representative of actual market power. In Iceland, one contract can drastically change the competitive landscape. In Iceland, the buyer side in Iceland is very concentrated, consisting of essentially two public hospitals, accounting for approximately 300 knee arthroplasty surgery per year.
- (612) Based on the Notifying Party's data, post-merger, there would be a number of smaller competitors left in the market, even if each of them would have a market share of less than 5%. Taken altogether these suppliers account for more than 40% of the market for revision knee implants in Iceland.
- (613) The additional findings set out in section 8.6.2.9 (Iceland) also apply to this market.
- (614) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for revision knee implants in Iceland.

Conclusion

- (615) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in Iceland.

Italy

- (616) According to the Notifying Party, in Italy, the total value of the market for revision knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a combined market share of approximately [30-40]*%, with Biomet contributing an increment of around [5-10]*%.
- (617) Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have non-negligible market shares over: J&J/DePuy ([10-20]*%), S&N ([5-10]*%) and Stryker ([5-10]*%), that is to say the three majors of the industry. Moreover, the market is populated by a number of other smaller firms such as Link, Wright Medical, Aesculap, Corin and Tornier. Over 2011-2013, Zimmer's position decreased from [30-40]*% to [30-40]*%, while Biomet's position also decreased from [5-10]*% to [5-10]*%.
- (618) Eucomed's data and the Commission's targeted market reconstruction show that the Notifying Party significantly underestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. However, the market reconstruction confirmed the presence of another six competitors in the market, two of them with a market share well above 10%, and one of them with a market share well above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (619) The additional findings set out in section 8.6.2.9 (Italy) also apply to this market.

- (620) The bidding data analysis performed on the limited number of observations available for revision knee implants highlighted that in Italy there were 24 suppliers taking part to the bidding competition in this product market. 13 companies proved to be successful since they won at least one lot.
- (621) Since the tender data did not allow controlling for the volume awarded, the Commission was unable to infer how these figures are representative of the market.³³⁵ However, they do suggest that the Italian competitive landscape is characterised by a larger number of suppliers and that a fringe of successful small players is present. Due to the data limitations the Commission has not been able to disentangle which suppliers were awarded big and important tenders and which among them won small and not very important tenders. Therefore, the bidding data analysis does not allow understanding precisely the competitive constraints imposed by each of the suppliers.
- (622) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for revision knee implants in Italy.

Conclusion

- (623) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in Italy.

Sweden

- (624) According to the Notifying Party, in Sweden, the total value of the market for revision knee implants amounted to EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of around [5-10]*%.
- (625) Post-merger, the merged entity would continue to face competition from a number of players. At least, three of those competitors would have non-negligible market shares: J&J/DePuy ([20-30]*%), Link ([10-20]*%) and Stryker ([5-10]*%). Based on the Notifying Party's data S&N is also marginally active in the Swedish market for revision knee implants. Over 2011-2013, Zimmer's position increased from [40-50]*% to [40-50]*%, while Biomet's position decreased from [5-10]*% to [5-10]*%.
- (626) Eucomed's data and the Commission's targeted market reconstruction show that the Notifying Party significantly overestimated the Parties' market shares. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction confirmed the presence of another three major players in the market, two of them with market shares well above 10%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (627) Finally, no concerns were raised by market participants in relation to the market for revision knee implants market investigation in relation to Sweden.

³³⁵ See above in recitals (409)-(412) for general caveats concerning the bidding analysis performed by the Commission.

Conclusion

- (628) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of revision knee implants in Sweden.

8.6.4. Total Knee Implants

- (629) As noted in paragraph (124), for the sake of completeness, the Commission also considered whether its competitive assessment would materially have changed by retaining a single product market encompassing both primary and revision knee implants, that is, an overall market for total knee implants. The result of this assessment shows that the merger significantly impedes effective competition in Denmark and Sweden, even under this hypothetical market definition.
- (630) Table 1 and Table 9 contain overviews of the Parties' and their competitors' main offerings in the markets for primary and revision knee implants.
- (631) The arguments contained in sections 8.6.2 and 8.6.3 also remain valid for this hypothetical product market in Denmark and Sweden.

8.6.4.1. Denmark

- (632) According to the Notifying Party, in Denmark, the total value of a hypothetical market for total knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of around [10-20]*%.

Table 14: Shares of value for total knee implants in Denmark

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[30-40]*%	[30-40]*%
Biomet	[20-30]*%	[20-30]*%	[10-20]*%
Merged Entity	[50-60]*%	[50-60]*%	[50-60]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Other players	[10-20]*%	[10-20]*%	[5-10]*%
Total	100%	100%	100%

Source: Commission's computation based on Form CO, Annex 6.2(a)

- (633) Based on the data provided by the Notifying Party, the merger would combine the number one and number three players, reinforcing Zimmer's position as market leader with a very large gap of approximately [30-40]*% between the merged entity and J&J/DePuy. Post-merger, there would be two other competitors left with market shares over [5-10]*%, namely J&J/DePuy ([20-30]*%) and Stryker ([5-10]*%). Finally, over 2011-2013, Zimmer's position increased from [20-30]*% to [30-40]*%, while Biomet's position decreased by [0-5]*%.

Views of the Notifying Party

- (634) The Notifying Party's arguments have already been set out in sections 8.6.2.9 (Denmark) and 8.6.3.4 (Denmark).

Commission's Assessment

- (635) Based on the Commission's market reconstruction, the Notifying Party slightly overestimated the merged entity's market share. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [20-30%]. Although the market reconstruction confirmed the presence of other three competitors in the market, the Notifying Party's representation of the market is not accurate. Indeed, only one of the remaining competitors has a meaningful market share with the other two players holding a share below 5%, which appears to have remained stable over time. The merger would thus effectively lead to a quasi 3-to-2 scenario.

Table 15: Parties' shares of value for total knee implants in Denmark

Suppliers	2009	2010	2011	2012	2013
Zimmer	[20-30%]	[20-30%]	[20-30%]	[30-40%]	[30-40%]
Biomet	[20-30%]	[20-30%]	[20-30%]	[20-30%]	[20-30%]
Merged Entity	[40-50%]	[40-50%]	[50-60%]	[50-60%]	[50-60%]

Source: Commission's targeted market reconstruction

- (636) The additional findings set out in sections 8.6.2.9 (Denmark) and 8.6.3.4 (Denmark) also apply to this market. In particular, the role of evidence-based medicine, the importance of long standing clinical data and the presence of a national registry greatly heightens the difficulties to enter this market.
- (637) The merger involves close competitors and leads to a combined market share of more than [50-60]*% in this market which is characterised by very high barriers to entry, limited buyer power and where remaining competitors are unlikely to exert sufficient competitive pressure on the merged entity and customers have limited possibilities of switching supplier.

Conclusion

- (638) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for total knee implants in Denmark through the creation or strengthening of a dominant position.

8.6.4.2. Sweden

- (639) According to the Notifying Party, in Sweden, the total value of a hypothetical market for total knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of around [10-20]*%.

Table 16: Shares of value for total knee implants in Sweden:

Suppliers	2011	2012	2013
Zimmer	[40-50]*%	[40-50]*%	[40-50]*%
Biomet	[10-20]*%	[10-20]*%	[10-20]*%
<i>Merged Entity</i>	<i>[50-60]*%</i>	<i>[60-70]*%</i>	<i>[50-60]*%</i>
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Other players%	[10-20]*%	[5-10]*%	[5-10]*%
Total	100%	100%	100%

Source: Commission's computation based on Form CO, Annex 6.2(a)

- (640) Based on the data provided by the Notifying Party, the merger would combine the number one and number three players, reinforcing Zimmer's position as market leader with a very large gap of approximately [30-40]*% between the merged entity and J&J/DePuy. Post-merger, there would be two other competitors left with market shares above 5%, J&J/DePuy ([20-30]*%) and Stryker ([5-10]*%). Finally, Zimmer's position increased by almost [0-5]*, while Biomet's position remained relatively stable.

Views of the Notifying Party

- (641) The Notifying Party's arguments have already been set out in sections 8.6.2.9 (Sweden) and 8.6.3.4 (Sweden).

Commission's Assessment

- (642) Based on the Commission's market reconstruction, the Notifying Party's estimate is relatively accurate. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [10-20%]. The merger would result in a quasi 4-to-3 scenario, where three players would account for most of the market, the merged entity being the market leader. Indeed, post-merger only two other competitors would remain with market shares above 5%.

Table 17: Parties' shares of value for total knee implants in Sweden

Suppliers	2009	2010	2011	2012	2013
Zimmer	[30-40%]	[40-50%]	[40-50%]	[40-50%]	[40-50%]
Biomet	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
<i>Merged Entity</i>	<i>[50-60%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[50-60%]</i>

Source: Commission's targeted market reconstruction

- (643) The additional findings set out in section 8.6.2.9 (Sweden) also apply to this market. In particular, the role of evidence-based medicine, the importance of long standing clinical data and the presence of a national registry greatly heightens the difficulties to enter this market.

- (644) The merger involves close competitors and leads to a combined market share of more than [50-60]*% in this market which is characterised by very high barriers to entry, limited buyer power and where remaining competitors are unlikely to exert sufficient competitive pressure on the merged entity and customers have limited possibilities of switching supplier.

Conclusion

- (645) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for total knee implants in Sweden through the creation or strengthening of a dominant position.

8.6.5. *Extreme Orthopaedics*

8.6.5.1. The Parties' and their competitors' products

- (646) With respect to extreme orthopaedics, Zimmer essentially competes with several products: the NexGen RH Knee, the MOST options System for Severe Bone Loss and the Zimmer Segmental System.
- (647) Biomet competes with its Rotating Hinge Knee and the Orthopaedic Salvage System. The Parties' main competitors' products are listed in Table 18 below.

Table 18: Overview of the Main Offerings for Extreme Orthopaedics Implants

Competitor	Extreme Orthopaedic knee implant products
Zimmer	NexGen RH Knee, MOST Options System for Severe Bone Loss and Segmental System
Biomet	Rotating Hinge Knee; Orthopaedic Salvage System
Stryker	Modular Rotating Hinge and Global Modular Replacement System
J&J/DePuy	S-ROM Noiles Rotating Hinge and Limb Preservation System
S&N	Legion Hinge Knee System
Aesculap	EnduRo Rotating Hinge Knee System
Link	Rotations EndoModell SL and MegaSystem C
Wright / Microport	Guardian Revision Hinge and Guardian Limb Salvage System
Tornier	HLS Noetos Rotating Hinge and HLS Tumor Hinge
Medacta	GMK Rotating Hinge knee
Stanmore	METS
Implantcast	Mutars
Exactech	AcuMatch M-Series Modular with InteGrip, Interspace Components

Source: Form CO and Commission's market investigation

8.6.5.2. Structure of the EEA markets for extreme orthopaedics implants

- (648) Based on the Notifying Party's submissions, the overall market for extreme orthopaedic implants accounted for approximately EUR [50-100]* million in 2013 at EEA level. In the same year, the Parties' sales amounted to approximately EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [20-30]*% by value at EEA level in this overall market, with Biomet contributing an increment of [5-10]*%.
- (649) Table 19 shows the position of the Parties at EEA level for the year 2013, and their relative importance against the other suppliers in the market. Besides the Parties and the other major suppliers of the industry, that is to say J&J/DePuy, S&N and Stryker, there are a number of firms which supply hinged knee and limb salvage implants such as Link and Implantcast.

Table 19: Market Shares for extreme orthopaedics implants by value at EEA-level in 2013

Suppliers	2013
Zimmer	[20-30]*%
Biomet	[5-10]*%

<i>Merged Entity</i>	[20-30]*%
Link	[20-30]*%
Stryker	[10-20]*%
J&J/DePuy	[10-20]*%
S&N	[5-10]*%
Implantcast	[5-10]*%
Other players	[5-10]*%
Total	100%

Source: Response to the Commission's RFI of 11 February 2015

- (650) At national level, according to the data provided by the Notifying Party, the merger would give rise to five Group 1 national markets, namely Belgium (including Luxembourg), Denmark, France, Spain and the United Kingdom.
- (651) In the absence of reliable data, the Commission carried out a targeted market reconstruction to validate, to the extent possible, the Notifying Party's estimates in relation to the overall extreme orthopaedics implants market. However, this exercise does not cover a number of EEA countries as explained in section 8.3. For these countries, the best estimates available remain those provided by the Notifying Party.
- (652) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group 1 national markets in Belgium (including Luxembourg), Denmark and France. In addition, the Commission found that also Austria would qualify as Group 1 national markets. Conversely, Spain and the United Kingdom would not qualify as Group 1 national markets.

8.6.5.3. General Competitive Assessment

8.6.5.4. Closeness of competition

The views of the Notifying Party

- (653) As explained in recital (560) the Notifying Party submits that the Parties are not each other's closest competitors in revision knee implants, including in extreme orthopaedics knee products.

The Commission's assessment

- (654) The in-depth market investigation provided evidence that the Parties are close competitors in the overall market for extreme orthopaedics.
- (655) The Commission rejects the Notifying Party's argument in relation to closeness of competition. Paragraph 28 of the Horizontal Merger Guidelines clearly focuses on the concept of "*merging firms [being] close competitors*", and not on each other's "closest" competitors.³³⁶ That said, as will be explained for example in recitals (672)-(677) below, the competitive dynamics in the market

³³⁶ Horizontal Merger Guidelines, paragraph 38.

for extreme orthopaedics implants appear to be different from other knee markets. This is due to a larger number of significant competitors already at EEA level and an uneven focus of those players (including the Parties) between hinged knee implants and limb salvage implants. Therefore, the impact of the removal of the pre-existing rivalry between the Parties will be better assessed at national level, based on their commercial patterns.

- (656) A review of the Parties' internal documents suggests that Zimmer and Biomet perceive each other as close competitors also in this market. In an internal document entitled "Knee Profiler" Zimmer identifies Biomet, [...] and [...] as the main competitors, at least, for hinged knee implants.³³⁷

Figure 18: [...]*

- (657) The comparison matrix in Figure 19 below, taken from the same internal document, shows which limb salvage products are the closest to Zimmer's Rotating Hinge Knee and Segmental System.³³⁸

Figure 19: [...]*

Conclusion

- (658) In light of the arguments set out in this section, the Commission takes the view that Zimmer and Biomet are close competitors in the market for extreme orthopaedic implants.

8.6.5.5. Customer Switching

- (659) The findings set out in section 8.6.2.5 regarding customer switching (difficulties faced and limited possibilities of switching suppliers) apply by analogy to extreme orthopaedics implants. However, in the case of extreme orthopaedics implants, surgeons seem more inclined to use solutions as customised as possible to the specific conditions of the patient, and will have less attachment to a particular brand.³³⁹

8.6.5.6. Elimination of an important competitive force

- (660) The findings set out in section 8.6.2.6 regarding the elimination of an important competitive force in the market apply by analogy to extreme orthopaedics implants. In particular, Biomet is considered one of the main innovators in the knee implants market, including extreme orthopaedics implants.

8.6.5.7. Countervailing buyer power

- (661) The findings set out in section 8.6.2.7 regarding countervailing buyer power apply by analogy to extreme orthopaedics implants. In particular, the trend towards tender-based procurement systems and GPOs is not as generalised as to shield all customers from higher prices or deteriorated competitive terms post-merger in the market for extreme orthopaedics.

8.6.5.8. Barriers to entry and expansion

- (662) The findings set out in section 8.6.2.8 regarding entry and expansion apply by analogy to extreme orthopaedics implants. In particular, extreme orthopaedics

³³⁷ Zimmer's internal documents, "Knee profiler", September 2012, page 403, ID 278.

³³⁸ Zimmer's internal documents, "Knee profiler", September 2012, page 453, ID 278.

³³⁹ Non-confidential minutes of the conference call with dr. Otto Robertsson of 5.12.2014, paragraph 18.

market is a very specific, niche market where only the five major players, as well as highly specialised companies have managed to enter so far.

8.6.5.9. Country-specific Competitive Assessment

- (663) At national level, according to the data provided by the Notifying Party, the merger would give rise to five Group 1 national markets, namely Belgium (including Luxembourg), Denmark, France, Spain and the United Kingdom.

Table 20: Extreme orthopaedics knee implants – Group 1 national markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>BE</i>	[30-40]*%	[20-30]*%	<i>[60-70]*%</i>	[1-50]*	Link ([10-20]*%), S&N ([5-10]*%), residual ([10-20]*%)
<i>DK</i>	[50-60]*%	[0-5]*%	<i>[50-60]*%</i>	[1-50]*	J&J/DePuy ([10-20]*%), Stryker ([5-10]*%), residual ([20-30]*%)
<i>FR</i>	[30-40]*%	[5-10]*%	<i>[30-40]*%</i>	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([20-30]*%), S&N ([5-10]*%), Wright ([5-10]*%), others
<i>ES</i>	[20-30]*%	[20-30]*%	<i>[40-50]*%</i>	[1-50]*	Link ([40-50]*%), J&J/DePuy ([5-10]*%), others
<i>UK</i>	[20-30]*%	[10-20]*%	<i>[30-40]*%</i>	[1-50]*	Link ([10-20]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), Stanmore ([5-10]*%), residual ([5-10]*%)
<i>EEA</i>	[20-30]*%	[5-10]*%	<i>[20-30]*%</i>	[50-100]*	Link ([20-30]*%), Stryker ([10-20]*%), J&J/DePuy ([10-20]*%), S&N ([5-10]*%), Implantcast ([5-10]*%), residual ([5-10]*%)

Source: Response to the Commission's RFI of 11 February 2015

- (664) In the absence of reliable data, the Commission carried out a targeted market reconstruction to validate, to the extent possible, the Notifying Party's estimates in relation to the overall extreme orthopaedics implants market. However, this exercise does not cover a number of EEA countries as explained in section 8.3. For these countries, the best estimates available remain those provided by the Notifying Party.
- (665) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group 1 national markets in Belgium (including Luxembourg), Denmark and France. In addition, the Commission found that also Austria would qualify as a Group 1 national markets. Conversely, Spain and the United Kingdom would not qualify as Group 1 national markets.

Austria

- (666) According to the Notifying Party, in Austria, the total value of the market for extreme orthopaedic implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of

approximately [20-30]*%, with Biomet contributing an increment of approximately [10-20]*%.

- (667) Post-merger, the merged entity would continue to face competition from a number of players. At least, five of those competitors would have non-negligible market shares: J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), Link ([10-20]*%), Implantcast ([10-20]*%) and S&N ([5-10]*%).
- (668) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party slightly underestimated the Parties' market shares in the market for extreme orthopaedics. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction confirmed the presence of another nine competitors in the market, with three strong competitors having a market share above 10% and two others having market shares above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (669) In terms of market entry, the Commission's market reconstruction confirmed the entry of two suppliers, which succeeded in entering and achieving meaningful market shares over the last five years.
- (670) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for extreme orthopaedic implants in Austria.

Conclusion

- (671) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Austrian market for extreme orthopaedic implants.

Belgium (including Luxembourg)

- (672) According to the Notifying Party, in Belgium (including Luxembourg), the total value of the market for extreme orthopaedic implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [60-70]*%, with Biomet contributing an increment of approximately [20-30]*%.
- (673) Post-merger, the merged entity would continue to face competition from a number of players. At least, two of those competitors would have non-negligible market shares: Link ([10-20]*%) and S&N ([5-10]*%). Other major players would have a market presence in Belgium (including Luxembourg), that is to say J&J/DePuy and Stryker, as well as some other firms such as Wright Medical and Tornier.
- (674) Eucomed's data and the Commission's targeted market reconstruction showed that the Notifying Party underestimated the Parties' market shares in the market for extreme orthopaedics. The Parties appear to have combined market shares of approximately [80-90%], with Biomet contributing an increment of approximately [30-40%]. The market reconstruction confirmed the presence of another five competitors in the market, one with a market share above 5%. All the major players are present in Belgium (including Luxembourg) in the market for extreme orthopaedics. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (675) Furthermore, due to the high market share, the Commission engaged in a more detailed analysis of the Parties' sales. Such analysis revealed that Zimmer and Biomet are not actually close competitors in Belgium (including Luxembourg). [...] accounts for the large majority of Zimmer's sales in this market, while Biomet's [...] accounts for most of Biomet's sales in this market. As shown above in recital (657), even assuming that these products form part of the same relevant product markets, they are not close substitutes.
- (676) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for extreme orthopaedic implants in Belgium (including Luxembourg).

Conclusion

- (677) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Belgian market for extreme orthopaedic implants.

Denmark

- (678) According to the Notifying Party, in Denmark, the total value of the market for extreme orthopaedic implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of approximately [0-5]*%.
- (679) Post-merger, the merged entity would continue to face competition from a number of players. Two of those competitors would have non-negligible market shares: J&J/DePuy ([10-20]*%) and Stryker ([5-10]*%). Link, a major player in this market, would also be present in Denmark.
- (680) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Notifying Party underestimated the Parties' market shares in the market for extreme orthopaedics. The Parties appear to have combined market shares of approximately [70-80%], with Biomet contributing an increment of approximately [0-5%]. The Commission takes note that the market share increment brought by the merger is very small, and therefore unlikely to change the competitive landscape of the Danish market for extreme orthopaedics. The market reconstruction also confirmed the presence of another four competitors in the market, including one strong competitor with a market share above 10% and one with a market share above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (681) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for extreme orthopaedic implants in Denmark.

Conclusion

- (682) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Danish market for extreme orthopaedic implants.

France

- (683) According to the Notifying Party, in France, the total value of the market for extreme orthopaedic implants amounted to EUR [1-50]* million in 2013. The

same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [5-10]*%.

- (684) Post-merger, the merged entity would continue to face competition from a number of players. At least, five of those competitors would have non-negligible market shares: J&J/DePuy ([20-30]*%), Stryker ([20-30]*%), S&N ([5-10]*%) and Wright ([5-10]*%)
- (685) Eucomed's data and the Commission's targeted market reconstruction indicated that the Notifying Party underestimated the Parties' market shares in the market for extreme orthopaedics. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [5-10%]. The market reconstruction confirmed the presence of another eight competitors in the market, two strong competitors with market shares above 10% and one other with a market share above 5%. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (686) In terms of market entry, the Commission's market reconstruction identified two entries in the French market for extreme orthopaedic implants. These suppliers succeeded in entering and achieving meaningful market shares over the last five years.
- (687) Finally, during the in-depth market investigation no concerns were raised by any market participants in relation to the market for extreme orthopaedic implants in France.

Conclusion

- (688) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the French market for extreme orthopaedic implants.

8.6.6. Hinged Knee Implants Segment

- (689) An overview of the Parties' products regarding a hypothetical market for hinged knee implants is already contained in Table 18 above.

8.6.6.1. Structure of the EEA market for hinged knee implants

- (690) Based on the Notifying Party's submissions, the narrower market for hinged knee implants accounted for EUR [50-100]* million at EEA level in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of [5-10]*%.
- (691) Table 21 shows the position of the Parties at EEA level for the year 2013, and their relative importance against the other suppliers in the market. Besides the Parties and the other major suppliers of the industry, that is to say J&J/DePuy, S&N and Stryker, Link appears to play an important role in this market.

Table 21: Market Shares for hinged knee implants by value at EEA-level in 2013

Suppliers	2013
Zimmer	[20-30]*%

Biomet	[5-10]*%
<i>Merged Entity</i>	<i>[30-40]*%</i>
Link	[20-30]*%
S&N	[10-20]*%
J&J/DePuy	[10-20]*%
Stryker	[5-10]*%
Other players	[10-20]*%
Total	100%

Source: Response to the Commission's RFI of 11 February 2015

- (692) At national level, according to the data provided by the Notifying Party, the merger would give rise to five Group 1 national markets, namely Belgium (including Luxembourg), Denmark, France, Spain and the United Kingdom.
- (693) In the absence of reliable data, the Commission carried out a targeted market reconstruction to validate, to the extent possible, the Notifying Party's estimates in the Form CO in relation to the overall extreme orthopaedics implants market. However, this exercise could not extend to the narrower sub-segments for hinged knee and limb salvage implants. This is because these products are either reported together by most manufacturers to Eucomed or reported inaccurately. Therefore, the Commission will assess the hypothetical market for hinged knee implants on the basis of the data provided by the Notifying Party.
- (694) As explained in paragraph (335), Aesculap filed a formal complaint in relation to the merger. Following an initial conference call on 14 August 2014, Aesculap made three written submissions on 26 August, 23 September and 11 December 2014, and met with the Commission on 17 November 2014.³⁴⁰ In its submissions, Aesculap argued that the merger would lead to a significant impediment of effective competition in a number of national markets. This is so because the merger entity would achieve high market shares in markets characterised by, among other things, limited possibilities to switch and significant entry barriers.
- (695) In its complaint, Aesculap in essence argued that the merger would lead to the creation or strengthening of a dominant position in the markets for all knee and hip implants. Aesculap's assessment is based on its own best estimates, which are in turn an aggregation of market intelligence and publicly available information.³⁴¹ However, according to the results of the in-depth market investigation and its targeted market reconstruction, the Commission has dispelled any concerns in relation to hips, while it has not retained a market definition encompassing an overall market for all knee implants.

³⁴⁰ Aesculap also contributed throughout the proceedings by replying to Commission's questionnaires and participating in other conference calls.

³⁴¹ Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.8.2014, page 15.

- (696) With respect to the market for hinged knee implants in particular, Aesculap raised similar concerns but based its assessment on Germany in particular, whose state of evolution would also be illustrative of the other EEA countries. After explaining that Zimmer is the market leader in Germany based on units sold, together or slightly in front of Link, Aesculap argued that market shares are not a good proxy of market power in this market because Zimmer is currently able to deliver considerably better and newer product than its competitors.³⁴²
- (697) In this regard, Aesculap heavily emphasises Zimmer's patent enforcement strategy, which would intend to shield off its market position and reduce competition in the market for hinged knee implants. In Aesculap's view, Zimmer holds patents in relation to its hinged knee implants which are difficult to circumvent and which could constitute barriers to entry on the market.³⁴³ The merger would then be part of such patent enforcement strategy, as Zimmer would acquire Biomet's patent portfolio and further even more such a strategy. Under this scenario, Aesculap concluded that Zimmer may in the near future be the only competitor capable of producing modern hinged knee implants.
- (698) The Commission assessed the merged entity's market position in a hypothetical market for hinged knee implants on a country-by-country by in section (698) below. The Commission considers that, due to its focus, that is to say Zimmer's current patent enforcement strategy further aggravated by the addition of Biomet's patent portfolio, Aesculap's complaint is too future and uncertain at this stage to be retained and, in any event, non-merger specific.³⁴⁴

8.6.6.2. Country-specific competitive assessment

- (699) At national level, according to the data provided by the Notifying Party, the merger would give rise to five Group 1 national markets, namely Belgium (including Luxembourg), Denmark, France, Spain and the United Kingdom.

Table 22: Hinged knee implants – Group 1 national markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
BE	[40-50]*%	[0-5]*%	[50-60]*%	[1-50]*	S&N ([5-10]*%), J&J/DePuy ([5-10]*%), Stryker ([5-10]*%), Link ([5-10]*%), Wright ([5-10]*%); Stöpler ([5-10]*%), residual ([10-20]*%)
DK	[50-60]*%	[0-5]*%	[50-60]*%	[1-50]*	J&J/DePuy ([20-30]*%), Link ([5-10]*%), residual ([10-20]*%)
FR	[30-40]*%	[0-5]*%	[30-40]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), S&N ([5-10]*%), Wright ([5-10]*%), residual ([10-20]*%)

³⁴² Aesculap, Competitive concerns regarding Zimmer's proposed acquisition of Biomet of 26.8.2014, page 24.

³⁴³ Non-confidential minutes of the conference call with Aesculap of 14.8.2014, paragraph 20.

³⁴⁴ Aesculap also complemented its complaint with an additional coordinated effects theory of harm. However, based on the results of the in-depth market investigation, the Commission considers that such a theory of harm is difficult to maintain in the case at hand, and is unlikely to meet the strict requirements set out by the by the European Courts in Case T-342/99 *Airtours v Commission*.

<i>ES</i>	[30-40]*%	[5-10]*%	[40-50]*%	[1-50]*	Link ([50-60]*%), J&J/DePuy ([5-10]*%), residual ([0-5]*%)
<i>UK</i>	[20-30]*%	[10-20]*%	[30-40]*%	[1-50]*	Link ([10-20]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), Stanmore ([5-10]*%), residual ([5-10]*%)
<i>EEA</i>	[20-30]*%	[5-10]*%	[30-40]*%	[50-100]*	Link ([20-30]*%), S&N ([10-20]*%), J&J/DePuy ([10-20]*%), Stryker ([5-10]*%), residual ([10-20]*%)

Source: Response to the Commission's RFI of 11 February 2015

Belgium (including Luxembourg)

- (700) According to the Notifying Party, in Belgium (including Luxembourg), the total value of the market for hinged knee implants amounted to EUR [1-50]* million in 2013, which represents only 3% of the overall hinged knee sales in the entire EEA. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of approximately [0-5]*%.
- (701) Post-merger, the merged entity would continue to face competition from a number of players. At least five of those competitors would have non-negligible market shares: S&N ([5-10]*%), J&J/DePuy ([5-10]*%), Stryker ([5-10]*%), Link ([5-10]*%) and Wright ([5-10]*%). Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (702) The Commission takes note that the market share increment brought by the merger is small, less than [5-10]*%, while four players above the market share increment would remain in the market. Therefore, it is unlikely that the merger would change the competitive landscape of the Belgian (including Luxembourg) market for hinged knee implants.
- (703) Finally, during the in-depth market investigation, except for a complaint lodged by a competitor, no concerns were raised by any other market participants in relation to the market for hinged knee implants in Belgium (including Luxembourg).

Conclusion

- (704) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Belgian market for hinged knee implants.

Denmark

- (705) According to the Notifying Party, in Denmark, the total value of the market for hinged knee implants amounted to EUR [1-50]* million in 2013, which represents only 2% of the overall hinged knee sales in the entire EEA. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Biomet contributing an increment of approximately [0-5]*%.
- (706) Post-merger, the merged entity would continue to face competition from a number of players. At least two of those competitors would have non-

negligible market shares: J&J/DePuy ([20-30]*%) and Link ([5-10]*%). Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

(707) The Commission takes note that the market share increment brought by the merger is very small, and therefore unlikely to change the competitive landscape of the Danish market for hinged knee implants.

(708) Finally, during the in-depth market investigation, except for a complaint lodged by a competitor, no concerns were raised by any other market participants in relation to the market for hinged knee implants in Denmark.

Conclusion

(709) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Danish market for hinged knee implants.

France

(710) According to the Notifying Party, in France, the total value of the market for hinged knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [0-5]*%.

(711) Post-merger, the merged entity would continue to face competition from a number of players. At least four of those competitors would have non-negligible market shares: J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), S&N ([5-10]*%) and Wright ([5-10]*%). Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

(712) The Commission takes note that the market share increment brought by the merger is small, and therefore unlikely to change the competitive landscape of the French market for hinged knee implants.

(713) Finally, during the in-depth market investigation, except for a complaint lodged by a competitor, no concerns were raised by any other market participants in relation to the market for hinged knee implants in France.

Conclusion

(714) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the French market for hinged knee implants.

Spain

(715) According to the Notifying Party, in Spain, the total value of the market for hinged knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [40-50]*%, with Biomet contributing an increment of approximately [5-10]*%.

(716) Post-merger, the merged entity would continue to face competition from a number of players. At least two of those competitors would have non-negligible market shares: Link ([50-60]*%) and J&J/DePuy ([5-10]*%). Other major players such as Stryker and S&N are also present in this market.

Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (717) Finally, during the in-depth market investigation, except for a complaint lodged by a competitor, no concerns were raised by any other market participants in relation to the market for hinged knee implants in Spain.

Conclusion

- (718) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Spanish market for hinged knee implants.

United Kingdom

- (719) According to the Notifying Party, in the United Kingdom, the total value of the market for hinged knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [10-20]*%.

- (720) Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have non-negligible market shares: Link ([10-20]*%), J&J/DePuy ([10-20]*%) and Stryker ([10-20]*%). Another major player such as S&N is present in the United Kingdom, as well as other smaller firms. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

- (721) Finally, during the in-depth market investigation, except for a complaint lodged by a competitor, no concerns were raised by any other market participants in relation to the market for hinged knee implants in the United Kingdom.

Conclusion

- (722) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the United Kingdom market for hinged knee implants.

8.6.7. *Limb Salvage Segment*

- (723) An overview of the Parties' products regarding a hypothetical market for limb salvage implants is already contained in Table 18 above.

8.6.7.1. Structure of the EEA market for limb salvage implants

- (724) Based on the Notifying Party's submissions, the narrower market for limb salvage implants accounted for EUR [1-50]* million at EEA level in 2013. In the same year, the Parties' sales amounted to approximately EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [20-30]*% by value at EEA level in this market, with Zimmer contributing an increment of [5-10]*%.

- (725) Table 14 below shows the position of the Parties at EEA level for the year 2013, and their relative importance against the other suppliers in the market. Besides the Parties and Stryker, Link and Implantcast appear to play an important role in this market. J&J/DePuy is also present across the EEA, even if the magnitude of such presence is comparable to that of a smaller firm, that is to say Stanmore.

Table 23: Market Shares for limb salvage implants by value at EEA-level in 2013

Suppliers	2013
Zimmer	[5-10]*%
Biomet	[10-20]*%
<i>Merged Entity</i>	<i>[20-30]*%</i>
Link	[20-30]*%
Implantcast	[10-20]*%
Stryker	[10-20]*%
Stanmore	[5-10]*%
J&J/DePuy	[5-10]*%
Other players	[5-10]*%
Total	100%

Source: Response to the Commission's RFI of 11 February 2015

- (726) At national level, according to the data provided by the Notifying Party, the merger would give rise to five Group 1 markets, namely Belgium (including Luxembourg), Denmark, France, Spain and the United Kingdom.
- (727) In the absence of reliable data, the Commission carried out a targeted market reconstruction to validate, to the extent possible, the Notifying Party's estimates in the Form CO in relation to the overall extreme orthopaedics implants market. However, this exercise could not extend to the narrower sub-segments for hinged knee and limb salvage implants. This is because these products are either reported together by most manufacturers to Eucomed or reported inaccurately. Therefore, the Commission will assess the hypothetical market for hinged knee implants on the basis of the data provided by the Notifying Party.

8.6.7.2. Country-specific competitive assessment

- (728) At national level, according to the data provided by the Notifying Party, the merger would give rise to five Group 1 markets, namely Belgium (including Luxembourg), Denmark, France, Spain and the United Kingdom.

Table 24: Limb salvage implants – Group 1 national markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>BE</i>	[0-5]*%	[70-80]*%	<i>[70-80]*%</i>	[less than 1]*	Link, Stryker, others
<i>DK</i>	[50-60]*%	[0-5]*%	<i>[50-60]*%</i>	[less than 1]*0	Stryker, Link, others
<i>FR</i>	[5-10]*%	[30-40]*%	<i>[30-40]*%</i>	[less than 1]*	Stanmore, J&J/DePuy, Stryker, Link, others

<i>ES</i>	[0-5]*%	[50-60]*%	[50-60]*%	[1-50]*	J&J/DePuy, Stryker, Link, Implantcast, Stanmore, others
<i>UK</i>	[20-30]*%	[10-20]*%	[30-40]*%	[1-50]*	J&J/DePuy, Stryker, Implantcast, Stanmore, others
<i>EEA</i>	[5-10]*%	[10-20]*%	[20-30]*%	[1-50]*	Link, Implantcast, Stryker, Stanmore, J&J/DePuy, others

Source: Response to the Commission's RFI of 11 February 2015

Belgium (including Luxembourg)

- (729) According to the Notifying Party, in Belgium (including Luxembourg), the total value of the market for limb salvage implants amounted to EUR [less than 1]* million in 2013, which represents only 3.5% of the overall limb salvage market in the entire EEA. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [70-80]*%, with Biomet contributing an increment of approximately [0-5]*%.
- (730) Post-merger, the merged entity would continue to face competition from a number of players. In particular, two strong competitors such as Link and Stryker would be present on this market. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.
- (731) Moreover, the Notifying Party pointed out that the small [0-5]*% market share increment is the result of the Zimmer's sale of only 2 limb salvage implants in this country, that is to say that Zimmer is at best marginally present in Belgium (including Luxembourg).
- (732) Finally, during the in-depth market investigation, no concerns were raised by any market participants in relation to the market for limb salvage implants in Belgium (including Luxembourg).

Conclusion

- (733) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Belgian (including Luxembourg) market for limb salvage.

Denmark

- (734) According to the Notifying Party, in Denmark, the total value of the market for limb salvage amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60%], with Biomet contributing an increment of approximately [0-5]*%.
- (735) Post-merger, the merged entity would continue to face competition from a number of players. At least two of those competitors would have non-negligible market shares: Stryker ([20-30]*%) and Link ([5-10]*%). The market would furthermore be populated by several smaller firms accounting for a market share of 16.5% altogether. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

(736) The Commission takes note that the market share increment brought by the merger is small, less than [0-5]*%, and therefore unlikely to change the competitive landscape of the Danish market for limb salvage implants

(737) Finally, during the in-depth market investigation, no concerns were raised by any market participants in relation to the market for limb salvage implants in Denmark.

Conclusion

(738) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Danish market for limb salvage.

France

(739) According to the Notifying Party, in France, the total value of the market for limb salvage amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of [30-40]*%, with Zimmer contributing an increment of [5-10]*%.

(740) Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have non-negligible market shares: Stanmore ([30-40]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%) and Link ([5-10]*%). Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

(741) The Commission takes note that the market share increment brought by the merger is moderate; it creates a new player with a market share below [40-50]*%, while three players well above the market share increment remain in the market. Therefore, it is unlikely that the merger would change the competitive landscape of the Danish market for limb salvage implants.

(742) Finally, during the in-depth market investigation, no concerns were raised by any market participants in relation to the market for limb salvage implants in France.

Conclusion

(743) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the French market for limb salvage.

Spain

(744) According to the Notifying Party, in Spain, the total value of the market for limb salvage amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [50-60]*%, with Zimmer contributing an increment of approximately [0-5]*%.

(745) Post-merger, the merged entity would continue to face competition from a number of players. At least two of those competitors would have non-negligible market shares: Link ([30-40]*%) Implantcast ([10-20]*%) and Stanmore ([10-20]*%). J&J/DePuy, Stryker, as well as other smaller firms would also be present in this market. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

(746) The Commission also takes note that the market share increment brought by the merger is small, less than [5-10]*%, while three players well above the market share increment would remain in the market. Therefore, it is unlikely that the merger would change the competitive landscape of the Danish market for limb salvage implants

(747) Finally, during the in-depth market investigation, no concerns were raised by any market participants in relation to the market for limb salvage implants in Spain.

Conclusion

(748) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the Spanish market for limb salvage.

United Kingdom

(749) According to the Notifying Party, in the United Kingdom, the total value of the market for limb salvage amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [30-40]*%, with Biomet contributing an increment of approximately [10-20]*%.

(750) Post-merger, the merged entity would continue to face competition from a number of players. At least three of those competitors would have non-negligible market shares: Stanmore ([20-30]*%), J&J/DePuy ([10-20]*%) and Stryker ([10-20]*%). Implantcast, as well as other smaller firms would remain active in this market. Therefore, the Commission considers that, post-merger, the merged entity would continue to face sufficient competitive constraints.

(751) Finally, during the in-depth market investigation, no concerns were raised by any market participants in relation to the market for limb salvage implants in the United Kingdom.

Conclusion

(752) In light of the arguments set out in this section, the Commission concludes that the merger is not likely to significantly impede effective competition in relation to the United Kingdom market for limb salvage.

8.6.8. Unicondylar Knee Implants

8.6.8.1. The Parties' and their competitors' products

(753) Zimmer competes with the Unicompartmental High-Flex Knee System ("ZUK"), which is a fixed bearing implant, and also sells another unicondylar implant, the Allegretto.

(754) Biomet competes with the Oxford Partial Knee, an extremely famous mobile bearing implant, and also sells the Vanguard M Partial Knee System, a fixed-bearing implant.

Table 25: Overview of the Main Offerings for Unicondylar Knee Implants

Competitor	Unicondylar knee implant products
Zimmer	Unicompartmental High-Flex Knee System and Allegretto Unicompartmental Resurfacing Knee
Biomet	Oxford Partial Knee and Vanguard M Partial Knee System

Competitor	Unicondylar knee implant products
Stryker	Triathlon PKR Partial Knee
J&J/DePuy	Sigma High Performance Partial Knee System
S&N	Journey Uni Unicompartmental Knee System and Accuris Uni Knee System
Aesculap	Univation Unicondylar Knee System
Tornier	HLS Uni Evolution
Corin	Uniglide™
Link	Endo Model Sled Prosthesis
Mathys	BalanSys Uni Knee
Conformis	iUni G2 Partial Knee
Adler	Genus Uni

Source: Form CO, pages 352-354 and Commission's investigation

- (755) Based on the Notifying Party's submissions, the market for partial knee implants amounts to approximately EUR [50-100]* million in 2013 at EEA level. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of [70-80]*% by value at EEA level in this market, with an increment of approximately [20-30]*%.³⁴⁵
- (756) The merger would give rise to 17 Group 1 markets, namely Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, and the United Kingdom. Table 26 shows the position of the Parties at the EEA level over the last three years against other two majors, that is to say J&J/DePuy and S&N.

Table 26: Market Shares for partial knee implants by value at EEA-level over the last three years

Suppliers	2011	2012	2013
Zimmer	[10-20]*%	[10-20]*%	[20-30]*%
Biomet	[50-60]*%	[40-50]*%	[50-60]*%
<i>Merged Entity</i>	<i>[70-80]*%</i>	<i>[60-70]*%</i>	<i>[70-80]*%</i>
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%

³⁴⁵

In Annex R.2 to the Form CO, the Notifying Party produced market shares regarding the Parties' unicompartmental sales. Such data did not identify competitors' sales and market shares, and therefore did not allow the Commission to carry out a proper competitive assessment. That said, even under this representation the merged entity's market share would have remained high or very high. In any event, the Commission carried out its own market reconstruction with respect to the markets at hand.

S&N	[0-5]*%	[0-5]*%	[0-5]*%
Other players	[10-20]*%	[10-20]*%	[5-10]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (757) In the absence of reliable data, the Commission carried out a market reconstruction to validate the estimates provided by the Notifying Party in the Form CO. However, this exercise does not cover a number of EEA countries as explained in section 8.3. According to the Commission's data, the market share of the merged entity post-merger would give rise to, at least, 15 Group 1 markets.³⁴⁶ In all those countries, the merged entity's market share would exceed [50-60]*%, reaching up to even [90-100%]*.
- (758) The in-depth market investigation provided evidence that the merger would raise competition concerns in relation to Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom, where the merged entity's market share significantly exceeds [50-60]*% and not enough competitors remain in the market.

8.6.8.2. General Competitive Assessment

Closeness of Competition

The views of the Notifying Party

- (759) The Notifying Party argues that, despite the very high market shares, their products are not close substitutes because they correspond to different surgical philosophies. Zimmer's ZUK is a fixed bearing knee, while Biomet's Oxford Knee is a mobile-bearing knee.³⁴⁷ In other words, their products would not be close substitutes, and therefore would not directly compete against each other. This is so because mobile bearing surgeons, and particularly "Oxford surgeons", are unlikely to switch to fixed bearing implants, and vice-versa.
- (760) In this regard, the Notifying Party submits that Biomet's Oxford Knee entails a less forgiving surgery compared to the implants offered by Biomet's competitors. For example, the unicondylar solutions proposed by J&J/DePuy with Sigma HP, Stryker with Triathlon, S&N with Journey, as well as several other competitors, would be more similar to Zimmer's ZUK than to Biomet's Oxford Knee because they are all fixed bearing designs. The Oxford Knee, as a mobile bearing design, in principle directly competes with products such as Corin's Uniglide, another mobile bearing design, as well as Aesculap's Univation and Amplitude's Uniscore, which both have a fixed bearing and a mobile bearing version.

³⁴⁶ These countries are: Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom.

³⁴⁷ To put it simply, the main difference between the two products is that the polyethylene insert placed in the middle of the implant is subject to less wear in a mobile bearing device because weight is spread across a large surface in consequence of the mobility of the device.

- (761) The Notifying Party further notes that Biomet's Oxford Knee is the "benchmark" product, and therefore any reference to it in Zimmer's internal documents is not an indication of closeness but only a sign of natural marketing strategy. By the same token, Biomet product would not regard Zimmer as an especially close competitor in this market. The Notifying Party tries to corroborate this argument by submitting quotes from its own and Biomet's internal documents.³⁴⁸

The Commission's Assessment

- (762) The in-depth market investigation provided evidence that the Parties are two leading players in the market for unicondylar knee implants, and certainly close competitors. In any event, and for the sake of clarity, there is no need for the Commission to reach the conclusion that the Parties are each other's closest competitors. The Commission makes reference to section 8.1 in this regard.
- (763) In particular, the information gathered during the in-depth market investigation, as well as the Parties' internal documents, show that Zimmer and Biomet currently own the two legacy products, which have - to some extent - even created the market for unicondylar knee implants. In the Notifying Party's own words, "*Biomet's Oxford knee has traditionally been – and still is – very successful and almost a "benchmark" product among partial knees*".³⁴⁹ Based on this, it is undisputed that the merger would remove the competitive pressure exerted by a major competitor of the magnitude of Zimmer over the current market leader.
- (764) The Notifying Party's depiction of Zimmer's ZUK and Biomet's Oxford Knee as such dissimilar products that surgeons would not switch from one to another does not reflect market reality. If that was the case, logic would dictate that a price increase in Biomet's Oxford Knee would trigger switching to other mobile bearing designs, but not to Zimmer's ZUK.³⁵⁰ If anything, this would be suggestive of two distinct product markets for fixed and mobile bearing designs. However, that is at odds with the position of the Notifying Party, namely a single market for all knee products. In particular, such a position would also contradict the statements in the Form CO according to which "*the Notifying Party agrees with the Commission's assessment that FB (fixed bearing) and MB (mobile bearing) belong to the same relevant product market*".³⁵¹
- (765) Regarding the competitive dynamics between fixed and mobile bearing unicondylar knee implants, the Commission also notes the following.
- (766) First, the Notifying Party overlooks that competition takes place at different levels in the market, and therefore focusing on the difficulty of switching from mobile bearing to fixed bearing designs depicts only part of a larger picture. This is because suppliers compete for young surgeons or, in any event,

³⁴⁸ Response to the Article 6(1)(c) Decision, paragraphs 483-484.

³⁴⁹ Response to the Article 6(1)(c) Decision, paragraph 480.

³⁵⁰ According to S&N, Biomet was indeed able to erode the market shares of suppliers such as Zimmer with its fixed bearing system, which suggests that surgeons can and do switch between the two segments. Non-confidential minutes of the conference call with S&N of 10.10.2014, paragraph 12.

³⁵¹ Form CO, 1338. See also Form CO, paragraph 1380 ("*... the competitive situation in these markets is dynamic enough to counteract any potential lessening of competition that the level of market shares would indicate*").

surgeons unfamiliar with unicondylar knee implants by proposing their own products and philosophies. For example, S&N explained that "*Biomet has also tried to expand its reach, trying to draw more and more surgeons originally opposed to unicondylar surgeries toward its Oxford knee philosophy*".³⁵²

- (767) Second, with respect to surgeons who are already familiar with unicondylar surgery and have an affiliation with a supplier, the substantial difference regards marketing strategy, which varies according to the product currently in use by a given surgeon. However, the pre-existing affiliation in no way calls into question the basic intent of suppliers to expand their market to new surgeons. As pointed out by J&J/DePuy, the unicondylar market is too small in size for focusing marketing efforts on a given fixed bearing surgeon instead of mobile bearing ones.³⁵³
- (768) In this regard, S&N pointed out "*Over the last 10 years, the market for unicondylar knees has seen the rise of Biomet as a leading player, particularly in the US. Biomet has focused its marketing efforts on its Oxford knee [...] and was able to successfully erode market shares of other suppliers, such as Zimmer with its fixed bearing system*".³⁵⁴
- (769) Another player, Lima, stated that "*fixed and mobile bearing implants can be considered two different philosophies, but they do compete against each other, and therefore are part of the same market*".³⁵⁵ Surgeons also confirmed that there is no scientific proof that mobile bearing implants are better than fixed bearing ones.³⁵⁶ Yet, mobile bearings require a more demanding and unforgiving procedure.
- (770) Stryker even considered that "*the distinction between mobile and fixed bearing is somehow artificial because mobile bearing implants tend to become fixed after some time. This is simply because tissue starts growing and the polyethylene component gets surrounded by such tissue and ultimately locked*".³⁵⁷
- (771) Finally, while it is conceivable that "Oxford surgeons" are harder to persuade due to the reputation and long standing clinical data of the Oxford Knee, the Notifying Party itself confirms that even those surgeons can - and are - targeted by other suppliers. Indeed, Biomet fears losing them to fixed bearing suppliers.
- (772) In the Response to the Article 6(1)(c) Decision, the Notifying Party itself stressed that, for Biomet, the [...]*.³⁵⁸ This is very informative because both Mako and Stryker are selling fixed bearing implants, and the Notifying Party even states that [...]*.³⁵⁹

³⁵² Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 12.

³⁵³ Non-confidential minutes of the conference call with J&J/DePuy of 7.11.2014, paragraph 24

³⁵⁴ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 12.

³⁵⁵ Non-confidential minutes of the conference call with Lima of 10.11.2014, paragraph 14.

³⁵⁶ Non-confidential minutes of the conference call with Prof. Migaud of University Hospital of Lille of 18.08.2014, paragraph 12; and Non-confidential minutes of the conference call with Prof. Marcacci of Istituto Ortopedico Rizzoli of 9.07.2014, paragraph 13.

³⁵⁷ Non-confidential minutes of the conference call with Stryker of 11.11.2014, paragraph 13.

³⁵⁸ Response to the Article 6(1)(c) Decision, paragraph 482-484. Mako was acquired by Stryker in December 2013.

³⁵⁹ Response to the Article 6(1)(c) Decision, paragraph 482.

(773) Moreover, a review of the Parties' internal documents shows that Zimmer and Biomet do regard each other as close competitors. For example, an internal document of Zimmer entitled "Knee Profiler" shows that Zimmer regards Biomet's Oxford Knee as the first competitor against its ZUK, [...]*.³⁶⁰

Figure 20: [...]*

(774) The same document also depicts Biomet's Oxford Knee as the first competitor of Zimmer's Allegretto, followed by [...]*.³⁶¹

Figure 21:[...]*

(775) Furthermore, as shown in Figure 22,³⁶² even if for the sake of argument Zimmer and Biomet were not to be considered as each other's closest competitor, it is undisputed that they are close ones. The matrix in Figure 22 below **Error! Reference source not found.** shows what products Zimmer regards as "best matches" against its own offering. Those implants are the ones produced by Biomet, [...]*. Contrary to the Notifying Party's claim, Zimmer does not single out any of the other competitors that would offer similar products such as [...]* or [...]*.

Figure 22: [...]*

(776) Finally, the Commission found further confirmation that Zimmer and Biomet are close competitors in unicondylar knee implants in the CRM dataset provided by the Parties. The data indeed showed that Biomet is considered as Zimmer's primary competitor in most of the sales opportunities recorded in the database.

(777) The Commission used the CRM database provided by the Parties to check which companies Zimmer identifies as primary competitors. The CRM database is gathered at the national level by each of the country managers. Only the United Kingdom and Germany have gathered the data in a systematic way and it is the only data which can be exploited. Therefore, the Commission restricted its analysis to the sales opportunities identified in Germany and the United Kingdom in 2013 and 2014.³⁶³ (Biomet submitted a CRM dataset containing information on sales opportunities in Austria, Germany, Denmark, Finland, Norway, Sweden and the Netherlands. However, many features of the data, such as the level of product aggregation, the number of sales opportunities recorded by country or by brand and per year, prevent the possibility to carry out a meaningful analysis.)

(778) Despite the argument raised by the Parties that Zimmer and Biomet are not closest competitors since their respective reference product in unicondylar knee, the ZUK and the Oxford knee, belong to different surgical philosophies (fixed bearing for the ZUK and mobile bearing for the Oxford knee). The CRM data analysis for the United Kingdom and Germany received from Zimmer, revealed that Zimmer was able to overcome Biomet in several sales opportunities without being the incumbent. This suggests that surgeons can switch between mobile and fixed bearing unicondylar implants and, therefore,

³⁶⁰ Zimmer's internal document, "Knee Profiler" of 2012-2009, page 33, ID278.

³⁶¹ Zimmer's internal document, "Knee Profiler" of 2012-2009, page 10, ID278.

³⁶² Zimmer's internal document, "Knee Profiler" of 2012-2009, page 48, ID278

³⁶³ The CRM data provided include information about sales opportunities identified in EEA countries over the time period 2011-2014. [...]*.

the Oxford knee and the ZUK are actually competing products.³⁶⁴ Furthermore, Zimmer considered, both in the United Kingdom and Germany, that Biomet was by far its primary competitor in the sales opportunities.³⁶⁵

- (779) Due to data availability issues, the CRM analysis was only performed for Germany and the United Kingdom. However, the Commission believes these key findings are revealing of the merging Parties' competitive interaction and can to some extent be extended to the all of the EEA area. It is safe to assume this in light of the significant qualitative evidence gathered throughout the market investigation supporting these findings and the market structure observed throughout the whole of the EEA which overwhelmingly shows that the Parties are the largest two players in nearly every country.
- (780) The key findings of the CRM analysis are presented in the country-specific assessment session.

Conclusion

- (781) In this light, the Commission concludes that Zimmer and Biomet are close competitors in the market for unicondylar knee implants, as per paragraph 28 of the Horizontal Merger Guidelines. Their closeness will be further articulated in the country-by-country analysis contained in sections 8.6.8.3.

Customer Switching

The views of the Notifying Party

- (782) The Notifying Party reiterates the arguments already set out above in section 8.6.2.5.

The Commission's Assessment

- (783) With respect to customer switching, the Commission makes reference to the arguments already set out in section 8.6.2.5. It is however informative to briefly describe the results of the in-depth market investigation because they openly clash with the arguments put forward by the Notifying Party in relation to unicondylar knee implants.
- (784) During the Commission's market investigation, only two customers (one in Austria and one in France) within a sample of twenty-two replied that they switched suppliers of unicondylar knee implants since 2012. The switch was usually due to surgeons' requirements and the need for clinical data. The fact that the new supplier was already serving the hospital with other orthopaedic implants appears to have played a role in their decision.³⁶⁶
- (785) Moreover, in line with the Commission's general findings, six out of ten customers explained that convincing surgeons to switch to another supplier of unicondylar knee implants was difficult or even extremely difficult due to, among other things, the need for clinical data and the fear of steep learning curves.³⁶⁷ Nine

³⁶⁴ Despite the lack of information on what company (other than Zimmer) is the incumbent, given the structure of the industry it seems reasonable to assume that whenever Zimmer is not the incumbent, the company which Zimmer sales representatives targeted as primary competitor is the current supplier of the hospital.

³⁶⁵ This finding is independent of whether Zimmer was the incumbent or not.

³⁶⁶ Responses to Questionnaire Q31 to hospitals, questions 37 - 38.

³⁶⁷ Responses to Questionnaire Q31 to hospitals, questions 41- 42.

out of twelve customers also pointed out that they would not take into account the clinical records developed by original products, when considering a "me-too" or "copy-cat" product.³⁶⁸ This is so because they believed that clinical results could not be transferred to the new products, and the track records of a given product are not as such a guarantee for another.

Conclusion

- (786) In light of the arguments set out in this section, it appears unlikely that customers might switch to other suppliers a significant portion of their purchases in a timely manner to constrain the merged entity's behaviour, in the event of a price increase - or a worsening of competitive terms - enforced the merged entity post-merger.

Elimination of an important competitive force

The views of the Notifying Party

- (787) The Notifying Party reiterates the arguments already set out above in section 8.6.2.6.

The Commission's Assessment

- (788) With respect to the elimination of an important competitive force, the Commission makes reference to the arguments already set out in section 8.6.2.6. The results of the in-depth market investigation openly clash with the arguments put forward by the Notifying Party in relation to unicondylar knee implants.
- (789) The in-depth market investigation provided evidence that Zimmer and Biomet are the most innovative competitors in the market for unicondylar knee implants. In the words of Esforax, an Italian distributor, "*Zimmer è - assieme a Biomet, produttrice del ginocchio Oxford, - leader nel campo delle protesi per il ginocchio*".³⁶⁹ Other majors such as S&N and J&J/DePuy are also mentioned, but not as often as the Parties.³⁷⁰ In addition, none of the smaller players which the Notifying Party refers to was singled out as being an important innovator in the market. Being an innovative player is regarded as particularly important because it allows a supplier to build up clinical data before its competitors, to establish brand recognition and reputation, and to develop its relationship with surgeons.³⁷¹

³⁶⁸ Responses to Questionnaire Q31 to hospitals, question 39.

³⁶⁹ Non-confidential minutes of the conference call with Esforax of 27.10.2014, paragraph 19 (*Zimmer is - together with Biomet, the manufacturer of the Oxford Knee, - a leader in the field of knee prostheses*).

³⁷⁰ Responses to Questionnaire Q30 on entry and innovation, question 37.

³⁷¹ Responses to Questionnaire Q30 on entry and innovation, question 38.

- (790) Finally, besides Zimmer and Biomet, a number of players have launched unicondylar knee products over the last few years, including some majors such as S&N and J&J/DePuy. Those players generally tried to produce fixed bearing products to (i) avoid head-on competition with Biomet and (ii) take advantage of the more friendly fixed-bearing philosophy. Some products, the so-called "me-too" or "copycat" products, also tried to leverage some degree of incremental innovation to persuade surgeons. However, the Commission's market reconstruction demonstrates that the results of all of those undertakings are largely unsuccessful or they have had very limited success. Therefore, it is highly unlikely that those players would exert a credible competitive pressure on the merged entity post-merger.

Conclusion

- (791) In view of the arguments set out in this section, the Commission concludes that the merger would negatively affect competition conditions through the elimination of an important competitive force, and even impact on the pace of innovation in the market.

Countervailing buyer power

The views of the Notifying Party

- (792) The Notifying Party reiterates the arguments already set out above in section 8.6.2.7.

The Commission's Assessment

- (793) With respect to buyer power, the Commission makes reference to the arguments already set out in section 8.6.2.7.

- (794) The in-depth market investigation provided evidence that many customers purchase (at least a significant part) of their orthopaedic implants, via tenders and other auctioning systems.³⁷² As regards buyer consolidation, while this phenomenon has reached significant levels in certain countries such as the United Kingdom and Germany, that is not yet true, at least to an equivalent degree, for the entire EEA.³⁷³ Therefore, it is undisputed that the trend towards tender-based procurement systems and GPOs is not as generalised as to shield all customers from higher prices or deteriorated competitive terms post-merger.

- (795) First, section 8.6.2.5 and recitals (783)-(786) show that switching is a rather difficult, cumbersome and infrequent phenomenon in this market. Therefore, the hypothetical exercise of buyer power already fails the "immediacy" condition set by the Horizontal Merger Guidelines.

³⁷² Responses to Questionnaire Q31 to hospitals, question 4.

³⁷³ Responses to Questionnaire Q31 to hospitals, question 3.

- (796) Second, with respect to the ability and incentives of customers to sponsor entry, the Commission considers that this strategy would require a level of sophistication that only few players could realistically exercise in this type of market, where the vast majority of players are stand-alone public hospitals. Retrospectively, sections 8.6.2.8 and recitals (802)-(806) explain that entry has played little or no role in this market over the last three to five years.
- (797) Even assuming the potential exercise of buyer power by the customers purchasing large volumes, there are a number of other non-price considerations that limit the real extent of any such buyer power in this market. During the in-depth market investigation, very few customers confirmed that, during commercial negotiations with their suppliers, they would threaten to switch to other suppliers or engage in other strategies to obtain a better price.³⁷⁴
- (798) Given that Zimmer's ZUK and Biomet's Oxford Knee are two legacy products, switching to another supplier is more difficult because it involves both price and non-price considerations such as brand loyalty, surgeons' philosophy, excellence of training programmes built over the years, etc. In particular, Biomet's Oxford Knee training courses attract world-wide specialists. As such *"if a surgeon believes in the Oxford knee philosophy or in the ZUK's philosophy, he will not switch unless the clinical results have worsened or there is a negative financial impact. There is little impact of the copycat products. In fact, it is unlikely that surgeons would switch to a copycat product of the ZUK or Oxford knee, especially when it does not have its own proven clinical results"*.³⁷⁵
- (799) Additionally, the entry of "me-too", "copycat" products or, in any event, smaller firms has not significantly influenced purchasing patterns at EEA level. Depending on the country, some smaller players have fared better than others. However, even in those countries, market structures still show quite clear Tier-1 player versus Tier-2 player dynamics. This means that purchasers' choices still remain largely bound to a few major suppliers. This might hold even truer, in the event further buyer power consolidation would take place because larger customers might require larger sellers with larger portfolios.

Conclusion

- (800) In light of the arguments set out in this section, the Commission concludes that buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.

Barriers to entry and expansion

The views of the Notifying Party

- (801) The Notifying Party reiterates the arguments already set out above in section 8.6.2.8.

The Commission's Assessment

³⁷⁴ Responses to Questionnaire Q31 to hospitals, question 6.

³⁷⁵ Non-confidential minutes of the conference call with NHS Commercial Procurement Collaborative of 30.10.2014, paragraph 16.

(802) With respect to entry, the Commission makes reference to the arguments already set out in section 8.6.2.8. The results of the in-depth market investigation openly clash with the arguments put forward by the Notifying Party in relation to unicondylar knee implants.

(803) The issue was explored in a number of conference calls with the Notifying Party's competitors. Below there are a few illustrative examples.

Lima, which is not active in this market, explained that "[...] *entering the market for unicondylar knee would be a major undertaking, and would require considerable effort and time. In particular, if Lima were to develop a unicondylar knee, this would take approximately two years. Lima regards this as a complex project. Even reverse engineering an existing implant, which is not part of Lima's philosophy and strategy, would not be a shortcut. This is because Lima would need to make sure that all components, separately and together, would deliver the same degree of reliability as the original implant*".³⁷⁶

Link stated that "[...] *a supplier producing primary total knees could certainly decide to enter the primary partial, but creating a design from scratch or even copying an existing design would require significant efforts in terms of R&D*".³⁷⁷ Link considered that, in general, the introduction of new products entails long pathways to market because a new implant, as well as a copy of another implant, is R&D intensive projects, which require years to accomplish.³⁷⁸

S&N, which has recently introduced a new unicondylar implant, explained that "*All things considered, producing a unicondylar knee is similar to producing a total implant. However, even when a company is active in the total knee segment, it still needs an R&D period which can last several years*".³⁷⁹

(804) In addition, the market investigation indicated that the presence in this market of players of the magnitude of Biomet, but also Zimmer, may also act as a non-negligible barrier or deterrence mechanism, which should not be underestimated.³⁸⁰

(805) The Commission market reconstruction is in line with the qualitative evidence gathered during the in-depth market investigation. This exercise has not singled out cases of significant entry or expansion over the last five years.

Conclusion

(806) In light of the arguments set out in this section, the Commission concludes that barriers to entry and expansion in the market for unicondylar knee implants are very high.

8.6.8.3. Country-specific Competitive Assessment

(807) Based on the Notifying Party's estimates, the merger would give rise to 17 Group 1 national markets, namely Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the

³⁷⁶ Non-confidential minutes of the conference call with Lima of 10.11.2014, paragraph 18.

³⁷⁷ Non-confidential minutes of the conference call with Link of 26.9.2014, paragraph 13.

³⁷⁸ Non-confidential minutes of the conference call with Link of 26.9.2014, paragraph 15.

³⁷⁹ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraph 16.

³⁸⁰ Non-confidential minutes of the conference call with S&N of 10.11.2014, paragraphs 12-13.

Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, and the United Kingdom.

Table 27: Unicodylar knee implants – Group 1 national markets – Market shares by value, 2013³⁸¹

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>AT</i>	[10-20]*%	[60-70]*%	[80-90]*%	[1-50]*	J&J/DePuy ([10-20]*%), S&N ([5-10]*%), Mathys ([5-10]*%), Stryker ([5-10]*%), others
<i>BE</i>	[30-40]*%	[30-40]*%	[70-80]*%	[1-50]*	J&J/DePuy ([5-10]*%), S&N ([5-10]*%), others
<i>CZ</i>	[5-10]*%	[90-100]*%	[90-100]*%	[less than 1]*	J&J/DePuy ([10-20]*%), Aesculap ([10-20]*%), S&N ([5-10]*%), others
<i>DK</i>	[0-5]*%	[60-70]*%	[60-70]*%	[1-50]*	J&J/DePuy ([30-40]*%), others
<i>EL</i> ³⁸²	[40-50]*% ⁷	[30-40]*%	[70-80]*%	[less than 1]*	J&J/DePuy ([10-20]*%), Tornier ([5-10]*%), Amplitude ([5-10]*%), others
<i>FI</i>	[0-5]*%	[90-100]*%	[90-100]*%	[less than 1]*	J&J/DePuy ([5-10]*%), others
<i>FR</i>	[20-30]*%	[40-50]*%	[70-80]*%	[1-50]*	J&J/DePuy ([10-20]*%), Tornier ([5-10]*%), Amplitude ([5-10]*%), others
<i>DE</i>	[10-20]*%	[60-70]*%	[70-80]*%	[1-50]*	J&J/DePuy ([10-20]*%), Link ([10-20]*%), others
<i>IT</i>	[40-50]*%	[10-20]*%	[60-70]*%	[1-50]*	S&N ([20-30]*%), J&J/DePuy ([5-10]*%), others
<i>NL</i>	[5-10]*%	[70-80]*%	[80-90]*%	[1-50]*	J&J/DePuy ([20-30]*%), others
<i>NO</i>	[0-5]*%	[60-70]*%	[70-80]*%	[1-50]*	J&J/DePuy ([20-30]*%), others
<i>PL</i>	[5-10]*%	[70-80]*%	[70-80]*%	[less than 1]*	J&J/DePuy ([10-20]*%), others
<i>PT</i>	[30-40]*%	[40-50]*%	[80-90]*%	[less than 1]*	J&J/DePuy ([20-30]*%), others
<i>ES</i>	[10-20]*%	[30-40]*%	[50-60]*%	[1-50]*	J&J/DePuy ([10-20]*%), others
<i>SE</i>	[20-30]*%	[50-60]*%	[80-90]*%	[less than 1]*	J&J/DePuy ([20-30]*%), others

³⁸¹

The Notifying Party was not able to provide reliable market shares for Slovenia.

³⁸²

The Notifying Party was not able to provide market share data for partial knee implants in Greece for the year 2013, and therefore the data relates to the year 2012.

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>UK</i>	[20-30]*%	[50-60]*%	[70-80]*%	[1-50]*	J&J/DePuy ([10-20]*%), others
<i>EEA</i>	[20-30]*%	[50-60]*%	[70-80]*%	[50-100]*	J&J/DePuy ([10-20]*%), S&N ([0-5]*%), others

Source: Form CO, Annex 6.2(a)

- (808) Through its targeted market reconstruction, the Commission was able to confirm that the merger would give rise to Group national 1 markets in Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom. In addition, the Commission found that also Norway would not qualify as Group 1 national markets.
- (809) The in-depth market investigation has shown that the merger significantly impedes effective competition in all the above Group 1 national markets.

Austria

Structure of the market

- (810) According to the Notifying Party, in Austria, the value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [80-90]*% in this market, with Zimmer contributing an increment of [10-20]*%.

Table 28: Shares of value for partial knee implants in Austria

Suppliers	2011	2012	2013
Zimmer	[10-20]*%	[10-20]*%	[10-20]*%
Biomet	[60-70]*%	[60-70]*%	[60-70]*%
<i>Merged Entity</i>	[80-90]*%	[80-90]*%	[80-90]*%
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
S&N	[5-10]*%	[5-10]*%	[5-10]*%
Mathys	[5-10]*%	[5-10]*%	[5-10]*%
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (811) Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately [60-70]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be few

competitors left with market shares above 5%, that is to say S&N, Mathys and Stryker. Finally, it is worth noting that, over the last three years, Zimmer has slightly increased its market share (by approximately +[0-5]*%), while Biomet lost a [0-5]*% market share but remained well above [50-60]*%.

Views of the Notifying Party

- (812) The Notifying Party argues that a number of competitors would have the capacity and resources to expand output in reaction to a potential increase of prices by the merged entity. Moreover, Zimmer also submits that it has been facing intense competition from competitors like Aesculap, which was able to provide better services. Finally, the changes in market shares illustrate the dynamic nature of competition and high degree of contestability of market shares on the Austrian unicondylar knee market.³⁸³
- (813) The Notifying Party further argues that there have been three new entrants into the knee market since 2011, with Brehm and Ceraver having entered in 2011 and Corin in 2012. Hence, the barriers to entry are not high and these companies will also pose a competitive constraint on the Parties.³⁸⁴
- (814) Based on this, the Notifying Party concludes that the merger would not significantly impede effective competition on the Austrian market for unicondylar knee implants.

The Commission's assessment

- (815) Based on the Commission's market reconstruction, the merged entity's market share would be slightly smaller than the Notifying Party's own estimates and range between [70-80%] in 2013. However, the merger would effectively lead to a quasi-3-to-2 scenario. The Notifying Party seems to have overestimated the market shares of its remaining competitors. Besides only one significant competitor, all the others would remain below [0-5%]. That said, the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 29: Parties' shares of value for unicondylar knee implants in Austria

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
Biomet	[70-80%]	[60-70%]	[60-70%]	[60-70%]	[60-70%]
<i>Merged Entity</i>	<i>[90-100%]</i>	<i>[80-90%]</i>	<i>[80-90%]</i>	<i>[80-90%]</i>	<i>[70-80%]</i>

Source: Commission's targeted market reconstruction

- (816) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants, and the merger would therefore eliminate an important source of rivalry in the Austrian market.
- (817) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are

³⁸³ Response to the Article 6(1)(c) Decision, paragraph 652 and ff.

³⁸⁴ Response to the Article 6(1)(c) Decision, paragraph 654.

particularly aggravated by the specific characteristics of the unicondylar knee market. An Austrian-based customer, who recently switched suppliers for unicondylar knee implants, explained that it was quite difficult to convince surgeons to change.³⁸⁵ Post-merger, customers generally indicated that they would not shift a portion of their purchases of unicondylar knee implants to alternative suppliers post-merger.³⁸⁶

- (818) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (819) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (820) As shown in recitals (802)-(806), barriers to entry and expansion in this market are very high. As regards Austria, only one competitor, Stanmore, indicated to have entered the Austrian market in 2011, with the METS, which is not however a unicondylar knee implant.³⁸⁷ The Commission's market reconstruction did not entirely confirm the entry of players such as Brehm, Ceraver and Corin in the Austrian market for unicondylar knee implants.
- (821) Therefore, the Commission considers that the merger would lead to an almost 3-to-2 scenario drastically reducing the number of players in the Austrian market. Other countervailing factors do not seem to be sufficient to constrain the merged entity's behaviour post-merger.

Conclusion

- (822) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Austria through the creation or strengthening of a dominant position.

Belgium (including Luxembourg)

Structure of the market

- (823) According to the Notifying Party, in Belgium (including Luxembourg), the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of [70-80]*% in this market, with Biomet contributing an increment of [30-40]*%.

³⁸⁵ Responses to Questionnaire Q31 to hospitals, question 41.

³⁸⁶ Responses to Questionnaire Q31 to hospitals, questions 44.5 and 45.

³⁸⁷ Responses to Questionnaire Q30 on entry and innovation.

Table 30: Shares of value for unicondylar knee implants in Belgium (including Luxembourg)

Suppliers	2011	2012	2013
Zimmer	[30-40]*%	[30-40]*%	[30-40]*%
Biomet	[30-40]*%	[20-30]*%	[30-40]*%
<i>Merged Entity</i>	<i>[60-70]*%</i>	<i>[60-70]*%</i>	<i>[70-80]*%</i>
J&J/DePuy	[5-10]*%	[5-10]*%	[5-10]*%
S&N	[5-10]*%	[5-10]*%	[5-10]*%
Mathys	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Tornier	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (824) Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately [60-70]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be only one competitor left with market shares above 5%, namely S&N. Finally, it is worth noting that, over the last three years, both Zimmer and Biomet have increased their market share by approximately [5-10]*% and [0-5]*% respectively.

Views of the Notifying Party

- (825) In Belgium (including Luxembourg), hospitals purchase orthopaedic products through individual commercial negotiations. However, due to pressure from the Government and insurance companies to limit healthcare spending through a reduction of the supplements payable by patients, hospitals are expected to adopt tender procedures in the future. The official reimbursement list prepared by the Ministry of Health indicates maximum selling prices and reimbursement levels for medical products.³⁸⁸
- (826) The Notifying Party argues that the changes in market shares illustrate the dynamic nature of competition and high degree of contestability of market shares on the Belgian unicondylar knee market.³⁸⁹
- (827) The Notifying Party submits that switching takes place on the market and provides two examples where hospitals switched from one supplier to Zimmer in 2013. In reply to an RFI it clarified that these switches relate to primary knee, not unicondylar knee.³⁹⁰
- (828) According to the Notifying Party, since 2009, there have been several new entrants to this national segment of the overall knee market, where Adler

³⁸⁸ Form CO, paragraphs 133-134.

³⁸⁹ Reply to the Article 6(1)(c) Decision, paragraph 657.

³⁹⁰ Reply to RFI of 8.10.2014.

joined in April 2009, C2F implants in 2012, as well as Arthrex and Lima in 2013. This indicates the ease of entry in the segment and that there are an increasing number of competitors that can restrain the Parties.

The Commission's assessment

- (829) Based on the Commission's market reconstruction, the merged entity's market share would be higher than the Notifying Party's own estimates and ranges between [70-80%] in 2013. The merger would effectively lead to a quasi-3-to-2 scenario as, apart from one other competitor, all the other players would remain below [0-5%]. That said, it is worth noting that the results of the Commission's market reconstruction do not differ materially from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 31: Parties' shares of value for unicondylar knee implants in Belgium (including Luxembourg)

Suppliers	2009	2010	2011	2012	2013
Zimmer	[20-30%]	[20-30%]	[20-30%]	[30-40%]	[30-40%]
Biomet	[30-40%]	[30-40%]	[30-40%]	[30-40%]	[30-40%]
<i>Merged Entity</i>	<i>[50-60%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[70-80%]</i>

Source: Commission's targeted market reconstruction

- (830) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Belgian market.
- (831) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market. One hospital in Belgium (including Luxembourg) indicated that it has recently switched from S&N's to Zimmer's total knee implant, but not unicondylar. However, the price was not the main factor in the switching decision, but rather the increased adaptability of Zimmer's product. Since both products of Zimmer and S&N share similar technology, the switch did not involve much re-training of staff, but it did involve substantial administrative and logistic costs.³⁹¹
- (832) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (833) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (834) As noted in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. As regards Belgium (including Luxembourg), only one competitor, Stanmore, indicated to have entered the Belgian knee implant market in 2011, without however specifying which

³⁹¹

Non-confidential minutes of the conference call with St Lucas Hospital of 10.10.2014, paragraphs 4-6.

segment of the overall knee market.³⁹² Based on the Commission's market reconstruction, it appears that the recent entrants mentioned by the Notifying Party such as Arthrex and Lima remain, if anything, only fringe players in the Belgian market for unicondylar knee implants.

- (835) In addition, one Belgian hospital, currently using Zimmer knee products, raised concerns about the merger because it feared that the merged entity would be likely to discontinue redundant product lines, and focus only on the most successful implants. According to this customer, this Decision would then restrict surgeons' choice to the detriment of patients.³⁹³
- (836) Therefore, the Commission considers that the merger would lead to a quasi 3-to-2 scenario drastically reducing the number of players in the Belgian market. Other countervailing factors do not seem to be sufficient to constrain the merged entity's behaviour post-merger.

Conclusion

- (837) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Belgium (including Luxembourg) through the creation or strengthening of a dominant position.

Czech Republic

Structure of the market

- (838) According to the Notifying Party, in the Czech Republic, the total value of the market for partial knee implant amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of [90-100]*% in this market, with Zimmer contributing an increment of around [5-10]*%.

³⁹² Responses to Questionnaire Q30 on entry and innovation.

³⁹³ Non-confidential minutes of the conference call with St Lucas Hospital, of 10.10.2014, paragraph 16.

Table 32: Shares of value for unicondylar knee implants in the Czech Republic

Suppliers	2011	2012	2013
Zimmer	[5-10]*%	[5-10]*%	[5-10]*%
Biomet	[80-90]*%	[90-100]*%	[90-100]*%
<i>Merged Entity</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
Aesculap	[10-20]*%	[10-20]*%	[10-20]*%
S&N	[5-10]*%	[5-10]*%	[5-10]*%
Tornier	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (839) Based on data provided by the Notifying Party, post-merger, the merger would combine the number one and number four players, creating an undisputed market leader with a very large gap of approximately [80-90]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be two other competitors left with market shares above 5%, namely Aesculap and S&N. Finally, it is worth noting that, over the last three years, Biomet's market shares slightly increased by [0-5]*%, while Zimmer's position decreased by [0-5]*%.

Views of the Notifying Party

- (840) The Notifying Party explains that, in the Czech Republic implants are reimbursed to hospitals in accordance with a price list called "Ciselnik VZP", which de facto serves as a maximum price list. Hospitals receive reimbursement based on the amount set out in this price list. There is therefore an incentive for the hospitals to negotiate lower prices with suppliers. Moreover, this country features a general trend towards hospital consolidation. As a result of these factors, hospitals are able to exert considerable buyer power on suppliers of medical devices.³⁹⁴
- (841) According to the Notifying Party, the market shares fluctuation illustrates the dynamic nature of competition on the Czech market, which is furthermore highly price-sensitive.³⁹⁵ The Notifying Party also submits that hospitals often switch suppliers, even if the examples provided essentially regard primary and revision knee implants.
- (842) Finally, the Notifying Party mentions a number of new entrants in the overall knee segment, but not in the unicondylar knee market specifically. Lima entered in January 2005, with Link following in 2005. By 2010, Implantcast

³⁹⁴ Form CO, paragraphs 154-155.

³⁹⁵ Reply to the Article 6(1)(c) Decision, paragraph 661.

had introduced its knee product and most recently in 2011 Mathys had entered as well.

The Commission's assessment

- (843) Based on the Commission's market reconstruction, the merged entity's market share would be slightly higher than the Notifying Party's own estimates and range between [90-100%] in 2013. The merger would practically lead to a monopoly in the Czech market for unicondylar knee implants. The Notifying Party seems to have overestimated the market shares of its remaining competitors, as none of the remaining players would have market shares above [0-5%]. That said, it is worth noting that the results Commission's market reconstruction do not differ materially from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 33: Parties' shares of value for unicondylar knee implants in the Czech Republic

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[5-10%]	[5-10%	[10-20%]	[5-10%]
Biomet	[70-80%]	[80-90%]	[90-100%]	[80-90%]	[90-100%]
<i>Merged Entity</i>	<i>[80-90%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

- (844) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Czech Republic unicondylar knee market.
- (845) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (846) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (847) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (848) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. As regards the Czech Republic, the entries put forward by the Notifying Party relate to total - mainly primary - knee implants, not unicondylar knee implants. The Commission's market reconstruction also indicates that Lima, Link, Implantcast and Mathys remain, if anything, fringe players in the Czech market for unicondylar knee market.³⁹⁶
- (849) Therefore, the Commission considers that the merger would lead to a monopoly in the Czech market for unicondylar knee implants. Other countervailing factors do not seem to be sufficient to constrain the merged entity's behaviour post-merger.

³⁹⁶

See also Responses to Questionnaire Q30 on entry and innovation.

Conclusion

- (850) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in the Czech Republic through the creation or strengthening of a dominant position.

Denmark

Structure of the market

- (851) According to the Notifying Party, in Denmark, the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [60-70]*% in this market, with Zimmer contributing an increment of [0-5]*%.

Table 34: Shares of value for unicondylar knee implants in Denmark

Suppliers	2011	2012	2013
Zimmer	[0-5]*%	[0-5]*%	[0-5]*%
Biomet	[70-80]*%	[70-80]*%	[60-70]*%
<i>Merged Entity</i>	<i>[70-80]*%</i>	<i>[70-80]*%</i>	<i>[60-70]*%</i>
J&J/DePuy	[30-40]*%	[30-40]*%	[30-40]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (852) Based on data provided by the Notifying Party, post-merger, there would be one other competitor left with a market share over 5%, namely J&J/DePuy ([30-40]*%). Biomet is number one in Denmark and the merger would reinforce this position. It is worth noting that, over the last three years, Zimmer has slightly increased its market share by [0-5]*%, while Biomet lost a [0-5]*% market share but remained well above [50-60]*%.

Views of the Notifying Party

- (853) In Denmark, approximately 95% of joint replacement procedures are performed in public hospitals and the remaining 5% in private hospitals. Over 80% of total sales on the Danish market are achieved through tendering. Hospitals have been exerting significant buyer power since they became concentrated at the regional level. For example for Biomet, prices have dropped by [10-20]*% to [20-30]*% since hospitals' supervision was

transferred from the counties to the regions. Hospitals' purchasing departments have been more focused on costs and prices as they set saving targets for tenders.³⁹⁷

- (854) According to the Notifying Party, the reasons underlying Zimmer's market share increase is the introduction of its unicondylar knee. This illustrates the dynamic nature of competition in the Danish market for unicondylar knee implants.³⁹⁸
- (855) The Notifying Party also submits that switching does take place in Denmark, as evidenced by the results of a recent tender where Zimmer won a knee account.³⁹⁹

The Commission's assessment

- (856) Based on the Commission's market reconstruction, the merged entity's market share would be much higher than the Notifying Party's own estimates, and range between [80-90%]. The Notifying Party seems to have overestimated the market shares of its remaining competitors. Post-merger, there would be only one competitor left on the market with a market share above 5%.

Table 35: Parties' shares of value for unicondylar knee implants in Denmark

Suppliers	2009	2010	2011	2012	2013
Zimmer	[0-5%]	[0-5%]	[0-5%]	[0-5%]*	[0-5%]
Biomet	[90-100%]	[80-90%]	[90-100%]	[90-100%]	[80-90%]
<i>Merged Entity</i>	<i>[90-100%]</i>	<i>[80-90%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[80-90%]</i>

Source: Commission's targeted market reconstruction

- (857) That said, it is worth noting that, despite a material difference between the results of the Commission's market reconstruction and the Notifying Party's estimates, both scenarios give rise to a presumption of dominance.
- (858) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Danish market.
- (859) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (860) In Denmark, one hospital indicated that, when a switch to another supplier occurs, it takes 15-20 surgery procedures for a surgeon to become familiar with the new product. Complications tend to decrease after those 15-20 surgery procedures, but it is difficult to generalise because much depends on the individual skill of the surgeon at hand and the type of implant being implanted. Therefore, it could not be excluded that even more surgery would be required. According to this customer, there are ongoing discussions in the Scandinavian

³⁹⁷ Form CO, paragraph 173.

³⁹⁸ Reply to the Article 6(1)(c) Decision, paragraph 665.

³⁹⁹ Form CO, paragraph 178.

countries on the safety of launching tenders every three to four years. This is so because such a trend may force hospitals to change suppliers more often than it was the case previously, thereby increasing risks for patients, which – according to this hospital - has been scientifically proven.⁴⁰⁰

- (861) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (862) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (863) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. As regards Denmark, one hospital explained that, when entering a market with a new implant, a company should also wait 5 to 10 years to gather all the necessary scientific data on its product's life cycle. This is a competitive feature common in the Scandinavian countries, which put a strong emphasis on evidence-based medicine. Evidence-based medicine (track records and other scientific evidence) does not favour copycat or me-too products, which do not constitute viable alternative options in Denmark. Such copycat or me-too products aim to prove that they are exactly the same as the original ones, but in fact they are not regarded as having equivalent own clinical results.⁴⁰¹

Conclusion

- (864) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Denmark through the creation or strengthening of a dominant position.

Finland

Structure of the market

- (865) According to the Notifying Party's estimate, in Finland, the total value of the market for partial knee implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] million for Zimmer and EUR [...] million for Biomet. The merged entity would have a market share of approximately [90-100]*%, with Zimmer contributing an increment of around [0-5]*%.

⁴⁰⁰ Non-confidential minutes of the conference call with Bispebjerg Hospital of 31.10.2014, paragraphs 9 and 10.

⁴⁰¹ Non-confidential minutes of the conference call with Bispebjerg Hospital of 31.10.2014, paragraphs 12 and 15.

Table 36: Shares of value for partial knee implants in Finland

Suppliers	2011	2012	2013
Zimmer	[0-5]*%	[0-5]*%	[0-5]*%
Biomet	[90-100]*%	[90-100]*%	[90-100]*%
<i>Merged Entity</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>
J&J/DePuy	[5-10]*%	[5-10]*%	[5-10]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (866) Based on data provided by the Notifying Party, post-merger, there would be only one competitor left with market shares over 5%, namely J&J/DePuy ([5-10]*%). Biomet is number one in Finland and the merger would reinforce this position. Finally, it is worth noting that, over the last three years, both Zimmer and Biomet slightly increased their market shares by [0-5]*% and [0-5]*% respectively.

Views of the Notifying Party

- (867) According to the Notifying Party, in Finland healthcare is mostly public, with only a small number of private hospitals. The majority of joint replacement procedures are performed in only five university hospitals. Tender procedures account for over 90% of total sales in this country. Reimbursement is based on a DRG system⁴⁰². In other words, hospitals are reimbursed per operation and the price of the implant is included in the price of the operation. Consequently, hospitals have an interest to lower the cost of products in order to preserve their margin.⁴⁰³
- (868) The Notifying Party explains that the reasons underlying Zimmer's market share increase over the last three years are linked to its securing of certain tender awards. According to Zimmer, while the changes in market share appear modest, they still illustrate the dynamic nature of competition in the Finnish market for unicondylar knee implants, and the contestability of market shares in this country, which is a bidding market with price-sensitive customers.⁴⁰⁴

The Commission's assessment

⁴⁰² Diagnosis related groups - under which hospital receive a lump sum payment per admission according to a tariff based on the category of diagnosis, usually do not require suppliers to apply separately for reimbursement status.

⁴⁰³ Form CO, paragraphs 191 and 193.

⁴⁰⁴ Reply to the Article 6(1)(c) Decision, paragraph 669.

- (869) Based on the Commission's market reconstruction, the merged entity's market share would be higher than the Notifying Party's own estimates, and range between [90-100%]. The merger would practically lead to a monopoly in the unicondylar knee market in Finland. The Notifying Party seems to have overestimated the market shares of its remaining competitors, as none of the remaining players would have market shares above [0-5%]. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 37: Parties' shares of value for unicondylar knee implants in Finland

Suppliers	2009	2010	2011	2012	2013
Zimmer	[0-5%]	[0-5%]	[0-5%]	[0-5%]	[0-5%]
Biomet	[90-100%]	[90-100%]	[90-100%]	[90-100%]	[90-100%]
<i>Merged Entity</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

- (870) Zimmer's internal documents also confirm that one major competitor, Stryker, has lost market shares in Denmark: "[...]".⁴⁰⁵
- (871) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Finnish market.
- (872) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (873) In Finland, one hospital indicated that when considering switching to copycats or me-too products for unicondylar knee implants, they would not take into account the clinical data of the original implant. It further noted that implant systems are not similar simply by design, so switching from one implant system to another has inherent risks.⁴⁰⁶
- (874) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (875) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (876) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high.

Conclusion

- (877) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee

⁴⁰⁵ See Zimmer's internal document entitled "2014 Operating Plan Nordics Executive Review" EU-00178255, slide 35, ID 3010.

⁴⁰⁶ Responses to Questionnaire Q31 to hospitals, questions 39 and 44.3.1.

implants in Finland through the creation or strengthening of a dominant position.

France

Structure of the market

- (878) According to the Notifying Party, in France, the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [70-80]*%, with Zimmer contributing an increment of around [20-30]*%.

Table 38: Shares of value for unicondylar knee implants in France

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[20-30]*%	[20-30]*%
Biomet	[40-50]*%	[40-50]*%	[40-50]*%
Merged Entity	[70-80]*%	[70-80]*%	[70-80]*%
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
Tornier	[5-10]*%	[5-10]*%	[5-10]*%
Amplitude	[5-10]*%	[5-10]*%	[5-10]*%
Medacta	[0-5]*%	[0-5]*%	[0-5]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Corin	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (879) Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately [60-70]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be few competitors left with market shares above 5%, namely Tornier and Amplitude. Finally, it is worth noting that, over the last three years, both Zimmer and Biomet have slightly increased their market share by [0-5]*% and [0-5]*% respectively.

Views of the Notifying Party

- (880) The Notifying Party notes that there are 1 301 hospitals in France, including 33 university hospitals, 556 public hospitals and 712 private hospitals/clinics. All

public hospitals in France are under a legal obligation to launch tenders. Almost all players in the French market would participate in such tenders.⁴⁰⁷

- (881) French hospitals are reimbursed per procedure, according to a DRG-based system. Joint reconstruction implants are however reimbursed on top of the cost of a procedure. The Comité Economique des Produits de Santé decides which products are included in the Liste des Produits et Prestations Remboursables ("LPPR"). Only those implants that are included in the LPPR can be reimbursed on top of the cost of a procedure. The LPPR also provides for maximum price at which implants can be charged (different categories of implants have different reimbursement prices). Thus, the Notifying Party notes that, to maximise their margins, hospitals have a strong incentive to negotiate lower prices for implants.⁴⁰⁸
- (882) According to the Notifying Party, the reasons underlying Zimmer's market share increase is the launching of new products. According to Zimmer, this market share fluctuation, even though modest, still illustrates the dynamic nature of competition in the French market, which would remain competitive post-merger.⁴⁰⁹

The Commission's assessment

- (883) Based on the Commission's market reconstruction, the merged entity's market share would be slightly smaller than the Notifying Party's own estimates and range between [70-80%] in 2013. The merger would effectively lead to a 4-to-3 scenario as the Notifying Party seems to have overestimated the market shares of its remaining competitors. Although two competitors would have market shares above [0-5%], these shares would be smaller than the increment brought about the merger. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 39: Parties' shares of value for unicondylar knee implants in France

Suppliers	2009	2010	2011	2012	2013
Zimmer	[20-30%]	[20-30%]	[20-30%]	[20-30%]	[20-30%]
Biomet	[40-50%]	[40-50%]	[40-50%]	[40-50%]	[40-50%]
Merged Entity	[70-80%]	[70-80%]	[70-80%]	[60-70%]	[70-80%]

Source: Commission's targeted market reconstruction

- (884) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the French market.
- (885) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are

⁴⁰⁷ Form CO, paragraph 199.

⁴⁰⁸ Form CO, paragraph 202.

⁴⁰⁹ Reply to the Article 6(1)(c) Decision, paragraph 672.

particularly aggravated by the specific characteristics of the unicondylar knee market.

- (886) In France, one hospital indicated that it has switched from S&N's Journey unicondylar implant to Tornier's unicondylar one in response to surgeons' requirements and clinical data. This switch was difficult due to gather all the required scientific evidence and clinical trials. It was also time-consuming because surgeons needed to be trained on new surgical procedures and get familiar with the new implants.⁴¹⁰
- (887) Two hospitals in France also indicated that they multi-source suppliers for unicondylar knee implants due to different patients' needs, different surgeons' requirements and security of supply. According to one of these hospitals, four suppliers are the absolute minimum necessary to ensure their effective multi-sourcing policy for unicondylar knee implants.⁴¹¹
- (888) The in-depth market investigation also indicated that the relationship between surgeons and distributors can play an important role in the choice of implants in France. This may have an impact on switching decisions. This is so because, sometimes, surgeons value very highly the service received from distributors, and follow distributors' choices even when there is a change of the actual brand being sold.⁴¹²
- (889) Furthermore, according to a key opinion leader in public hospitals across France switches are limited because there is a general concern regarding the possible adverse effects of frequent changes. In any case, most surgeons are generally reluctant to switch, unless a design has gone out of production or s/he experienced drawbacks.⁴¹³
- (890) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (891) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (892) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. Lima indicated that it entered France with a *total* knee implant in 2004.⁴¹⁴ However, as explained in recital (73) above, Lima considers that entering the market with a unicondylar knee implant is a major undertaking that requires considerable time and effort.⁴¹⁵

Conclusion

- (893) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in France through the creation or strengthening of a dominant position.

⁴¹⁰ Responses to Questionnaire Q31 to hospitals, questions 38, 41 and 42.

⁴¹¹ Responses to Questionnaire Q31 to hospitals, question 44.

⁴¹² Non-confidential minutes of the conference call with Vitalia of 25.07.2014, paragraphs 8-10.

⁴¹³ Non-confidential minutes of the conference call with Prof. Migaud of University Hospital of Lille of 18.08. 2014, paragraphs 8 and 14.

⁴¹⁴ Responses to Questionnaire Q30 to competitors on entry and innovation, question 1 (Lima's response). See also Non-confidential minutes of the conference call with Lima of 10.11.2014, paragraph 24.

⁴¹⁵ Non-confidential minutes of the conference call with Lima of 10.11. 2014, paragraph 18.

Germany

Structure of the market

- (894) According to the Notifying Party, in Germany, the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share around [70-80]*%, with Zimmer contributing an increment of around [10-20]*%.

Table 40: Shares of value for unicondylar knee implants in Germany

Suppliers	2011	2012	2013
Zimmer	[5-10]*%	[5-10]*%	[10-20]*%
Biomet	[60-70]*%	[50-60]*%	[60-70]*%
Merged Entity	[70-80]*%	[60-70]*%	[70-80]*%
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Mathys	[0-5]*%	[0-5]*%	[0-5]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Corin	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (895) Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately [60-70]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would only one competitor left with market shares above 5%, namely Link. Finally, it is worth noting that, over the last three years, both Zimmer and Biomet slightly increased their market shares by [0-5]*% and [0-5]*% respectively.

Views of the Notifying Party

- (896) According to the Notifying Party, 80-90% of German hospitals are currently organised into purchasing groups. Following the merger with Rhön completed in 2014, Helios is the largest group on the market representing 117 hospitals. Approximately 80% of hospitals' requirements are secured by framework contracts negotiated by the groups.⁴¹⁶

⁴¹⁶ Form CO, paragraph 210.

- (897) The Government sets price for joint arthroplasty interventions in accordance with a DRG-based system and hospitals (both public as well as private in case of patients with public health insurance) are reimbursed for the entire procedure, regardless of the price paid by a hospital for the implant actually purchased. According to the Notifying Party, this system creates a strong incentive for hospitals to maximize their margins by sourcing implants at the lowest price. DRG reimbursement levels included in the so-called INEK⁴¹⁷ List are subject to yearly reductions, which further reinforces the downward pressure on prices.⁴¹⁸
- (898) The Notifying Party also submits switching is far from uncommon in Germany, and provides some examples. For instance, the University of Freiburg switched its unicondylar knee supplier from J&J/DePuy to Biomet in July 2011. More recently, the Loretto Hospital of Freiburg also switched its unicondylar knee supplier from J&J/DePuy to Biomet in March 2013.
- (899) Moreover, according to the Notifying Party buyer power consolidation is particularly significant in Germany. This is so because more than 80% of sales are generated with GPOs, which are very effective in reducing suppliers' prices.

The Commission's assessment

- (900) Based on the Commission's market reconstruction, the merged entity's market share would be broadly in line with the Notifying Party's own estimates. The merger would effectively lead to a 4-to-3 scenario because the Notifying Party seems to have overestimated the market shares of some its remaining competitors. Only two other players would have market shares above [0-5%]. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 41: Parties' shares of value for unicondylar knee implants in Germany

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[5-10%]	[5-10%]	[5-10%]	[10-20%]
Biomet	[50-60%]	[60-70%]	[60-70%]	[60-70%]	[60-70%]
Merged Entity	[60-70%]	[70-80%]	[70-80%]	[70-80%]	[70-80%]

Source: Commission's targeted market reconstruction

- (901) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the German market.
- (902) Furthermore, the CRM analysis carried out by the Commission showed that Biomet is the company which is most frequently identified as primary competitor in Germany in 2013. As shown in Table 42, Zimmer overwhelmingly considers Biomet to be its main rival in about [50-60]*% of

⁴¹⁷ Institute for the Hospital Remuneration System.
⁴¹⁸ Form CO, paragraph 214.

the sales opportunities involving unicondylar knee implants both in 2013 and in 2014.

Table 42: Primary Competitor Analysis, Unicondylar Knee Implants (Germany, 2013)

Primary Competitor	Frequency	Percentage
Biomet	[...]*	[50-60]**%
Aesculap	[...]*	[10-20]**%
S&N	[...]*	[10-20]**%
Arthrex	[...]*	[0-5]**%
Conformis	[...]*	[0-5]**%
J&J DePuy	[...]*	[0-5]**%
Other	[...]*	[0-5]**%
Stryker	[...]*	[0-5]**%
Total	[...]*	

Source: Zimmer CRM data

Table 43: Primary Competitor Analysis, Unicondylar Knee Implants (Germany, 2014)

Primary Competitor	Frequency	Percentage
Biomet	[...]*	[50-60]**%
S&N	[...]*	[20-30]**%
Aesculap	[...]*	[5-10]**%
Link	[...]*	[5-10]**%
Mako	[...]*	[5-10]**%
None	[...]*	[5-10]**%
Total	[...]*	

Source: Zimmer CRM data

- (903) When restricting the CRM sample to those sales opportunities for which the outcome is known (Table 44 below), the analysis proved that Zimmer was able to win against Biomet at least [10-20]**% of the times ([...]*) and in none of these Zimmer was the current supplier of the hospital. This suggests that, despite the different surgical philosophies of mobile and fixed bearing knee implants, customers and surgeons switch between them, and supports the idea that Zimmer and Biomet, with their ZUK and the Oxford knee, are close

competitors.⁴¹⁹ Aesculap appears as the company against whom Zimmer won most opportunities. However, this is misleading since out of the [...] instances where Biomet was perceived as the primary competitor (see Table 42 and Table 43 above) only in [...] instances the outcome is properly recorded in the CRM dataset (see below), whereas in [...] out of the [...] observations where Aesculap was Zimmer's primary competitor the outcome of the sales process is properly recorded in the CRM dataset.

Table 44: Primary competitor analysis - Lost and won opportunities, Unicdylar knee (Germany 2013 and 2014)

Primary Competitor	Frequency	Percentage	Zimmer Incumbent	Primary Competitor	Frequency	Percentage	Zimmer Incumbent
<u>Lost Opportunities</u>				<u>Won Opportunities</u>			
Biomet	[...]*	[10-20]*%	[0-5]*%	Aesculap	[...]*	[20-30]*%	[20-30]*%
Arthrex	[...]*	[5-10]*%	[0-5]*%	Biomet	[...]*	[10-20]*%	[0-5]*%
Conformis	[...]*	[5-10]*%	[0-5]*%	S&N	[...]*	[10-20]*%	[0-5]*%
Mako	[...]*	[5-10]*%	[90-100]*%	J&J/DePuy	[...]*	[5-10]*%	[0-5]*%
				Other	[...]*	[5-10]*%	[0-5]*%
Total	[...]*	[30-40]*%		Total	[...]*	[60-70]*%	

*Sales opportunities for which the outcome is known: [...]**

Source: Zimmer CRM data

- (904) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicdylar knee market.
- (905) In Germany, one market participant explained that switches in the knee segment (including unicdylar knee implants) are rare. This is because transitioning between suppliers is costly and takes time. For example, a hospital seeking to switch suppliers in the market for knee implants would need between 3 and 6 months to retrain surgeons and the remainder of the staff on the new products. This is because bids must be assessed, not only for the implants, but also for the correspondent tools and instrumentation.⁴²⁰
- (906) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (907) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.

⁴¹⁹ Although the dataset does not have information on the identity of the incumbent, given the structure of the industry, it seems reasonable to assume that, whenever Zimmer is not the incumbent, the sale representatives would consider the current supplier to be Zimmer's primary competitor.

⁴²⁰ Non-confidential minutes of the conference call with Helios Kliniken of 22.07.2014.

(908) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. Based on the Commission's market investigation, some players such as Lima and DJO entered the German market, in 2005 and 2010, respectively, but none of them offer unicondylar knee implants.

Conclusion

(909) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Germany through the creation or strengthening of a dominant position.

Greece

Structure of the market

(910) According to the Notifying Party, [...] * [less than 1] * million in 2012. The same year, the Parties' sales amounted to EUR [...] * for Zimmer and [...] * for Biomet. The merged entity would have a market share of approximately [70-80] *% in this market, with Biomet contributing an increment of around [30-40] *%.

Table 45: Shares of value for unicondylar knee implants in Greece

Suppliers	2011	2012	2013 ⁴²¹
Zimmer	[70-80] *%	[40-50] *%	-
Biomet	[20-30] *%	[30-40] *%	-%
Merged Entity	[90-100] *%	[70-80] *%	-
J&J/DePuy	[10-20] *%	[10-20] *%	-
Tornier	[5-10] *%	[5-10] *%	-
Amplitude	[5-10] *%	[5-10] *%	-
S&N	[0-5] *%	[0-5] *%	-
Medacta	[0-5] *%	[0-5] *%	-
Total	100%	100%	-

Source: Form CO, Annex 6.2(a)

(911) Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately [60-70] *% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be two competitors left with market shares above 5%, that is to say Tornier and Amplitude. Finally, it is worth noting that, over the last two years, Biomet increased

⁴²¹ The Notifying Party was not able to provide market share data for partial knee implants in Greece for the year 2013.

its market shares by [10-20]*%, while Zimmer has lost [20-30]*%, but still keeping a considerable market share of approximately [40-50]*%.

Views of the Notifying Party

(912) According to the Notifying Party, the majority of the Greek hospitals (about 85%) are public, and they are therefore particularly susceptible to the cost-cutting measures put in place in the context of the well-known economic crisis. Public hospitals source their implants in two ways: by means of competitive public tenders or using the "price observatory" system, which was implemented as part of the agreement between the Greek State and the Troika to reduce public spending. This system regulates the maximum price that public hospitals can pay for their implants ("NHS List Prices"). Suppliers are not able to negotiate prices above the regulated maximum. Quite to the contrary, they regularly price below the NHS List Prices to win orders. In Greece, reimbursements are provided for the entire implant's price as long as it is approved by the "price observatory".⁴²²

(913) The Notifying Party also explains that the significant changes in the Parties' market shares show the dynamic nature of competition in the Greek market for unicondylar knee implants. The entire demand of public hospitals is currently tendered centrally and market shares may shift significantly in a short period of time, demonstrating a high degree of contestability.⁴²³

The Commission's assessment

(914) Based on the Commission's market reconstruction, the merged entity's market share would be higher than the Notifying Party's own estimates, and range between [90-100%]. The merger would effectively lead to a monopoly in the market as the Notifying Party seems to have overestimated the market shares of its remaining competitors. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by the Notifying Party, which would in any event give rise to a presumption of dominance.

Table 46: Parties' shares of value for unicondylar knee implants in Greece

Suppliers	2009	2010	2011	2012	2013
Zimmer	[40-50%]	[50-60%]	[70-80%]	[40-50%]	[10-20%]
Biomet	[40-50%]	[30-40%]	[20-30%]	[30-40%]	[80-90%]
Merged Entity	[90-100%]	[90-100%]	[90-100%]	[80-90%]	[90-100%]

Source: Commission's targeted market reconstruction

(915) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Greek market.

(916) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are

⁴²² Form CO, paragraphs 221-222.

⁴²³ Reply to the Article 6(1)(c) Decision, paragraph 682.

particularly aggravated by the specific characteristics of the unicondylar knee market.

(917) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor. One of Zimmer's internal documents entitled "*Export Tactics Knee & personalised Solution 2014*" also shows that S&N exited the Greek market for knee implants as of 2013, suggesting that the overall number of players is indeed much narrower than represented by the Notifying Party.⁴²⁴

(918) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.

(919) As noted in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high.

Conclusion

(920) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Greece through the creation or strengthening of a dominant position.

Italy

Structure of the market

(921) According to the Notifying Party's estimates, in Italy, the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [60-70]*%, with Biomet contributing an increment of around [10-20]*%.

⁴²⁴ See Zimmer's internal document *Export Tactics Knee & personalised Solution 2014*, slide 21, ID3010.

Table 47: Shares of value for unicondylar knee implants in Italy

Suppliers	2011	2012	2013
Zimmer	[40-50]*%	[40-50]*%	[40-50]*%
Biomet	[10-20]*%	[10-20]*%	[10-20]*%
Merged Entity	[60-70]*%	[60-70]*%	[60-70]*%
S&N	[20-30]*%	[20-30]*%	[20-30]*%
J&J/DePuy	[5-10]*%	[5-10]*%	[5-10]*%
Link	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

(922) Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately [40-50]*% between the merged entity and S&N. Besides S&N, post-merger there would be only one competitor left with market shares above 5%, that is to say J&J/DePuy. Finally, it is worth noting that, over the last three years, both Zimmer's and Biomet's market shares have remained relatively stable.

Views of the Notifying Party

(923) The Notifying Party explains that joint reconstruction interventions are performed by: (a) public hospitals (60% of the Italian orthopaedic market); (b) private hospitals offering healthcare services reimbursed from the public budget (35% of the Italian orthopaedic market); and (c) private hospitals without reimbursement contracts (mainly for privately-insured patients, 5% of the Italian orthopaedic market). Italy is largely a bidding market where up to 95% of all public hospital contracts are awarded through tender procedures, organised by either individual hospitals or, increasingly, groups of hospitals or regional groupings of hospitals.⁴²⁵

(924) According to the Notifying Party, while the changes in market share appear modest given the large market size, a number of switches did indeed take place in the Italian market. However, out of the [...] switches submitted by the Notifying Party only [...] regarded unicondylar knee implants, [...].⁴²⁶

The Commission's assessment

⁴²⁵ Form CO, paragraph 252.

⁴²⁶ Reply to Commission' RFI of 08.10.2014.

- (925) Based on the Commission's market reconstruction, the merged entity's market shares would be the same as the Notifying Party's own estimates. Similarly, the merger would lead to a 4-to-3 merger since the other players in the market would remain below 5%. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 48: Parties' shares of value for unicondylar knee implants in Italy

Suppliers	2009	2010	2011	2012	2013
Zimmer	[40-50%]	[40-50%]	[40-50%]	[40-50%]	[40-50%]
Biomet	[20-30%]	[20-30%]	[10-20%]	[10-20%]	[10-20%]
Merged Entity	[60-70%]	[60-70%]	[60-70%]	[60-70%]	[60-70%]

Source: Commission's targeted market reconstruction

- (926) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Italian market.
- (927) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (928) Based on the in-depth market investigation hospitals, the Commission understands that in Italy hospitals multi-source unicondylar knee implants for reasons such as security of supply, price competition and clinical needs. However, none of the five hospitals that replied to the Commission's questionnaires recently switched suppliers for unicondylar knee implants.⁴²⁷ This is in line with surgeons' reluctance to change implants, once they obtain experience and positive outcomes.⁴²⁸
- (929) In addition, in Italy the relationship between distributors and surgeons plays an important role in competitive dynamics, which must not be underestimated. Such relationship is built upon loyalty over the years, and is even conceivable that a surgeon may follow the switch of her/his distributor from one supplier to another. However, distributors are also usually bound to a specific supplier and a specific area or region by exclusivity clauses.⁴²⁹
- (930) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (931) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.

⁴²⁷ Responses to Questionnaire Q31 to hospitals, questions 37, 43 and 44.

⁴²⁸ Non-confidential minutes of the conference call with Medi Tecnika of 23.10.2014, paragraph 4; Non-confidential minutes of the conference call with Esforax of 27.10.2014, paragraphs 16-17.

⁴²⁹ Non-confidential minutes of the conference call with Medi Tecnika of 23.10.2014, paragraphs 5-6 and 12.

(932) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. Based on the in-depth market investigation, some players such as Implantcast and DJO have entered the Italian market over the last years, but none of them offer unicondylar knee implants.

Conclusion

(933) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Italy through the creation or strengthening of a dominant position.

Netherlands

Structure of the market

(934) According to the Notifying Party's estimates, in the Netherlands, the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties' combined market share is around [80-90]*%, with Zimmer contributing an increment of approximately [5-10]*%.

Table 49: Shares of value for unicondylar knee implants in the Netherlands

Suppliers	2011	2012	2013
Zimmer	[5-10]*%	[5-10]*%	[5-10]*%
Biomet	[60-70]*%	[60-70]*%	[70-80]*%
<i>Merged Entity</i>	<i>[70-80]*%</i>	<i>[70-80]*%</i>	<i>[80-90]*%</i>
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Mathys	[0-5]*%	[0-5]*%	[0-5]*%
Corin	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

(935) Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately [5-10]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be no other competitor with market shares above 5%. Finally, it is worth noting that, over the last three years, Zimmer's market shares have remained relatively stable, while Biomet's shares increased by [10-20]*%.

Views of the Notifying Party

- (936) The Notifying Party explains that, in the Netherlands, hospitals receive reimbursement based on a DRG-based system, and that the implant prices are included in the cost of a given type of procedure. This system creates downward pressure on prices, which is supported by both hospital administration and surgeons.⁴³⁰
- (937) The Notifying Party submits that the Dutch market for unicondylar knee implants has grown, and this will more likely lead to more competitors entering the market in the future. It further notes that there are low barriers to entry in the market, as evidenced by the numerous competitors that have entered the overall knee market. In 2007, Stryker, J&J/DePuy and MicroPort had first entered the market, followed by Implantcast and Mathys in 2008, and B&H Medical and S&N in 2009 and 2012, respectively.

The Commission's assessment

- (938) Based on the Commission's market reconstruction, the merged entity's market share would be bigger than the Notifying Party's own estimates, and range between [90-100%]*. The merger would effectively lead to a quasi-3-to-2 scenario as it seems that only one remaining competitor would have market shares above [0-5%]*. That said, despite the fact that the results of the Commission's market reconstruction differ from the scenario proposed by the Notifying Party, both scenarios would in any event give rise to a presumption of dominance.

Table 50: Parties' shares of value for unicondylar knee implants in the Netherlands

Suppliers	2009	2010	2011	2012	2013
Zimmer	[5-10%]	[5-10%]	[5-10%]	[5-10%]	[5-10%]
Biomet	[60-70%]	[70-80%]	[70-80%]	[70-80%]	[80-90%]
Merged Entity	[70-80%]	[80-90%]	[80-90%]	[80-90%]	[90-100%]

Source: Commission's targeted market reconstruction

- (939) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Dutch market.
- (940) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (941) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (942) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (943) As noted in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. Based on the in-depth market

⁴³⁰ Form CO, paragraph 278.

investigation, the Commission understands that Mathys entered the Dutch market in 2006. Although customers were convinced by clinical data (engineering tests, cadaveric surgery, etc.) and the quality of the new products,⁴³¹ Mathys is estimated by the Notifying Party as having gained only 2% market share since 2006. Based on the Commission's market reconstruction, the other players that entered the Dutch market do not offer unicondylar knee implants.

Conclusion

- (944) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in the Netherlands through the creation or strengthening of a dominant position.

Poland

Structure of the market

- (945) According to the Notifying Party, in Poland, the total value of the market for partial knee implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [70-80]*%, with Zimmer contributing an increment of around [5-10]*%.

Table 51: Shares of value for unicondylar knee implants in Poland

Suppliers	2011	2012	2013
Zimmer	[5-10]*%	[0-5]*%	[5-10]*%
Biomet	[60-70]*%	[50-60]*%	[70-80]*%
Merged Entity	[70-80]*%	[50-60]*%	[70-80]*%
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
Mathys	[0-5]*%	[0-5]*%	[0-5]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (946) Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately [50-60]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be no other competitor left with market

⁴³¹ Responses to Questionnaire Q30 on entry and innovation, questions 12 and 17.

shares above 5%. Finally, it is worth noting that, over the last three years, both Zimmer and Biomet have slightly increased their market share by [0-5]*%.

Views of the Notifying Party

- (947) The Notifying Party explains that the whole Polish market is covered by tenders since both public and private hospitals performing surgery financed by the public budget are required by law to tender their requirements. Accordingly, approximately 95% of the Parties' sales in Poland are achieved through public tenders.⁴³²
- (948) The Ministry of Health sets a reimbursement price for each joint reconstruction device and the hospitals are reimbursed by the National Healthcare Fund based on the number of procedures performed, regardless of the price actually paid for the device. As hospitals are able to pocket the difference between the set maximum reimbursement price and the price actually paid for an implant (where the latter is lower), there is an incentive for hospitals to source their supplies for the lowest possible price.⁴³³
- (949) According to the Notifying Party, Zimmer's market share increase since 2011 is the consequence of some new accounts. The changes in the Parties' market shares show the dynamic nature of competition in the Polish market for unicondylar knee implants, which is a bidding, very price-sensitive market.⁴³⁴

The Commission's assessment

- (950) Based on the Commission's market reconstruction, the Notifying Party's estimates are relatively accurate. However, the merger would effectively lead to a quasi-3-to-2 scenario because Zimmer seems to have overestimated the market shares of its remaining competitors. Besides only one significant competitor, all the others would remain below 5%. That said, it is worth noting that the results Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 52: Parties' shares of value for unicondylar knee implants in Poland

Suppliers	2009	2010	2011	2012	2013
Zimmer	[5-10%]	[5-10%]	[5-10%]	[0-5%]	[5-10%]
Biomet	[60-70%]	[60-70%]	[60-70%]	[50-60%]	[70-80%]
<i>Merged Entity</i>	<i>[70-80%]</i>	<i>[60-70%]</i>	<i>[70-80%]</i>	<i>[50-60%]</i>	<i>[70-80%]</i>

Source: Commission's targeted market reconstruction

- (951) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Polish market.
- (952) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are

⁴³² Form CO, paragraph 296.

⁴³³ Form CO, paragraph 298.

⁴³⁴ Reply to the Article 6(1)(c) Decision, paragraph 698.

particularly aggravated by the specific characteristics of the unicondylar knee market. In Poland, none of the respondents to the in-depth market investigation indicated to have switched suppliers of unicondylar knee implants recently.⁴³⁵

- (953) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (954) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (955) As noted in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. Based on the Commission's market reconstruction, the entrants mentioned by the Notifying Party in their submissions either do not offer unicondylar knee implants or are fringe players in this market.

Conclusion

- (956) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Poland through the creation or strengthening of a dominant position.

Portugal

Structure of the market

- (957) According to the Notifying Party, in Portugal, the total value of the market for partial knee implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [80-90]*%, with Zimmer contributing an increment of around [30-40]*%.

⁴³⁵ Responses to Questionnaire Q31 to hospitals, questions 37 and 38.

Table 53: Shares of value for unicondylar knee implants in Portugal

Suppliers	2011	2012	2013
Zimmer	[0-5]*%	[10-20]*%	[30-40]*%
Biomet	[80-90]*%	[50-60]*%	[40-50]*%
<i>Merged Entity</i>	<i>[80-90]*%</i>	<i>[60-70]*%</i>	<i>[80-90]*%</i>
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
Tornier	[0-5]*%	[0-5]*%	[0-5]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (958) Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately [60-70]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be no other competitor left with market shares above 5%. Finally, it is worth noting that, over the last three years, Zimmer has considerably increased its market share by [30-40]*%, while Biomet lost approximately a [40-50]*% market share.

Views of the Notifying Party

- (959) The Notifying Party explains that, in Portugal, 65% of hospitals are public and 35% are private. Portugal is primarily a bidding market. Approximately 80% of purchasing takes place through tenders. Hospitals are reimbursed on the basis of a DRG system, and reimbursement premia also cover implant prices. As result of cost-containment measures adopted by the Portuguese government, all public hospitals have been required to negotiate obtain price reductions with suppliers. This has led to reductions in implant prices of at least 15% per year.⁴³⁶
- (960) According to the Notifying Party, the Portuguese market is particularly volatile, with Zimmer gaining a [30-40]*% market share since 2011. The reason underlying Zimmer's market share increase was Zimmer competitive pricing, which led to the award of some tenders. The significant changes in the Parties' market shares show the dynamic nature of competition in the Portuguese market for unicondylar knee implants.

The Commission's assessment

⁴³⁶ Form CO, paragraphs 305-307.

- (961) Based on the Commission's market reconstruction, the Notifying Party's estimates are relatively accurate. Post-merger, there would be only one competitor left with market shares above 5%, while the rest of the competitors would have market shares below 5%. Therefore the merger would lead to a quasi 3-to-2 merger. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 54: Parties' shares of value for unicondylar knee implants in Portugal

Suppliers	2009	2010	2011	2012	2013
Zimmer	[5-10%]	[5-10%]	[0-5%]	[10-20%]	[30-40%]
Biomet	[60-70%]	[60-70%]	[80-90%]	[40-50%]	[40-50%]
Merged Entity	[60-70%]	[70-80%]	[80-90%]	[60-70%]	[80-90%]

Source: Commission's targeted market reconstruction

- (962) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Portuguese market.
- (963) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market. In Portugal, none of the respondents to the in-depth market investigation indicated to have switched suppliers of unicondylar knee implants recently.⁴³⁷
- (964) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (965) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (966) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high.

Conclusion

- (967) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Portugal through the creation or strengthening of a dominant position.

Slovenia

- (968) The Notifying Party could not provide reliable data relating to the total value of the Slovenian market for partial knee implants. Slovenia was also not one of the countries included in the Commission's market reconstruction. The Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet in 2013.

⁴³⁷ Responses to Questionnaire Q31 to hospitals, questions 37 and 38.

- (969) According to the Notifying Party's estimate, the Commission understands that the merged entity would have a market share potentially above [50-60]*%, with Zimmer contributing an increment of approximately [40-50]*%. Post-merger, at least three major players, that is to say J&J/DePuy, S&N and Stryker should be active in this country. However, the Commission was not able to gauge the concrete extent of such presence.
- (970) In any event, in light of the commitments offered by the Notifying Party to address the Commission's concerns regarding other Group 1 national markets and the removal of the entire overlap brought about by the merger in the EEA market for unicondylar knee implants resulting from the commitments, it is not necessary to reach a definitive conclusion in this regard.

Spain

Structure of the market

- (971) According to the Notifying Party, in Spain, the total value of the market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The Parties' market share is around [50-60]*%, with Zimmer contributing an increment of around [10-20]*%.

Table 55: Shares of value for unicondylar knee implants in Spain

Suppliers	2011	2012	2013
Zimmer	[10-20]*%	[10-20]*%	[10-20]*%
Biomet	[40-50]*%	[30-40]*%	[30-40]*%
Merged Entity	[60-70]*%	[50-60]*%	[50-60]*%
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (972) Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately [40-50]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be no other competitors left with market shares above 5%.

Views of the Notifying Party

- (973) The Notifying Party explains that, in Spain, 70% of hospitals are public and 30% are private. As a general rule, hospitals in Spain buy joint replacement implants by means of three systems: a) general tender procedures or homologation processes; b) authorized product list procedures; and c)

individual commercial negotiations with suppliers. The Spanish healthcare system is regional and is operated by the 17 autonomous communities of Spain.

- (974) According to the Notifying Party, it is particularly easy to enter the Spanish knee market, as evidenced by the numerous entrants such as Aesculap (2006), Amplitude (2006), Ceraver (2005), Corin (2010), Exactech (2010), Lafitt (2009), MBA (2010), Mathys (2011), Medacta (2005), Samo (2011), Surgival (2006) and Tornier (2007). Hence, there is already competitive constraint exerted by the current competitors, which is further strengthened by the numerous new market entrants in this market.⁴³⁸

The Commission's assessment

- (975) Based on the Commission's market reconstruction, the Notifying Party's estimates are relatively accurate. Post-merger, there would only be two other competitors with market shares above 5%, while the remaining competitors would have market shares below 5%. The merger would therefore lead to a quasi 3-to-2 scenario in the Spanish market for unicondylar knee implants.

Table 56: Parties' shares of value for unicondylar knee implants in Spain

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
Biomet	[40-50%]	[40-50%]	[40-50%]	[30-40%]	[40-50%]
<i>Merged Entity</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>	<i>[50-60%]</i>	<i>[50-60%]</i>

Source: Commission's targeted market reconstruction

- (976) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Spanish market.
- (977) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (978) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (979) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (980) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. In Spain, the in-depth market investigation did not confirm the entry of several smaller firms in the Spanish market for unicondylar knee implants. Based on the in-depth market investigation, the Commission understands that Mathys entered the Spanish market through a distributor.⁴³⁹ Mathys launched its unicondylar knee implant

⁴³⁸ Reply to the Article 6(1)(c) Decision, paragraph 710.

⁴³⁹ Responses to Questionnaire Q30 on entry and innovation, questions 1 and 3.

in Spain in 2006.⁴⁴⁰ Although customers were convinced by clinical data (engineering tests, cadaveric surgery, etc.) and the quality of the new products,⁴⁴¹ Mathys is estimated by the Notifying Party as having gained a very small market share since 2006. Based on the Commission's market reconstruction, the other entrants mentioned by the Notifying Party either do not offer unicondylar knee implants or are fringe players in this market.

Conclusion

- (981) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Spain through the creation or strengthening of a dominant position.

Sweden

Structure of the market

- (982) According to the Notifying Party, in Sweden, the total value of the market for partial knee implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [80-90]*%, with Zimmer contributing an increment of around [20-30]*%.

Table 57: Shares of value for unicondylar knee implants in Sweden

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[20-30]*%	[20-30]*%
Biomet	[40-50]*%	[50-60]*%	[50-60]*%
Merged Entity	[70-80]*%	[70-80]*%	[80-90]*%
J&J/DePuy	[20-30]*%	[20-30]*%	[20-30]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (983) Based on data provided by the Notifying Party, the merger would combine the number one and number three players, creating an undisputed market leader with a very large gap of approximately [50-60]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be no other competitor left with market shares above 5%. Finally, it is worth noting that, over the last three years, Zimmer has slightly decreased its market share by [0-5]*%, while Biomet won an [5-10]*% market share.

Views of the Notifying Party

⁴⁴⁰ Responses to Questionnaire Q30 on entry and innovation, question 12.

⁴⁴¹ Responses to Questionnaire Q30 on entry and innovation, questions 12 and 17.

- (984) The Notifying Party explains that, in Sweden, 84% of hospitals are public and 16% are private. Public hospitals are required to purchase products through public tenders, except when the value of the purchase is very low. Larger private hospitals also use tenders. Correspondingly, more than 90% of total sales in Sweden are performed through tenders.⁴⁴²
- (985) Under the Swedish reimbursement system, the government decides on a specific reimbursement price for a treatment. This price is received by the hospital and covers the entire operation. The reimbursement price is usually fixed. This creates an incentive for the public hospitals to negotiate very seriously the price of the implants. Based on this, the Notifying Party submits that Sweden is a very price-sensitive environment
- (986) According to the Notifying Party, the market share fluctuations indicate the volatility of market shares in a tender market such as Sweden, where market shares are constantly contestable.⁴⁴³

The Commission's assessment

- (987) Based on the Commission's market reconstruction, the merged entity's market share would be smaller than the Notifying Party's estimates. Post-merger, there would be two competitors left with market shares above 5%, while the remaining competitors would have market shares below 5%. The merger would lead to a quasi 3-to-2 scenario in the Swedish market for unicondylar knee implants.

Table 58: Parties' shares of value for unicondylar knee implants in Sweden

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[20-30%]	[20-30%]	[10-20%]	[10-20%]
Biomet	[40-50%]	[40-50%]	[50-60%]	[50-60%]	[50-60%]
<i>Merged Entity</i>	<i>[60-70%]</i>	<i>[70-80%]</i>	<i>[70-80%]</i>	<i>[60-70%]</i>	<i>[60-70%]</i>

Source: Commission's targeted market reconstruction

- (988) The Swedish registry plays a crucial role when choosing implants and suppliers in Sweden. It heavily limits the number of suppliers a hospital can buy from. In the overall knee segment (including unicondylar knees), Zimmer and Biomet rank among the few firms with highly respected ranking in the Swedish registry.⁴⁴⁴ This is so because the Swedish market is very conservative, and surgeons rely heavily on evidence-based medicine. In particular, surgeons pay particular attention to track records and clinical evidence, while being aware that the outcome of their surgery will be evaluated in the national arthroplasty registry. Consequently, surgeons would not risk trying a new brand of a unicondylar knee implant without a solid track record to support it.⁴⁴⁵

⁴⁴² Form CO, paragraph 342.

⁴⁴³ Reply to the Article 6(1)(c) Decision, paragraph 713.

⁴⁴⁴ Non-confidential minutes of the conference call with Blekinge Hospital of 24.10.2014, paragraphs 20-21.

⁴⁴⁵ Non-confidential minutes of the conference call with Doctor Robertsson of Lund University Hospital of 05.12.2014, paragraph 22.

- (989) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the Swedish market.
- (990) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market. In Sweden, none of the respondents to the in-depth market investigation indicated to have switched suppliers of unicondylar knee implants recently.⁴⁴⁶
- (991) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (992) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (993) As shown in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. The in-depth market investigation indicated that entry into Swedish market is difficult, in particular because the role of the Swedish registry is very important in the choice of suppliers, making entry with a new product very hard. More in detail, to be considered as a reliable and reputed source of supply, a supplier must be in the registry-top results. This is however difficult to achieve, particularly when just entering the market without a solid track record.
- (994) In addition, a copycat or me-too product will have to start its own registry track record from the beginning because it cannot profit from the track record of the original product it follows.⁴⁴⁷ This has also been confirmed by a customer, which stated that "*copycat products which do not have their own track record are not considered reliable enough, as they are not ranked in the registries*".⁴⁴⁸
- (995) One key opinion leader confirmed that market entry in Sweden is very difficult. A new supplier will need to show that the new product has good long term results and this is very time consuming. Even if a company were to offer a lower price, it would take years before it could actually participate in a tender and compete on an equal footing with the main suppliers.⁴⁴⁹
- (996) Some hospitals raised concerns about the merger since Zimmer and Biomet will become dominant in the overall segment for knee implants, as well as in the market for unicondylar knee implants. Generally, customers fear the merger will cause price increases, reduce competition and will result in a 3-to-2 scenario.⁴⁵⁰ Similarly, one key opinion leader raised concerns about the merger since Zimmer and Biomet are regarded each other's closest competitors and

⁴⁴⁶ Responses to Questionnaire Q31 to hospitals, question 37.

⁴⁴⁷ Non-confidential minutes of the conference call with Blekinge Hospital of 24.10.2014, paragraph 24.

⁴⁴⁸ Non-confidential minutes of the conference call with LT Bleckinge of 27.10.2014, paragraph 5.

⁴⁴⁹ Non-confidential minutes of the conference call with Dr. Robertsson of Lund University Hospital of 25.06.2014, paragraphs 27-28.

⁴⁵⁰ Non-confidential minutes of the conference call with VGR of 28.10.2014, paragraph 11; Non-confidential minutes of the conference call with Blekinge Hospital of 24.10.2014, paragraph 27; and Non-confidential minutes of the conference call with LT Bleckinge of 27.10.2014, paragraph 8.

entry of new players is extremely difficult due to the conservative nature of the Swedish market.⁴⁵¹

Conclusion

- (997) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in Sweden through the creation or strengthening of a dominant position.

United Kingdom

Structure of the market

- (998) According to the Notifying Party, in the United Kingdom, the total value of the British market for partial knee implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of approximately [70-80]*%, with Zimmer contributing an increment of around [20-30]*%.

Table 59: Shares of value for unicondylar knee implants in the United Kingdom

Suppliers	2011	2012	2013
Zimmer	[10-20]*%	[10-20]*%	[20-30]*%
Biomet	[50-60]*%	[50-60]*%	[50-60]*%
Merged Entity	[60-70]*%	[60-70]*%	[70-80]*%
J&J/DePuy	[10-20]*%	[10-20]*%	[10-20]*%
Corin	[0-5]*%	[0-5]*%	[0-5]*%
Stryker	[0-5]*%	[0-5]*%	[0-5]*%
S&N	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (999) Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately Based on data provided by the Notifying Party, the merger would combine the number one and number two players, creating an undisputed market leader with a very large gap of approximately [50-60]*% between the merged entity and J&J/DePuy. Besides J&J/DePuy, post-merger there would be no other competitor left with market shares above 5%. Finally, it is worth noting that, over the last three years, Zimmer has increased its market share [5-10]*%, while Biomet lost a [5-10]*% market share but remained above [50-60]*%.

Views of the Notifying Party

⁴⁵¹ Non-confidential minutes of the conference call with Professor Kärholm of 02.07.2014, paragraph 16.

- (1000) The Notifying Party explains that approximately 80% of orthopaedic procedures in the United Kingdom are undertaken by the public National Health Service ("NHS"). The NHS as a public body is obliged to purchase based on competitive tender procedures. Private hospitals (which account for approximately 20% of all orthopaedic procedures) are not obliged to tender out their procurement contracts. Nonetheless they are highly price-sensitive and negotiate fiercely to decrease implant prices in order to increase their margins. Private hospitals are awarded contracts by the NHS to perform procedures based on competitive bids.⁴⁵²
- (1001) According to the Notifying Party, the British market for unicondylar knee implants appears to be rather volatile, with Zimmer gaining a [5-10]*% market share since 2011. Therefore, it is clear that other players can enter and take advantage of fluctuating market shares to establish their position.⁴⁵³

The Commission's assessment

- (1002) Based on the Commission's market reconstruction, the merged entity's market share would be larger than the Notifying Party's own estimates, but still in the range of [70-80%]*. The merger would lead to a quasi 3-to-2 scenario, where only two players (that is, the merged entity and another competitor) would have [90-100%]* of the market. That said, it is worth noting that the results of the Commission's market reconstruction do not materially differ from the scenario proposed by Notifying Party, which would in any event give rise to a presumption of dominance.

Table 60: Parties' shares of value for unicondylar knee implants in the United Kingdom

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[20-30%]
Biomet	[60-70%]	[60-70%]	[60-70%]	[60-70%]	[50-60%]
Merged Entity	[80-90%]	[70-80%]	[70-80%]	[70-80%]	[70-80%]

Source: Commission's targeted market reconstruction

- (1003) As noted in recitals (762)-(781), Zimmer and Biomet are close competitors in the market for unicondylar knee implants. The merger would therefore eliminate an important source of rivalry in the United Kingdom market.
- (1004) The CRM analysis carried out by the Commission showed that Biomet is the company which is most frequently identified by Zimmer as primary competitor in the United Kingdom in 2013. As shown in Table 61 and Table 62 below, Zimmer considers Biomet to be its main rival in about [70-80]*% in 2013 and [60-70]*% in 2014 of the sales opportunities involving partial knee implants. Zimmer appears to consider only two other companies (J&J/DePuy and Mathys) as a threat for the business opportunities identified.

⁴⁵² Form CO, paragraph 352.

⁴⁵³ Reply to 6(1) c decision, paragraph 716.

Table 61: Primary Competitor Analysis, Unicondylar Knee Implants (Great Britain, 2013)

Primary Competitor	Frequency	Percentage
Biomet	[...]*	[70-80]*%
J&J/DePuy	[...]*	[10-20]*%
Mathys	[...]*	[10-20]*%
Total	[...]	

Source: Zimmer CRM data

Table 62: Primary Competitor Analysis, Unicondylar Knee Implants (Great Britain, 2014)

Primary Competitor	Frequency	Percentage
Biomet	[...]*	[60-70]*%
J&J/DePuy	[...]*	[10-20]*%
Mathys	[...]*	[5-10]*%
S&N	[...]*	[0-5]*%
Stryker	[...]*	[0-5]*%
Total	[...]	

Source: Zimmer CRM data

- (1005) When restricting the CRM sample to those sales opportunities for which the outcome is known (Table 63 below), one is only left with business opportunities that Zimmer won in 2013 and 2014. However, the analysis is meaningful in showing that Zimmer often overcame Biomet ([...]* sale opportunities) while being the incumbent in only [...]* cases. As already highlighted for Germany, this seems to suggest that customers switch from mobile and fixed bearing knee implants and therefore the ZUK and the Oxford knee are actually close substitutes.⁴⁵⁴

Table 63: Primary competitor analysis - Won opportunities, Unicondylar knee (Great Britain 2013 and 2014)⁴⁵⁵

Primary Competitor	Frequency	Percentage	Zimmer Incumbent
Biomet	[...]*	[60-70]*%	[10-20]*%
J&J DePuy	[...]*	[10-20]*%	[0-5]*%

⁴⁵⁴ [...]*, given the structure of the industry, it seems reasonable to assume that, whenever Zimmer is not the incumbent, the sale representatives would consider the current supplier to be Zimmer's primary competitor.

⁴⁵⁵ There are no observations for lost sales opportunities.

Primary Competitor	Frequency	Percentage	Zimmer Incumbent
Mathys	[...]*	[10-20]*%	[0-5]*%
S&N	[...]*	[5-10]*%	[0-5]*%
Stryker	[...]*	[5-10]*%	[0-5]*%
Total	[...]*		

*Sales opportunities for which the outcome is known: [...]**

Source: Zimmer CRM data

- (1006) As noted in recitals (783)-(786), switching is generally a complex process in this market for the reasons generally set out for total knee implants, which are particularly aggravated by the specific characteristics of the unicondylar knee market.
- (1007) As noted in recitals (788)-(791), the merger would remove one important innovative force in the market, as well as one sizeable competitor.
- (1008) As noted in recitals (793)-(800), buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.
- (1009) As noted in recitals (802)-(806), barriers to entry and expansion in the market for unicondylar knee implants are very high. One hospital explained that it takes quite a commitment for a supplier to develop a unicondylar knee implant and persuade surgeons to switch to it. This is true even for suppliers which are currently active in total knee implants because the nature of the two surgery procedures is different.⁴⁵⁶
- (1010) Finally, several customers in the United Kingdom raised concerns about the proposed merger in relation to the market for unicondylar knee implants because Zimmer and Biomet are two strong players and are regarded as each other's main competitors.⁴⁵⁷

Conclusion

- (1011) On this basis, the Commission considers that the proposed merger would significantly impede effective competition on the market for unicondylar knee implants in the United Kingdom through the creation or strengthening of a dominant position.

⁴⁵⁶ Non-confidential minutes of the conference call with NHS Commercial Collaborative Platform of 30.10.2014, paragraph 17.

⁴⁵⁷ Non-confidential minutes of the conference call with the Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust of 5.11.2014, paragraph 11; Non-confidential minutes of the conference call with NHS Commercial Collaborative Platform of 30.10.2014, paragraph 22; Non-confidential minutes of the conference call with NHS Wales of 29.10.2014, paragraph 13; and Non-confidential minutes of the conference call with Nuffield Health of 30.10.2014, paragraph 13.

8.6.9. Patello-femoral Implants

8.6.9.1. The Parties' and their competitors' products

(1012) On this market, Zimmer offers the Zimmer Gender Solutions Patello-Femoral Joint (PFJ) System, while Biomet competes through its Vanguard PFR Patello-femoral Replacement system. The Parties' main competitors' products are listed in Table 64 below.

Table 64: Overview of the Main Offerings for Patello-femoral implants

Competitor	Patello-femoral implant products
Zimmer	Zimmer Gender Solutions Patello-Femoral Joint (PFJ) System
Biomet	Vanguard PFR Patello-femoral Replacement system
Stryker	Avon patello-femoral
J&J/DePuy	LCS PFJ
S&N	Journey PFJ
Arthrex	iBalance PFJ System
Wright / Microport	Femoro Patella Vialli FPV
Arthosurface	Patello-femoral Hemicap

Source: Form CO and Commission's market investigation

8.6.9.2. Structure of the patello-femoral knee implants market in the EEA

(1013) Based on the Notifying Party's submissions, the patello-femoral implants market accounted for approximately EUR [1-50]* million in 2013 at EEA level. In the same year, the Parties' sales amounted to approximately EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of approximately [30-40]*% by value at EEA level in this overall market, with Biomet contributing an increment of [5-10]*%.

(1014) Biomet is not an important player in this segment, having achieved sales of [...] at EEA level and [...] in volume in 2013. Therefore, the merger is unlikely to significantly change the competitive landscape in this segment.

(1015) Table 65 shows the position of the Parties at EEA level for the year 2013, and their relative importance against the other suppliers in the market. Besides the Parties and the other major suppliers of the industry, that is to say J&J/DePuy, S&N, Stryker, the market features other non-negligible players such as Wright/Microport.

Table 65: Market Shares for patello-femoral implants by value at EEA-level in 2013

Suppliers	2013
Zimmer	[20-30]*%
Biomet	[5-10]*%

<i>Merged Entity</i>	<i>[30-40]*%</i>
Stryker	[20-30]*%
S&N	[10-20]*%
J&J/DePuy	[10-20]*%
Wright/Microport	[5-10]*%
Other players	[5-10]*%
Total	100%

Source: Response to the Commission's RFI of 11 February 2015

- (1016) At national level, according to the data provided by the Notifying Party, the merger would give rise to nine Group 1 national markets, namely Austria, Belgium (including Luxembourg), the Czech Republic, Finland, France, Germany, Italy, the Netherlands, Portugal and Spain.
- (1017) In the absence of reliable data, the Commission carried out a market reconstruction for patello-femoral knee implants. However, this exercise does not cover a number of EEA countries as explained in section 8.3. According to the Commission's data, the market share of the merged entity post-merger would give rise to 8 Group 1 national markets. These countries are: Austria, Belgium (including Luxembourg), the Czech Republic, France, Germany, Italy, the Netherlands and Portugal. Additionally, the market reconstruction confirmed that Finland does not qualify as a Group 1 national market.

8.6.9.3. General Competitive Assessment

Closeness of competition

The views of the Notifying Party

- (1018) The Notifying Party submits that the Parties are not particularly close competitors in the market for patello-femoral implants. All suppliers, including the Parties, offer similar products which are close alternatives to each other. As the Parties' products do not have any distinct characteristics which would distance them from other companies' products, the rivalry between them does not specifically generate competition in the market.

The Commission's assessment

- (1019) The in-depth market investigation provided evidence that the Parties are two leading players in the market for patello-femoral implants, and certainly close competitors.
- (1020) The Commission rejects the Notifying Party's argument in relation to closeness of competition. Paragraph 28 of the Horizontal Merger Guidelines clearly focuses on the concept of "*merging firms [being] close competitors*".⁴⁵⁸ This market, just like the overall knee segment in general, is characterised by the presence of five major players (or majors), which may as well be seen as closely competing against each other as suggested by the Notifying Party. The

⁴⁵⁸ Horizontal Merger Guidelines, paragraph 38.

elimination of a close competitor can reasonably be expected to lower the competitive pressure currently in force in the market.

- (1021) Moreover, the Notifying Party does not - and cannot - deny the existing competitive relationship between itself and Zimmer. As pointed out by the Horizontal Merger Guidelines, "[...] *the fact that rivalry between the parties has been an important source of competition on the market may be a central factor in the analysis [...]*". Therefore, the Commission concludes that the concept of closeness does bear relevance to the analysis in this case.
- (1022) A number of suppliers are active in the EEA on the market for patello-femoral implants. These include all the major manufacturers, S&N, J&J/DePuy, Stryker, as well as a number of smaller competitors such as Arthrex and Wright/Microport.
- (1023) Zimmer's internal documents identify Biomet as one of its key competitors as regards patello-femoral implants. Thus, as it can be noted from Figure 23 below, in its internal document "Knee Profiler"⁴⁵⁹ Zimmer ranks Biomet as its number [...] * key competitors in patello-femoral implants, behind [...] *.

Figure 23: [...]*

Conclusion

- (1024) In light of the arguments set out in this section, the Commission takes the view that Zimmer and Biomet are close competitors in patello-femoral implants.

Customer Switching

- (1025) The findings set out in section 8.6.2.5 regarding customer switching (difficulties to switch and limited possibilities of switching supplier) apply by analogy to patello-femoral knee implants. Overall, as shown in recital (1022) above, the number of companies producing such implants is more limited than in the case of primary knee implants.

Elimination of an important competitive force

- (1026) The findings set out in section 8.6.2.6 regarding the elimination of an important competitive force in the market apply by analogy to patello-femoral knee implants. In particular, Biomet is considered one of the main innovators in the knee implants market, including patello-femoral implants.

Countervailing buyer power

- (1027) The findings set out in section 8.6.2.7 regarding countervailing buyer power apply by analogy to patello-femoral knee implants. In particular, the trend towards tender-based procurement systems and GPOs is not as generalised as to shield all customers from higher prices or deteriorated competitive terms post-merger in the market for revision implants.

Barriers to entry and expansion

- (1028) The findings set out in section 8.6.2.8 regarding entry and expansion apply by analogy to patello-femoral knee implants. The difficulties to enter this market are illustrated in particular by the reduced number of players which have developed such a product.

⁴⁵⁹ Zimmer's internal documents, "Knee profiler", September 2012, page 21, ID 278.

8.6.9.4. Country-specific Competitive Assessment

(1029) According to the data provided by the Notifying Party, the merger would give rise to nine Group 1 national markets, namely Austria, Belgium (including Luxembourg), the Czech Republic, Finland, France, Germany, Italy, the Netherlands, Portugal and Spain.

Table 66: Patello-femoral implants – Group 1 national markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million)	Competitors
<i>AT</i>	[30-40]*%	[0-5]*%	[30-40]*%	[less than 1]*	Alphamed ([20-30]*%), Stryker ([10-20]*%), S&N ([10-20]*%), J&J/DePuy ([5-10]*) others ([10-20]*%)
<i>BE</i>	[40-50]*%	[5-10]*%	[50-60]*%	[less than 1]*	S&N ([30-40]*%), J&J/DePuy ([0-5]*%), Stopler ([0-5]*%), Stryker ([0-5]*%), Wright ([0-5]*%)
<i>CZ</i>	[0-5]*%	[30-40]*%	[30-40]*%	[less than 1]*	S&N ([10-20]*%), Wright ([5-10]*%), Stryker ([0-5]*%), J&J/DePuy ([0-5]*%), others ([30-40]*%)
<i>DE</i>	[30-40]*%	[10-20]*%	[40-50]*%	[less than 1]*	S&N ([20-30]*%), J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), Aesculap ([5-10]*%)
<i>FI</i>	[20-30]*%	[10-20]*%	[30-40]*%	[less than 1]*	Stryker ([50-60]*%), J&J/DePuy ([10-20]*%)
<i>FR</i>	[20-30]*%	[5-10]*%	[30-40]*%	[less than 1]*	J&J/DePuy ([10-20]*%), Stryker ([5-10]*%), S&N ([0-5]*%), Wright ([0-5]*%), others ([30-40]*%)
<i>IT</i>	[40-50]*%	[5-10]*%	[40-50]*%	[less than 1]*	S&N ([30-40]*%), J&J/DePuy ([20-30]*%), Stryker ([5-10]*%)
<i>NL</i>	[40-50%]	[10-20]*%	[50-60]*%	[less than 1]*	S&N ([20-30]*%), Stryker ([10-20]*%), J&J/DePuy ([10-20]*%)
<i>PT</i>	[10-20]*%	[10-20]*%	[30-40]*%	[less than 1]*	S&N ([30-40]*%), others ([30-40]*%)
<i>EEA</i>	[20-30]*%	[5-10]*%	[30-40]*%	[1-50]*	Stryker ([20-30]*%), S&N ([10-20]*%), J&J/DePuy ([10-20]*%), Wright ([5-10]*%), residual ([5-10]*%)

Source: Response to the Commission's RFI of 11 February 2015

(1030) In the absence of reliable data, the Commission carried out a market reconstruction for patello-femoral knee implants. However, this exercise does not cover a number of EEA countries as explained in section 8.3. According to the Commission's data, the market share of the merged entity post-merger would give rise to 8 Group 1 national markets. These countries are: Austria, Belgium (including Luxembourg), the Czech Republic, France, Germany, Italy, the Netherlands and Portugal. Additionally, the market reconstruction confirmed that Finland does not qualify as Group 1 national market.

Austria

- (1031) According to the data provided by the Notifying Party, in Austria, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties have combined market shares of around [30-40]*% in the patello-femoral implants market, with Biomet contributing an increment of around [0-5]*%. Post-merger, there would be four other strong competitors left in the market: Alphamed ([20-30]*%), Stryker ([10-20%]), S&N ([10-20]*%) and J&J/DePuy ([5-10]*%).
- (1032) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly underestimated their market shares. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an insignificant increment of approximately [0-5%]. The market reconstruction largely confirmed the presence of another two strong competitors in the market, one of them with a market share higher than that of the merged entity and the other with a market share over 5%. It is likely that these competitors would continue to constrain the merged entity following the merger.
- (1033) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in Austria.

Conclusion

- (1034) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

Belgium (including Luxembourg)

- (1035) According to the data provided by the Notifying Party, in Belgium (including Luxembourg), the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties have combined market shares of around [50-60]*% in the patello-femoral implants market, with Biomet contributing an increment of around [5-10]*%. Post-merger, there would be other competitors in the market: S&N ([30-40]*%), J&J/DePuy ([0-5]*%), Stöpler ([0-5]*%), Stryker ([0-5]*%) and Wright/Microport ([0-5]*%).
- (1036) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly underestimated their market shares. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of another five competitors in the market, including the three other majors, one of which having a significant market share [30-40]% and two others with a market share above 5%. It is likely that these competitors would continue to constrain the merged entity following the merger.
- (1037) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in Belgium (including Luxembourg).

Conclusion

- (1038) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

Czech Republic

- (1039) According to the data provided by the Notifying Party, in the Czech Republic, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The Parties have combined market shares of around [30-40]*% in the patello-femoral implants market, with Zimmer contributing an increment of around [0-5]*%. Post-merger, there would be four other competitors left in the market: S&N ([10-20]*%), Wright/Microport ([5-10]*%), Stryker ([0-5]*%) and J&J/DePuy ([0-5]*%).
- (1040) Eucomed's data and the Commission's targeted market reconstruction indicate that the Parties significantly underestimated their market shares. The Parties appear to have combined market shares of approximately [90-100%], with Zimmer contributing an increment of approximately [10-20%].
- (1041) The market reconstruction also shows that the market share of the Parties has significantly varied over the last five years, from [0-5]% in 2009, when the market leader was S&N, to [90-100]% in 2013. This situation is explained by the extremely low number of patello-femoral implants which are sold in the Czech Republic. Therefore, given the low volumes purchased on this market, market shares may not be a representation of the real market power of each of the competitors present. One contract can drastically change the competitive landscape, which is demonstrated by the evolution of the market share of the merged entity in the last five years.
- (1042) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in the Czech Republic.

Conclusion

- (1043) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

France

- (1044) According to the data provided by the Notifying Party, in France, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. According to the data provided by the Notifying Party, the Parties have combined market shares of around [30-40]*% in the patello-femoral implants market, with Biomet contributing an increment of around [5-10]*%. Post-merger, there would be other competitors left in the market: J&J/DePuy ([10-20]*%), Stryker ([5-10]*%), S&N ([0-5]*%) and Wright ([0-5]*%).
- (1045) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties underestimated their market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of another five competitors in the market, three of which have a market share higher than 10%. It is likely that these competitors would continue to constrain the merged entity following the merger.
- (1046) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in France.

Conclusion

- (1047) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

Germany

- (1048) According to the data provided by the Notifying Party, in Germany, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties would have combined market shares of around [40-50]*% in the patello-femoral implants market, with Biomet contributing an increment of around [10-20]*%. Post-merger, there would be three other strong competitors left in the market: S&N ([20-30]*%), J&J/DePuy ([20-30]*%), Stryker ([10-20]*%) and Aesculap ([5-10]*%).
- (1049) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly underestimated their market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of another three competitors in the market, two of which have a market share higher than 10%. It is likely that these competitors would continue to constrain the merged entity following the merger.
- (1050) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in Germany.

Conclusion

- (1051) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

Italy

- (1052) According to the data provided by the Notifying Party, in Italy, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties would have combined market shares of around [40-50]*% in the patello-femoral implants market, with Biomet contributing an increment of around [5-10]*%.]*Post-merger, there would be three other strong competitors left in the market: S&N ([30-40]*%), J&J/DePuy ([20-30]*%), Stryker ([5-10]*%).
- (1053) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly underestimated their market shares. The Parties appear to have combined market shares of approximately [50-60%], with Biomet contributing an increment of approximately [5-10%]. The market reconstruction largely confirmed the presence of another four competitors in the market, two of which have a market share higher than 10%, and one a market share above 5%. It is likely that these competitors would continue to constrain the merged entity following the merger.
- (1054) Furthermore, the market reconstruction revealed the recent entry of one other competitor in this segment.
- (1055) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in Italy.

Conclusion

- (1056) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

Netherlands

- (1057) According to the data provided by the Notifying Party, in the Netherlands, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties have combined market shares of around [50-60]*% in the patello-femoral implants market, with Biomet contributing an increment of around [10-20]*%. Post-merger, there would be four other competitors left with market shares over [10-20]*%. These are S&N ([20-30]*%), Stryker ([10-20]*%) and J&J/DePuy ([10-20]*%).
- (1058) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly underestimated their market shares. The Parties appear to have combined market shares of approximately [60-70%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of three other players in the market, all with a market share higher than 10%. It is likely that the constraint imposed especially by these competitors would not be changed following the merger.
- (1059) Furthermore, the market reconstruction revealed the recent entry of two other competitors in this segment.
- (1060) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in the Netherlands.

Conclusion

- (1061) On the basis of the arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

Portugal

- (1062) According to the data provided by the Notifying Party, in Portugal, the total value of the market for patello-femoral implants amounted to EUR [less than 1]* million in 2013, representing [0-5]*% of the EEA-wide patello-femoral sales. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Parties have combined market shares of around [30-40]*% in the patello-femoral implants market, with Biomet contributing an increment of around [10-20]*%. Post-merger, there would be other competitors in the market including S&N ([30-40]*%).
- (1063) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties underestimated their market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of other three competitors in the market, with two of them having market share higher than 10%. It is likely that the constraint imposed especially by these competitors would not be changed following the merger.
- (1064) Finally, no concerns were raised by participants to the market investigation in relation patello-femoral implants in Portugal.

Conclusion

(1065) On the basis of arguments set out in this section, it is not likely that the proposed merger would significantly impede effective competition.

8.6.10. Conclusion – Knee implants

(1066) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition through the creation or strengthening of a dominant position in relation to primary knee implants in Denmark and Sweden, revision knee implants in Denmark, as well as in relation to unicondylar knee implants in Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden and the United Kingdom.

8.7. Elbow Implants

8.7.1. Overview of the market for elbow implants

(1067) The EEA market for elbow implants is relatively small in comparison to the markets for large reconstructive joints (hips and knees). Based on estimates submitted by the Notifying Party and the Parties' sales data, the total EEA market size was approximately EUR [1-50]* million in 2013, which corresponds to approximately [...] elbow implants, and represents only [0-5]*% of the EEA market for overall hip implants and [0-5]*% of the market for overall knee implants.

(1068) The elbow arthroplasty is a considerably more difficult procedure than hip and shoulder arthroplasty, in that it requires more practice and skill to perform. Also, fewer surgeons practice elbow arthroplasty than those who practice hip and knee arthroplasty. The Phase I market investigation showed that elbow surgery is considered from difficult to very difficult surgery. In reply to the market investigation, surgeons stated that certain implants require particular experience, "[a]natomical landmarks can be complex on the elbow segment", "[e]lbow surgery is always difficult".⁴⁶⁰ According to Lima, "[t]he market for elbows is a very specific one because not so many surgeons perform this kind of surgery due to its technical nature".⁴⁶¹

(1069) According to the Notifying Party, a number of suppliers are present in various EEA countries, including Link, Stryker, and Tornier. However, the importance of those players by sales - taken either individually or jointly - appears limited.

8.7.2. Structure of the elbow implants market

(1070) Based on estimates of the Notifying Party and the Parties' sales data, the total EEA market size was approximately EUR [1-50]* million in 2013. In a market encompassing all elbow implants, the merged entity would have a market share of approximately [70-80]*% at EEA level. The merger gives rise to 12 Group 1 national markets: Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, France, Germany, Italy, Norway, Portugal, Spain, Sweden and the United Kingdom.

(1071) In the absence of reliable data, the Commission carried out a targeted market reconstruction exercise during the market investigation in order to validate the

⁴⁶⁰ Responses to Questionnaire Q2 to customers, question 17.

⁴⁶¹ Non-confidential minutes of the conference call with Lima of 25.09.2014.

estimates provided in the Form CO. The Commission's targeted market reconstruction does not cover all EEA countries.

- (1072) Eucomed's data and the Commission's targeted market reconstruction, confirmed the Group 1 national markets for elbow implants to which the merger would give rise. However, both sources demonstrated that the Parties underestimated significantly their market shares in almost all Group 1 countries. Therefore, it appears that the Parties would enjoy larger market shares post-merger, their competitors' market shares being significantly lower.

8.7.3. *The Parties' and their competitors' products*

- (1073) Zimmer manufactures one implant called Coonrad/Morrey total elbow (or "C/M total elbow"). This is a semi-constrained implant that is indicated for both primary and revision interventions. It is indicated to treat post-traumatic and rheumatoid arthritis and trauma reconstruction. Zimmer also produces the GSB III Elbow System, which is a semi-constrained elbow implant treating the same pathologies. Zimmer is planning to introduce the Nexel Elbow in 2014 in the EEA.
- (1074) Biomet supplies one elbow replacement implant called Discovery Elbow. This is a semi-constrained implant. The Discovery Elbow is designed to reproduce natural elbow anatomy and restore elbow mechanics. It is suited both for fractures and degenerative pathologies. Biomet also manufactures unconstrained elbow systems such as the iBP, Liverpool, K Elbow and Kudo. Furthermore, Biomet markets an elbow system for the resurfacing of the lateral compartment of the elbow, namely the LRE Elbow System.
- (1075) As regards other market players, the Parties submit that:
- (a) Tornier manufactures an elbow replacement implant called Latitude. This product is convertible, that is, it can be either semi-constrained or unconstrained. To adapt the product to be semi-constrained only an additional pin is inserted in the hinge, connecting two components together.
 - (b) Stryker manufactures an elbow replacement semi-constrained implant called the Solar Elbow System. The implant is indicated to treat rheumatoid, traumatic and degenerative arthritis. Stryker also manufactures the Souter-Strathclyde Elbow Replacement, which is an unconstrained elbow implant.
 - (c) Link manufactures an elbow replacement semi-constrained implant called the Endo-Model Elbow Prosthesis.
 - (d) Implantcast supplies an elbow replacement unconstrained implant called NESSimplavit Elbow System. In this implant only the soft tissues restrict the range of motion and the intact ligaments and tendons stabilise the joint.

8.7.4. *General Competitive Assessment*

- (1076) The Commission has assessed whether the merger is likely to lead to horizontal non-coordinated effects in (i) an overall market for elbow implants (comprising both semi-constrained and unconstrained elbow implants); and (ii) a market comprising only semi-constrained elbow implants).
- (1077) The present merger will create or strengthen the market leader on the overall market for elbow implants in all Group 1 countries. The merged entity will have particularly high market shares of above [60-70]*% and will continue to account for a significant portion of the EEA market in the foreseeable future. In addition, the market share increments brought about by the proposed merger in

the Parties' share will exceed [20-30]*% in 8 Group 1 countries. The Parties' market shares on the overall market for elbow implants have been stable or increasing in 9 Group 1 countries, and only slightly decreasing in 3 Group 1 countries in the last three years.

- (1078) The proposed merger will also give rise to a very concentrated market structure and will eliminate one of the two currently most aggressive players leading to the creation of a merged entity which will have fewer incentives to price aggressively. This will very likely result into a significant relaxation of the competitive pressure on the market. Further, the other elbow implants competitors are only fringe players, with the exception of Tornier. However, it is unlikely that the latter will have the ability to compete with and effectively threaten the merged entity, given surgeons "stickiness" to their preferred elbow implants and difficulties to switch.
- (1079) The market reconstruction exercise undertaken by the Commission, in conjunction with Eucomed's data indicates that the Parties have significantly underestimated their respective competitive positions and market shares in the markets for elbow implants, having therefore largely overestimated those of their competitors. The merger will result in a considerably more concentrated market than that estimated by the Parties, in some Group 1 countries leading to a monopoly. More specifically, the Parties will have more than [90-100]*% market share in 7 Group 1 countries, and more than [60-70]*% in the other 5 Group 1 countries. The remaining competitors would not be able to replace the loss of competition created by the merger, as the remaining competitors are only marginally present in most of the Group 1 countries.
- (1080) The different factors that led the Commission to identify the above outlined competition concerns in recital (1079) are explained in the following subsections 8.7.4.1 onwards. First the Commission assesses the competitive positions of the Parties and their competitors (section 8.7.4.1). The Commission then sets out the closeness of competition between the Parties (section 8.7.4.2). Then the Commission examines whether it is feasible and realistic for customers to switch to alternative suppliers of elbow implants (section 8.7.4.3). The Commission in turn assesses whether the proposed merger will lead to the elimination of an important competitive force (section 8.7.4.4). The Commission finally assesses the buyers' countervailing power (section 8.7.4.5) and barriers to entry and expansion (section 8.7.4.6).

8.7.4.1. The Parties are the two leading players facing very limited competition

The views of the Notifying Party

- (1081) The Parties argue that multiple strong competitors exist post-merger. Specific reference is made to Link, Stryker and Tornier each of which have, according to the Parties, an elbow replacement market share of [5-10]*-[10-20]*% in various EEA countries. Stryker and Link are present in many EEA countries and Tornier is also a significant competitor in Austria, Belgium (including Luxembourg), Luxembourg, France, Italy, Netherlands and the UK. These competitors collectively have the scale and EEA-wide presence to be considered viable alternative suppliers to the Merging Parties.⁴⁶²

⁴⁶² Form CO, paragraph 681.

The Commission's Assessment

- (1082) The argument of the Parties, concerning the presence of multiple strong competitors in the overall market for elbow implants post-merger, is only partially confirmed in their internal documents. Apart from Zimmer, Biomet perceives only [...] as a competitive threat for its elbow implants. Indeed, it states "[...]"⁴⁶³. Zimmer, on the other hand, as the market leader in elbow implants, considers only Biomet as a credible competitor.
- (1083) Apart from the Parties' internal documents, both Eucomed's data, as well as the Commission's targeted market reconstruction indicate a different competitive reality in the market for elbow implants from that indicated by the Notifying Party. As described in recital (1079), the Parties have significantly underestimated their market shares, resulting in a considerable overestimation of their competitors' position. More specifically, the Commission notes that Stryker and Link only have a marginal presence, if at all, in the EEA as far as elbow implants are concerned.⁴⁶⁴ Similarly, the other competitor that the Parties claim will continue to exercise a strong competitive constraint post-merger, Tornier, also has considerably smaller presence in the market for elbow implants in Group 1 countries than that indicated by the Parties.
- (1084) Furthermore, smaller, regional players cannot be considered as credible competitors which will constrain the merged entity. The Parties failed to name regional, smaller players active in any Group 1 national market for elbow implants. Customer switching events provided by the Parties in relation to orthopaedic implants do not mention any switching in the area of elbow implants, let alone switching to a small, regional supplier of elbow implants.⁴⁶⁵ In addition, nothing in the in-depth market investigation suggested that the Parties, Tornier or Link are subject to competitive pressure by smaller, regional players. Furthermore, none of the customers responding to the market investigation indicated that they purchase elbow implants from any such smaller regional players.
- (1085) The Commission has also examined the Parties' competitive position in the narrower potential market for semi-constrained elbow implants only (to the exclusion of unconstrained elbow implants). The Notifying Party submitted market share estimates of a potential semi-constrained market based on Zimmer estimates of sales size and competitors' shares.⁴⁶⁶ The Commission's market reconstruction established that these estimates were largely inaccurate, in that they allocated a significant proportion of market share to "other/residual" competitors (reaching between 40-50%, depending on the EEA country). This allocation meant that the Parties' market shares were significantly underestimated. The Commission's market reconstruction has examined the actual sales of elbow implants in each EEA country and has assessed to what extent these sales relate to semi-constrained or unconstrained elbow implants on the basis of the relevant brand sold by the Parties and their competitors.

⁴⁶³ Biomet internal docs - BIO-0333, slide 6.

⁴⁶⁴ According to Link, elbow implants represent less than 10% of its total sales. See Non-confidential minutes of the conference call with Link of 26.09.2014 and 28.10.2014.

⁴⁶⁵ Responses to request for information Q16 – switching events, dated 08.10.2014.

⁴⁶⁶ Responses to Q11, Annex 3.

- (1086) The Commission notes that the sales of unconstrained elbow products are residual, when compared to semi-constrained implants. Approximately 72% of the overall elbow implant market in the EEA consists of the sales of semi-constrained implants, with only 27% of the sales in unconstrained elbow implants. For example, Biomet's 2013 sales of unconstrained elbow implants in the EEA were just EUR [...]*, which represented only [0-5]*% of its elbow sales.⁴⁶⁷
- (1087) The Commission also notes that the main competitors' products referred to in the Parties internal documents are either semi-constrained elbow implants (such as [...]*) or convertible elbow implants (such as [...]*).
- (1088) The Parties position thus would not be different, if the market were to exclude unconstrained elbow implants and focus only on semi-constrained elbow implants.
- (1089) Finally, the Commission notes that in the narrower market for unconstrained elbow implants, the Parties do not overlap, as Zimmer is not currently active.

Conclusion

- (1090) Taking into account the results of the targeted market reconstruction and the market investigation, as well as supporting evidence provided by the Parties, the Commission considers that there is no firm ground to conclude that the merged entity would be effectively constrained by a sufficient number of credible players in any of the Group 1 countries.
- (1091) Contrary to hip and primary knee implants, the market for elbow implants is relatively niche, with few competitors active. The two main competitors currently are the Parties and to a lesser extent Tornier. A few local competitors are active in some countries on a case by case basis but their presence is very small and geographically limited.
- (1092) The Commission preliminarily concludes that post-merger, the merged entity will be the market leader on the overall market for elbow implants in all Group 1 countries. With particularly high market shares of [60-70]*% or more which are well above the second largest player Tornier, increments that exceed [20-30]*% in 8 Group 1 countries and stable market shares in 9 Group 1 countries (market shares slightly decreased in 3 Group 1 countries) in the last three years, the proposed merger will give rise to a very concentrated market structure and will eliminate the two currently most aggressive players in the market by combining them in one sole entity. The structure of each Group 1 national market, including the competitive position of the Parties and their competitors will be analysed on a country-by-country basis in section 8.7.5 below.
- (1093) The Commission's assessment is still applicable if the market is defined more narrowly to include semi-constrained implants only. The position of the Parties and their competitors in this narrower product market will also be analysed on a country-by-country basis in section 8.7.5 below.

⁴⁶⁷ Zimmer does not supply unconstrained elbow implants.

8.7.4.2. Closeness of Competition

The views of the Notifying Party

- (1094) In the Form CO, the Notifying Party does not advance any arguments claiming that the elbow implants of Biomet and Zimmer are not close competitors.
- (1095) In the Response to the Article 6(1)(c) Decision, the Notifying Party claims that the fact that both Parties market semi-constrained elbow implants does not automatically make them each other's closest competitors. In the Response to the Article 6(1)(c) Decision the Parties claim that since Stryker manufactures a semi-constrained implant called the Solar Elbow System, Link markets an elbow implant called Endo-Model Elbow Prosthesis, and Tornier manufactures an elbow replacement implant called Latitude which is convertible to become either semi-constrained or unconstrained, all competitors are "close competitors" to one another.⁴⁶⁸
- (1096) The Notifying Party also claims that their internal documents demonstrate that all competitors are considered as potentially close and that there is nothing suggesting that the Parties' products would be viewed by surgeons as the closest alternative to one another.⁴⁶⁹
- (1097) Furthermore, the Notifying Party notes that surgeons are able to operate on any implant once they have undergone basic training on standard elbow anatomy, physiology and pathology. The Notifying Party does not believe that most surgeons are trained to implant Zimmer's elbows and concludes that the fact that Zimmer offers some training for elbow procedures sheds little light on whether Zimmer and Biomet are closest competitors.⁴⁷⁰

The Commission's Assessment

- (1098) The Commission considers that there are a number of elements suggesting that the Parties are close competitors in the market for elbow implants.
- (1099) Contrary to what the Notifying Party submits,⁴⁷¹ the Commission is not required, for the purposes of finding non-coordinated effects to show that the merging parties are each other's closest competitors on the relevant markets. The Horizontal Merger Guidelines refer to merging firms being "close competitors" as opposed to being each other's closest competitors, as submitted by the Notifying Party.⁴⁷²
- (1100) It is undisputed that the Parties are the two market leaders in elbow implants in all Group 1 national markets and as described in recital (1102) below compete strongly against each other. The third competitor Tornier is much further apart in terms of market presence. In particular, the Parties manufacture, not merely semi-constrained elbow implants, but the number one and number two semi-constrained elbow systems in the EEA, which are both cemented and compete directly against each other's. This is illustrated by significant shifts in the Parties' market shares over the 2011-2013 period.

⁴⁶⁸ Response to the Article 6(1)(c) Decision, paragraphs 724-726.

⁴⁶⁹ Response to the Article 6(1)(c) Decision, paragraphs 727-734.

⁴⁷⁰ Response to the Article 6(1)(c) Decision, paragraphs 735-739.

⁴⁷¹ Response to the Article 6(1)(c) Decision, paragraphs 735-739.

⁴⁷² Horizontal Merger Guidelines, heading for paragraphs 28 to 30.

- (1101) More specifically, over the 2011-2013 period, in Austria Zimmer's position shifted from [50-60]% in 2011, to [40-50]% in 2012, to [50-60]% in 2013, while Biomet's position shifted from [40-50]% in 2011, to [40-50]% in 2012, to [40-50]% in 2013. Despite such fluctuations, the Parties' combined market share remained stable at approximately [90-100]%, which suggest that the Parties are losing sales against each other while maintaining their joint market share. The same phenomenon is observed in the Czech Republic, Denmark, France, Norway, Portugal and Spain. Given that the Parties compete in principle with their respective best-selling elbow product, Zimmer with Coonrad/Morrey Elbow and Biomet with Discovery, as it is demonstrated in the country-by-country competitive assessment in sections 8.7.5 to 8.7.5.12 below, such shifts in the Parties' market shares without losing any sales to third competitors evidence a high degree of substitutability between the Parties' products, and therefore the fact that the Parties are close competitors.
- (1102) Numerous internal documents suggest that the Parties monitor each other closely and confirm that the Parties consider each other as close competitors.
- (1103) Already from 2008-2009 Biomet recognised that Zimmer had the first position in the market for elbows with Coonrad/Morrey and GSB III. [...]*.⁴⁷³
- (1104) Furthermore, in its EMEA Extremities business plan 2013-2017,⁴⁷⁴ Zimmer assesses the status and strategy of its competitors. In relation to elbows, Zimmer states that Biomet is "*[a]ggressively winning market share in Elbow market [...]**". No other competitor poses a threat to Zimmer according to its 2013-2017 business plan:

Figure 24: [...]*

- (1105) In its Quarterly Business Review dated 16 October 2012,⁴⁷⁵ Zimmer provides a competitive update, mentioning Biomet as "*aggressively target[ing] the [...]* elbow system in an attempt to win market share in Elbow market*". No other competitor is mentioned as a threat to Zimmer's elbow implants.
- (1106) More recently, in its 2013 EMEA Strategic Plan Meeting,⁴⁷⁶ Zimmer considers only Biomet as a "*[v]ery strong competitor overall*" in relation to extremities. This is also confirmed by the October 2013 Quarterly Business Review prepared by the extremities business unit where Zimmer states that "*Biomet [...] continues to be [...]**".⁴⁷⁷ In the executive summary of the July 2013 Quarterly Business Review prepared by the extremities business unit, Zimmer states that "*Biomet [...]* Still Work To Be Done*".⁴⁷⁸ In the same report, as well as in the April 2013 Quarterly Business Review prepared by the extremities

⁴⁷³ Biomet internal docs - BIO-0333, slide 6.

⁴⁷⁴ Response to RFI - Internal documents - 20.10.2014 - ID 152 - 001 EMEA Extremities Business Plan 2013-2017 LOW, page 41.

⁴⁷⁵ Response to RFI14 - Internal documents production - ID 036 - DOC 5 101612 Extremities QBR, page 18.

⁴⁷⁶ Response to RFI14 - Internal documents production - ID 235 - 2014-2018 EMEA Strat Plan, slide 25.

⁴⁷⁷ Response to RFI14 - Internal documents production - ID 033 - DOC 4 101513 EXTREMITIES QBRs, slide 15.

⁴⁷⁸ Response to RFI14 - Internal documents production - ID 019 - DOC 2 071813 Extremities QBR QTR2, slide 2.

business unit, it is clearly mentioned that Biomet is "[c]ontinuing to grow significantly in Extremities and is currently [...] competitor".⁴⁷⁹

- (1107) Zimmer in a SWOT analysis of extremities, compares all key competitors in the market concluding that only Zimmer and Biomet are Strong competitors in elbows.⁴⁸⁰ In the same document, Zimmer describes Biomet as "[a]ggressively winning market share in Elbow market [...]". There is no mention of any other competitive threat as far as elbows are concerned.⁴⁸¹
- (1108) The fact that the Parties consider each other as close competitors is also reflected in Biomet's internal documents. In its Business Planning Workbook for the Financial Year 2009, Biomet "[t]arget[s] Zimmer [...]".⁴⁸² Biomet perceives Zimmer as the market leader [...] and places itself in the second position [...] in the third position [...].⁴⁸³
- (1109) Biomet in an internal competitor update report referred to the forthcoming launch of Zimmer's NEXEL Total Elbow Replacement and urged the team "to be proactive in protecting the Discovery Elbow business [...]". The report compares the technology and features of Nexel with those of Discovery, pointing out that both have a posterior assembly mechanism designed to enable humeral and ulna components to be cemented separately. Also, they both use flexible reamers.⁴⁸⁴
- (1110) In a Business Development Meeting dated 27 February [2014], Biomet compares its [...] to Zimmer's [...], stating that "Zimmer is coming soon with a new elbow with posterior fixation".⁴⁸⁵ This is also confirmed in the Fiscal Year 2015 Business Plan, where Biomet refers to [...] elbow. The presentation mentions the market shares of Zimmer ([40-50]%) and Tornier ([10-20]%), placing itself in the position number two following Zimmer with 2013 market share of [30-40]%.⁴⁸⁶
- (1111) The direct comparison of Biomet's Discovery and Zimmer's C/M System is also confirmed in Biomet's Global Quarterly Market Review. According to Biomet "Coonrad-Morrey has dominated this market in Europe with an estimated [60-70]% market share. We have started to tackle this with Discovery [...]".⁴⁸⁷
- (1112) In its Sales Guide, Biomet compares its Discovery elbow system to the products of its competitors. Biomet considers Zimmer and [...] as its competitors. Throughout the presentation Zimmer's Coonrad/Morrey is compared side by side with Biomet's Discovery.⁴⁸⁸

⁴⁷⁹ Response to RFI14 - Internal documents production - ID 019 - DOC 2 071813 Extremities QBR QTR2, slide 15, and Response to RFI14 - Internal documents production - ID 034 - DOC 5 041613 Extremities QBR QTR1, slide 14.

⁴⁸⁰ Response to RFI14 - Internal documents production - ID 153 - SWOTs Extremities, page 5.

⁴⁸¹ Response to RFI14 - Internal documents production - ID 153 - SWOTs Extremities, page 7.

⁴⁸² RFI 03 (Market Access Documents) - list - BPW FY09 UK, slide 63.

⁴⁸³ Biomet internal docs - BIO-0333, slide 6.

⁴⁸⁴ Biomet internal docs - BIO-0346.

⁴⁸⁵ Biomet's response to RFI of 28/10/2014 - Q27 - ListUSB - BIOE-10071801, page 1.

⁴⁸⁶ Biomet's response to RFI of 28/10/2014 - Q27 - ListUSB - BIOE-00000768, page 5.

⁴⁸⁷ M.7265/ID1868/M.7265 - Zimmer-Biomet - Commission Request of Oct 6 (Q14) - Biomet Docs.zip/Extremities, slide 28.

⁴⁸⁸ Biomet internal docs - BIO-0330.

- (1113) In its Sales Guide dated April 2014, Biomet mentions only [...] and Zimmer's Coonrad/Morrey and Nexel as the competitors of its Discovery elbow system.⁴⁸⁹
- (1114) Secondly, as described in recital (1172), historically, elbow implants developed from completely constrained to semi-constrained. Against this background, the Parties decided to rationalise⁴⁹⁰ their elbow portfolios and to focus their marketing efforts to their [...] semi-constrained products, namely Zimmer's Coonrad/Morrey Elbow and Biomet's Discovery. These two products have been for many years number one and number two in the market for elbow implants. In addition [...].⁴⁹¹
- (1115) In the commercialisation plan of [...], Biomet puts among its strategic goals to "[b]e better positioned with an updated total elbow to fend off the new Zimmer [...]*". Biomet recognises that "[t]he "new" Zimmer [...]* has been rumored to be launching for some time and will continue to be the biggest threat to the [...]*". Biomet perceives the competitive landscape as "small with Zimmer ([60-70]*%) and Tornier ([5-10]*-[10-20]*%) as the only competition". In the same document, Biomet compares [...] with Zimmer's [...] as well as [...]. Furthermore, in relation to Zimmer's [...], Biomet recognises that "[i]t is going to be a challenge to compete with due to the large market share and design updates".⁴⁹²
- (1116) The fact that Zimmer and Biomet are close competitors is also confirmed by the market investigation. The Commission conducted conference calls with key competitors and customers of the Parties. Accordingly, Implantcast⁴⁹³ and Lima⁴⁹⁴ as competitors, and NHS Commercial Procurement Collaborative were of the opinion that the Parties are each other's main competitors with very few credible alternatives.⁴⁹⁵

Conclusion

- (1117) The Commission concludes that in a niche market such as the market for elbow implants, where only one or two alternative suppliers are active, without a plethora of alternative elbow systems, Zimmer and Biomet are indeed close competitors and perceive themselves as such.

8.7.4.3. Customer Switching

The views of the Notifying Party

- (1118) The Notifying Party is of the opinion that hospitals can easily switch between suppliers of elbow implants since all the surgeon needs is the manual with the respective surgical technique and the actual instrument set.⁴⁹⁶

⁴⁸⁹ Biomet internal docs - BIO-0325, page 15.

⁴⁹⁰ Biomet internal docs - BIO-0522, slide 22.

⁴⁹¹ See Annex 6.2 - Pipeline - Biomet - Answer to Question 50 of the RFI dated 14-07-14 and Biomet internal docs - BIO-0522, slide 24.

⁴⁹² Biomet internal docs - BIO-0322, page 1.

⁴⁹³ Non-confidential minutes of the conference call with Implantcast of 9.10.2014.

⁴⁹⁴ Non-confidential minutes of the conference call with Lima of 25.09.2014.

⁴⁹⁵ Non-confidential minutes of the conference call with NHS Commercial Procurement Collaborative of 30.10.2014.

⁴⁹⁶ Response to the Article 6(1)(c) Decision, paragraphs 741-743.

- (1119) The Notifying Party further observes that price considerations play an increasing role in hospitals' purchase decisions. According to the Notifying Party, this evolution appears to place disproportionate emphasis on surgeons' preferences for the choice of implant suppliers. As a result, price-related factors take increasingly precedent over surgeons' preferences.⁴⁹⁷
- (1120) The Notifying Party claims that there will be no loss of competition between the merging parties, and that to the extent that surgeons/hospitals would be reluctant to switch from their existing provider, the merger will not change the competitive landscape on the market.⁴⁹⁸

The Commission's Assessment

- (1121) In the market for elbow implants, characterised by particularly high market shares, limited credible alternatives, and high barriers to entry, hospitals and surgeons do not have strong alternative suppliers to switch to. In a number of Group 1 national markets, the Parties are the only players and currently available alternative suppliers and in most of the remaining Group 1 national markets there is only a marginal presence of another competitor.
- (1122) This is evidenced in the Parties' internal documents.⁴⁹⁹ Biomet for example is not concerned about other competitors in the market for elbow implants and states that [...]*.⁵⁰⁰
- (1123) Furthermore, the market for elbow implants is characterised by very high prices.⁵⁰¹ Accordingly, as it has been indicated by the market investigation, from a supply-side perspective, track record is the criterion that has been ranked by most competitors as the most important or second most important relevant factor for hospitals to switch, to another supplier of elbow implants, not price. In a market characterised by its small size, partly due to the fact that the elbow is a very difficult joint for surgeons to address (see also section 8.7.4.6 below),⁵⁰² surgeons who do not perform elbow prosthesis as part of their standard, everyday practice, would not risk sacrificing quality over price considerations. This is confirmed by Biomet's internal documents. In analysing the product characteristics of Zimmer's Coonrad/Morrey in the Commercialization Plan of its Discovery ONE which is foreseen to be launched in October 2015, Biomet recognises that "*[s]urgeons have been trained with this system and due to lower volumes often don't want to learn a new system so they stay using what they are comfortable with*".⁵⁰³

Conclusion

- (1124) The Commission concludes that in a market with particularly high market shares, with limited credible alternative suppliers, switching is difficult. This is

⁴⁹⁷ Response to the Article 6(1)(c) Decision, paragraphs 744-745.

⁴⁹⁸ Response to the Article 6(1)(c) Decision, paragraph 746.

⁴⁹⁹ See also section 0.

⁵⁰⁰ Biomet internal docs - BIO-0333, slide 6.

⁵⁰¹ According to NHS Wales, this market is a niche market so far but at some point, given the current level of prices, either it will not be offered to patients anymore or volume discounts will have to be considered by suppliers (Non-confidential minutes of the conference call with NHS Wales of 29.10.2014). This is also confirmed by NHS Commercial Procurement Collaborative (Non-confidential minutes of the conference call with NHS Commercial Procurement Collaborative of 30.10.2014).

⁵⁰² Non-confidential minutes of the conference call with Exactech of 10.10.2014.

⁵⁰³ Biomet internal docs - BIO-0322, page 1.

exacerbated by the fact that switching in relation to elbow implants would require new training for surgeons.

8.7.4.4. Elimination of an important competitive force

The views of the Notifying Party

- (1125) The Notifying Party claims that the merger would not eliminate an important competitive force and stresses the existence of elbow pipeline products.⁵⁰⁴
- (1126) Furthermore, the Notifying Party believes that since the market for elbow implants is less mature, this makes it easier for all players in the markets to develop new or innovative products. The Notifying Party is of the opinion that innovation in this market comes from smaller players which have a better capacity in observing the market developments and are faster in taking initiatives and adopting their production.⁵⁰⁵
- (1127) The Notifying Party also claims that customers would benefit from a wider variety of elbow implants post-merger as Aesculap and Lima indicated that they would enter the market.⁵⁰⁶

The Commission's Assessment

- (1128) The Parties are the two leading competitors in elbow implants. They are both very strong and currently are each other's competitive constraint. The lack of variety in elbow implants is also highlighted by an industry association report covering France, Germany, Italy and the United Kingdom highlighted "*the growing opportunities due to the lack of effective products for treating specific fracture sites such as [...] elbows [...]. Because [elbow] products are gaining popularity among physicians throughout Europe, companies that are able to develop and launch these devices will be at a competitive advantage over the forecast period*".⁵⁰⁷
- (1129) In addition, the in-depth market investigation provided evidence that many hospitals prefer to multi-source their requirements of elbow implants, the principal reason for this being security of supply.⁵⁰⁸ Multi-sourcing implies that there are at least two alternative suppliers in the market. Some respondents indicated that they consider the absolute minimum number of suppliers in the market to ensure an effective multi-sourcing policy for elbow implants to be three.⁵⁰⁹

Conclusion

- (1130) In light of the arguments set out in this section, the Commission concludes that the merger eliminates one of the major competitors in the market for elbow implants.

⁵⁰⁴ Response to the Article 6(1)(c) Decision, paragraph 748.

⁵⁰⁵ Response to the Article 6(1)(c) Decision, paragraph 749.

⁵⁰⁶ Response to the Article 6(1)(c) Decision, paragraph 751.

⁵⁰⁷ Biomet's response to RFI of 28/10/2014 - Q27 - ListUSB - BIOE-10002165, page 36.

⁵⁰⁸ Responses to Questionnaire Q31 to hospitals, question 69.

⁵⁰⁹ Responses to Questionnaire Q31 to hospitals, question 70.4.

8.7.4.5. Countervailing buyer power

The views of the Notifying Party

- (1131) The Notifying Party claims that if customers can exert some pressure on suppliers of large joints to submit competitive bids, they can certainly apply the same pressure on small joint suppliers.⁵¹⁰

The Commission's Assessment

- (1132) The Commission notes at the outset that in the market for elbow implants, which is characterised by particularly high market shares, limited credible alternatives, and high barriers to entry, the buyer power of hospitals and surgeons is not credible.
- (1133) In addition, contrary to hip and knee implants for which there is more demand, elbows are usually purchased via direct negotiations or at least through regional hospital grouping or purchasing groups because of smaller quantities needed, according to the market investigation. Indicatively, 15 hospitals do not use tenders for the purchase of elbow implants. 10 hospitals obtain their elbow implants requirements through tenders.⁵¹¹
- (1134) As regards buyer aggregation, while this trend has been popular in certain countries such as the United Kingdom and Germany, that is not yet true for the all of the EEA.⁵¹² Therefore, the Commission considers that the trend towards tender-based procurement systems and GPOs is not as generalised as to shield all customers from higher prices or deteriorated competitive terms post-merger. This is confirmed by the Notifying Party's responses to the Commission's request for information dated 14 July 2014. The Parties submit that in Belgium (including Luxembourg) there are no tenders. In Austria, the vast majority of hospital requirements for orthopaedic supplies are procured via direct commercial negotiations with the interested suppliers.⁵¹³
- (1135) As described in section 8.7.4.3, while there has been a shift in the Parties' market shares in the last three years, the Parties' combined market share has remained relatively stable in all Group 1 national countries. This means that post-merger switching to an alternative supplier, other than the combined entity will prove very difficult. During the 2011-2013 period, the Parties as market leaders have been gradually gaining market share from their only credible competitor, Tornier. The exceptions are Germany, Norway, Portugal, and Sweden. However even in these countries Tornier gained a limited market share. In any event, it appears that post-merger there will be only one or two leading competitors supplying elbow implants, and therefore market transparency will be promoted and countervailing buyer power will be weakened.
- (1136) The argument of the Parties that if customers can exert some pressure on suppliers of large joints to submit competitive bids, they can certainly apply the same pressure on elbow suppliers does not stand if customers have only one or two leading alternative choices of suppliers.

⁵¹⁰ Response to the Article 6(1)(c) Decision, paragraph 752.

⁵¹¹ Responses to Questionnaire Q2 to customers, question 29.

⁵¹² Responses to Questionnaire Q31 to hospitals, question 3.

⁵¹³ Responses by the Notifying Party to Commission's request for information of 14.07.2014.

- (1137) Furthermore, it is true that the market for elbow implants is characterised by very high prices. According to NHS Wales, this market is a niche market so far but at some point, given the current level of prices, either it will not be offered to patients anymore or volume discounts will have to be considered by suppliers.⁵¹⁴ This is also confirmed by NHS Commercial Procurement Collaborative.⁵¹⁵ It follows that in a small market where there is not enough competition to drive prices down even if the best-selling products exist for more than thirty years, countervailing buyer power is limited.
- (1138) Finally, contrary to knees, neither the Parties nor the market investigation indicated the existence of "me-too", "copycat" products. In any event, smaller firms have not influenced purchasing patterns at EEA level. This means that purchasers' choices still remain largely bound to the Parties as major suppliers. This would hold true, in the event further buyer power aggregation would take place because larger customers require larger sellers with larger portfolios.

Conclusion

- (1139) In light of the arguments set out in this section, the Commission concludes that buyer power is unlikely to constrain the merged entity's behaviour to offset sufficiently potential adverse effects on competition post-merger.

8.7.4.6. Barriers to entry and expansion

The views of the Notifying Party

- (1140) The Notifying Party claims that there is scope for new products to come to market, and in addition, existing suppliers can expand geographically to neighbouring markets.⁵¹⁶
- (1141) In relation to market entry, the Notifying Party stresses that the market is dynamic, and is bound to evolve in years to come. The Notifying Party provides the examples of Aesculap and Lima who indicated their interest to enter the elbow market.
- (1142) Furthermore, the Notifying Party claims that elbow implants are Class III products, and obtaining a CE mark will not take longer than one to four months, that is, a lot shorter than the anticipated 6-12 months alleged by the Commission.⁵¹⁷
- (1143) The Notifying Party also considers that apart from the requirement to show a track record of successful procedures, customers will take into account also other factors such as price, the track record of the companies in other implants or even the need to support the limited innovation in this industry. The Notifying Party believes that this is the case where hospitals reserve a portion of their budget to acquire innovative products.⁵¹⁸
- (1144) The Notifying Party claims that competitors' responses indicate that a lengthy track record is not required for entering small joints market, such as elbows,

⁵¹⁴ Non-confidential minutes of the conference call with NHS Wales of 29.10.2014.

⁵¹⁵ Non-confidential minutes of the conference call with NHS Commercial Procurement Collaborative of 30.10.2014.

⁵¹⁶ Response to the Article 6(1)(c) Decision, paragraph 753.

⁵¹⁷ Response to the Article 6(1)(c) Decision, paragraph 755.

⁵¹⁸ Response to the Article 6(1)(c) Decision, paragraph 756.

making the market for elbows more accessible in comparison to the relevant markets for other segments.⁵¹⁹

- (1145) In relation to expansion from a neighbouring country, the Notifying Party is of the opinion that there are fewer barriers than new entry. The Notifying Party claims that engaging sales representatives is a low cost option that is common in the industry and that can be implemented in a matter of months. Reputational issues are circumvented through a partnership with a capable distributor. In addition, track record (registries, clinical studies) can be used across national borders.⁵²⁰
- (1146) Regarding the increased difficulties smaller competitors might be encountering, the Notifying Party submits that these actually are some of the most resilient competitors the Parties are facing. The example of Lima's and Aesculap's future entry supports this according to the Notifying Party.⁵²¹

The Commission's Assessment

- (1147) The Commission notes that the elbow implants market is very concentrated and only a limited number of competitors are present.
- (1148) Lima, a relatively new competitor, recently attempted to establish an international presence in orthopaedic implants.⁵²² Lima plans to market its elbow system by the end of 2015 / beginning of 2016 and aims to achieve 10% market shares by the end of 2020.⁵²³ Despite this, Lima confirmed the difficulties in entering the elbow implants market. According to Exactech, the small size of this market is partly due to the fact that the elbow is a very difficult joint for surgeons to address, and too small a market to be profitable for smaller firms.⁵²⁴
- (1149) First, the difficulty of the elbow implant is also demonstrated by the training strategy of Implantcast. Implantcast states that for easy implants (for example, primary hips), the number of trainings is not high and their duration is usually one day. For more complex implants surgeons are invited in a reference centre where they attend up to 20 surgery procedures. For elbows in particular, the surgeons make a "visitation", that is, they visit others countries, they collect incidents, and then they conduct the surgery.⁵²⁵ According to Lima, "*[t]he market for elbows is a very specific one because not so many surgeons perform this kind of surgery due to its technical nature and therefore training and education is going to be necessary*".⁵²⁶ The Phase I market investigation showed that both semi-constrained and unconstrained elbow surgery procedures are considered from difficult to very difficult surgery. In reply to the investigations, surgeons stated that certain implants require particular experience, "*Anatomical landmarks can be complex on the elbow segment*", "*Elbow surgery is always difficult*" etc.⁵²⁷

⁵¹⁹ Response to the Article 6(1)(c) Decision, paragraph 756.

⁵²⁰ Response to the Article 6(1)(c) Decision, paragraphs 759-760.

⁵²¹ Response to the Article 6(1)(c) Decision, paragraph 761.

⁵²² Non-confidential minutes of the conference call with Lima of 05.08.2014.

⁵²³ Response to the Article 6(1)(c) Decision, paragraph 754.

⁵²⁴ Non-confidential minutes of the conference call with Exactech of 10.10.2014.

⁵²⁵ Non-confidential minutes of the conference call with Implantcast of 09.10.2014.

⁵²⁶ Non-confidential minutes of the conference call with Lima of 25.09. 2014.

⁵²⁷ Responses to Questionnaire Q2 to customers, question 17.

- (1150) Second, the costs that a smaller firm will entail in entering the elbow market are an important factor since the Phase I market investigation indicated that a supplier is not able to produce and market effectively all different types of elbow implants without adjusting significantly its assets, making additional investments or strategic decisions, or incurring in significant time delays. This is supported by four competitors, only one claiming the opposite. A French competitor stated in particular that "*a complete portfolio of elbow implant[s] will need significant investment for a company in term of manufacturing, development and operational*". This is also the opinion of an Italian competitor.⁵²⁸
- (1151) A third point is the requirement of clinical data in the absence of registries covering elbow implants. Lima, which does not currently manufacture elbow implants, claims that it plans to enter this market soon and that it is relatively positive mainly because there are less restrictive requirements to participate in such market, especially towards clinical data.
- (1152) However, as established by the Phase I market investigation, from a supply-side perspective, respondents to the market investigation indicated that quality / track record, innovation, the training of surgeons, the range of the product portfolio, the post-sales and OR support are the main criteria that competitors consider relevant for hospitals to switch suppliers of elbow implants. Price is considered a relevant criterion but by many respondents is not seen as the main deciding factor.⁵²⁹ Track record is the criterion that has been ranked by most competitors as the most important or second most important factor.⁵³⁰
- (1153) This is supported by data gathered by the internal documents of the Parties. Zimmer considers as the main advantage of its Coonrad/Morrey total elbow implant the fact that it carries "19 years of clinical history/success", and of its GSB III elbow system the fact that it carries "21 years of clinical history/success".⁵³¹
- (1154) Zimmer, in its Competitive Selling Guide compares its Coonrad/Morrey Elbow to Biomet's [...] and to [...]. Throughout the guide, Zimmer points out that the key strength of its elbow implant is the fact that it is backed by more than 30 years of clinical history. The guide lists all the [...] clinical studies funded by Zimmer.⁵³²

Figure 25: [...]

- (1155) Fourth, in order for a supplier of elbow implants to enter and establish its position in the EEA, a full product range will be required. In Figure 26 below **Error! Reference source not found.** Zimmer in its Final EU marketing plan,⁵³³ points out the strengths of its elbow implants.

⁵²⁸ Responses to Questionnaire Q1 to competitors, question 70.

⁵²⁹ Responses to Questionnaire Q1 to competitors, question 94.

⁵³⁰ Responses to Questionnaire Q1 to competitors, question 94.

⁵³¹ DOC-000000565.pdf – RFI 03 (Market Access Documents) - list - M.7265 - Annex 1a - ES - Final EU Marketing Plan 2005 v 2, Table 45.

⁵³² Response to RFI14 - Internal documents production - ID 376 - Elbow Sales Aid rev5(UK) Jul14, slide 6.

⁵³³ DOC-000000565.pdf – RFI 03 (Market Access Documents) - list - M.7265 - Annex 1a - ES - Final EU Marketing Plan 2005 v 2, Table 45.

Figure 26: [...]*

- (1156) It appears that one of the most important strengths of its elbow implants as perceived by Zimmer, apart from clinical data and loyalty and respect from the market, is the breadth of its portfolio to be able to provide variety of sizes and combinations for all patients and indications. However, the Commission notes that a full product range is more important for more commoditised products, such as hip and knee implants, where large volumes are negotiated / tendered and therefore more patients need to be covered. For elbow implants the Commission considers that sales force and training capacity are far more important competitive advantages and therefore barriers to entry.
- (1157) The Commission therefore finds that new entry is very difficult in the market for elbow implants and the requirement of clinical data constitutes a very high barrier to entry.
- (1158) An additional reason for high barriers to entry is elbow implants' high revision rates. Given the small size of the elbow market, surgeons are not used to perform elbow prosthesis surgery. According to the director of the orthopaedic department for shoulder and elbow at the Instituto Clinico Humanitas, Professor Castagna, elbow surgery is the less common comparing to all the other joint implants (that is, hip, knee and shoulder).⁵³⁴ The Commission notes that even the market leaders' implants already have high revision rates. Therefore, it would be even more difficult for surgeons to trust (and receive training on) a new entrant with no track record and clinical data where well established players have not yet perfected their elbow implants.
- (1159) Aesculap, a German competitor with worldwide presence that focuses mainly in Europe, sells hips and knees and considers entering the elbow market. However, it considers that "*[i]n order for a manufacturer to enter another product market in which the company is not currently active, two to three years of development are necessary*". Aesculap also underlined there may be Intellectual Property Rights restrictions which prevent the product to be authorised. However, apart from the registration process, Aesculap underlines that training of the product users is also essential and high efforts must be placed on that aspect. Aesculap believes that "*[i]n total for an experienced manufacturer to launch a product in the market it would take about three to five years before realizing sales, if they have access to the necessary patents*".⁵³⁵
- (1160) Responses to the in-depth market investigation indicated one competitor who entered six EEA countries with an elbow implant in 2010.⁵³⁶ The Parties, in cooperation with their regional managers provided in their response to Commission's request for information Q16 examples of customers switching to alternative suppliers of orthopaedic implants. However no switching event was provided in relation to elbow implants.⁵³⁷

⁵³⁴ Non-confidential minutes of the conference call with Professor Alessandro Castagna of Instituto Clinico Humanitas of 10.07.2014.

⁵³⁵ Non-confidential minutes of the conference call with Aesculap of 14.08.2014.

⁵³⁶ Responses to Questionnaire Q30 on entry and innovation.

⁵³⁷ Responses to request for information Q16 – switching events, dated 08.10.2014.

Conclusion

(1161) On this basis, the Commission concludes that buyer power is unlikely to constrain the merged entity's behaviour sufficiently to offset potential adverse effects on competition post-merger.

8.7.5. Country-specific Competitive Assessment

(1162) At national level, on the basis of the market share estimates submitted by the Parties, the merger would give rise to 12 Group 1 national markets: Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, France, Germany, Italy, Norway, Portugal, Spain, Sweden and the United Kingdom. The Parties have combined market shares in these markets ranging from approximately [60-70]*% (in Germany) to [90-100]*% (in the United Kingdom) and merger increments ranging between approximately [0-5]*% (in Portugal) and [30-40]*% (in Austria).

Table 67: Elbow implants – Group 1 markets – Market shares by value, 2013

]*	Zimmer	Biomet	Combined	Market size (EUR million) ⁵³⁸	Competitors
<i>AT</i>	[50-60]*%	[30-40]*%	[80-90]*%	[less than 1]*	Stryker ([10-20]*%), Link ([5-10]*%)
<i>BE</i>	[70-80]*%	[10-20]*%	[90-100]*%	[less than 1]*	Tornier ([10-20]*%)
<i>CZ</i>	[30-40]*%	[60-70]*%	[90-100]*%	[less than 1]*	Stryker ([20-30]*%), J&J/DePuy ([10-20]*%), Link ([10-20]*%)
<i>DK</i>	[50-60]*%	[20-30]*%	[70-80]*%	[less than 1]*	Stryker ([10-20]*%), Link ([10-20]*%)
<i>FR</i>	[60-70]*%	[10-20]*%	[70-80]*%	[less than 1]*	Tornier ([10-20]*%), Stryker ([5-10]*%)
<i>DE</i>	[30-40]*%	[20-30]*%	[50-60]*%	[1-50]*	Stryker ([20-30]*%), Link ([10-20]*%)
<i>IT</i>	[40-50]*%	[20-30]*%	[70-80]*%	[less than 1]*	Tornier ([20-30]*%), Link ([5-10]*%)
<i>NO</i>	[5-10]*%	[70-80]*%	[80-90]*%	[less than 1]*	Stryker ([10-20]*%), Link ([10-20]*%)
<i>PT</i>	[0-5]*%	[80-90]*%	[80-90]*%	[less than 1]*	Stryker ([10-20]*%), Link ([10-20]*%)
<i>ES</i>	[60-70]*%	[10-20]*%	[70-80]*%	[less than 1]*	Stryker ([10-20]*%), Link ([10-20]*%)
<i>SE</i>	[30-40]*%	[30-40]*%	[60-70]*%	[less than 1]*	Stryker ([20-30]*%), Link ([10-20]*%)]*

⁵³⁸

Form CO, (estimates of the Parties).

UK	[50-60]*%	[30-40]*%	[90-100]*%	[1-50]*	Tornier ([10-20]*%)
EEA	[40-50]*%	[30-40]*%	[70-80]*%	[1-50]*	Tornier ([10-20]*%), Stryker ([5-10]*%), Link ([5-10]*%)

Source: Form CO

- (1163) In each of the Group 1 national markets, the merged entity will be the number one player, with a significantly larger market share than the next market player.
- (1164) The Notifying Party submits that a multiple strong competitors exist post-merger, including Link, Stryker and Tornier each of which have a total elbow replacement market share of [5-10]*-[10-20]*% in various EEA countries. The Notifying Party states that Stryker and Link are present in many EEA countries and Tornier is also a significant competitor in Austria, Belgium (including Luxembourg), France, Italy, the Netherlands and the United Kingdom. According to the Notifying Party, these competitors collectively have the scale and EEA-wide presence to be considered as viable alternative suppliers to the Parties.⁵³⁹
- (1165) Whereas the Notifying Party attributes to Stryker from [5-10]*% (in France) to [20-30]*% (in Germany) in 9 out of the 12 Group 1 national markets, and to Link from [5-10]*% (in Italy) to [10-20]*% (in Germany and Spain) in 9 out of the 12 Group 1 national markets, the Commission's targeted market reconstruction confirmed that Stryker and Link have a marginal/very limited presence in elbow implants in all EEA countries and cannot be considered as credible competitors.

8.7.5.1. Austria

Structure of the market

- (1166) According to the Notifying Party, in Austria the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1167) Over the 2011-2013 period Zimmer's position decreased from [50-60]*% to [50-60]*%, while Biomet's position decreased from [30-40]*% to [30-40]*%, according to the data provided by the Parties.

⁵³⁹ Form CO, paragraph 681(a).

Table 68: Shares of value for elbow implants in Austria

Suppliers	2011	2012	2013
Zimmer	[50-60]*%	[40-50]*%	[50-60]*%
Biomet	[30-40]*%	[40-50]*%	[30-40]*%
<i>Merged Entity</i>	<i>[90-100]*%</i>	<i>[80-90]*%</i>	<i>[80-90]*%</i>
Stryker	[10-20]*%	[10-20]*%	[10-20]*%
Link	[5-10]*%	[5-10]*%	[5-10]*%
Tornier	[0-5]*%	[0-5]*%	[0-5]*%
Other players	-	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1168) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5%, namely Stryker ([10-20]*%) and Link ([5-10]*%), which will be significantly weaker in terms of market share compared to the merged entity. Zimmer and Biomet are number one and number two in Austria and the merger will reinforce this position creating a gap of [60-70]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1169) The Parties claim that procurement of elbow implants in Austria is carried out primarily by regional purchasing federations which negotiate for all hospitals within the county. Exceptionally, individual hospitals negotiate directly with suppliers. Negotiations with procuring groups usually take place once a year. According to the Parties, hospitals in Austria are largely financed through the Austrian DRG system and the cost of elbow implants is included in the general cost of surgery, rather than reimbursed separately. This gives the hospitals a strong incentive to reduce the cost of implants, because doing so increases hospitals margin at surgery level.
- (1170) In addition, the Parties claim that the buyer side in Austria is significantly consolidated given the purchasing model based on regional hospital grouping. The strong buyer side exerts considerable buyer power on the suppliers by negotiating in parallel in several suppliers and playing them against each other with the assistance of consulting companies. Especially in Austria, hospitals and surgeons are keen on ensuring a dual-sourcing strategy, in order to be able to negotiate for price and to prevent any back-orders (supply shortages).⁵⁴⁰
- (1171) The Parties put forward the entry of Tornier in 2008 as an example of low barriers to entry to the Austrian elbow market.⁵⁴¹

⁵⁴⁰ Response to the Article 6(1)(c) Decision, paragraph 767.

⁵⁴¹ Response to the Article 6(1)(c) Decision, paragraph 768.

The Commission's Assessment

- (1172) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Austria. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 69: Parties' shares of value for elbow implants in Austria

Suppliers	2009	2010	2011	2012	2013
Zimmer	[40-50%]	[50-60%]	[50-60%]	[40-50%]	[50-60%]
Biomet	[50-60%]	[40-50%]	[40-50%]	[40-50%]	[40-50%]
<i>Merged Entity</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

- (1173) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Austria. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1174) The merger would lead to a 3-to-2 merger, as the Notifying Party seems to have overestimated the market share of the remaining competitors.
- (1175) In Austria, Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [90-100]*% of the total sales of elbow implants in Austria.
- (1176) As mentioned in section 8.7.4.2 above, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow, followed by Tornier's Latitude. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Austria and would lead to a situation where there is only one player, Tornier, would be present in the market, however, as the target market reconstruction demonstrated, unable to effectively constrain the merged entity.
- (1177) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Austria are predominantly sales of semi-constrained elbow implants.
- (1178) As shown in section 8.7.4.3, switching in elbows is difficult. Specifically in Austria, none of the five hospitals that responded to the market investigation recently switched suppliers in elbows.⁵⁴² With the exception of one hospital that uses Biomet elbow implants, they all use Zimmer as their main supplier of elbow implants.⁵⁴³ One respondent keeps Biomet as a back-up option and another respondent uses Tornier as a back-up option, for elbow implants.⁵⁴⁴

⁵⁴² Responses to Questionnaire Q31-Questionnaire to hospitals, question 63.

⁵⁴³ Responses to Questionnaire Q31-Questionnaire to hospitals, question 60.

⁵⁴⁴ Responses to Questionnaire Q31 to hospitals, questions 69 70.

However, the latter uses Tornier only in one in ten elbow surgery procedures.⁵⁴⁵

- (1179) As shown in section 8.7.4.6, barriers to entry in the elbow market are high due to different factors such as obtaining the necessary regulatory approvals, the importance of proving clinical data for any orthopaedic implant brought to the market, difficulties to convince surgeons to try new products etc. In Austria, no competitor in the in-depth market investigation indicated to have entered the elbow implants market in the last eight years.⁵⁴⁶
- (1180) Contrary to what the Notifying Party claims on the procurement of elbow implants, Zimmer's regional manager stated that extremities like elbows are still purchased through direct negotiations in all 11 Austrian counties. The Notifying Party itself submits in its response to the Commission's request for information dated 14 July 2014 that in Austria, the vast majority of hospital requirements for orthopaedic supplies are procured via direct commercial negotiations with the interested suppliers. The Notifying Party states that although in the next 2-3 years all Austrian counties will be expected to adopt a tender procedure for hip and knee implants, "*[c]ontracts for the supply of extremities implants are currently awarded only by means of direct negotiations*".⁵⁴⁷ Indeed, the tender samples which are provided in Annex 3 to the Notifying Party's response, and which the Notifying Party claims to be representative, concern only hip and knee prostheses.
- (1181) This is also confirmed by Wiener Krankenanstaltenverbund (KAV) which purchases elbow implants through direct negotiations.⁵⁴⁸ This evidence contradicts the argument of the Parties that only exceptionally individual hospitals negotiate directly with suppliers as far as elbow implants are concerned and that the buyer side in Austria is significantly consolidated given the purchasing model based on regional hospital grouping leading to strong buyer power.
- (1182) Contrary to the Parties' reference of Tornier as an indication of barriers to entry to the Austrian elbow market being low, the targeted market reconstruction demonstrates that Tornier's elbow implant achieves marginal sales and that Tornier is not able to exert a competitive constraint on the Parties' elbow implants. This holds true from 2010 onwards.
- (1183) Regarding barriers to entry to the Austrian elbow market, one respondent to the in-depth market investigation stressed the importance of Zimmer's Coonrad/Morrey's long follow up studies in the literature and highest survival rate. This is in line with the Parties' internal documents where Biomet, analysing the product characteristics of Zimmer's [...] in the Commercialization Plan of its [...] which is foreseen to be launched in [...], recognises that "[s]urgeons have been trained with this system and due to lower volumes often don't want to learn a new system so they stay using what they are comfortable with".⁵⁴⁹

⁵⁴⁵ Responses to Questionnaire Q31 to hospitals, questions 70.

⁵⁴⁶ Responses to Questionnaire Q30 on entry and innovation.

⁵⁴⁷ Response by the Notifying Party to Commission's request for information of 14.07. 2014, pages 45-46.

⁵⁴⁸ Non-confidential translation from German of the response to the questions sent on 07.08.2014 to KAV – Wiener Krankenanstaltenverbund.

⁵⁴⁹ Biomet internal docs - BIO-0322, page 1.

Conclusion

- (1184) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Austria, through the creation or strengthening of a dominant position.

8.7.5.2. Belgium (including Luxembourg)

Structure of the market

- (1185) According to the Notifying Party in Belgium (including Luxembourg) the value of the market for elbow implants amounted to EUR [les than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1186) Over the 2011-2013 period, Zimmer's position slightly decreased from [70-80]*% to [70-80]*%, while Biomet's position increased from [5-10]*% to [10-20]*%, according to the data provided by the Parties.

Table 70: Shares of value for elbow implants in Belgium (including Luxembourg)

Suppliers	2011	2012	2013
Zimmer	[70-80]*%	[70-80]*%	[70-80]*%
Biomet	[5-10]*%	[10-20]*%	[10-20]*%
<i>Merged Entity</i>	<i>[80-90]*%</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>
Tornier	[10-20]*%	[10-20]*%	[10-20]*%
Other players	[5-10]*%	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1187) Based on data provided by the Notifying Party, post-merger, there will be only one other competitor, Tornier ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Zimmer and Biomet are number one and number two in Belgium (including Luxembourg) and the merger will reinforce this position creating a gap of [80-90]*% between the merged entity and Tornier.

The views of the Notifying Party

- (1188) The Notifying Party argue that hospitals in Belgium (including Luxembourg) purchase elbow implants via direct negotiations with suppliers. However, due to pressure from the Belgian government and insurance companies to limit healthcare spending, hospitals are expected to adopt tender procedures in the near future. Orthopaedic implants, including elbow implants, are reimbursed in accordance with a fixed tariff. Hospitals typically do not negotiate prices with suppliers of medical devices, thus the price competition is very limited. On the other hand, competitors in the Belgian market fiercely negotiate at the level of

additional services, such as OR support. Yet, due to the price regulation the Parties will not be able to raise prices post-merger.⁵⁵⁰

The Commission's Assessment

- (1189) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Belgium (including Luxembourg). Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 71: Parties' shares of value for elbow implants in Belgium (including Luxembourg)

Suppliers	2009	2010	2011	2012	2013
Zimmer	[50-60%]	[70-80%]	[70-80%]	[70-80%]	[70-80%]
Biomet	[20-30%]	[10-20%]	[5-10%]	[10-20%]	[10-20%]
<i>Merged Entity</i>	<i>[80-90%]</i>	<i>[80-90%]</i>	<i>[80-90%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

- (1190) The merger would lead to a 3-to-2 merger, however with Tornier lagging far behind the merged entity, as the targeted market reconstruction confirmed.
- (1191) In Belgium (including Luxembourg), Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [90-100]*%, while iBP represents [0-5]*% of its total sales of elbow implants in Belgium (including Luxembourg).
- (1192) As mentioned above in section 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow, followed by Tornier's Latitude. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Belgium (including Luxembourg) and would lead to a situation where there is only one player, Tornier, would be present in the market. However, as the targeted market reconstruction demonstrated, Tornier has only a limited share of this market. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Tornier would not be in a position to effectively constrain the merged entity.
- (1193) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Belgium (including Luxembourg) are predominantly sales of semi-constrained elbow implants.
- (1194) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1195) As shown in section 8.7.4.6, barriers to entry in the elbow market are high due to different factors such as obtaining the necessary regulatory approvals, the importance of proving clinical data for any orthopaedic implant brought to the market, difficulties to convince surgeons to try new products etc. In Belgium (including Luxembourg), no competitor in the in-depth market investigation

⁵⁵⁰ Response to the Article 6(1)(c) Decision, paragraph 773.

indicated to have entered the elbow implants market during the last eight years.⁵⁵¹

- (1196) According to the Notifying Party in its Response to the Article 6(1)(c) Decision as well as to Commission's request for information dated 14 July 2014, in Belgium (including Luxembourg) there are no tenders and hospitals purchase elbow implants via direct negotiations with suppliers.

Conclusion

- (1197) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Belgium (including Luxembourg), through the creation or strengthening of a dominant position.

8.7.5.3. Czech Republic

Structure of the market

- (1198) According to the Notifying Party, in the Czech Republic the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1199) Over the 2012-2013 period Zimmer's position increased from [10-20]*% to [30-40]*%, while Biomet's position increased from [50-60]*% to [60-70]*%, according to the data provided by the Parties.

Table 72: Shares of value for elbow implants in the Czech Republic

Suppliers	2011	2012	2013
Zimmer	[50-60]*%	[10-20]*%	[30-40]*%
Biomet	[70-80]*%	[50-60]*%	[60-70]*%
Merged Entity	[90-100]*%	[60-70]*%	[90-100]*%
Stryker	[10-20]*%	[20-30]*%	[20-30]*%
J&J/DePuy	[5-10]*%	[10-20]*%	[10-20]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	-	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1200) Based on data provided by the Notifying Party, post-merger, there will be three other competitors with market shares over 5%, namely Stryker ([20-30]*%), J&J/DePuy ([10-20]*%) and Link ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Zimmer and

⁵⁵¹ Responses to Questionnaire Q30 on entry and innovation.

Biomet are number one and number two in the Czech Republic and the merger will reinforce this position creating a gap of [70-80]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1201) In the Czech Republic, elbow implants are typically procured by means of direct negotiations, separately from other implants. Czech hospitals are reimbursed in accordance with a list called "Ciselnik VZP" and receive the amount specified in the list regardless of the price negotiated with the supplier. There is therefore a strong incentive for hospitals to negotiate lower prices. In addition, the consolidation of the buyer side in the Czech Republic is increasing and currently, the largest purchasing group accounts for approximately [10-20]*% of Zimmer's sales. Furthermore, the role of surgeon's preference in the implant selection is declining and hospital administrations have become more influential in purchasing decisions. These trends have been affecting prices for orthopaedic implants and were recognised in Zimmer's internal documents as a threat: "Threats: Change of decision makers - from surgeons to managements Price pressure Healthcare budget constrain(t)s Decreasing surgeon power".⁵⁵²
- (1202) Accordingly, surgeons in the Czech Republic are likely to switch elbow implants suppliers as evidenced by the significant decrease in Zimmer's market share from [50-60]*% to [30-40]*% over the past two years.⁵⁵³
- (1203) The ease of entry and expansion into the Czech market is evidenced by the entry of Link in 2004, J&J/DePuy in 2008 and Biomet in as recent as 2010. These examples show that entry into the market is not only feasible, but that it actually occurs in reality. As mentioned above in recital (1202), Zimmer lost market shares to both Stryker and J&J/DePuy, illustrating that new entrants can have a significant impact on competition in the market.⁵⁵⁴

The Commission's Assessment

- (1204) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in the Czech Republic. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

⁵⁵² Response to the Article 6(1)(c) Decision, paragraph 777.

⁵⁵³ Response to the Article 6(1)(c) Decision, paragraph 778.

⁵⁵⁴ Response to the Article 6(1)(c) Decision, paragraph 779.

Table 73: Parties' shares of value for elbow implants in the Czech Republic

Suppliers	2009	2010	2011	2012	2013
Zimmer	[90-100%]	[10-20%]	[40-50%]	[20-30%]	[30-40%]
Biomet	[5-10%]	[80-90%]	[50-60%]	[70-80%]	[60-70%]
<i>Merged Entity</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

- (1205) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in the Czech Republic. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013. In addition, J&J/DePuy confirmed that it is not present in the EEA as regards elbow implants.⁵⁵⁵
- (1206) The merger would effectively lead to a monopoly in the Czech Republic.
- (1207) In the Czech Republic the parties compete with their best-selling products. Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in the Czech Republic.
- (1208) As mentioned above in section 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in the Czech Republic and would lead to a situation where no other player able to effectively constrain the merged entity would be present in the market.
- (1209) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in the Czech Republic are predominantly sales of semi-constrained elbow implants.
- (1210) As shown in section 8.7.4.3, switching in elbows is difficult. Furthermore, as the targeted market investigation indicated, there is no other credible supplier in the elbow market in the Czech Republic for customers to switch to.
- (1211) As shown in section 8.7.4.6, barriers to entry in the elbow market are high due to different factors such as obtaining the necessary regulatory approvals, the importance of proving clinical data for any orthopaedic implant brought to the market, difficulties to convince surgeons to try new products etc. In the Czech Republic, no competitor in the in-depth market investigation indicated to have entered the elbow implants market during the last eight years.⁵⁵⁶
- (1212) As submitted by the Parties, elbow implants in the Czech Republic are typically procured by means of direct negotiations, separately from other implants.

⁵⁵⁵ Responses to Questionnaire Q1 to competitors, question 4.4.

⁵⁵⁶ Responses to Questionnaire Q30 on entry and innovation.

Conclusion

- (1213) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in the Czech Republic, through the creation or strengthening of a dominant position.

8.7.5.4. Denmark

Structure of the market

- (1214) According to the Notifying Party, in Denmark the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1215) Over the 2011-2013 period Zimmer's position decreased from [60-70]*% to [50-60]*%, while Biomet's position increased from [10-20]*% to [20-30]*%, according to the data provided by the Parties.

Table 74: Shares of value for elbow implants in Denmark

Suppliers	2011	2012	2013
Zimmer	[60-70]*%	[50-60]*%	[50-60]*%
Biomet	[10-20]*%	[10-20]*%	[20-30]*%
<i>Merged Entity</i>	<i>[70-80]*%</i>	<i>[70-80]*%</i>	<i>[70-80]*%</i>
Stryker	[10-20]*%	[10-20]*%	[10-20]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	-	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1216) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5%, namely Stryker ([10-20]*%) and Link ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Zimmer and Biomet are number one and number two in Denmark and the merger will reinforce this position creating a gap of [60-70]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1217) Even though over 80% of total sales of orthopaedic products on the Danish market are achieved through tendering, the purchase of elbows forms an exception thereto. In particular, elbows have been recently increasingly excluded from tender procedures due to the low volume of sales. However, given the specificities of the Danish national market, this deviation could be interpreted as leaving more possibilities for customers to shift suppliers more

easily, to the extent that hospitals would be less bound by contracts of standard duration and specific requirements.⁵⁵⁷

- (1218) The dynamic nature of the market and intense competition is well illustrated by significant shifts in the parties' market shares.

The Commission's Assessment

- (1219) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Denmark. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 75: Parties' shares of value for elbow implants in Denmark

Suppliers	2009	2010	2011	2012	2013
Zimmer	[70-80%]	[80-90%]	[60-70%]	[60-70%]	[50-60%]
Biomet	[10-20%]	[10-20%]	[20-30%]	[20-30%]	[30-40%]
Merged Entity	[90-100%]	[90-100%]	[80-90%]	[80-90%]	[80-90%]

Source: Commission's targeted market reconstruction

- (1220) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Denmark. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1221) The targeted market reconstruction demonstrated a different competitive landscape than the one submitted by the Notifying Party. There would be only one competitor left post-merger with market shares significantly lower than the merged entity. The merger would lead to a 3-to-2 merger.
- (1222) In Denmark the parties compete with their best-selling products. Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in Denmark.
- (1223) As mentioned above in section 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Denmark.
- (1224) In relation to the shift in the parties' market shares as an indication of intense competition in the market for elbow implants, the Commission notes that according to the targeted market reconstruction, the Parties' market shares remained stable over the 2011-2013 period. This confirms the fact that the Parties' best-selling products compete aggressively against each other's, as seen in section 8.7.4 above. Eliminating the biggest competitor of Zimmer in the Danish elbow market, leaving only one competitor in the market who is lagging behind, would negate any dynamic nature of the market and sense of competition in an already concentrated market.

⁵⁵⁷ Response to the Article 6(1)(c) Decision, paragraph 789.

- (1225) The Danish market for orthopaedic implants in general and for elbow implants in specific, is a conservative market, as the case is for all the Nordic countries (Denmark, Iceland, Norway, Sweden, and Finland to a less extent).⁵⁵⁸ According to Bispebjerg Hospital, this type of conservatism is aimed at guaranteeing higher care for patients. In Denmark, doctors have to go through a great deal of evidence to conclude that an implant is of high quality.⁵⁵⁹
- (1226) According to Bispebjerg Hospital, for a completely new product, the minimum scientific evidence accepted in Denmark is the RSA studies, which in any event last two to three years, and are very expensive. That said, preference would however go to the products with the highest level of evidence.
- (1227) Although there is no national registry covering elbow implants, evidence-based medicine (track records and scientific evidence) also apply to elbows. For this reason Bispebjerg Hospital does is of the opinion that copycat products do not constitute a viable alternative in Denmark. Such implants aim to prove that they are exactly the same as the original ones, but in fact do not have their own clinical results. Evidence-based medicine is one of the reasons why small companies are not successful in Denmark. For those companies, it is more difficult to enter the Danish market, because they need to provide the surgeons with hard science. Large companies may do this more easily.
- (1228) The Commission therefore considers that barriers to entry to the Danish market for elbow implants are particularly high. A new supplier will incur significant delays of two to three years minimum and will compete primarily on quality which needs to be backed up by expensive clinical studies. This explains why Zimmer considers as its main strength of its elbow implants the fact that it is backed by more than 30 years of clinical history.⁵⁶⁰ Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.
- (1229) Furthermore, as submitted by the Notifying Party, elbow implants in Denmark are procured by means of direct negotiations, separately from other implants due to the low volume of sales.
- (1230) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1231) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Denmark are predominantly sales of semi-constrained elbow implants.

Conclusion

- (1232) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Denmark, through the creation or strengthening of a dominant position.

⁵⁵⁸ See also paragraphs (1350)-(1357).

⁵⁵⁹ Non-confidential minutes of the conference call with Bispebjerg Hospital of 31.10.2014, paragraph 13.

⁵⁶⁰ Response to RFI14 - Internal documents production - ID 376 - Elbow Sales Aid rev5(UK) Jul14, slide 6.

8.7.5.5. France

Structure of the market

- (1233) According to the Notifying Party, in France the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1234) Over the 2011-2013 period Zimmer's position increased from [50-60]*% to [60-70]*%, while Biomet's position decreased from [10-20]*% to [10-20]*%, according to the data provided by the Parties.

Table 76: Shares of value for elbow implants in France

Suppliers	2011	2012	2013
Zimmer	[50-60]*%	[50-60]*%	[60-70]*%
Biomet	[10-20]*%	[10-20]*%	[10-20]*%
Merged Entity	[70-80]*%	[70-80]*%	[70-80]*%
Tornier	[10-20]*%	[10-20]*%	[10-20]*
Stryker	[5-10]*%	[5-10]*%	[5-10]*%
Other players	[0-5]*%	[0-5]*%	[0-5]*%
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1235) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5% namely Tornier ([10-20]*%) and Stryker ([5-10]*%), which will be significantly weaker in terms of market share, compared to the merged entity. The merged entity will be the clear market leader in the elbow implant market in France creating a gap of [50-60]*% between the merged entity and Tornier.

The views of the Notifying Party

- (1236) Public hospitals in France are obliged to tender their requirements. Private clinics procure elbow implants by means of direct negotiations. The Notifying Party estimates that approximately 57% of the market demand for elbows is tendered. The main criteria in tenders are price, quality and level of service. The result of the competitive tendering process is a decrease in prices, with prices sometimes being even 60% lower than the ones specified in the reimbursement LPPR lists.⁵⁶¹
- (1237) French hospitals are reimbursed per performed procedure, according to DRG levels and price for implants, including elbow implants, are reimbursed on top of the procedure and uniform prices apply to all products falling within each generic category. Reimbursement levels for implants included in the LPPR provide for maximum price at which implants can be offered and typically, due to the prominence of tender procedures prices actually paid by public hospitals

⁵⁶¹ Response to the Article 6(1)(c) Decision, paragraph 801.

are much lower than those specified in the LPPR list. Private hospitals that pay less than the listed LPPR price have to return 50% of that cost saving to the public budget. However, they still keep 50% of that reduction.⁵⁶²

- (1238) In summer 2013, the orthopaedic industry through the trade associations has negotiated a new three year price arrangement with the CEPS. The agreement provides that the prices for elbow implants will decrease by 3%. Notably, the negotiated decreases will apply also to the prices provided for in the already concluded contracts.⁵⁶³
- (1239) The procurement methods and budgetary pressures result in a very competitive environment for the suppliers of elbow implants. In addition, as described in the Form CO, both private and public sector are rapidly consolidating what reinforces the countervailing buyer power exerted on implant suppliers.⁵⁶⁴
- (1240) Finally, the market for elbow implants is so small (approximately 500 units per year) that one lost or won contract can significantly change the market structure and thus, market shares are not a good proxy of the market power.⁵⁶⁵

The Commission's Assessment

- (1241) Eucomed's data and the Commission's targeted market reconstruction confirmed the Parties' market shares in France. However both sources indicated a different picture in terms of the Parties' competitors. More specifically, the Parties significantly underestimated Tornier's market position in the French market for elbows.

Table 77: Parties' shares of value for elbow implants in France

Suppliers	2009	2010	2011	2012	2013
Zimmer	[60-70%]	[50-60%]	[50-60%]	[50-60%]	[60-70%]
Biomet	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
Merged Entity	[80-90%]	[70-80%]	[70-80%]	[70-80%]	[70-80%]

Source: Commission's targeted market reconstruction

- (1242) The targeted market reconstruction indicated that Stryker has a marginal/very limited presence in elbow implants in France. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1243) The merger would lead to a 3-to-2 merger, as the Notifying Party seems to have overestimated the market share of the remaining competitors.
- (1244) In France Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants, while GSB Elbow represents only [0-5]*%. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in France.

⁵⁶² Response to the Article 6(1)(c) Decision, paragraph 802.

⁵⁶³ Response to the Article 6(1)(c) Decision, paragraph 803.

⁵⁶⁴ Response to the Article 6(1)(c) Decision, paragraph 804.

⁵⁶⁵ Response to the Article 6(1)(c) Decision, paragraph 805.

- (1245) As mentioned in section 8.7.4.2 above, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow, followed by Tornier's Latitude. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in France and would lead to a situation where only one player, Tornier, would be present in the market, however, as the target market reconstruction demonstrated, lagging behind. It would be difficult for Tornier to effectively constrain the merged entity. Other players are only marginally active or not active at all in France. Tornier's market shares are stable during the last three years.
- (1246) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1247) Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.
- (1248) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in France are predominantly sales of semi-constrained elbow implants.

Conclusion

- (1249) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in France, through the creation or strengthening of a dominant position.

8.7.5.6. Germany

Structure of the market

- (1250) According to the Notifying Party, in Germany the value of the market for elbow amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1251) Over the 2011-2013 period Zimmer's position decreased from [40-50]*% to [30-40]*%, while Biomet's position increased from [20-30]*% to [20-30]*%, according to the data provided by the Parties.

Table 78: Shares of value for elbow implants in Germany

Suppliers	2011	2012	2013
Zimmer	[40-50]*%	[40-50]*%	[30-40]*%
Biomet	[20-30]*%	[20-30]*%	[20-30]*%
Merged Entity	[60-70]*%	[60-70]*%	[50-60]*%
Stryker	[20-30]*%	[20-30]*%	[20-30]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	[5-10]*%	[0-5]*%	[5-10]*%

Total	100%	100%	100%
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Source: Form CO, Annex 6.2(a)

- (1252) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5%, namely Stryker ([20-30]*%) and Link ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Zimmer and Biomet are number one and number two in Germany and the merger will reinforce this position creating a gap of [30-40]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1253) The Notifying Party submits that the German market is characterised by the presence of buying groups which have an ability to significantly influence prices. Typically, hospitals belonging to purchasing groups (or those which outsource procurement of medical devices to such groups, including public hospitals) source all their requirements for implants through the joint procurement process; however, some private groups allow their members to procure part of their needs directly from suppliers.⁵⁶⁶
- (1254) According to the Notifying Party, German purchasing groups exert considerable buyer power on suppliers and their bargaining position has enabled them to consistently drive prices down and even to impose changes to industry standards relating to the provision of OR support and delivery of instruments. Purchasing groups are known for sophisticated and aggressive negotiating techniques, and often require suppliers to renegotiate agreed prices before termination of contracts. More than [80-90]*% of Parties' sales in Germany are via contracts with purchasing groups; Zimmer's largest purchasing group accounted for [10-20]*% of total sales. Framework contracts with purchasing groups are typically awarded to a limited number of suppliers (usually, up to five and three in case of Helios) for each product category, for a period of up to five years. In case of certain groups, notably Sana, selection criteria tend to be limited to price considerations. As framework contracts do not guarantee any given volume of sales, competition between suppliers takes place at two levels: the level of purchasing groups and the level of individual hospitals which can choose between products of all suppliers awarded with framework contracts.⁵⁶⁷
- (1255) The Government sets price for joint arthroplasty interventions in accordance with the DRG classification and hospitals (both public as well as private in case of patients with public health insurance) are reimbursed for each performed procedure, regardless of the price actually paid for the implanted device. As the hospitals' margin on each procedure depends on the price actually paid for an implant, there is a strong incentive for hospitals to source their supplies for the lowest possible price. DRG reimbursement levels included in the INEK List are subject to yearly reductions which further reinforces the downward pressure on prices.⁵⁶⁸

⁵⁶⁶ Response to the Article 6(1)(c) Decision, paragraph 783.

⁵⁶⁷ Response to the Article 6(1)(c) Decision, paragraph 783.

⁵⁶⁸ Response to the Article 6(1)(c) Decision, paragraph 784.

- (1256) Budgetary pressures as well as fierce competition in the market resulted in very significant shifts in the market shares over the 2011-2013 period. The Parties' combined market share in Germany has decreased from [90-100]*% in 2011 to [50-60]*% in 2013. Zimmer's position decreased from [60-70]*% to [30-40]*% while Biomet's position decreased from [30-40]*% to [10-20]*%. This decrease marks losses to[...]*.⁵⁶⁹

The Commission's Assessment

- (1257) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Germany. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 79: Parties' shares of value for elbow implants in Germany

Suppliers	2009	2010	2011	2012	2013
Zimmer	[40-50%]	[40-50%]	[40-50%]	[40-50%]	[40-50%]
Biomet	[20-30%]	[20-30%]	[20-30%]	[20-30%]	[20-30%]
<i>Merged Entity</i>	<i>[70-80%]</i>	<i>[70-80%]</i>	<i>[70-80%]</i>	<i>[70-80%]</i>	<i>[60-70%]</i>

Source: Commission's targeted market reconstruction

- (1258) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Germany. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1259) The targeted market reconstruction demonstrated a different competitive landscape than the one submitted by the Notifying Party. There would be only one competitor left post-merger with market shares significantly lower than the merged entity. The merger would lead to a 3-to-2 merger.
- (1260) In Germany Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants, while GSB Elbow represents only [5-10]*%. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants while iBP Elbow represents [0-5]*%, Liverpool Elbow represents [0-5]*% in Germany.
- (1261) As mentioned above in recital 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Germany.
- (1262) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Germany are predominantly sales of semi-constrained elbow implants.
- (1263) In relation to the shift in the parties' market shares as an indication of intense competition in the market for elbow implants, the Commission notes that

⁵⁶⁹ Response to the Article 6(1)(c) Decision, paragraph 785.

according to the targeted market reconstruction, the Parties' market shares remained relatively stable over the 2011-2013 period and in any event did not shift for more than [5-10]*%. The market shares of competitors also remained stable over the same period.

- (1264) Furthermore, competitors that are active in Germany, such as Link which has a limited, marginal presence in elbow implants pointed out the different competitive dynamics depending on the different EEA countries, by illustrating that competition in countries like France is based on long-term relationship between hospitals and suppliers, which explains why a supplier can survive being a local player. However Link distinguished the German market as requiring full product portfolios as a result of its highly consolidated buyer side.
- (1265) The latter coincides with the Notifying Party's argument, however it entails that barriers to entry are particularly high in Germany and a new supplier of elbow implants would have to be able to provide a breadth of elbow portfolio equal to that of Zimmer's which currently has a variety of sizes and combinations for all patients and indications.
- (1266) In addition, HELIOS, a key purchasing group consisting of 111 hospitals explained that when the procurement framework is set up, member hospitals within HELIOS will have to comply with it. Price lists are drawn up and fixed by HELIOS are then circulated among hospitals, which are in turn bound to the contractual framework and cannot negotiate better prices on their own. Although this may result to implants being imposed on surgeons who may not be familiar with them, HELIOS submits that since surgeons are already involved from early on in the process, via the medical committees where they make a pre-selection of preferred suppliers, and therefore switches to completely different products or philosophies are very rare.⁵⁷⁰ Thus, although price is an important factor in choosing a supplier of elbow implants, the process is in any event driven by surgeons' preference.
- (1267) The Commission also notes that although the German system of buyer groups may have a better negotiating position influence prices as opposed to direct negotiations, switching to an alternative supplier takes considerably more time. In the example of HELIOS purchasing group that represents 111 hospitals, switching to an alternative supplier of orthopaedic implants would take from 6 to 12 months, as opposed to 3 to 6 months that it would take for an individual hospital to switch.⁵⁷¹
- (1268) In any event, the Commission considers that the above arguments in recital (1257) onwards have limited application to elbow implants, simply because there is not enough choice of suppliers in the German market. In addition, any new entrant in the German market for elbow implant would have to be approved by the medical expert committees, before being eligible to compete with the Parties. Medical expert committees (there are currently 24 such committees) consist of the chief doctor for each market segment from each hospital of the purchasing group. According to HELIOS these committees set the quality criteria and other technical requirements that all medical devices will have to meet in order to qualify for purchases. Quality standards also

⁵⁷⁰ Non-confidential minutes of the conference call with HELIOS Kliniken Hospital Group of 22.07.2014.

⁵⁷¹ Non-confidential minutes of the conference call with HELIOS Kliniken Hospital Group of 22.07.2014.

include factors such as the innovativeness of the products, because HELIOS strives to use state of the art technology. Overall, as far as endo-prostheses are concerned, most suppliers on the shortlist usually have comparable quality.⁵⁷² At that stage the price criterion is not at stake. Therefore, a new supplier of elbow implants would be *prima facie* eligible to compete with the Parties only if it is able to prove that their elbows are of equal quality to Zimmer's and Biomet's elbow implants.

- (1269) The conservative nature of the German market is reflected by a German competitor, Aesculap, with worldwide presence that focuses mainly in Europe and specifically in Germany. According to Aesculap, "*customers are in general very conservative and rather reluctant to accept a new product. Although switching from a company to another is not totally uncommon, it requires a lot of efforts and good argumentation to convince both the surgeons and the hospitals*".⁵⁷³
- (1270) Aesculap states in relation to breadth of portfolio that "*Another issue is that a smaller manufacturer may not be able economically to cover all possible products and philosophies whilst companies such as the Parties can afford to have wider portfolios. For Group purchasing organisations (GPOs) such as large hospitals, this is a very important issue. GPOs are moving along the ideas of "bigger is better" and "one-stop-shop", focusing on a strategy of "less suppliers but full range", because it creates more synergies. In other words they prefer to purchase products from companies with a full range portfolio. Other important factors as price, quality and results are also considered. Customers increasingly tend to reduce their vendors lists to between 2 and 3 suppliers. With Zimmer/Biomet and Johnson & Johnson being on the reduced vendors list, smaller competitors with a smaller portfolio will be foreclosed. Even with a significant price reduction, smaller competitors could not convince customers that require a "one-stop-shop"*".⁵⁷⁴
- (1271) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1272) Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.

Conclusion

- (1273) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Germany, through the creation or strengthening of a dominant position.

8.7.5.7. Italy

Structure of the market

- (1274) According to the Notifying Party, in Italy the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.

⁵⁷² Non-confidential minutes of the conference call with HELIOS Kliniken Hospital Group of 22.07.2014.

⁵⁷³ Non-confidential minutes of the conference call with Aesculap of 14.08.2014, paragraph 21.

⁵⁷⁴ Non-confidential minutes of the conference call with Aesculap of 14.08.2014, paragraph 22.

- (1275) Over the 2011-2013 period Zimmer's position increased from [40-50]*% to [40-50]*%, while Biomet's position remained relatively stable at approximately [20-30]*%, according to the data provided by the Parties.

Table 80: Shares of value for elbow implants in Italy

Suppliers	2011	2012	2013
Zimmer	[40-50]*%	[50-60]*%	[40-50]*%
Biomet	[20-30]*%	[20-30]*%	[20-30]*%
Merged Entity	[70-80]*%	[70-80]*%	[70-80]*%
Tornier	[20-30]*%	[20-30]*%	[20-30]*%
Link	[5-10]*%	[5-10]*%	[5-10]*%
Other players	-	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1276) Based on data provided by the Notifying Party, post-merger there would be two other competitors with market shares over 5%, namely Tornier ([20-30]*%) and Link ([5-10]*%), which would be significantly weaker, in terms of market share, compared to the merged entity. Biomet and Zimmer are number one and number two in Italy and the merger will reinforce this position creating a gap of [50-60]*% between the merged entity and Tornier.
- (1277) The Commission notes that this position is different from the respective markets for total knee and hip implants in Italy, where there is a number of active competitors who are able to exercise a competitive constraint.

The views of the Notifying Party

- (1278) Joint reconstruction interventions are performed by: (a) public hospitals (60% of the Italian orthopaedic market), (b) private hospitals offering healthcare services reimbursed from the public budget (35% of the Italian orthopaedic market) and (c) private hospitals without reimbursement contracts (mainly for privately insured patients) (5% of the Italian orthopaedic market). Italy is largely a bidding market where up to 50-60% of market demand for orthopaedic implants is tendered, by either individual hospitals or, increasingly, groups of hospitals or regional groupings of hospitals. In light of this bidding market, over the 2012-2013 period, the Parties' combined market share in Italy has decreased from [70-80]*% in 2012 to [70-80]*% in 2013. Zimmer's position decreased from [50-60]*% to [40-50]*%, while Biomet's position decreased from [20-30]*% to [20-30]*%.⁵⁷⁵
- (1279) As hospitals are reimbursed based on the DRG system and price of implants is included in the value set for a given procedure, hospitals have a strong incentive to source their supplies at the lowest possible price. Accordingly, price ceilings are being imposed in an increasing number of tenders. In

⁵⁷⁵ Response to the Article 6(1)(c) Decision, paragraph 809.

addition, due to increasing budgetary pressures, a number of initiatives have been undertaken with a view to reducing prices of orthopaedic implants.⁵⁷⁶

- (1280) Private hospitals engage in individual negotiations with suppliers from which they may choose one or more suppliers for a specific contract. Even though surgeon preference is a factor to be considered, it is declining in importance due to price pressures. The decision on which implant to purchase lies mostly with the hospital administration and is based primarily on price. Indeed, aggressive negotiating techniques by the consolidated buyer sector have resulted in a significant downward pressure on implant prices, which as a result may be up to 40% lower for private hospitals than for public hospitals. Accordingly, the intense price competition will prevent the Merged Entity from raising prices post-merger.⁵⁷⁷

The Commission's Assessment

- (1281) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Italy. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 81: Parties' shares of value for elbow implants in Italy

Suppliers	2009	2010	2011	2012	2013
Zimmer	[50-60%]	[50-60%]	[40-50%]	[50-60%]	[50-60%]
Biomet	[10-20%]	[20-30%]	[20-30%]	[20-30%]	[20-30%]
Merged Entity	[70-80%]	[80-90%]	[70-80%]	[80-90%]	[70-80%]

Source: Commission's targeted market reconstruction

- (1282) The targeted market reconstruction indicated that Link has a marginal/very limited presence in elbow implants in Italy. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1283) The merger would lead to a 3-to-2 merger, as the Notifying Party seems to have overestimated the market share of the remaining competitors.
- (1284) In Italy the parties compete with their best-selling products. Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in Italy, where LRE represents [0-5]*%.
- (1285) As mentioned above in recital 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow, followed by Tornier's Latitude. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Italy and would lead to a situation where only one player, Tornier, would be present in the market. However, as the targeted market reconstruction

⁵⁷⁶ Response to the Article 6(1)(c) Decision, paragraph 810.

⁵⁷⁷ Response to the Article 6(1)(c) Decision, paragraph 811.

demonstrated, Tornier has only a limited share of this market. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Tornier would not be in a position to effectively constrain the merged entity.

- (1286) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Italy are predominantly sales of semi-constrained elbow implants.
- (1287) In relation to Notifying Party's claim that the shift in the parties' market shares is an indication of intense competition in the market for elbow implants, the Commission considers that according to the targeted market reconstruction, the Parties' market shares remained stable over the 2011-2013 period. This confirms the fact that the Parties' best-selling products compete aggressively against each other's, as seen in section 8.7.4.2 above.
- (1288) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1289) Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.

Conclusion

- (1290) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Italy, through the creation or strengthening of a dominant position.

8.7.5.8. Norway

Structure of the market

- (1291) According to the Notifying Party, in Norway the total value of the overall elbow market was EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1292) Over the 2011-2013 period Zimmer's position decreased from [10-20]*% to [5-10]*%, while Biomet's position shifted from [70-80]*% in 2011, to [70-80]*% in 2012, and to [70-80]*% in 2013, according to the data provided by the Parties.

Table 82: Shares of value for elbow implants in Norway

Suppliers	2011	2012	2013
Zimmer	[10-20]*%	[5-10]*%	[5-10]*%
Biomet	[70-80]*%	[70-80]*%	[70-80]*%
Merged Entity	[90-100]*%	[80-90]*%	[80-90]*%
Stryker	[5-10]*%	[10-20]*%	[10-20]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	-	-	-

Total	100%	100%	100%
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Source: Form CO, Annex 6.2(a)

(1293) Based on data provided by the Notifying Party, post-merger there would be two other competitors with market shares over 5%, namely Stryker ([10-20]*%) and Link ([10-20]*%), which would be significantly weaker in terms of market share, compared to the merged entity. The merged entity would be the clear market leader in the elbow implant market in Norway and the merger will create a gap of [70-80]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1294) Even though over 80% of total sales of orthopaedic products on the Norwegian market are achieved through tendering, the purchase of elbows forms an exception thereto. However, given the specificities of the Norwegian national market, this deviation could be interpreted as leaving more possibilities for customers to shift suppliers more easily, to the extent that hospitals would be less bound by contracts of standard duration and specific requirements. Indeed, market shares in Norway are not stable, as illustrated by recent shifts in the Parties' market position. Over the 2011-2013 period, the Parties' combined market share in Norway decreased from [80-90]*% in 2011 to [70-80]*% in 2013 and over the same period Zimmer's position decreased from [10-20]*% to [5-10]*%, whereas and Biomet's fell from [70-80]*% to [60-70]*%.⁵⁷⁸
- (1295) Finally, given that the Norwegian elbow market is very small and market share can shift easily, so they are not a good proxy of the market power.⁵⁷⁹

The Commission's Assessment

(1296) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Norway. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 83: Parties' shares of value for elbow implants in Norway

Suppliers	2009	2010	2011	2012	2013
Zimmer	[5-10%]	[5-10%]	[10-20%]	[5-10%]	[5-10%]
Biomet	[90-100%]	[90-100%]	[80-90%]	[90-100%]	[80-90%]
<i>Merged Entity</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

(1297) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Norway. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.

⁵⁷⁸ Response to the Article 6(1)(c) Decision, paragraph 815.
⁵⁷⁹ Response to the Article 6(1)(c) Decision, paragraph 816.

- (1298) The targeted market reconstruction demonstrated a different competitive landscape than the one submitted by the Notifying Party. There would be only one competitor left post-merger with market shares significantly lower than the merged entity. The merger would lead to a 3-to-2 merger.
- (1299) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties in Norway are predominantly sales of semi-constrained elbow implants.
- (1300) As shown in section 8.7.4.3, switching in elbows is difficult. Furthermore, as the targeted market investigation indicated, there is no other credible supplier in the elbow market in Norway for customers to switch to.
- (1301) As shown in section 8.7.4.6, barriers to entry in the elbow market are high due to different factors such as obtaining the necessary regulatory approvals, the importance of proving clinical data for any orthopaedic implant brought to the market, difficulties to convince surgeons to try new products etc. In Norway no competitor in the in-depth market investigation indicated to have entered the elbow implants market during the last eight years.⁵⁸⁰

Conclusion

- (1302) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Norway, through the creation or strengthening of a dominant position.

8.7.5.9. Portugal

Structure of the market

- (1303) According to the Notifying Party, in Portugal the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet
- (1304) Over the 2011-2013 period Zimmer's position decreased from [10-20]*% to [0-5]*%, while Biomet's position increased from [70-80]*% to [80-90]*%, according to the data provided by the Parties.

Table 84: Shares of value for elbow implants in Portugal

Suppliers	2011	2012	2013
Zimmer	[10-20]*%	[10-20]*%	[0-5]*%
Biomet	[70-80]*%	[60-70]*%	[80-90]*%
Merged Entity	[80-90]*%	[70-80]*%	[80-90]*%
Stryker	[10-20]*%	[10-20]*%	[10-20]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	-	-	-

⁵⁸⁰ Responses to Questionnaire Q30 on entry and innovation.

Total	100%	100%	100%
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Source: Form CO, Annex 6.2(a)

- (1305) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5%, namely Stryker ([10-20]*%) and Link ([10-20]*%), [10-20]*%) and Link ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. The merged entity will be the clear market leader in the elbow implant market in Portugal and the merger will create a gap of 64% between the merged entity and Stryker.

The views of the Notifying Party

- (1306) Even though approximately 80% of total sales of orthopaedic products on the Portuguese market are achieved through tendering, the purchase of elbows forms an exception thereto. However, given the specificities of the Portuguese national market, this deviation could be interpreted as leaving more possibilities for customers to shift suppliers more easily, to the extent that hospitals would be less bound by contracts of standard duration and specific requirements.⁵⁸¹
- (1307) Hospitals are reimbursed for performed procedure on the DRG basis and set reimbursement values also cover the price of elbow implants. While in the public system the price of the implant is entirely reimbursed, in the private system it is covered up to 90%.⁵⁸²
- (1308) In general, the Portuguese market has been heavily affected by the financial and economic crisis and the resulting public spending cuts. As result of cost containment measures adopted by the Portuguese government, all public hospitals have been required to obtain price reductions from suppliers, which has led in particular to reductions in implant prices of at least [10-20]% per year.⁵⁸³
- (1309) Hospitals in Portugal are undergoing consolidation by concentrating specialties and closing down small units. The buyer side is already concentrated, for example, the top 10 hospitals represent [30-40]*% of Biomet's sales, while Zimmer's largest customer ([...]*) represents [10-20]*% of its sales. Increasing consolidation reinforces the negotiating position of hospitals and let them exert even stronger downward pressure on prices.⁵⁸⁴
- (1310) Due to intense competition, market shares in Portugal are not stable, as illustrated by recent shifts in the Parties' market position.

The Commission's Assessment

- (1311) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Portugal. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

⁵⁸¹ Response to the Article 6(1)(c) Decision, paragraph 820.

⁵⁸² Response to the Article 6(1)(c) Decision, paragraph 821.

⁵⁸³ Response to the Article 6(1)(c) Decision, paragraph 822.

⁵⁸⁴ Response to the Article 6(1)(c) Decision, paragraph 823.

Table 85: Parties' shares of value for elbow implants in Portugal

Suppliers	2009	2010	2011	2012	2013
Zimmer	[10-20%]	[10-20%]	[10-20%]*	[10-20%]	[0-5%]
Biomet	[20-30%]	[60-70%]	[80-90%]	[70-80%]	[90-100%]
<i>Merged Entity</i>	<i>[30-40%]</i>	<i>[80-90%]</i>	<i>[90-100%]</i>	<i>[80-90%]</i>	<i>[90-100%]</i>

Source: Commission's targeted market reconstruction

- (1312) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Portugal. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1313) The targeted market reconstruction demonstrated a different competitive landscape than the one submitted by the Notifying Party. There would be only one competitor left post-merger with market shares significantly lower than the merged entity. The merger would lead to a 3-to-2 merger.
- (1314) In Portugal the parties compete with their best-selling products. Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [80-90]*% of its total sales of elbow implants in Portugal, whereas iBP Elbow represents [10-20]*% and Liverpool Elbow represents [0-5]*%.
- (1315) As mentioned above in recital 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Portugal and would lead to a situation where there is only one player.
- (1316) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Portugal are predominantly sales of semi-constrained elbow implants.
- (1317) In relation to the shift in the parties' market shares as an indication of intense competition in the market for elbow implants, the Commission notes that according to the targeted market reconstruction, the Parties' combined market shares remained stable over the 2011-2013 period. This confirms the fact that the Parties' best-selling products compete aggressively against each other's, as seen in section 8.7.4.2 above. Eliminating the biggest competitor of Zimmer in the Portuguese elbow market, leaving only one competitor in the market that is lagging far behind, would negate any dynamic nature of the market and sense of competition in an already concentrated market.
- (1318) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1319) Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.

Conclusion

- (1320) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on

the market for elbow implants in Portugal, through the creation or strengthening of a dominant position.

8.7.5.10.Spain

Structure of the market

- (1321) According to the Notifying Party, in Spain the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1322) Over the 2011-2013 period, Zimmer's position increased from [40-50]*% to [60-70]*%, while Biomet's position increased from [5-10]*% to [10-20]*%, according to the data provided by the Parties.

Table 86: Shares of value for elbow implants in Spain

Suppliers	2011	2012	2013
Zimmer	[40-50]*%	[60-70]*%	[60-70]*%
Biomet	[5-10]*%	[10-20]*%	[10-20]*%
<i>Merged Entity</i>	<i>[50-60]*%</i>	<i>[80-90]*%</i>	<i>[70-80]*%</i>
Stryker	[10-20]*%	[5-10]*%	[10-20]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	[10-20]*%	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1323) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5%, namely Stryker ([10-20]*%) and Link ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Biomet and Zimmer are number one and number two in Spain and the merger will reinforce this position creating a gap of [60-70]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1324) In Spain, public hospitals procure elbow implants either by means of tender procedures or individual commercial negotiations. Private hospitals procure implants from suppliers approved by insurance companies or negotiate with suppliers directly. The Notifying Party estimates that approximately 50% of the market demand for elbow implants is procured via public tender procedures and that this proportion is likely to increase. Tenders vary from one region to another but typically price is the sole or the main criterion in the selection suppliers in all regions. Public hospitals are reimbursed by regional healthcare authority and are under significant budgetary pressures. Consequently, they look for savings in spending on costly devices such as implants. Private hospitals are typically financed by private insurance groups which negotiate prices with implant suppliers on behalf of hospitals. The insurance group are

powerful and exert significant pressure on the suppliers in order to reduce prices.⁵⁸⁵

- (1325) The Notifying Party submits that because a large portion of the market demand is put up for tenders, market shares in Spain are volatile as evidenced by the increase in Zimmer's market share from [50-60]*% in 2011 to [60-70]*% in 2013 and the increase in Biomet's market share over the same period from [10-20]*% to [20-30]*%.⁵⁸⁶
- (1326) In terms of volume, the Spanish market for elbow implants is particularly low. Notably, Zimmer sells less than [...] elbow implants per year and Biomet unit sales account for [...] elbow implants. Accordingly, market shares could shift easily.⁵⁸⁷

The Commission's Assessment

- (1327) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Spain. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 87: Parties' shares of value for elbow implants in Spain

Suppliers	2009	2010	2011	2012	2013
Zimmer	[50-60%]	[50-60%]	[50-60%]	[70-80%]	[60-70%]
Biomet	[20-30%]	[10-20%]	[10-20%]	[10-20%]	[20-30%]
<i>Merged Entity</i>	<i>[70-80%]</i>	<i>[70-80%]</i>	<i>[60-70%]</i>	<i>[80-90%]</i>	<i>[80-90%]</i>

Source: Commission's targeted market reconstruction

- (1328) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Spain. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.
- (1329) The targeted market reconstruction demonstrated a different competitive landscape than the one submitted by the Notifying Party. There would be only one competitor left post-merger with market shares significantly lower than the merged entity. The merger would lead to a 3-to-2 merger.
- (1330) In Spain the parties compete with their best-selling products. Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in Spain.
- (1331) As mentioned above in recital 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow. The merger therefore would eliminate an

⁵⁸⁵ Response to the Article 6(1)(c) Decision, paragraph 794.

⁵⁸⁶ Response to the Article 6(1)(c) Decision, paragraph 795.

⁵⁸⁷ Response to the Article 6(1)(c) Decision, paragraph 796.

important competitor to Zimmer's C/M Elbow in Spain and would lead to a situation where there is only one player.

- (1332) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Spain are predominantly sales of semi-constrained elbow implants.
- (1333) In relation to the shift in the parties' market shares as an indication of intense competition within tenders in the market for elbow implants, as well as to the small size of the Spanish elbow market, the Commission notes that the market shares of the Parties have been consistently high in the past five years and that they have been growing relative to their competitors. Eliminating the biggest competitor of Zimmer in the Spanish elbow market, leaving only one competitor in the market which is lagging far behind, would negate any dynamic nature of the market and sense of competition in an already concentrated market.
- (1334) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1335) Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.

Conclusion

- (1336) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Spain, through the creation or strengthening of a dominant position.

8.7.5.11.Sweden

Structure of the market

- (1337) According to the Notifying Party, in Sweden the value of the market for elbow implants amounted to EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1338) Over the 2011-2013 period, Zimmer's position increased from [20-30]*% to [30-40]*%, while Biomet's position decreased from [40-50]*% to [30-40]*%, according to the data provided by the Parties.

Table 88: Shares of value for elbow implants in Sweden

Suppliers	2011	2012	2013
Zimmer	[20-30]*%	[30-40]*%	[30-40]*%
Biomet	[40-50]*%	[30-40]*%	[30-40]*%
Merged Entity	[60-70]*%	[70-80]*%	[60-70]*%
Stryker	[20-30]*%	[10-20]*%	[20-30]*%
Link	[10-20]*%	[10-20]*%	[10-20]*%
Other players	[0-5]*%	-	-

Total	100%	100%	100%
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Source: Form CO, Annex 6.2(a)

- (1339) Based on data provided by the Notifying Party, post-merger, there will be two other competitors with market shares over 5%, namely Stryker ([20-30]*%) and Link ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Biomet and Zimmer are number one and number two in Sweden and the merger will reinforce this position creating a gap of [40-50]*% between the merged entity and Stryker.

The views of the Notifying Party

- (1340) The Notifying Party claims that Sweden is a bidding market where market shares may rapidly change as a result of a tender won or lost. Tenders are organised by large purchasing authorities at a regional level and approximately 85% of market demand for elbow implants is tendered in such procedures. Accordingly, market shares in Sweden are very volatile as illustrated by the decrease in the Parties' individual as well as combined market share, as illustrated in recital (1338).⁵⁸⁸
- (1341) Furthermore, according to the Notifying Party, given the very high level of concentration, buyers in Sweden have a significant power which they use to lower prices and drive competition between implant suppliers.⁵⁸⁹
- (1342) Moreover, the Notifying Party states that hospitals in Sweden are reimbursed according to the national health system which decides a specific amount for a given procedure. Accordingly, hospitals remain under pressure to contain spending on costly medical devices, rendering Sweden a very price-sensitive market.⁵⁹⁰

The Commission's Assessment

- (1343) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in Sweden. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 89: Parties' shares of value for elbow implants in Sweden

Suppliers	2009	2010	2011	2012	2013
Zimmer	[30-40%]	[30-40%]	[20-30%]	[40-50%]	[30-40%]
Biomet	[40-50%]	[40-50%]	[40-50%]	[40-50%]	[40-50%]
Merged Entity	[80-90%]	[70-80%]	[70-80%]	[80-90%]	[70-80%]

Source: Commission's targeted market reconstruction

- (1344) The targeted market reconstruction indicated that Stryker and Link have a marginal/very limited presence in elbow implants in Sweden. In light of that

⁵⁸⁸ Response to the Article 6(1)(c) Decision, paragraph 828.
⁵⁸⁹ Response to the Article 6(1)(c) Decision, paragraph 829.
⁵⁹⁰ Response to the Article 6(1)(c) Decision, paragraph 830.

fact and of the significant barriers for customers to switch, the Commission considers that Stryker and Link would not be in a position to effectively constrain the merged entity. This holds true for the entire period of 2009-2013.

- (1345) The targeted market reconstruction demonstrated a different competitive landscape than the one submitted by the Notifying Party. There would be only one competitor left post-merger with market shares significantly lower than the merged entity. The merger would lead to a 3-to-2 merger.
- (1346) In Sweden Zimmer's C/M Elbow represents [80-90]*% of its total sales of elbow implants, whereas GSB Elbow represents [10-20]*%. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in Sweden, whereas K Elbow represents [0-5]*%.
- (1347) As mentioned in recital 8.7.4.2 above, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in Sweden and would lead to a situation where there is only one player.
- (1348) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in Sweden are predominantly sales of semi-constrained elbow implants.
- (1349) Västra Götalandsregionen Regionservice (VGR), which covers 19 hospitals submits that it does not expect any new entrant in the market for elbow implants in the future.
- (1350) Professor Kärrholm, from the University of Gothenburg (Sweden's second largest university) describes the Scandinavian market as conservative, with Sweden and Norway being the most conservative and Finland being the least conservative. Professor Kärrholm believes it is for this reason that Finland shows higher revision rates than Sweden and Norway.⁵⁹¹
- (1351) As regards Sweden, Professor Kärrholm explained that hospitals tend to stick to limited types of implants. The choice of those implants is very much based on the surgeons' preferences. This is also confirmed by Blekinge Orthopedic Department which explains the conservatism of Nordic countries and why price is, contrary to what the Notifying Party claims, *not* the decisive factor: "Even though price is important, the hospital will never buy a product just because it is cheaper. The hospital is conservative because using a product that is not good enough can cause a catastrophe. As you only find out that the product is not working well after 5-10 years (when revisions are needed), the product will be used in many surgery procedures by that time and therefore many patients will suffer from the bad implant and need revisions. That explains the ultra-conservatism of the surgeons/hospital who will always buy products with a good reputation".⁵⁹²
- (1352) As a consequence, hospitals do not switch between suppliers of implants very often. This can happen when a new implant performs better and this success is very well documented. In this regard, a track record covering the last 10-15

⁵⁹¹ Non-confidential minutes of the conference call with Professor Kärrholm from the University of Gothenburg of 02.07.2014.

⁵⁹² Non-confidential minutes of the conference call with Blekinge Orthopaedic Department of 24.10.2014.

years is a "must" to be considered reliable. Obviously, this particular setting makes it difficult for new players to penetrate this market.

- (1353) In explaining the costs incurred by hospitals when switching to an alternative supplier of orthopaedic implants, Professor Kärrholm referred to the amount of surgery it takes to for a surgeon to master a new implant. According to Professor Kärrholm, it takes approximately 10 to 15 surgery procedures for a surgeon to be comfortable with a new implant and between 20-25 surgery procedures to fully master it. The amount of time required by this process can vary significantly from surgeon to surgeon. For instance, in a hospital where 30-40 surgery procedures are performed per year, only 5-10 surgery procedures per year may be attributed to a specific surgeon. This means that a surgeon may take two years to fully master an implant. This time lag can cause a number of consequences.
- (1354) In the short term, the number of revision surgery procedures will increase, which in turn has an impact on hospital costs. Moreover, the switch also increases the risk of mistakes, given that, particularly during the first surgery procedures, surgeons may not fully master the new implant and instruments and the approach required to insert it.
- (1355) In this regard, Professor Kärrholm explained that there are articles showing that in the event of a switch to a new implant, the risk of revision surgery increases by 15-30%.⁵⁹³ In addition, the cost of revision surgery can be between 50 to 100% more expensive than the cost of a primary implant. Consequently, at least in Sweden hospitals are very reluctant in switching to a new supplier of medical devices. This Decision will entail a large computation, where the cost of the implant is only one factor. In fact, the cost of an implant is only a small part of a total costs faced by a hospital. For primary implants, this part may represent between 15-25%, whereas for revision implants this percentage can grow up to 25-30%. However, there are instances where a given patient still has enough bone stock and tissue so that a primary implant can be used instead of a revision implant.
- (1356) The Commission notes the situation is exacerbated in elbow implants. Due to the fact that the market for elbow implants is a niche market of small size, and elbow surgery is the least known and performed prosthesis surgery, a given hospital can perform considerably less than 30-40 surgery procedures per year. This would increase the learning curve for a surgeon to master an elbow implant, and would in turn prolong increased revision rates and additional costs to the hospital.
- (1357) Professor Kärrholm raised concerns in relation to the merger since it would result in the elimination of an important supplier such as Zimmer in the Swedish market where entry of new players is extremely difficult due to its conservative nature.
- (1358) As shown in section 8.7.4.3, switching in elbows is difficult and requires specific surgeon training.
- (1359) Moreover, the Commission refers to its findings regarding market entry (section 8.7.4.6) which also applies to the Danish market for elbow implants.

⁵⁹³ Peltola M, Malmivaara A, Paavola M. Hip prosthesis introduction and early revision risk. A nationwide population-based study covering 39,125 operations. *Acta Orthop.* 2013 Feb;84(1):25-31

Conclusion

- (1360) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in Sweden, through the creation or strengthening of a dominant position.

8.7.5.12. United Kingdom

Structure of the market

- (1361) According to the Notifying Party, in the United Kingdom the value of the market for elbow implants amounted to EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1362) Over the 2011-2013 period, Zimmer's position remained largely the same over this period, from [50-60]*% to [50-60]*%, while Biomet's position remained constant at approximately [30-40]*%, according to the data provided by the Parties.

Table 90: Shares of value for elbow implants in the United Kingdom

Suppliers	2011	2012	2013
Zimmer	[50-60]*%	[50-60]*%	[50-60]*%
Biomet	[30-40]*%	[30-40]*%	[30-40]*%
<i>Merged Entity</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>	<i>[90-100]*%</i>
Tornier	[10-20]*%	[10-20]*%	[10-20]*%
Link	[0-5]*%	[0-5]*%	[0-5]*%
Other players	-	-	-
Total	100%	100%	100%

Source: Form CO, Annex 6.2(a)

- (1363) Based on data provided by the Notifying Party, post-merger, there will be one other competitor left with market shares over 5%, namely Tornier ([10-20]*%), which will be significantly weaker in terms of market share, compared to the merged entity. Biomet and Zimmer are number one and number two in the United Kingdom and the merger will reinforce this position creating a gap of [70-80]*% between the merged entity and Tornier.

The views of the Notifying Party

- (1364) According to the Notifying Party, the United Kingdom is a bidding market where approximately 64% of the market demand for elbow implants is procured via public tenders. Often, the procedures are organised by buying groups rather than individual hospitals. Due to the NHS cost containment plan, and planned reduction in the healthcare spending by 20 billion over five years (the plan started in 2009) United Kingdom hospitals have been under very significant pricing pressure and have sought to reduce spending on medical devices such as elbow implants. Accordingly, hospitals largely rely on tenders, and more and more often select a single supplier for a given product line and would switch to alternative (cheaper) suppliers. Consequently, United

Kingdom hospitals have significant buyer power and would be able to constrain the Parties post-merger.⁵⁹⁴

The Commission's Assessment

- (1365) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties significantly underestimated their market shares in the United Kingdom. Therefore, it appears that the Parties enjoy larger market shares, their competitors' market shares are significantly lower, and there is not enough competition in the market that would be able to constrain the merged entity.

Table 91: Parties' shares of value for elbow implants in the United Kingdom

Suppliers	2009	2010	2011	2012	2013
Zimmer	[50-60%]	[50-60%]	[50-60%]	[50-60%]	[50-60%]
Biomet	[30-40%]	[30-40%]	[30-40%]	[30-40%]	[30-40%]
<i>Merged Entity</i>	<i>[80-90%]*</i>	<i>[90-100%]*</i>	<i>[90-100%]*</i>	<i>[90-100%]*</i>	<i>[90-100%]*</i>

Source: Commission's targeted market reconstruction

- (1366) The merger would lead to a 3-to-2 merger, however with Tornier lagging far behind the merged entity, as the targeted market reconstruction confirmed.
- (1367) In the United Kingdom the parties compete with their best-selling products. Zimmer's C/M Elbow represents [90-100]*% of its total sales of elbow implants, whereas GSB Elbow represents [0-5]*%. Biomet's Discovery Elbow represents [90-100]*% of its total sales of elbow implants in the United Kingdom, whereas iBP Elbow represents [0-5]*%, and Liverpool Elbow and K Elbow represent [0-5]*% each.
- (1368) As mentioned above in section 8.7.4.2, Zimmer's C/M Elbow closest competitor is Biomet's Discovery Elbow, followed by Tornier's Latitude. The merger therefore would eliminate an important competitor to Zimmer's C/M Elbow in the United Kingdom and would lead to a situation where there is only one player, Tornier, would be present in the market. However, as the targeted market reconstruction demonstrated, Tornier has only a limited share of this market. In light of that fact and of the significant barriers for customers to switch, the Commission considers that Tornier would not be in a position to effectively constrain the merged entity.
- (1369) The position would be largely the same if the market were to include only semi-constrained elbow implants, as the sales of the Parties and their competitors in the United Kingdom are predominantly sales of semi-constrained elbow implants.
- (1370) As shown in section 8.7.4.3, switching in elbows is difficult. Furthermore, as the targeted market investigation indicated, there is no other credible supplier in the elbow market in the United Kingdom for customers to switch to.
- (1371) As shown in section 8.7.4.6, barriers to entry in the elbow market are high due to different factors such as obtaining the necessary regulatory approvals, the

⁵⁹⁴ Response to the Article 6(1)(c) Decision, paragraph 834.

importance of proving clinical data for any orthopaedic implant brought to the market, difficulties to convince surgeons to try new products etc. In the United Kingdom no competitor in the in-depth market investigation indicated to have entered the elbow implants market during the last eight years.⁵⁹⁵

- (1372) The in-depth market investigation provided evidence that the market for elbow implants is not as competitive as the hip, primary knee and revision knee implants markets and that more competition is needed. Zimmer and Biomet are the "default and obvious choices for surgeons".⁵⁹⁶
- (1373) Furthermore, the Royal Bournemouth and Christchurch hospitals NHS foundation trust that satisfies its elbow implants requirements from Zimmer, stressed that "Zimmer is the market leader of the elbow implants market in the UK" and that "Zimmer and Biomet are the only two real competitors in the United Kingdom elbow market". The Royal Bournemouth and Christchurch hospitals NHS foundation trust is of the opinion that Zimmer and Biomet have really strong competition between each other and raised concern in particular regarding elbows.⁵⁹⁷
- (1374) An example that demonstrates that surgeon's choice in the United Kingdom is valued more than the pricing criterion in choosing a supplier is that "[c]urrently Bradford [hospital] is buying elbow implants from Zimmer and shoulder implants from Zimmer and some from Biomet. They buy shoulder implants from both Zimmer and Biomet because of clinical preference and consensus on a single source was not reached among all surgeons".

Conclusion

- (1375) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition on the market for elbow implants in the United Kingdom, through the creation or strengthening of a dominant position.

8.7.6. Conclusion – Elbow implants

- (1376) On the basis of the arguments set out in this section, the Commission concludes that the proposed merger would significantly impede effective competition through the creation or strengthening of a dominant position in relation to elbow implants in Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, France, Germany, Italy, Norway, Portugal, Spain, Sweden and the United Kingdom.

8.8. Hip Implants

8.8.1. Overview of the market for hip implants

- (1377) In the EEA, the market for hip implants is the largest by sales comparing to the other reconstructive joint implants, such as knee, shoulder and elbow implants. According to the Parties, in 2013 the total value of the hips implant market was EUR [over 1,000]* million.⁵⁹⁸ The market for hip implants has become increasingly commoditised. Today, this is a fully mature market with no major

⁵⁹⁵ Responses to Questionnaire Q30 on entry and innovation.

⁵⁹⁶ Non-confidential minutes of the conference call with NHS Wales of 29.10.2014.

⁵⁹⁷ Non-confidential minutes of the conference call with the Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust of 5.11.2014.

⁵⁹⁸ Form CO, table 34.

innovation over the last two decades other than incremental improvements and with a number of competitors with a broad portfolio of similar products.

- (1378) In the 1970s and early 1980s, Zimmer and a handful of other companies developed proprietary designs that helped them achieve important positions in the hip market.⁵⁹⁹ In those times, hip products were distinguishable in terms of different attributes, such as technical uniqueness, quality or brand. All patents on these original products expired in the 1990s. Since then, companies started copying each other's products and numerous new companies have entered the market.
- (1379) The products that are no longer covered by patents are copied extensively by other implant suppliers. Copies are not only marketed by the large companies (including Zimmer), but also by the regional competitors. The designs of these products are practically identical to the originators' products.⁶⁰⁰
- (1380) The suppliers in the hip segment have also increasingly been outsourcing the key technologies, resulting in further commoditisation of the market for hip implants. The production of reamers, trays, instruments, cross-linking, etc. has now largely been outsourced to third parties. The commoditisation of the hip segment is further evidenced by the fact that a number of original equipment manufacturers ("OEMs") copy the originator's implants, such as stems, ceramic heads and polyethylene raw materials, and sell them to suppliers that brand them and sell them on to customers as their own.
- (1381) Broad availability of copies, outsourcing of key technology to third parties, and incremental innovation have led to a hip market, in which competitors, with EEA-wide, regional, as well as local presence, all offer a full portfolio of similar products.

8.8.2. *The Parties' and their competitors' products*

- (1382) Most competitors on the market are able to offer primary and revision hip implants. The portfolio of all large suppliers but Zimmer also includes resurfacing hip implants (that is, Stryker, J&J/DePuy, S&N and Biomet).⁶⁰¹ Zimmer completely stopped producing and marketing resurfacing hip implants, [...].⁶⁰²
- (1383) Zimmer's [...] hip implant products [...] introduced in the market during the last ten years are the following: Continuum Cup, Avenir Stem, and Fitmore Stem.
- (1384) The Continuum Cup belongs to Zimmer's World Cup system and is part of Zimmer's rationalisation strategy. It may be used for primary and revision surgery. It offers faster recovery and enhances the autonomous bone growth. For the surgeons the Continuum Cup provides shorter surgery time and lower risk of infections. In terms of the material of the cup Zimmer is still the only company with trabecular metal, which is superior to all other materials. Regenerex of Biomet competes directly with Continuum Cup. The Parties' internal documents indicate that the Parties' main competitors offer the following hip implants that compete with Continuum Cup: (a) Tritanium cup of

⁵⁹⁹ Presentation of Oriol Lacorte, slides 27-29.

⁶⁰⁰ Presentation of Oriol Lacorte, slides 30-86.

⁶⁰¹ Form CO, paragraph 864.

⁶⁰² Form CO, paragraph 869; Response to the Article 6(1)(c) Decision, paragraph 166.

Stryker (b) R3 cup Stiktite coating of S&N, and (c) Trabecular Titanium of Lima.⁶⁰³

(1385) Biomet's [...] hip implant products [...] introduced in the market during the last ten years are the following: Exceed ABT Acetabular System, Exception Stem, and Ringloc E1.

(1386) Exceed ABT Acetabular System is a cementless hip replacement acetabular shell with poly, ceramic and metal liners. It is Vitamin E infused which protects against oxidation. It competes directly with Trilogy AB from Zimmer. The Parties' internal documents indicate that the Parties' competitors offer the following hip implants that compete with Exceed ABT Acetabular System: (a) Pinnacle of DePuy, and (b) Trident of Stryker.⁶⁰⁴

(1387) Table 92 below provides examples of the hip implants offered by the Parties and their main competitors.

Table 92: Hip implants offered by the Parties and their main competitors

Supplier	Primary	Revision	Resurfacing
Zimmer	CPT, Alloclassic Zweymüller, Fitmore, CLS Spotorno, Trilogy, Allofit, Continuum, Maxera, MMC	Trilogy, Allofit, Continuum, MMC, ZMR, Revitan, Wagner SL	-
Biomet	Ringloc, Arcom, Max Ti, Answer, Balance, Bi-Metric, Bio-Groove, Generation 4, Integral, Taperloc, Microplasty, Progressive, RX 90, Stanmore, Mallory-Head, Taperloc, Rx 90, Tri-Spike, Universal, Vision, G7 Acetabular cup GTS, Exception and Mallory-Head, Avantage, Exceed	Arcos, Bi-Metric, Hyperion, Integral, PLR, Reach, Rx 90, Mallory-Head, Tri-Polar, Freedom, Healey, Par 5, Recovery, Mallory Head, McLaughlin, Regenex, Offset, Exact, Uption Complete.	ReCap
Stryker	Trident, ABG II, Exeter, Accolade TMZF	Restoration, Modular Revision Hip System, Restoration HA Hip Stem, GMRS Proximal Femur Modular Replacement System	Cormet Resurfacing System.
J&J/DePuy	Pinnacle, Corail	ReClaim, CoRail, GripTion	ASR
S&N	Accord, Anthology, CPCS, R3, Reflection Cup, SMF, Verilast, Polarcup	Accord, CPCS, R3, Redapt, Reflection Cup, SMF, Verilast	Birmingham Hip Resurfacing System.
Link	C.F.P. Hip Prosthesis Stem, Classic Uncemented, Standard C, Standard D, Lubinus Classic Plus, Lubinus SP II Standard P, Standard M, Dysplasia Stem, T.O.P. Hip Acetabular Cup, BetaCup Press-fit Acetabular Cup TiCaP, CombiCup Hip Acetabular Cup System, Screw-in Acetabular Cup	MP Reconstruction Prosthesis, SPII Long Prosthesis Stems, Revision Stem, MEGASYSTE M-C, Endo-Model Saddle Prosthesis, CombiCup R Revision Cup, Endo-Model Partial Pelvis Replacement	-

⁶⁰³ Responses to Commission's request for information of 04.09.2014 - M.7265 - Annex 1a - (NL) Continuum Brand Format.

⁶⁰⁴ Responses to Commission's request for information Q03 (Market Access Documents) - list - Hip Campaign_Sales Guide_Exceed ABT_EN.

	Systems, McMinn Acetabular Reconstruction Cup, Lubinus Hip Acetabular Cup, IP Acetabular Cup, FC + FAL Hip Acetabular Cup, Endo-Model Artificial Cup		
Lima	Friendly, Logica	CL Revision	-
Aesculap	Aesculap Total Hip Solution, Unisyn Hip System	Unisyn Hip System	-
Mathys	CBC Stem, CBH Stem, CCA Straight Stem, Centris Stem, twinSys Stem, stellaris Stem, RM Cup, SeleXys Cup	CBC Stem, CBH Stem, CBK Revision Stem, Modular Revision, RM Cup	-

Source: Form CO

8.8.3. Structure of the hip implants market

- (1388) According to the Parties' estimates,⁶⁰⁵ total EEA sales for all hip implants were EUR [over 1,000]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. In a market encompassing all hip implants, the merged entity would become the market leader with a market share of just over [30-40]*% at EEA level.⁶⁰⁶
- (1389) The Notifying Party submits that, at EEA level, five global American suppliers play a major role, that is, Zimmer, Biomet, J&J/DePuy, Stryker and S&N. In addition, a number of small- to medium-sized suppliers, such as Aesculap, Lima, Mathys, Wright/Micropost, Medacta and Link are present in a large number of EEA countries, generally with their own versions of existing successful implants.

Table 93: Shares of value for hip implants in the EEA

Competitor	EEA market share
Zimmer	[20-30]*%
J&J/DePuy	[10-20]*%
Stryker	[10-20]*%
S&N	[10-20]*%
Biomet	[5-10]*%
Aesculap	[5-10]*%
Lima	[0-5]*%
Mathys	[0-5]*%
Wright / Microport	[0-5]*%
Medacta	[0-5]*%

⁶⁰⁵ Form CO, Annex 6.1(a), page 4.

⁶⁰⁶ Form CO, table 34.

Competitor	EEA market share
Link	[0-5]*%

Source: Form CO

(1390) Table 94 exhibits the presence of competitors with EEA and regional presence for hip implants. However, the Commission notes that there are also local players which are exhibited in section 8.8.5.

Table 94: EEA and regional suppliers' presence in EEA

Supplier	EEA presence
Zimmer	Austria, Belgium (including Luxembourg), Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, UK, Bulgaria, Cyprus, Croatia, Estonia, Lithuania, Romania, Slovakia, Slovenia, Iceland
Biomet	Austria, Belgium (including Luxembourg), Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, UK, Bulgaria, Cyprus, Lithuania, Romania, Slovakia, Slovenia, Cyprus, Iceland
J&J/DePuy	Austria, Belgium (including Luxembourg), Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, UK, Bulgaria, Cyprus, Croatia, Estonia, Lithuania, Romania, Slovakia, Slovenia, Iceland
Stryker	Austria, Belgium (including Luxembourg), Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, UK, Bulgaria, Cyprus, Estonia, Lithuania, Romania, Slovakia, Slovenia, Iceland
S&N	Austria, Belgium (including Luxembourg), Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, UK, Bulgaria, Cyprus, Estonia, Iceland, Latvia, Lithuania, Romania, Slovakia, Slovenia, Ireland
Aesculap	Belgium (including Luxembourg), Czech Republic, Denmark, Germany, Greece, Hungary, Ireland, Italy, Poland, Portugal, Spain.
Lima	Austria, Croatia, Czech Republic, France, Greece, Italy, Netherlands, Poland, Portugal, Spain, Slovenia, UK
Mathys	Austria, Belgium (including Luxembourg), Czech Republic, France Germany, Greece, Italy, Netherlands, Spain
Wright / Microport	Austria, Belgium (including Luxembourg), Czech Republic, Denmark, Finland, France, Italy, Poland, Portugal, Spain, UK
Medacta	Austria, Belgium (including Luxembourg), France, Italy, Greece, Spain, UK
Link	Belgium (including Luxembourg), Denmark, Estonia, Finland, Germany, Italy, Lithuania, Norway, Spain, Sweden, Lithuania, Slovenia, Iceland, UK

Source: Form CO

(1391) Based on the Notifying Party's submission, most suppliers of hip implants are active in primary, revision and partial hip implants alike.⁶⁰⁷ They also offer solutions for all different pathologies.⁶⁰⁸

⁶⁰⁷ Form CO, table 25.

⁶⁰⁸ Form CO, paragraph 883.

8.8.4. General Competitive Assessment

8.8.4.1. The views of the Notifying Party

- (1392) The Notifying Party argues that large players as well as new entrants and small, regional players pose an important competitive constraint on Zimmer and Biomet, aggressively competing with high quality products and routinely winning business from both Parties. As regards new entrants and other small players, the Notifying Party claims that irrespective of their limited market shares such competitors collectively have the scale and EEA-wide presence to be considered viable alternative suppliers to the merged entity. Furthermore, according to the Notifying Party, most products in the hip implant market are largely interchangeable in the eyes of hospital and to some extent surgeons, thus all existing suppliers, including regional and local ones, are likely to impose strong competitive constraints on the Parties.⁶⁰⁹
- (1393) The Notifying Party is of the view that barriers to entry and expansion are low since entry and expansion has frequently occurred in the last five years, creating thus opportunities for new entrants and other players. Entry in the market for hip implants is easy, according to the Notifying Party, because there are no significant technological barriers and because of its highly commoditised nature with an extensive number of me-too products. In the absence of intellectual property protection (that is, patents), all competitors offer the same range of hip implants and instruments. The Notifying Party also notes that innovation is only incremental in relation to hip implants and that intra-brand mix and matching is a common feature of the market.⁶¹⁰
- (1394) Furthermore, the market for hip implants is characterised by pro-competitive hospital purchasing patterns (for example, large purchasing organisations, such as regional hospital purchasing aggregators) and strong countervailing buyer power (the Notifying Party argues that hospitals purchase from multiple sources and play different suppliers against each other to achieve lower prices) and that the downward pricing pressures applying across the entire health sector render the likelihood of price increases unlikely.⁶¹¹
- (1395) The Notifying Party also claims that Zimmer and Biomet are not each other's closest competitors because of the commoditised nature of this market that has as a result that the Parties face many "close" competitors, hence the notion of "close competitor" bears little relevance to assess the effect of the merger.⁶¹²

8.8.4.2. The Commission's Assessment

Closeness of competition

- (1396) As described in section 8.8.1 above, compared to the other orthopaedic implants markets, the market for hip implants has, over the decades, become increasingly commoditised. Broad availability of copies, outsourcing of key technology to third parties, and incremental innovation have led to a hip market, in which competitors, with EEA-wide, regional, as well as local presence, all offer a full portfolio of similar products, such as stems of all different sizes, all different kinds of heads and cups. In relation to implant

⁶⁰⁹ Response to the Article 6(1)(c) Decision, paragraph 142, and Form CO, paragraph 853.

⁶¹⁰ Response to the Article 6(1)(c) Decision, paragraph 142, and Form CO, paragraph 853.

⁶¹¹ Response to the Article 6(1)(c) Decision, paragraph 142, and Form CO, paragraph 853.

⁶¹² Response to the Article 6(1)(c) Decision, paragraph 142, and Form CO, paragraph 853.

instruments (mainly consisting of rasps, handles and reamers), these are implant-specific, since, for instance, a rasp must fit precisely the form of the stem implant, and a reamer must precisely fit the radius of the cup. Although every competitor offers its own sets of rasps, other instruments, such as reamers have standard sizes and are produced by a number of companies, including OEMs. There are also other generic instruments used in hip replacement surgery, such as a regular hammer which is owned by the hospitals.

- (1397) Furthermore, there are numerous suppliers in the EEA in the market for hip implants, of EEA, regional and local presence. These competitors all offer a wide and diverse portfolio of hip products. This was also confirmed by the market investigation.⁶¹³
- (1398) Specifically, there are at least twenty main suppliers of hip products on the EEA market and at least three OEMs manufacturing such products. In particular, the main competitors in the hip market in the EEA include Amplitude, Aesculap, Ceraver, Corin Group, FH Orthopedics, Groupe Lépine, Implanet, J&J/DePuy, JRI Orthopaedics, Lima Corporate, Mathys Ltd Bettlach, Medacta, Microport, Orthodynamics, Permedica Manufacturing, Peter Brehm, S&N, Speetec Implantate, Stanmore Implants, Stryker, Tornier and Waldemar Link. Table 95 below clearly shows that all companies are offering a broad portfolio of virtually all hip products.

Table 95: Parties' and Competitors' hip portfolio

Product	Zimmer	Biomet	J&J/DePuy	Stryker	Smith&Nephew	Amplitude	Aesculap	Ceraver	Corin Group	Corin	Fh Orthopedics	Groupe Lépine Implants	Nternational	Jri Rthopaedics	Lima Corporate	Mathys Ltd	Medacta	Orthodynamics	Permedica	Peter Brehm	Speetec	Stanmore	Tornier	Waldemar Link	Wright / Microport
Cemented Primary Stems	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cementless Primary Stems	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Metal Heads	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ceramic Heads	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Metal Cups	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ceramic Liner	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

⁶¹³ Responses to Questionnaire Q1 to competitors, question 33.1.

Polyethylene Cups	✓	✓	✓	✓	✓	✓			✓	✓			✓			✓	✓	✓	✓		
Dual Mobility	✓	✓	✓	✓	✓	✓			✓	✓			✓	✓	✓	✓	✓			✓	
Revision Cups	✓	✓	✓	✓	✓	✓	✓			✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
Standard Liner	✓	✓	✓	✓	✓	✓	✓			✓	✓						✓	✓	✓		✓
XLPE Liner	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓			✓			✓
Antioxydant Poly Liners	✓	✓	✓						✓						✓						
Revision Stems	✓	✓	✓	✓	✓	✓	✓			✓	✓			✓	✓	✓	✓	✓	✓	✓	✓

Source: Response to the Article 6(1)(c) Decision

- (1399) Finally, it appears from the Parties' internal documents that they do not consider each other's as close competitors.
- (1400) The Avenir stem was specifically developed and put on the market to compete with J&J/DePuy's [...] * stem. Zimmer's internal documents show that Zimmer's goal in launching the Avenir stem was to "provide [its] customers with such a stem [similar to [...] *]".⁶¹⁴ A number of country-specific internal presentations also confirm this point.⁶¹⁵
- (1401) In addition, Zimmer's internal documents⁶¹⁶ show that Zimmer considers at least six other competitors to have a hip implant comparable to the Avenir stem. Avenir's launch plan does not differentiate between competitors and does not single out Biomet.⁶¹⁷ Internal documents also show that Zimmer only offers the Avenir stem in standard and lateral versions, while most other competitors (including Biomet) offer it also in cemented and revision versions.⁶¹⁸ Therefore, in this segment, Biomet appears to be a closer competitor to other companies (such as [...] * and [...] *) that all offer cemented and revision versions of the Avenir-like stems. Furthermore, internal documents confirm that Zimmer is aware of the competition from medium-sized local competitors in this segment, since it includes in its internal presentation a statement that "in all countries, many local manufacturers" have a "wide offer of different versions" of Avenir-like products.⁶¹⁹

⁶¹⁴ (EEA) Avenir cemented Phase 1 Review", submitted in response to RFI 3, slide 38; (EEA) Avenir cementless Business_Plan, submitted in response to RFI 3, slide 2.

⁶¹⁵ (ES) - In-market Product Plans 2011, submitted in response to RFI 3, slide 23; United Kingdom – Avenir Challenge, submitted in response to RFI 3, slide 1.

⁶¹⁶ (EEA) Avenir cemented Phase 1 Review, submitted in response to RFI 3, slide 39; Avenir Cemented Ph 1 Review Presentation, submitted in response to RFI 3, slide 39.

⁶¹⁷ (EEA) Avenir cementless Business_Plan, submitted in response to RFI 3.

⁶¹⁸ (EEA) Avenir cemented Phase 1 Review, submitted in response to RFI 3, slide 39; Avenir Cemented Ph 1 Review Presentation, submitted in response to RFI 3, slide 39.

⁶¹⁹ (EEA) Avenir cemented Phase 1 Review, submitted in response to RFI 3, slide 39.

- (1402) Zimmer has also issued a "standard conversation" text to guide its sales force when selling the Avenir stem.⁶²⁰ The document includes a scenario for new customers, a scenario for existing Zimmer customers and a scenario for [...] or [...] users (both [...] products). There is no scenario that would help the sales force target Biomet users.
- (1403) Biomet considered J&J/DePuy and not Zimmer to be its "target competitor" in the 2009 business plan prepared for Austria, Italy and Spain.⁶²¹ Similarly, DePuy was in general considered to be the main competitive threat for Biomet in its 2011 Business Plan, which also describes Stryker as an important competitor, but fails to mention Zimmer.⁶²²
- (1404) Biomet in its internal documents does not consider any of Zimmer's products as a close competitor to *Exceed ABT*, one of its [...] hip implant products. In its presentation of November 2010 on this product, Biomet lists the competitors and describes their presences in this segment. While Biomet singles out J&J/DePuy and Stryker as close competitors, Zimmer is not mentioned.⁶²³ This is confirmed by another presentation dating back to 2008, in which Biomet prepared a SWOT analysis for all competitors of Exceed ABT and Zimmer was again not mentioned.⁶²⁴
- (1405) The same can be observed for another of Biomet's [...] Exception Stem. Biomet prepared a number of presentations in which it described its competitors in the Exception stem segment and made no mention of Zimmer. It appears from these documents that Exception Stem is in close competition with [...] products.⁶²⁵ In another document, Biomet singled out [...] and [...] products as competing closely with Exception, while Zimmer's products are not even mentioned.⁶²⁶ In its Hip Campaign Sales Guide, Biomet discussed its competitors' products that it deems to compete with Exception. Again, it described [...] and [...] product, while Zimmer is not mentioned.⁶²⁷
- (1406) Based on the arguments set out in this section, the Commission concludes that Zimmer and Biomet are not each other's closest competitors in the market for hip implants.

Customer Switching

- (1407) Customer switching depends on various factors, such as on the size of the market and number of credible alternative suppliers available, on the role of surgeon's preference in the procurement process, on the procurement process itself (duration of tender contracts, multi-sourcing, etc.), as well as national registries and track records, in the absence of which, a given implant might not qualify to participate in tenders in specific countries. In addition, customer

⁶²⁰ (ES) - 2013-06 Avenir Cemented Launch Input, submitted in response to the follow up request to RFI 3, slide 43.

⁶²¹ Biomet - BPW FY09 Austria, BPW FY09 Italy, and BPW FY09 Spain, slides 96 - 97.

⁶²² Biomet - Biomet EMEA – Business Plan 2011, page 24.

⁶²³ Biomet - Exceed ABT Presentation Nov'2010, pages 42-51.

⁶²⁴ Biomet - Marketingplan Taperloc und Exceed ABT 2008, pages 15, 24.

⁶²⁵ Biomet - Exception Marketing Manual.ppt and Hip_Campaign_Sales_Guide_Exception_FR, pages 16 - 18.

⁶²⁶ Biomet - Exception Training 9 October (NXPowerLite), pages 54 - 56.

⁶²⁷ Biomet - Hip Campaign Sales Guide Exception, page 15.

switching dynamics are different for implants purchased outside tenders, through direct negotiations.

- (1408) Even if, as noted in recital (360), scientific literature suggests that switching to new suppliers of orthopaedic implants may temporarily increase the risk of revisions in the future, the market investigation provided evidence that in the hip implants market switching is easier and occurs more often than in other joint implants markets. This is due to the fact that surgeons are trained to use hip implants from more than one supplier. In addition, hip arthroplasty is the oldest and most widespread surgery compared to other types of joint arthroplasty surgery. The overall demand in volume for hip implants is higher than other implants and multi-sourcing is common practice. Higher volumes provide hospitals' procurement departments with more room to manoeuvre and greater economic incentive to convince their surgeons to use different suppliers in order to benefit from better pricing. The higher volumes in the hips market also justify the investment made on the supply-side to train surgeons.
- (1409) The situation is different in smaller markets where small volumes do not justify neither procurement departments' efforts to persuade surgeons to use different suppliers, nor suppliers' investment in surgeons' training. In addition, in these less commoditised markets, the complexity of the procedures and hence the risk of revision is higher.
- (1410) Because of the commoditised nature and maturity of the market for hip implants, "me-too" hip products are more widely available, known and used in comparison to other joint implant markets.
- (1411) The Notifying Party provided a non-exhaustive list of switching events in hospitals for hip implants across the EEA countries, exhibited in Table 96 below. The table covers the period between January 2010 and today. The first column indicates the total number of cases observed, while the second to fourth columns focus on switching episodes between the Parties, respectively classified as occurring in relation with Group 1 national markets, non-Group 1 national markets, or switching episodes in which the switch involves the Parties, but other competitors are also supplying the products concerned to the same customer. [...]*

Table 96: Breakdown of switching events for hip implants, January 2010 - present

EEA Country	Number Of Switching Cases	Switching Between The Parties		
		Group 1	Non-Group 1	Switching Partially To Other Suppliers (Either Group)
Austria	[...]*	[...]*	[...]*	[...]*
Belgium (including Luxembourg)	[...]*	[...]*	[...]*	[...]*
Czech Republic	[...]*	[...]*	[...]*	[...]*
Denmark	[...]*	[...]*	[...]*	[...]*
Finland	[...]*	[...]*	[...]*	[...]*
France	[...]*	[...]*	[...]*	[...]*

EEA Country	Number Of Switching Cases	Switching Between The Parties		
		Group 1	Non-Group 1	Switching Partially To Other Suppliers (Either Group)
Germany	[...]*	[...]*	[...]*	[...]*
Greece	[...]*	[...]*	[...]*	[...]*
Hungary	[...]*	[...]*	[...]*	[...]*
Ireland	[...]*	[...]*	[...]*	[...]*
Iceland	[...]*	[...]*	[...]*	[...]*
Italy	[...]*	[...]*	[...]*	[...]*
Netherlands	[...]*	[...]*	[...]*	[...]*
Norway	[...]*	[...]*	[...]*	[...]*
Poland	[...]*	[...]*	[...]*	[...]*
Portugal	[...]*	[...]*	[...]*	[...]*
Slovenia	[...]*	[...]*	[...]*	[...]*
Spain	[...]*	[...]*	[...]*	[...]*
Sweden	[...]*	[...]*	[...]*	[...]*
UK	[...]*	[...]*	[...]*	[...]*
Total	[...]*	[...]*	[...]*	[...]*

Source: Response to the Article 6(1)(c) Decision

- (1412) The market investigation also provided evidence that customer switching is possible for hip implants. Out of [...]* customers, [...]* customers actually changed supplier since 2012, usually following a tender.⁶²⁸ The switching rate is lower in other orthopaedic implants markets.
- (1413) The country-specific competitive analysis in section (1424) below includes all switching instances indicated by the market investigation, provided by the Notifying Party, and confirmed where possible by the Commission's targeted market reconstruction.
- (1414) In view of the arguments set out in this section, the Commission concludes that switching appears feasible for hip implants, mainly because of the large size of

⁶²⁸ Non-confidential minutes of the conference call with Bleckinge Hospital, of 24.10.2014, paragraph 3; and Non-confidential minutes of the conference call with PPSA NHS, of 11.11.2014, paragraph 24. Responses to Questionnaire Q31 to hospitals, question 10. More in detail, two customers in Austria, one customer in the Czech Republic, one customer in Finland, one customer in France, one customer in Greece, one customer in Italy, three customers in Portugal, one customer in Sweden, and one customer in the United Kingdom.

the market, its commoditised nature and maturity, and the fact that surgeons are trained to use hip implants of more than one supplier.

Countervailing buyer power

- (1415) As demonstrated above in section 8.8.1 above, the market for hip implants is mature and characterised by its commoditised nature, due to broad availability of copies, outsourcing of key technology to third parties, and incremental innovation in the market for hip implants.
- (1416) Competitor respondents to the market investigation provided evidence that, in principle, customers of orthopaedic products typically exercise their bargaining power during commercial negotiations by threatening to switch to other suppliers.⁶²⁹ Therefore, especially in the market for hip implants, customers can exercise their bargaining power during commercial negotiations more credibly. This applies to both tenders as well as direct negotiations and is evidenced by customer switching which is feasible and frequent in the market for hip implants.
- (1417) In addition, the in-depth market investigation provided evidence that the majority of hospitals (27 respondents out of 39, representing 79%) multi-source their needs for hip implants and believe that 3-4 suppliers is the minimum necessary to ensure an effective multi-sourcing policy for these implants.⁶³⁰ Therefore, threatening to switch to other hip suppliers is well founded in this market.
- (1418) In comparison with the other orthopaedic implants, the Commission concludes that buyer power is more likely to constrain the merged entity's behaviour in relation to hip implants. This is mainly because of the large size of the market and larger pool of competitors, its commoditised nature and maturity and therefore more products for customers to choose from, and the fact that hospitals switch, multi-source and their surgeons are trained to use hip implants of more than one supplier.

Barriers to entry and expansion

- (1419) A supplier that is already active in hip implants in any given EEA country will face no regulatory barrier in entering another EEA country with the very same hip implant. This entails that the supplier has already obtained the CE certification in the EEA country where it is present.⁶³¹
- (1420) Similarly, selling a new hip implant in an EEA country where a supplier is already present with other orthopaedic implants is "*relatively easy*", according to J&J/DePuy. Stryker commented that introducing a new product in a country in which a supplier is already present would be made easier due to the fact that "*the supplier already has infrastructure in place and is familiar with market access processes in the country*".⁶³²
- (1421) Entering a market with a new product would be more difficult due to the need of obtaining regulatory approvals, particularly for suppliers with no established

⁶²⁹ Responses to Questionnaire Q1 to competitors, question 105.

⁶³⁰ Responses to Questionnaire Q31 to hospitals, question 17.

⁶³¹ Responses to Questionnaire Q1 to competitors, question 108.2.

⁶³² Responses to Questionnaire Q1 to competitors, question 108.7.

presence because of the need of establishing distribution channels, hiring training force, etc.

- (1422) As described in section 8.5.1 above, regulatory requirements are lower for devices where equivalence to existing products on the market has been established. This is the case for "me-too" products, which are more common in the hip implants market than in other joint implants markets.
- (1423) The Commission takes into account the commoditised nature of the market, owed to broad availability of copies, outsourcing of key technology to third parties, and incremental innovation. Hospitals also appear to be ready to switch to other suppliers to hip implants, and often multi-source their requirements from more than one hip implants supplier.
- (1424) Given the arguments set out in this section, the Commission concludes that barriers to entry in relation to the market for hip implants are in general low, and clearly lower than other orthopaedic implants.

8.8.5. Country-specific Competitive Assessment

- (1425) At national level, on the basis of the market share estimates submitted by the Parties, the merger would give rise to 11 Group 1 national markets: Austria, the Czech Republic, Denmark, Finland, Germany, Lithuania, the Netherlands, Portugal, Romania, Slovenia and Spain. In 2013, the total value of these Group 1 national markets was approximately EUR [500-600]* million, and the Parties' sales in these markets amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The Parties have combined market shares in these markets ranging from approximately [30-40]*% (in Germany) to [70-80]*% (in Romania) and merger increments ranging between approximately [0-5]*% (in Germany) and [20-30]*% (in the Netherlands).

Table 97: All hip implants – Group 1 markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁶³³	Competitors
<i>AT</i>	[20-30]*%	[5-10]*%	[30-40]*%	[1-50]*	J&J/DePuy ([10-20]*%), Medacta ([10-20]*%), S&N ([5-10]*%), Mathys ([5-10]*%), Stryker ([5-10]*%), residual ([5-10]*%)
<i>CZ</i>	[20-30]*%	[10-20]*%	[40-50]*%	[1-50]*	Aesculap ([20-30]*%), Lima ([5-10]*%), Beznoska ([5-10]*%)
<i>DK</i>	[10-20]*%	[30-40]*%	[50-60]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), S&N ([5-10]*%)
<i>FI</i>	[10-20]*%	[20-30]*%	[40-50]*%	[1-50]*	J&J/DePuy ([30-40]*%), Stryker ([10-20]*%), S&N ([5-10]*%)
<i>DE</i>	[30-40]*%	[0-5]*%	[30-40]*%	[200-300]*	S&N ([10-20]*%), Aesculap ([10-20]*%), J&J/DePuy ([10-20]*%), Mathys ([5-10]*%)

⁶³³

Source: Form CO, (estimates of the Parties).

<i>LT</i>	[10-20]*%	[30-40]*%	[50-60]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), Link ([10-20]*%), S&N ([5-10]*%)
<i>NL</i>	[20-30]*%	[20-30]*%	[50-60]*%	[50-100]*	S&N ([10-20]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%)
<i>PT</i>	[10-20]*%	[10-20]*%	[30-40]*%	[1-50]*	J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), S&N ([10-20]*%)
<i>RO</i>	[60-70]*%	[10-20]*%	[70-80]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([5-10]*%), Stryker ([5-10]*%)
<i>SL</i>	[30-40]*%	[10-20]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), S&N ([5-10]*%), Stryker ([5-10]*%), Lima ([5-10]*%)
<i>ES</i>	[20-30]*%	[10-20]*%	[30-40]*%	[100-200]*	S&N ([10-20]*%), J&J/DePuy ([5-10]*%), Stryker ([5-10]*%), residual ([10-20]*%)
<i>EEA</i>	[20-30]*%	[5-10]*%	[30-40]*%	[over 1,000]*	J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), S&N ([10-20]*%)

Source: Form CO

- (1426) In each of the Group 1 national markets, the merged entity will be the number one player, often with a significantly larger market share than the next market player.
- (1427) The Notifying Party submits that a large number of competitors will continue to exert significant competitive constraint on the merged entity. Other major competitors are present on the market, such as J&J/DePuy, Stryker, S&N, and other fringe players.

8.8.5.1. Austria

- (1428) According to the Notifying Party, in Austria, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1429) Over the 2011-2013 period, Zimmer's position decreased from [40-50]*% to [20-30]*%, and Biomet's position decreased from [10-20]*% to [5-10]*%.
- (1430) The Parties have combined market shares of approximately [30-40]*%, with Biomet contributing an increment of approximately [5-10]*%. Post-merger and apart from certain residual competitors, there will be five other competitors left with market shares over 5%, namely J&J/DePuy, Medacta, and S&N, Mathys and Stryker. Zimmer and Biomet are number one and number five in Austria.
- (1431) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly overestimated their market shares. The Parties appear to have combined market shares of approximately [30-40]*%, with Biomet contributing an increment of approximately [5-10]*%. The market reconstruction largely confirmed the presence of another seven competitors with market shares of above 5% or slightly below 5%, with at least three having market shares of above the overlap, and therefore able to constrain the merged entity post-merger. This is also supported by the decrease in the

Parties' combined market share over the 2011-2013 period which was confirmed by the Commission's targeted market reconstruction.

- (1432) The Market investigation provided evidence switching in the hip implants market from Biomet to Medacta,⁶³⁴ due to the fact that the price of the new supplier was significantly lower, of a price difference of at least [20-30]*%.⁶³⁵ The Commission notes that the Notifying Party identified [...] instances of customers switching suppliers in the Austrian market for hip implants during the period 2012-2013.⁶³⁶
- (1433) In terms of market entry, the Notifying Party claims that the entry of Mediform and Medacta into the Austrian market in 2005 and 2006 respectively, and by Brehm in 2010 shows that entry into the Austrian market for hip implants is feasible.⁶³⁷ According to the Commission's targeted market reconstruction, only one entrant succeeded in entering the Austrian market for hip implants and achieved meaningful market shares in the last five years.
- (1434) The Commission therefore considers that in the Austrian market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1435) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Austria.

8.8.5.2. Czech Republic

- (1436) According to the Notifying Party, in the Czech Republic, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1437) Over the 2011-2013 period, Zimmer's position decreased from [20-30]*% to [20-30]*%, while Biomet's position remained essentially the same, moving from [10-20]*% to [10-20]*%.
- (1438) The Parties have combined market shares of approximately [40-50]*% in the overall hip market, with Biomet contributing an increment of approximately [10-20]*%. Post-merger, there will be three other competitors left with market shares over 5%, namely Aesculap, Lima, and Beznoska. Zimmer and Biomet are number one and number three in the Czech Republic.
- (1439) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties slightly overestimated their market shares. The Parties appear to have combined market shares of approximately [30-40%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of another three competitors one having bigger market share than the overlap and another having market shares of above 10%. This is also supported by the decrease in the Parties' combined market share over the 2011-2013 period which was confirmed by the Commission's targeted market reconstruction.

⁶³⁴ Responses to Questionnaire Q2 to customers, question 38.

⁶³⁵ Responses to Questionnaire Q2 to customers, question 39.

⁶³⁶ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶³⁷ Response to the Article 6(1)(c) Decision, paragraph 243, and Form CO, paragraph 1024.

- (1440) Although the Parties both underestimated and overestimated in some instances the market shares of their competitors, the Commission's targeted market reconstruction indicated that Aesculap will be a strong competitor, able to constrain the merged entity, with market shares very close to the merged entity. Lima will also be a significant competitor post-merger. The Commission notes that the Notifying Party identified [...] instances of customers switching suppliers in the market for hip implants in the Czech Republic during the period 2011-2014.⁶³⁸
- (1441) In terms of market entry, the Parties claim that the entry of Lima in 2005 and Implantcast and Mathys in 2010 and 2011 respectively, shows that entry into the market for hip implants in the Czech Republic is feasible.⁶³⁹ The Commission's targeted market reconstruction indeed confirmed these entries, as well as the fact that Lima succeeded in entering the market for hip implants in the Czech Republic and achieved meaningful market shares in the last four years.
- (1442) The Commission therefore considers that in the market for hip implants it is likely that these established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1443) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in the Czech Republic.

8.8.5.3. Denmark

- (1444) According to the Notifying Party, in Denmark, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1445) Over the 2011-2013 period, Zimmer's position slightly decreased from [10-20]*% to [10-20]*%, while Biomet's position increased from [30-40]*% to [30-40]*%.
- (1446) The Parties' combined market share threshold exceeds [50-60]*% in this market. The merged entity holds market share of approximately [50-60]*%, with Zimmer contributing an increment of approximately [10-20]*%. Post-merger, there will be two competitors with market shares higher than the increment, namely J&J/DePuy ([20-30]*%) and Stryker ([10-20]*%) and one other competitor, S&N, with market shares over 5%. Zimmer and Biomet are number four and number one in Denmark.
- (1447) Eucomed's data and the Commission's targeted market reconstruction indicated that the Parties slightly underestimated their market shares. The Parties appear to have combined market shares of approximately [50-60]*%, with Zimmer contributing an increment of approximately [10-20]*%. The market reconstruction confirmed that the merger is a five-to-four merger. Post-merger there will be three other competitors left, one with bigger market share than the overlap ([20-30]*%), and the other two with market shares over 5%, and therefore able to constrain the merged entity post-merger. There are also two

⁶³⁸ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶³⁹ Response to the Article 6(1)(c) Decision, paragraph 251, and Form CO, paragraph 1056.

small competitors. The market reconstruction confirmed the increase in the Parties' combined market share over the 2011-2013 period.

- (1448) Switching in the Danish market for hip implants is feasible. The Notifying Party identified [...] instances of customers switching suppliers in the Danish market for hip implants, during the period 2013-2014.⁶⁴⁰ [...].
- (1449) In addition, hospitals and hospital groups in Denmark exert significant buyer power on suppliers since the buyer side is highly consolidated. For Zimmer, the top ten hospitals represent over [70-80]% of its sales, and the largest customer alone represents [10-20]%. For Biomet, the top ten hospitals represent [60-70]% of its sales and the largest purchasing group alone represents [40-50]%.
- (1450) The Commission therefore considers that in the Danish market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1451) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Denmark.

8.8.5.4. Finland

- (1452) According to the Notifying Party, in Finland, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1453) Over the 2011-2013 period, Zimmer's position slightly decreased from [10-20]% to [10-20]%, while Biomet's position decreased from [20-30]% to [20-30]%.
- (1454) The Parties have combined market shares of approximately [40-50]% in the overall hip market, with Zimmer contributing an increment of approximately [10-20]%. Post-merger, there will be one competitor as big as the merged entity, and two smaller ones with market shares between [5-10]% and [10-20]%, namely J&J/DePuy, Stryker, and S&N. Zimmer and Biomet are number three and number two in Finland.
- (1455) Eucomed's data and the Commission's targeted market reconstruction largely the Parties' market shares. Although the market reconstruction gave a different picture of the competitive landscape, post-merger there will be four competitors, two of them with bigger market shares than the overlap, and one with a market share of above 10%. The decrease in the Parties' combined market share over the 2011-2013 period was confirmed by the Commission's targeted market reconstruction.
- (1456) The market investigation indicated that customers in Finland do not in principle consider Zimmer and Biomet as close competitors in the market for hip implants.⁶⁴¹ The Market investigation, also confirmed switching in the hip

⁶⁴⁰ Response to the RFI Q16 of 08.10.2014- Switching Events.

⁶⁴¹ Responses to Questionnaire Q2 to customers, question 47.

implants market.⁶⁴² The Commission notes that the Notifying Party identified [...] instances of customers switching suppliers in the Finnish market for hip implants during the period 2012-2014.⁶⁴³

- (1457) In terms of market entry, the Notifying Party claims that the entry of Implantcast and Serf-Dedienne in 2008 and 2011 respectively, shows that entry into the Finnish market for hip implants is feasible.⁶⁴⁴ However the Commission's targeted market reconstruction did not confirm that such entries were indeed successful, in that they achieved meaningful market shares in the last five years.
- (1458) The Commission considers that in the Finnish market for hip implants, it is likely that the established players would continue to constrain the merged entity post-merger.

Conclusion

- (1459) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Finland.

8.8.5.5. Germany

- (1460) According to the Notifying Party, in Germany, the total value of the overall hip market was EUR [200-300]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1461) Over the 2011-2013 period, Zimmer's position remained stable at approximately [30-40]*%, and Biomet's position remained essentially the same, moving from [0-5]*% to [0-5]*%.
- (1462) The Parties have combined market shares of approximately [30-40]*% in the overall hip market, with Biomet contributing an increment of approximately [0-5]*%. Post-merger there will be four significant competitors left, namely S&N ([10-20]*%), Aesculap ([10-20]*%), J&J/DePuy ([10-20]*%) and Mathys ([5-10]*%).
- (1463) Eucomed's data and the Commission's targeted market reconstruction confirmed the estimated market shares for the Parties. The market reconstruction indicated that post-merger there will be another three competitors left with market shares bigger than the overlap and of above [10-20]*%.
- (1464) Furthermore, according to Zimmer's CRM dataset for Germany, as shown in Table 98, the distribution of sales opportunities involving hip implants in Germany in 2013 reveals that three competitors were each identified by Zimmer in more than 15% of all sales opportunities as Zimmer's primary competitors in 2013, namely J&J/DePuy, Aesculap and S&N. Biomet was identified as Zimmer's main rival on just [0-5]*% of the opportunities. Three other players, namely Stryker, Link and Mathys, were more often perceived as primary competitors than Biomet.

⁶⁴² Responses to Questionnaire Q2 to customers, question 38.

⁶⁴³ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶⁴⁴ Response to the Article 6(1)(c) Decision, paragraph 264.

Table 98: Primary Competitor Analysis, Hip Implants (Germany, 2013)

Primary Competitor	Frequency	Percentage	Zimmer Incumbent
J&J/DePuy	[...]*	[20-30]*%	[50-60]*%
Aesculap	[...]*	[10-20]*%	[60-70]*%
S&N	[...]*	[10-20]*%	[60-70]*%
Stryker	[...]*	[5-10]*%	[60-70]*%
Link	[...]*	[5-10]*%	[50-60]*%
Mathys	[...]*	[0-5]*%	[70-80]*%
Biomet	[...]*	[0-5]*%	[50-60]*%
13 other suppliers	[...]*	[20-30]*%	N/A
Total number of sale opportunities	[...]*		

Source: Zimmer CRM data

(1465) In 2014 the picture is very similar, as shown in Table 99. Biomet only appears as Zimmer's primary competitor in [5-10]*% of the occasions and S&N and J&J/DePuy are overwhelmingly Zimmer's main competitors followed up by Aesculap and Stryker. Overall, the Commission observes that Zimmer does not appear to perceive Biomet as its closest competitor in the German market for hip implants.

Table 99: Primary Competitor Analysis, Hip Implants (Germany, 2014)

Primary Competitor	Frequency	Percentage	Zimmer Incumbent
S&N	[...]*	[20-30]*%	[50-60]*%
J&J/DePuy	[...]*	[20-30]*%	[40-50]*%
Aesculap	[...]*	[5-10]*%	[10-20]*%
Stryker	[...]*	[5-10]*%	[50-60]*%
Biomet	[...]*	[5-10]*%	[40-50]*%
Link	[...]*	[5-10]*%	[30-40]*%
8 other suppliers	[...]*	[20-30]*%	N/A.
Total number of sale opportunities	[...]*		

Source: Zimmer CRM data

(1466) The Market investigation also confirmed switching in the hip implants market.⁶⁴⁵ The Commission notes that the Notifying Party identified [...]*

⁶⁴⁵ Responses to Questionnaire Q2 to customers, question 38.

instances of customers switching suppliers in the German market for hip implants during the period 2012-2014.⁶⁴⁶

- (1467) In terms of market entry, the Notifying Party claims that the entry of Implantec in 2012 and the recent entry of Atesos shows that entry into the German market for hip implants is feasible.⁶⁴⁷
- (1468) The Commission therefore considers that in the German market for hip implants, it is likely that the established players would continue to constrain the merged entity post-merger.

Conclusion

- (1469) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Germany.

8.8.5.6. Lithuania

- (1470) According to the Notifying Party, in Lithuania, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1471) Over the 2011-2013 period, Zimmer's market share increased from [10-20]*% to [10-20]*%, and Biomet's from [10-20]*% to [30-40]*%.
- (1472) The Parties' combined market share is approximately [50-60]*%, with Zimmer contributing an increment of approximately [10-20]*%. Post-merger there will be four other competitors with one having market share bigger than the overlap, namely J&J/DePuy ([20-30]*%), Stryker ([10-20]*%), Link ([10-20]*%), and S&N ([5-10]*%). Zimmer and Biomet are number three and number one in Lithuania.
- (1473) The Commission's targeted market reconstruction does not cover Lithuania.
- (1474) The Commission notes that in Lithuania tender awarded supply contracts are of short duration (12 months) which puts successful bidders under competitive pressure as they do not secure an achieved market position and require suppliers to regularly test their offers in tenders.⁶⁴⁸
- (1475) In terms of market entry, the Notifying Party claims that the entry of S&N and Mathys into the Lithuanian market in 2008 and 2013 respectively, shows that entry is feasible.⁶⁴⁹ The Commission notes that Lithuania is among the smallest EEA markets for hip implants, along with Romania and Slovenia, and as a result market shares can shift significantly as a result of a few wins or losses.
- (1476) Furthermore, according to Zimmer, [...] became very quickly a significant competitive force in the Lithuanian market, and is "*[s]till pushing commercial hips in [...] and [...] in Lithuania*".⁶⁵⁰

⁶⁴⁶ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶⁴⁷ Response to the Article 6(1)(c) Decision, paragraph 273, and Form CO, paragraph 1104.

⁶⁴⁸ Response to the Article 6(1)(c) Decision, paragraph 278.

⁶⁴⁹ Response to the Article 6(1)(c) Decision, paragraph 279, and Form CO, paragraph 1152.

⁶⁵⁰ ID259, submitted in Response to RFI 14, page 1.

- (1477) The Commission considers that in the Lithuanian market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1478) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Lithuania.

8.8.5.7. The Netherlands

- (1479) According to the Notifying Party, in the Netherlands, the total value of the overall hip market was EUR [50-100]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1480) Over the 2011-2013 period, Zimmer's market share in the Netherlands slightly increased from [20-30]*% to [20-30]*%, while Biomet's position remained essentially the same, moving from [20-30]*% to [20-30]*%.
- (1481) The Parties' combined market share is approximately [50-60]*%, with Zimmer contributing an increment of approximately [20-30]*%. Post-merger there will be three other large competitors left with significant market shares namely S&N ([10-20]*%), J&J/DePuy ([10-20]*%), and Stryker ([10-20]*%).
- (1482) Eucomed's data and the Commission's targeted market reconstruction indicated that the Parties slightly overestimated their market shares. The Parties appear to have combined market shares of approximately [40-50%], with Zimmer contributing an increment of approximately [20-30%]. The market reconstruction largely confirmed the presence of another five competitors with market shares of above 5%, with at least three having market shares of above 10%, and therefore able to constrain the merged entity post-merger. German purchasing groups, like Prospitalia and Clinic Partners, are also active in the Dutch market, exerting further buyer pressure on suppliers.⁶⁵¹ Furthermore, Zimmer in its internal documents noted that [...] is "aggressive in the hip fracture market, offering [...] for [...] Euros".⁶⁵²
- (1483) The Commission notes that the Notifying Party identified [...] instances of customers switching suppliers in the Dutch market for hip implants during the period 2008-2014.⁶⁵³ Out of [...] instances, only [...] of these switches occurred between the Parties.
- (1484) In terms of market entry, the Notifying Party claims that the entry of Lima, Biomet and Zimmer in 2011, 2013 and 2014 respectively, shows that entry into the Dutch market for hip implants is feasible.⁶⁵⁴ However, the Commission's targeted market reconstruction did not confirm a successful entry of Lima in the Dutch market for hip implants.
- (1485) The Commission considers that in the Dutch market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

⁶⁵¹ Supplementary Submission on specific markets of 17.02.2015, paragraph 17.

⁶⁵² ID248, submitted in Response to RFI 14, page 3.

⁶⁵³ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶⁵⁴ Response to the Article 6(1)(c) Decision, paragraph 284.

Conclusion

- (1486) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in the Netherlands.

8.8.5.8. Portugal

- (1487) According to the Notifying Party, in Portugal, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1488) Over the 2011-2013 period, the Parties' combined market share in Portugal decreased from [40-50]*% to [30-40]*%. Zimmer's position decreased from [20-30]*% to [10-20]*%, and Biomet's position decreased from [20-30]*% to [10-20]*%.
- (1489) The Parties have combined market shares of approximately [30-40]*% in the overall hip market, with Biomet contributing an increment of approximately [10-20]*%. Post-merger there will be three other competitors left with market shares over 5%, namely J&J/DePuy, Stryker, and S&N. Zimmer and Biomet are number two and number three in Portugal.
- (1490) Eucomed's data and the Commission's targeted market reconstruction confirmed the Parties' market share estimates. The market reconstruction also indicated the presence of another four competitors with market shares of above 5%, with at least three having market shares of above 10%, and therefore able to constrain the merged entity post-merger. This is also supported by the decrease in the Parties' combined market share over the 2011-2013 period which was confirmed by the Commission's targeted market reconstruction.
- (1491) The Commission notes that the Notifying Party identified [...] instances of customers switching suppliers in the Austrian market for hip implants in 2014.⁶⁵⁵ Only [...] of these switches occurred between Zimmer and Biomet.
- (1492) In terms of market entry, the Notifying Party claims that the entry of Lima and UOC/U2 into the Portuguese market in 2008 and 2011 respectively, as well as the entry of Stryker and Arthrex in recent years, shows that entry into the Portuguese market for hip implants is feasible.⁶⁵⁶ The Commission's targeted market reconstruction, confirmed that Lima succeeded in entering the Portuguese market for hip implants and achieved meaningful market shares in the last five years.
- (1493) The Commission therefore considers that in the Portuguese market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1494) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Portugal.

⁶⁵⁵ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶⁵⁶ Response to the Article 6(1)(c) Decision, paragraph 292; Form CO, paragraph 1190.

8.8.5.9. Romania

- (1495) According to the Notifying Party, in Romania, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1496) Over the 2011-2013 period, Zimmer's position increased from [40-50]*% to [60-70]*%, and Biomet's position slightly increased from [10-20]*% to [10-20]*%.
- (1497) The Parties' combined market share is of approximately [70-80]*%, with Biomet contributing an increment of approximately [10-20]*%. Post-merger there will be three other large competitors left (J&J/DePuy, S&N and Stryker) with one having market share bigger than the overlap, namely J&J/DePuy, as well as other smaller competitors (Tornier, Lima and Link). Zimmer and Biomet are number one and number three in Romania.
- (1498) The Commission's targeted market reconstruction does not cover Romania.
- (1499) In terms of market entry, the Notifying Party claims that Zimmer itself entered the Romanian market in 2005,⁶⁵⁷ long after Biomet, and already in 2011 had achieved market shares of [40-50]*%. Furthermore, according to the Notifying Party, the recent entry of Tornier, Lima and Link shows that entry into the Romanian market for hip implants is feasible.⁶⁵⁸ Indeed, according to Zimmer's internal documents, new entry has been a noticeable trend in the region in that "[n]ewcomers like AAP, Wright, Implantcast, Medacta, and Intraplant" are "trying to get in with [...]".⁶⁵⁹ The Commission notes that Romania is among the smallest EEA markets for hip implants, along with Lithuania and Slovenia, and as a result market shares can shift significantly as a result of a few wins or losses.
- (1500) The Commission considers that in the Romanian market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1501) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Romania.

8.8.5.10. Slovenia

- (1502) According to the Notifying Party, in Slovenia, the total value of the overall hip market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1503) Over the 2011-2013 period, Zimmer's market share slightly decreased from [30-40]*% to [30-40]*%, while Biomet entered the market successfully in 2012 and achieved a market share of [10-20]*% in 2013.
- (1504) The Parties have combined market shares of approximately [40-50]*%, with Biomet contributing an increment of approximately [10-20]*%. Post-merger there will be three other large significant competitors left, with one having a

⁶⁵⁷ Response to the Article 6(1)(c) Decision, paragraph 297.

⁶⁵⁸ Form CO, paragraph 1205.

⁶⁵⁹ ZM-EU-00006073, submitted in Response to RFI 28, slide 12.

market share bigger than the overlap, namely J&J/DePuy ([20-30]*%), and two with market shares in the region of [10-20]*%, namely S&N ([5-10]*%), and Stryker ([5-10]*%). A smaller competitor, Lima ([5-10]*%), is also present in this market. Zimmer and Biomet are number one and number three in Slovenia.

- (1505) The Commission's targeted market reconstruction does not cover Slovenia.
- (1506) The Commission notes that the Notifying Party identified [...] instances of customers switching suppliers in the Slovenian market for hip implants in 2013.⁶⁶⁰
- (1507) In terms of market entry, the Notifying Party claims that the entry of S&N and Stryker in 2006 and 2008 respectively, as well as Mathys in the last two years, shows that entry into the Slovenian market for hip implants is feasible.⁶⁶¹ The Notifying Party also provides that Biomet entered the Slovenian market for hip implants in 2012 and managed to obtain market shares of [10-20]*% in 2013. The Commission notes that Lithuania is among the smallest EEA markets for hip implants, along with Romania and Slovenia, and as a result market shares can shift significantly as a result of a few wins or losses.
- (1508) The Commission therefore considers that in the Slovenian market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1509) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Slovenia.

8.8.5.11.Spain

- (1510) According to the Notifying Party, in Spain, the total value of the overall hip market was EUR [100-200]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1511) Over the 2011-2013 period, Zimmer's market share decreased from [20-30]*% to [20-30]*%, and Biomet's from [10-20]*% to [10-20]*%.
- (1512) The Parties have combined market shares of approximately [30-40]*%, with Biomet contributing an increment of approximately [10-20]*%. Post-merger there will be three other large significant competitors left, namely S&N ([10-20]*%), J&J/DePuy ([5-10]*%), and Stryker ([5-10]*%), as well as a number of smaller competitors that account for 12% of the market. Zimmer and Biomet are number one and number three in Spain.
- (1513) Eucomed's data and the Commission's targeted market reconstruction confirmed that the Parties underestimated their market shares. The Parties appear to have combined market shares of approximately [40-50%], with Biomet contributing an increment of approximately [10-20%]. The market reconstruction largely confirmed the presence of another three competitors with market shares of above 10%, and a number of smaller competitors. The Commission's targeted market reconstruction indicated that the combined market shares of the Parties slightly increased over the 2011-2013 period.

⁶⁶⁰ Response to the RFI Q16 of 08.10.2014 - Switching Events.

⁶⁶¹ Response to the Article 6(1)(c) Decision, paragraph 303, and Form CO, paragraph 1211.

- (1514) [...]*.⁶⁶²
- (1515) In terms of market entry, the Notifying Party claims that the entry of Surgical and Medacta in 2005, Samo in 2006, Mathys and Exactech in 2010, and Corin in 2012 shows that entry into the Spanish market for hip implants is feasible.⁶⁶³ The Notifying Party also provides a list of entrants that entered the Spanish market for hip implants during the last five years, namely Integra, Future Implants, Medcomtech, and OSTEAL Ibérica, S.A.⁶⁶⁴ According to the Commission's targeted market reconstruction, only one entrant succeeded in achieving meaningful market shares.
- (1516) The Commission considers that in the Spanish market for hip implants, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Conclusion

- (1517) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in Spain.

8.8.6. Conclusion – Hip implants

- (1518) The Commission considers that barriers to entry and expansion in the market for hip implants are not significant enough to prevent remaining and potential competitors from efficiently constraining the merged entity. This is also evidenced by numerous instances of customers switching suppliers for hip implants, which is not as usual as with other orthopaedic implants.
- (1519) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of hip implants in any of the Group 1 national markets.

8.9. Shoulder Implants

8.9.1. Overview of the market for shoulder implants

- (1520) According to the Notifying Party, the EEA market for the overall shoulder implants is relatively small, amounting to EUR [100-200]* million in 2013. The most important segment in the overall shoulder market is the one for reverse shoulder implants with sales amounting to EUR [50-100]* million followed by degenerative shoulder implants with sales of EUR [1-50]* million and fracture shoulder implants with sales of EUR [1-50]* million.
- (1521) The shoulder implant market is a relatively new segment compared to other orthopaedic markets, such as hips and knees. As such, it continues to grow as suppliers continue to develop innovative implants, such as the reverse prosthesis, to expand their product portfolio. The main competitors for the shoulder market are J&J/DePuy, Tornier, Zimmer, Biomet, S&N, Lima, Exactech, Arthrex, Mathys, as well as others.⁶⁶⁵

⁶⁶² Response to the Article 6(1)(c) Decision, paragraph 306.

⁶⁶³ Response to the Article 6(1)(c) Decision, paragraph 310.

⁶⁶⁴ Form CO, paragraph 1220.

⁶⁶⁵ Others include Accumed, Ceraver, Coring Group, DJO Global, IntegraLifeSciences, Stryker, Tecres and Waldemar Link.

8.9.2. The Parties' and their competitors' products

- (1522) Zimmer manufactures the following shoulder prostheses: (i) *Zimmer Anatomical Shoulder System* (used to treat fracture and degenerative conditions), (ii) *Trabecular Metal ("TM") Shoulder System* (it does not distinguish fractures from degenerative pathologies), (iii) *Bigliani/Flatow Complete Shoulder Solution Family* (standard shoulder solutions), (iv) *Sidus* stemless shoulder and (v) *Durom* Shoulder cup. The last two are a method of humeral resurfacing and are used to treat degenerative conditions.
- (1523) Biomet supplies the following shoulders prostheses: (i) *Comprehensive Total Shoulder System* (ii) *Comprehensive Fracture System*, (iii) *Comprehensive Reverse Shoulder System*, (iv) *Comprehensive Segmental Revision System*, (v) *Copeland Shoulder Humeral Head Resurfacing*, (vi) *Copeland EAS Humeral Resurfacing Head*, (vii) *TESS Total Evolutive Shoulder System*, (viii) *Comprehensive Nano Stemless Shoulder* and (ix) *The Signature Glenoid System* (a patient-specific surgical positioning guide which offers a tailored approach in surgery).
- (1524) Table 100 below provides a list of the Parties' and competitors' shoulder implants:

Table 100: Parties' and competitors' shoulder implants

Supplier	Fracture	Degenerative	Reverse
Zimmer	Anatomical Shoulder Fracture System	Anatomical Shoulder System	Anatomical Shoulder Inverse/Reverse System
	Trabecular Metal Humeral Stem		Trabecular Metal Reverse Shoulder System
Biomet	Comprehensive Fracture System	Comprehensive Reverse Shoulder System Comprehensive Nano Stemless Shoulder	Comprehensive Total Shoulder System
	TESS Total Evolutive Shoulder System		
Tornier	Aequalis Fracture	Aequalis Cemented; Aequalis Press-Fit	Aequalis Reversed; Aequalis Reverse Fracture
J&J/DePuy	Epoca Shoulder Arthroplasty System		Delta XTEND Reverse Shoulder System
Lima	Anatomic	Trauma	SMR Reverse HP System; SMR Reverse
Arthrex	Univers Shoulder Fracture System	Univers II Total Shoulder System	Univers Revers Technique
Stryker	ReUnion HA Fracture System	Solar Shoulder	

Supplier	Fracture	Degenerative	Reverse
S&N	Promos Standard Shoulder System		Promos Reverse Shoulder System
DJO	Turon Modular Shoulder System		RSP Monoblock; RSP Reverse Shoulder Prosthesis
Integra	Titan Modular Shoulder system		Integra Titan Reverse Shoulder System
Mathys	Affinis Fracture	Affinis total Shoulder Endoprosthesis	Affinis Inverse

Source: Form CO

8.9.3. General Competitive Assessment

- (1525) The Notifying Party claims that in the overall shoulder implants, the Parties' activities are constrained by a significant number of strong alternative suppliers for overall shoulder implants. According to the Notifying Party, the three biggest players that compete strongly in the overall shoulder implants at EEA level are J&J/DePuy, Tornier and Lima.⁶⁶⁶
- (1526) The Notifying Party further submits that the Parties are not each other's closest competitors. Zimmer's [...] products are TM Reverse and the Anatomical Shoulder Solution System that closely compete with products supplied by J&J/DePuy and Lima in particular. Biomet's [...] products are in the Comprehensive System, including all segments (fracture, degenerative and reverse). These products compete with Zimmer's, but also with those of other major players such as J&J/DePuy (*Global* and *Delta*), Tornier (*Aequalis*), Exatech (*Equinox*) and DJO (*Encore*).
- (1527) The respondents to the market investigation indicated that the closest competitors of Zimmer are (in order of importance) J&J/DePuy, Tornier and Biomet. Similarly, Biomet's closest competitors are J&J/DePuy, Tornier and Zimmer.⁶⁶⁷ The results of the market investigation suggest that, even though the Parties are not each other's closest competitors, some rivalry between Zimmer and Biomet in the overall market for all shoulder implants exist.
- (1528) Additionally, DJO notes that the most innovative competitors in the shoulder implants market are Stryker, J&J/DePuy and Zimmer, while Mathys perceives Tornier, Lima and J&J/DePuy as the most innovative competitors.⁶⁶⁸
- (1529) In an internal document entitled "*SWOTs Extremities*",⁶⁶⁹ Zimmer considers [...]*, Biomet and [...]* as the strongest competitors, while [...]* and [...]* are seen as middle range competitors. [...]* and [...]* are perceived as weak competitors. Although [...]* is considered as middle competitor, the Notifying

⁶⁶⁶ Form CO, paragraph 488.

⁶⁶⁷ Responses to Questionnaire Q1 to Competitors, question 107 and responses to Questionnaire Q2 to Customers, question 47.

⁶⁶⁸ Responses to Questionnaire Q30 on entry and innovation, question 37.

⁶⁶⁹ See Zimmer's internal document "*SWOTs Extremities*", ID1929, slide 5.

Party notes in the same internal document that [...] has an "aggressive push into shoulder reconstruction, [...]"⁶⁷⁰

- (1530) Other Zimmer's internal documents indicate a wide range of competitors in the overall shoulder market ([...]), as well as a variety of competitors per type of implant/pathology.⁶⁷¹ Similarly, Biomet's internal documents show that the main threat to its shoulder portfolio are [...] implant and [...] innovative products ([...]).⁶⁷² [...] is considered an innovative competitor by Zimmer, while [...] pursues a strategy of launching new shoulder implants. Other competitors such as [...] are all developing new shoulder systems according to the Notifying Parties' internal documents.⁶⁷³
- (1531) In view of the arguments set out in this section, it can be concluded that although Zimmer and Biomet are strong competitors, they are not each other closest competitors in the overall shoulder implants market and there are enough alternative suppliers that would continue to constrain the Parties post-merger.
- (1532) With respect to entry, evidence suggests that shoulder implants encounter less entry barriers compared to other orthopaedic implants. For example, one competitor indicated that the requirements to participate in the market are less restrictive in the small joints, especially towards clinical data since smaller joints are less mature compared to larger joints.⁶⁷⁴ This statement is further supported by one of Zimmer's internal documents that points out that "barriers to entry are easing in the shoulder market".⁶⁷⁵

8.9.4. Overall Shoulder Implants

8.9.4.1. Structure of the overall shoulder implants market

- (1533) According to the Notifying Party, total EEA sales for all shoulder implants were EUR [100-200] million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. In a market encompassing all shoulder implants, the merged entity would have a market share of [20-30]% at EEA level, with Biomet contributing an increment of [5-10]%. There are three suppliers with market shares above the increment, namely J&J/DePuy ([20-30]%), Tornier ([10-20]%) and Lima ([10-20]%), as well as other smaller players such as Arthrex, Mathys, S&N and Stryker. The market shares of the Parties have remained stable over the period 2011-2013.

⁶⁷⁰ See Zimmer's internal document "SWOTs Extremities", ID1929, slide 5.

⁶⁷¹ See Zimmer's internal document "EMEA Extremities Business plan 2013-2017", ID1929, slide 41.

⁶⁷² See Biomet's internal document "Grow Shoulder Market Share With Comprehensive Platform and Anchor Portfolio", ID 1421, slide 7.

⁶⁷³ See Zimmer's internal document "Extremity Sales Training October 2013"; ID2773, slide 3.

⁶⁷⁴ Non-confidential minutes of the conference call with Lima of 05.08.2014, paragraph 8.

⁶⁷⁵ See Zimmer's internal document "SWOTs Extremities", M.7265/ID1929, slide 2.

Table 101: All shoulders implants – Group 1 markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁶⁷⁶	Competitors
<i>CZ</i>	[30-40]*%	[10-20]*%	[40-50]*%	[less than 1]*	Lima ([40-50]*%), J&J/DePuy ([5-10]*%), S&N ([5-10]*%), Prospan ([5-10]*%)
<i>FI</i>	[20-30]*%	[20-30]*%	[40-50]*%	[1-50]*	J&J/DePuy ([40-50]*%)
<i>PL</i>	[20-30]*%	[30-40]*%	[50-60]*%	[less than 1]*	J&J/DePuy ([10-20]*%), Lima ([10-20]*%), S&N ([5-10]*%), Stryker ([5-10]*%)
<i>EEA</i>	[10-20]*%	[5-10]*%	[20-30]*%	[100-200]*	J&J/DePuy ([20-30]*%), Tornier ([10-20]*%), Lima ([10-20]*%), Arthrex ([5-10]*%)

Source: Form CO, Annex 6.2(a)

8.9.4.2. Country-specific Competitive Assessment

Czech Republic

- (1534) In the Czech Republic the total value of the overall shoulder market was EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1535) Over the 2011-2013 period, Zimmer's market share increased from [10-20]*% to [30-40]*%, while Biomet's increased from [10-20]*% to [10-20]*%. The Parties have a combined market share of [40-50]*%. The Merger gives rise to an increment of [10-20]*%
- (1536) Based on Zimmer's data, post-merger, one competitor with a market share significantly bigger than the increment will remain ([40-50]*%), together with three other competitors (J&J/DePuy, S&N, Prospan). Additionally, regional players such as Beznoska s.r.o. will represent a competitive constraint on the Parties.
- (1537) The market reconstruction data shows however a different picture. In particular, the Parties combined market shares do not lead to a Group 1 affected national market in the overall shoulder market in the Czech Republic.
- (1538) According to the results of the market reconstruction, hospitals in the Czech Republic indicated that switching to a new supplier can take place within one year or less and has occurred in the past. Finally, none of the hospitals raised concerns about the merger.⁶⁷⁷

Conclusion

- (1539) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals in the Czech Republic raised concerns about the merger in relation to shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for

⁶⁷⁶ Source: Form CO, (estimates of the Parties).

⁶⁷⁷ Responses to Questionnaire Q2 to Customers, questions 38, 44 and 45.

shoulder implants in the Czech Republic. Furthermore, the market reconstruction shows that the Czech Republic is not a Group 1 affected national market for shoulder implants.

Finland

- (1540) In Finland, the total value of the overall shoulder market was EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1541) Over the 2011-2013 period Zimmer's market share decreased from [20-30]*% to [20-30]*%, while Biomet's decreased from [20-30]*% to [20-30]*%.
- (1542) Based on Zimmer's data the Parties have a combined market share of [40-50]*% in the overall shoulder markets, with an increment of [20-30]*% from Biomet. Post-merger, one competitor with a market share significantly bigger than the increment will remain, namely J&J/DePuy ([40-50]*%), plus Tornier ([0-5]*%) and Stryker ([0-5]*%). The market reconstruction shows however higher market shares for some of the competitors present in the market than the market shares estimated by the Notifying Party.
- (1543) The internal documents of the Parties also indicate that apart from Tornier and J&J/DePuy, which has continued to decrease price level significantly on major recon products⁶⁷⁸ and initiated a strong marketing campaign of being the biggest player and valued partner in orthopaedics,⁶⁷⁹ Arthrex is also active in the shoulder implants market in Finland.⁶⁸⁰
- (1544) Furthermore, hospitals in Finland indicated that switching to a new supplier can take place within one year or less and has occurred in the past. In addition, none of the customers raised concerns about the possible effects of the merger in the shoulder market in Finland.⁶⁸¹

Conclusion

- (1545) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals in Finland raised concerns about the merger in relation to shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for shoulder implants in Finland.

Poland

- (1546) In Poland, the total value of the overall shoulder market was EUR [less than 1]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The Polish market for shoulder implants has been growing from 279 surgery procedures in 2010 to [...] in 2013.⁶⁸²

⁶⁷⁸ Feedback from J&J/DePuy representatives "Main target is to increase sales volume on cost of accepting low product pricing level. The revenue has to cover daily operational company cost".

⁶⁷⁹ Company sponsors 20 surgeons to AAOS congress and is investing on remarkable presence in the coming national orthopaedic meeting and in NOF congress. See Zimmer's internal document "SER Finland 2014", ID 3010.

⁶⁸⁰ See Biomet's internal document BIO 0299.

⁶⁸¹ Responses to Questionnaire Q2 to Customers, questions 38, 44 and 55.

⁶⁸² Reply to the Article 6(1)(c) Decision, paragraph 924.

- (1547) Over the 2011-2013 period Zimmer's market share increased from [10-20]*% to [20-30]*%, while Biomet's increased from [10-20]*% to [30-40]*%.
- (1548) The Parties have a combined market share of [50-60]*% in the overall shoulder markets, with an increment of [20-30]*% from Zimmer. Post-merger, there will be four other competitors left with market shares over 5%. These are J&J/DePuy ([10-20]*%), Lima ([10-20]*%), S&N ([5-10]*%) and Stryker ([5-10]*%).
- (1549) The market reconstruction data shows a combined market share of the merger entity of [60-70]% and very volatile market shares for all competitors for the last five years. It also indicates the presence of two other competitors with meaningful market shares and one recent entry in 2013.

Conclusion

- (1550) Given the volatility of market shares, the presence of up to six competitors post-merger, the fact that the market for shoulder implants is growing in Poland creating opportunities for new entrants or expansion, and that none of the hospitals in Poland raised concerns about the merger in relation to shoulder implants,⁶⁸³ it can be concluded that the merger is not likely to significantly impede effective competition in the market for shoulder implants in Poland.

8.9.5. Degenerative Shoulder Implants

8.9.5.1. Structure of the market

- (1551) According to the Parties' estimates, total EEA sales for degenerative shoulder implants were EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity has a market share of [30-40]*% at EEA level.

Table 102: Degenerative shoulders implants – Group 1 markets – Market shares by value in 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁶⁸⁴	Competitors
<i>BE</i>	[10-20]*%	[30-40]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), Tornier ([20-30]*%), Mathys ([10-20]*%), Arthrex ([5-10]*%)
<i>CZ</i>	[30-40]*%	[60-70]*%	[90-100]*%	[less than 1]*	Lima ([40-50]*%), J&J/DePuy ([5-10]*%), Prospan ([5-10]*%), S&N ([5-10]*%)
<i>FI</i>	[10-20]*%	[40-50]*%	[50-60]*%	[less than 1]*	J&J/DePuy ([40-50]*%)
<i>ES</i>	[10-20]*%	[10-20]*%	[30-40]*%	[1-50]*	Lima ([20-30]*%), J&J/DePuy ([10-20]*%), Tornier ([10-20]*%), S&N ([5-10]*%)
<i>NL</i>	[10-20]*%	[20-30]*%	[30-40]*%	[1-50]*	Tornier ([30-40]*%), J&J/DePuy ([20-30]*%), Mathys ([10-20]*%)

⁶⁸³ Responses to Questionnaire Q2 to Customers, question 55 and responses to Questionnaire Q1 to Competitors, question 20.

⁶⁸⁴ Source: Form CO, (estimates of the Parties).

PL	[30-40]*%	[20-30]*%	[60-70]*%	[less than 1]*	J&J/DePuy ([10-20]*%), Lima ([10-20]*%), S&N ([5-10]*%), Stryker ([5-10]*%)
SE	[20-30]*%	[20-30]*%	[50-60]*%	[1-50]*	J&J/DePuy ([30-40]*%), Tornier ([10-20]*%)
UK	[5-10]*%	[30-40]*%	[40-50]*%	[1-50]*	J&J/DePuy ([20-30]*%), Tornier ([10-20]*%), Lima ([10-20]*%), DJO ([5-10]*%)
EEA	[10-20]*%	[20-30]*%	[30-40]*%	[1-50]*	J&J/DePuy ([20-30]*%), Tornier ([10-20]*%), Lima ([10-20]*%), Arthrex ([5-10]*%)

Source: Form CO, Annex 6.2(a)

8.9.5.2. Country-specific Competitive Assessment

Belgium (including Luxembourg)

- (1552) In Belgium (including Luxembourg), the total value of the degenerative shoulder market is EUR [1-50]* million, representing [0-5]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1553) Over the 2011-2013 period, Zimmer's market shares increased from [10-20]*% to [10-20]*%, while Biomet's remained stable.
- (1554) The Parties have a combined market share of [40-50]*% with an increment of [10-20]*% from Zimmer. Post-merger, three other competitors will remain with market shares that exceed or are equal to the increment (J&J/DePuy, Tornier, Mathys), together with other smaller players such as Arthrex, as well as the local suppliers Shark and Orthoteam.⁶⁸⁵ According to Zimmer's internal document, in Belgium (including Luxembourg), [...] is becoming "*more and more active in knee (uni) & shoulder arthroplasty business*".⁶⁸⁶
- (1555) With respect to entry, in Belgium (including Luxembourg), sales of shoulder implants are concluded through direct negotiations between suppliers and hospitals, making expansion easy for small players as they do not need to secure bulk purchasing contracts with large buying groups which attempt to negotiate discounts on high-volume purchases.
- (1556) Furthermore, none of the customers in Belgium (including Luxembourg) raised concerns about the effects of the merger on the market for shoulder implants in Belgium (including Luxembourg).⁶⁸⁷
- (1557) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals raised concerns about the merger in relation to degenerative shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for shoulder implants in Belgium (including Luxembourg).

⁶⁸⁵ Reply to the article 6(1)c Decision, paragraph 929.

⁶⁸⁶ See Zimmer's internal document "*BI-EMEA: Competitive Activities Report, March 2014*", ID 2024, slide 1.

⁶⁸⁷ Responses to Questionnaire Q2 to customers, question 55.

Czech Republic

- (1558) In the Czech Republic, the total value of the degenerative shoulder market is EUR [less than 1]* million, representing [0-5]*% of total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1559) Over the 2011-2013 period Zimmer's market share increased from [5-10]*% to [30-40]*%, while Biomet's increased from [10-20]*% to [60-70]*%. The evolution of the Parties' position evidences the volatility of market shares in the Czech Republic.
- (1560) Based on Zimmer's data, the Parties have a combined market share of [90-100]*% (this figure is however overstated)⁶⁸⁸, with an increment of [30-40]*% from Zimmer. Post-merger, there will be one competitor with market shares that the Parties estimate above the increment (Lima: [40-50]*%) as well as three other smaller competitors with market shares above 5%, namely J&J/DePuy, S&N and Prospan, and the regional player Beznoska s.r.o. The fact that market reconstruction in the overall shoulder implants indicates that the Parties have combined market shares of only [10-20]*%, excluding the Czech Republic from the Group 1 affected national markets, together with the Parties' reference to the presence of a number of competitors in the market, is a strong indication that Zimmer has significantly overestimated the Parties' market shares.
- (1561) The arguments set out in the section on the overall shoulders in the Czech Republic apply to the degenerative shoulder implants.

Conclusion

- (1562) Given the volatility of market shares, the presence of other competitors in the market for shoulder implants and that none of the hospitals in the Czech Republic raised concerns about the merger in relation to degenerative shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in the Czech Republic.

Finland

- (1563) In Finland, the total value of the degenerative shoulder market is EUR [less than 1]* million, representing [0-5]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1564) Over the 2011-2013 period Zimmer's market share decreased from [30-40]*% to [10-20]*%, while Biomet's increased from [20-30]*% to [40-50]*%.
- (1565) Based on Zimmer's data, the Parties have a combined market share of [50-60]*% with an increment of [10-20]*% from Zimmer. Post-merger, one competitor with a market share significantly higher than the increment will remain (J&J/DePuy, [40-50]*%).

⁶⁸⁸

In some cases, the aggregate sales derived from Eucomed surveys are marked as confidential and the corresponding data are suppressed. As a result, while the Parties' sales for some segments will reflect the entirety of their sales, the total segment sales may be missing contribution from a component which was suppressed. In these cases, the Parties' segment value shares will be overstated.

- (1566) The Parties' market shares might be however overestimated since the market reconstruction for the overall shoulder market shows the presence of another two significant competitors present in this country with a portfolio of products including degenerative shoulder implants. Therefore these players have or might have sales in this market.
- (1567) The arguments set out in the section on the overall shoulders in Finland apply to the degenerative shoulder implants.

Conclusion

- (1568) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals raised concerns about the merger in relation to degenerative shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in Finland.

Netherlands

- (1569) In the Netherlands, the total value of the degenerative shoulder market is EUR [1-50]*, representing [0-5]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1570) Over the 2011-2013 period Zimmer's market share increased from [10-20]*% to [10-20]*%, while Biomet's increased from [10-20]*% to [20-30]*%.
- (1571) The Parties have a combined market share of [30-40]*% with an increment of [10-20]*% from Zimmer. Post-merger, two other competitors with market shares significantly bigger than the increment will remain (Tornier, [30-40]*% and J&J/DePuy, [20-30]*%), as well as Mathys with a [10-20]*% market share.
- (1572) One hospital in the Netherlands raised concerns about a possible price increase for orthopaedic implants and reduction of alternatives in the market.⁶⁸⁹ Based on the information provided by the Parties, there will be enough alternative suppliers for shoulder implants that will be able to offer a complete portfolio of shoulder implants should the merged entity decide to increase prices or reduce their portfolio. The presence of three other competitors, namely Tornier, J&J/DePuy and Mathys will not allow the merged entity to influence the price or other dimensions of competition.

Conclusion

- (1573) Given the presence of other competitors in the market for shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in the Netherlands.

Poland

- (1574) In Poland, the total value of the degenerative shoulder market is EUR [less than 1]* million, representing [0-5]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.

⁶⁸⁹ Non-confidential minutes of the conference call with St. Anna Zorggroep Hospital of 6.11.2014.

- (1575) Over the 2011-2013 period Zimmer's market share increased from [0-5]*% to [30-40]*%, while Biomet's increased from [10-20]*% to [20-30]*%. The evolution of the Parties' position evidences the volatility of market shares in Poland.
- (1576) The Parties have a combined market share of [60-70]*% with an increment of [20-30]*% from Zimmer. Post-merger, there will be five other competitors with market shares above 5%. These are J&J/DePuy ([10-20]*%), Lima ([10-20]*%), S&N ([5-10]*%) and Stryker ([5-10]*%).
- (1577) The arguments set out in the section on the overall shoulders in Poland apply to the degenerative shoulder implants.

Conclusion

- (1578) Given the volatility of market shares, the presence of other competitors in the market for shoulder implants and that none of the hospitals in Poland⁶⁹⁰ raised concerns about the merger in relation to degenerative shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in Poland.

Spain

- (1579) In Spain, the total value of the degenerative shoulder market is EUR [1-50]* million, representing [0-5]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1580) Over the 2011-2013 period Zimmer's market share increased from [10-20]*% to [10-20]*%, while Biomet's increased from [10-20]*% to [10-20]*%.
- (1581) The Parties have a combined market share of [30-40]*% with an increment of [10-20]*% from Zimmer. Post-merger, two competitors with market shares above the increment will remain, namely Lima ([20-30]*%) and J&J/DePuy ([10-20]*%), as well as two other competitors with market shares above 5%, namely Tornier ([10-20]*%) and S&N ([0-5]*%).
- (1582) According to the results of the market investigation, switching to a new supplier can take places within one year or less and has occurred in the past.⁶⁹¹ The Parties' closest competitors are (in order of importance) MBA Incorporado, Stryker and Medcomtech.⁶⁹² Finally, none of the customers in Spain raised concerns about the possible effects of the merger on the market for shoulder implants in Spain.

Conclusion

- (1583) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals in Spain raised concerns about the merger, it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in Spain.

⁶⁹⁰ Responses to Questionnaire Q2 to customers, questions 55.

⁶⁹¹ Responses to Questionnaire Q2 to customers, questions 38 and 44.

⁶⁹² Responses to Questionnaire Q1 to competitors, questions 47.

Sweden

- (1584) In Sweden, the total value of the degenerative shoulder market is EUR [1-50]* million, representing [0-5]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1585) Over the 2011-2013 period Zimmer's market share decreased from [20-30]*% to [20-30]*%, while Biomet's increased from [10-20]*% to [20-30]*%.
- (1586) The Parties have a combined market share of [50-60]*% with an increment of [20-30]*% from Zimmer. Post-merger, one competitor with a market share bigger than the increment (J&J/DePuy: [30-40]*%) will remain, together with other competitors with smaller market shares (Tornier: [10-20]*% and S&N: [0-5]*%). The market reconstruction shows that at least four other non-Eucomed suppliers are present on the Swedish overall shoulder market. As these players have degenerative implants in their product portfolio, they have or might have sales in this market. Therefore, it is likely that the Parties' market shares are overestimated.
- (1587) According to the results of the market investigation, switching to a new supplier can take place within one year or less and has occurred in the past⁶⁹³ (for example, Lima has recently entered the Swedish market without direct operations in Sweden, but via an arrangement with Link).⁶⁹⁴The Parties' closest competitors are (in order of importance) Swemac, Tornier and Arthrex.⁶⁹⁵

Conclusion

- (1588) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals in Sweden raised concerns about the merger in relation to degenerative shoulder implants,⁶⁹⁶ it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in Sweden.

United Kingdom

- (1589) In the United Kingdom, the total value of the degenerative shoulder market is EUR [1-50]*million, representing [20-30]*% of the total degenerative sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1590) Over the 2011-2013 period Zimmer's market share increased from [5-10]*% to [5-10]*%, while Biomet's increased from [10-20]*% to [30-40]*%.
- (1591) The Parties have a combined market share of [40-50]*% with an increment of [5-10]*% from Zimmer. Post-merger, three other competitors with market shares above the increment will remain, namely J&J/DePuy ([20-30]*%), Tornier ([10-20]*%) and Lima ([10-20]*%), as well as another smaller player, DJO, with a market share of ([5-10]*)%

⁶⁹³ Responses to Questionnaire Q2 to customers, questions 38 and 44.

⁶⁹⁴ Form CO, para. 588.

⁶⁹⁵ Responses to Questionnaire Q1 to competitors, questions 47.

⁶⁹⁶ One customer indicated that post-merger the merged entity will probably rationalise its shoulder implants portfolio.

(1592) Switching to a new supplier can take place within one year or less and has occurred in the past, and surgeons are trained to perform procedures with orthopaedic products from different suppliers, usually two or three suppliers.⁶⁹⁷

Conclusion

(1593) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals raised serious concerns⁶⁹⁸ about the merger in relation to degenerative shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for degenerative shoulder implants in the United Kingdom.

8.9.6. Fracture Implants

8.9.6.1. Structure of the market

(1594) According to the Parties' estimates, total EEA sales for fracture shoulder implants were EUR [1-50]* million in 2013. The same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. The merged entity would have a market share of [20-30]*% at EEA level.

Table 103: Fracture shoulders implants – Group 1 markets – Market shares by value in 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁶⁹⁹	Competitors
BE	[10-20]*%	[30-40]*%	[50-60]*%	[less than 1]*	J&J/DePuy ([20-30]*%), Tornier -[20-30]*%), Mathys ([10-20]*%), Arthrex ([5-10]*%)
EEA	[10-20]*%	[10-20]*%	[20-30]*%	[1-50]*	J&J/DePuy ([20-30]*%), Tornier ([10-20]*%), Lima ([10-20]*%), Arthrex ([5-10]*%)

Source: Form CO, Annex 6.2(a)

Belgium (including Luxembourg)

(1595) In Belgium (including Luxembourg), the total value of the fracture shoulder market is EUR [less than 1]* million, representing [0-5]*% of the total fracture sales in the EEA. The Parties' sales amount to EUR [...]* for Zimmer and EUR [...]* for Biomet.

(1596) Over the 2011-2013 period Zimmer's market share decreased from [20-30]*% to [10-20]*%, while Biomet's increased from [0-5]*% to [30-40]*%.

(1597) Based on Zimmer's data, the Parties have combined market shares of [50-60]*% with an increment of [10-20]*% from Zimmer. Post-merger, two other competitors with market share bigger than the increment will remain, namely J&J/DePuy, Tornier, as well as other smaller competitors such as Mathys and Arthrex.

⁶⁹⁷ Responses to Questionnaire Q2 to customers, questions 38, 41 and 44.

⁶⁹⁸ Some competitors and one customer indicated that post-merger the merged entity will probably rationalise its shoulder implants portfolio.

⁶⁹⁹ Source: Form CO, (estimates of the Parties).

- (1598) The arguments set out in the section on the degenerative shoulder implants in Belgium (including Luxembourg) apply to the fracture shoulder implants in Belgium (including Luxembourg).
- (1599) Biomet's successful entry in the Belgian market evidences that entry and switching are feasible in Belgium (including Luxembourg) and that market shares are contestable. In addition, a number of large significant competitors are already present in the market and none of the hospitals in Belgium (including Luxembourg) raised concerns about the merger in relation to fracture implants.

Conclusion

- (1600) Therefore, it can be concluded that the merger is not likely to significantly impede effective competition in the market for fracture shoulder implants in Belgium (including Luxembourg).

8.9.7. *Reverse Implants*

8.9.7.1. Structure of the market

- (1601) According to the Parties' estimates, total EEA sales for reverse shoulder implants were EUR [50-100]* million in 2013. The same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. The merged entity would have a market share of [10-20]*% at EEA level. The market shares of the Parties have remained stable over the period 2011-2013.
- (1602) According to Zimmer's internal documents, in the vast majority of countries reverse shoulders represent much more than [50-60]*% of the entire shoulder market and Zimmer owns only [10-20]*% of it.⁷⁰⁰

⁷⁰⁰ See Zimmer's internal document "Extremities in Spain", slide 9, ID3010.

Table 104: Reverse shoulders implants – Group 1 markets – Market shares by value in 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁷⁰¹	Competitors
<i>CZ</i>	[30-40]*%	[5-10]*%	[40-50]*%	[less than 1]*	Lima ([40-50]*%), J&J/DePuy ([5-10]*%), S&N ([5-10]*%), Prospan ([5-10]*%)
<i>FI</i>	[30-40]*%	[0-5]*%	[30-40]*%	[less than 1]*	J&J/DePuy ([40-50]*%)
<i>PL</i>	[20-30]*%	[30-40]*%	[50-60]*%	[less than 1]*	J&J/DePuy ([10-20]*%), Lima ([10-20]*%), S&N ([5-10]*%), Stryker ([5-10]*%)
<i>EEA</i>	[10-20]*%	[0-5]*%	[10-20]*%	[50-100]*	J&J/DePuy ([20-30]*%), Tornier ([10-20]*%), Lima ([10-20]*%), Arthrex ([5-10]*%), Mathys ([5-10]*%)

Source: Form CO, Annex 6.2(a)

8.9.7.2. Country-specific Competitive Assessment

Czech Republic

- (1603) In the Czech Republic, the total value of the reverse shoulder market is EUR [less than 1]* million, representing [0-5]*% of the total reverse implant sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1604) Over the 2011-2013 period Zimmer's market share increased from [10-20]*% to [30-40]*%, while Biomet's increased from [0-5]*% to [5-10]*%.
- (1605) The Parties have a combined market share of [40-50]*% with an increment of [5-10]*% from Biomet. Post-merger, there will be four other competitors with market shares above 5%. These are Lima ([40-50]*%), J&J/DePuy ([5-10]*%), S&N ([5-10]*%) and Prospan ([5-10]*%). Additionally, regional players such as Beznoska s.r.o. will represent a competitive constraint on the Parties. The fact that market reconstruction in the overall shoulder implants indicates that the Parties have combined market shares of only [10-20]*%, excluding the Czech Republic from the Group 1 affected national markets, together with the Parties' reference to the presence of a number of competitors in the market, is a strong indication that Zimmer has significantly overestimated the Parties' market shares.
- (1606) The arguments set out in the section on the overall shoulder implants in the Czech Republic apply to the reverse shoulder implants in the Czech Republic.

Conclusion

- (1607) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals raised concerns about the merger in relation to reverse shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for reverse shoulder implants in the Czech Republic.

⁷⁰¹ Source: Form CO, (estimates of the Parties).

Finland

- (1608) In Finland, the total value of the reverse shoulder market is EUR [less than 1]* million, representing [0-5]*% of total reverse implant sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1609) Over the 2011-2013 period Zimmer's market share decreased from [30-40]*% to [30-40]*%, while Biomet's increased from [0-5]*% to [0-5]*%.
- (1610) The Parties have a combined market share of [30-40]*% with Biomet contributing an increment of [0-5]*%. Post-merger, there will be one competitor, J&J/DePuy ([40-50]*%), as big as the merged entity. Stryker and Tornier are smaller players, each having a [0-5]*% market share. The market reconstruction for the overall shoulder implants market shows that there are two other competitors present in the market with reverse implants in their portfolio. Therefore, it is likely that the Parties' market shares are overestimated.
- (1611) The arguments set out in the section on the overall shoulder implants in Finland apply to the reverse shoulder implants in Finland.

Conclusion

- (1612) Given the presence of other competitors in the market for shoulder implants and that none of the hospitals in Finland raised concerns about the merger in relation to reverse shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for reverse shoulder implants in Finland.

Poland

- (1613) In Poland, the total value of the reverse shoulder market is EUR [less than 1]* million, representing [0-5]*% of total reverse sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1614) Over the 2011-2013 period, Zimmer's market share decreased from [20-30]*% to [20-30]*%, while Biomet's increased from [10-20]*% to [30-40]*%.
- (1615) The Parties have a combined market share of [50-60]*% with Zimmer contributing an increment of [20-30]*%. Post-merger, there will be four other competitors with market shares above 5%. These are J&J/DePuy ([10-20]*%), Lima ([10-20]*%), S&N ([5-10]*%) and Stryker ([5-10]*%). The market reconstruction in the overall shoulder implants indicates that other competitors that do not report to Eucomed, are also present in the Polish shoulder implants market. Among these, one competitor has reverse implants in its product portfolio, therefore it has or might have sales in this market. Therefore it is likely that the Parties' market shares in this market are overestimated.
- (1616) The arguments set out in the section on the overall shoulder implants in Poland apply to the reverse shoulder implants in Poland.

Conclusion

- (1617) Given the presence of other competitors in the market for shoulder implants and that neither hospitals nor competitors raised concerns about the merger in relation to shoulder implants, it can be concluded that the merger is not likely to significantly impede effective competition in the market for reverse shoulder implants in Poland.

8.9.8. Conclusion – Shoulder implants

- (1618) The Commission concludes that the proposed merger does not significantly impede effective competition in relation to the market for shoulder implants, including the sub-segments of degenerative, fracture, and reverse shoulder implants thereof, in any of the Group 1 national markets.

8.10. Other Products

8.10.1. Bone Cement

8.10.1.1. Overview of the market for bone cement

- (1619) As described in section 7.1.5.1 above, bone cement may vary according to the antibiotic mix (antibiotic and non-antibiotic) and the level of viscosity (high and low viscosity).
- (1620) The antibiotic bone cement market is significantly bigger than the non-antibiotics bone cement, representing 95% of the overall bone cement market in the EEA. The non-antibiotic bone cement covers only the remaining 5% of the market. Similarly, high viscosity bone cement represents 91% of the market, whereas the remaining 9% of the market is split between medium and low viscosity bone cement.⁷⁰²
- (1621) According to the Notifying Party, the extended use of bone cement with antibiotics is partly due to the strong evidence published by the Swedish and Norwegian national arthroplasty registries showing the prophylactic effect of using antibiotics formulations in primary interventions.⁷⁰³ Similarly, the shift of demand from low or medium viscosity to high viscosity cement is partly due to the Norwegian Arthroplasty Register showing that bone cements of a higher viscosity yield better long-term results than lower viscosity formulations.⁷⁰⁴
- (1622) The Notifying Party submits that barriers to entry in the bone cement market are lower than in the joint implants markets, in particular because the process of acquiring the CE mark is essentially a simple auditing process ensuring the quality of the products. Furthermore, a simple registration of an existing product supplied by a third-party manufacturer typically takes just a few weeks. In view of the availability of OEMs offering broad portfolio of bone cement formulations, including cement with antibiotic, the regulatory delay cannot be considered as a barrier to entry.⁷⁰⁵
- (1623) Given its largely homogeneous characteristics, bone cement is often viewed as a commoditised product and is particularly exposed to pricing pressures, especially in difficult market conditions. Consequently, the introduction of innovative products in the bone cement segment is a rare event, with real innovations being launched within an 8-10 year frequency range.

8.10.1.2. The Parties and their competitors' products

- (1624) [...] * the *Hi-Fatigue* line which is sourced from a third-party manufacturer, aap Implantate.⁷⁰⁶ Exceptionally, Zimmer Inc. (Warsaw, Indiana) produces

⁷⁰² Non-confidential minutes of the conference call with Heraeus of 29.09.2014 and Non-confidential minutes of the conference call with Tecres of 07.10.2014.

⁷⁰³ Reply to the Article 6(1)(c) Decision, paragraph 1009.

⁷⁰⁴ Reply to the Article 6(1)(c) Decision, paragraph 1016.

⁷⁰⁵ Reply to the Article 6(1)(c) Decision, paragraph 1061.

⁷⁰⁶ Zimmer has an exclusive distribution agreement with aap Implantate.

Osteobond bone cement which is sold in Italy. According to the Notifying Parties, Zimmer does not possess significant production capabilities or special techniques that would enhance the merged entity's competitive position.

- (1625) Biomet offers a range of bone cements with variations aimed at providing optimised solutions for specific applications. This is supported by well-established activities in research and development of bone cements, which have helped Biomet position itself as one of the leading bone cement suppliers.
- (1626) The Notifying Party asserts that, while Biomet is one of the largest competitors, Zimmer is mainly active throughout the EEA through a product which is manufactured by a third-party. Therefore, the Notifying Party submits that the interaction between Zimmer and Biomet is not driving the dynamic nature of the market.

Table 105: Parties' and competitors' bone cement products

Suppliers	Bone Cement
Zimmer	Hi-Fatigue, Hi-Fatigue G, Osteobond
Biomet	Biomet Bone Cement, Optipac, Refobacin
Heraeus	Palacos, Palamed, Copal
J&J/DePuy	DePuy CMW, DePuy CMW Gentamicin, Smartset
Tecres	CEMEX RX/XL/Isoplastic/Genta/System/Green/Vancogenx
Stryker	Simplex P Bone Cement, Simplex P SpeedSet, Simplex P with Tobramycin
S&N	Versabond
Teknimed	Cemfix, Gentafix
Groupe Lepine	Fix, Aminofix
aap Biomaterials	C~ment, BonOs R, Genta C~ment, BonOs R Genta
Mathys	cemSys
Medacta	Medacta-Cem

Source: Reply to the Article 6(1)(c) Decision

8.10.1.3. Structure of the bone cement market

- (1627) According to the Parties' estimates, total EEA sales for all bone cement were EUR [50-100]* million in 2013. That same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet. Non-antibiotic bone cement represents only [0-5]*% of the Parties' total sales of bone cement.
- (1628) In a market encompassing all bone cements, the merged entity would have a market share of [40-50]*% at EEA level, with an increment of only [0-5]*% from Zimmer.

Table 106: Bone cement – Group 1 markets – Market shares by value in 2013⁷⁰⁷

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁷⁰⁸	Competitors
<i>BE</i>	[5-10]*%	[30-40]*%	[40-50]*%	[1-50]*	Heraeus ([20-30]*%), Stryker ([20-30]*%), J&J/DePuy ([5-10]*%), Mathys ([5-10]*%)
<i>CZ</i>	[5-10]*%	[30-40]*%	[40-50]*%	[1-50]*	Heraeus ([30-40]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), Lima ([5-10]*%)
<i>EL</i>	[0-5]*%	[40-50]*%	[40-50]*%	[less than 1]*	Heraeus ([40-50]*%), J&J/DePuy ([10-20]*%), Tecres ([10-20]*%)
<i>IT</i>	[10-20]*%	[30-40]*%	[40-50]*%	[1-50]*	Heraeus ([20-30]*%), Tecres ([10-20]*%), Stryker ([10-20]*%), J&J/DePuy ([5-10]*%)
<i>PT</i>	[5-10]*%	[40-50]*%	[40-50]*%	[less than 1]*	Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), Tecres ([5-10]*%)
<i>EEA</i>	[0-5]*%	[40-50]*%	[40-50]*%	[50-100]*	Heraeus ([20-30]*%), J&J/DePuy: ([10-20]*%), Stryker ([10-20]*%)

Source: Form CO, Annex 6.2(a)

8.10.1.4. General Competitive Assessment

- (1629) The Notifying Party submits the biggest competitive constraint on Biomet in each of the Group 1 national markets are strong competitors such as Heraeus Medical, Tecres, Stryker and J&J/DePuy, each of whom compete more closely with Biomet than Zimmer does. In fact, the high degree of similarity between Heraeus' and Biomet's [...] products, that is, Palacos and Refobacin, is a consequence of their former cooperation in the development and production of the cement marketed under the brand Refobacin Palacos R. The product was manufactured by Heraeus Kulzer and distributed by Biomet.⁷⁰⁹
- (1630) [...]*. The *Hi-Fatigue* cement is a high-viscosity cement (with or without antibiotics) formulated for knee, hip and shoulder replacement including surface replacement. However, the performance of *Hi-Fatigue* is not supported by published clinical results which could put it on an equal competitive footing with the market leaders.⁷¹⁰
- (1631) The respondents to the market investigation acknowledged that the presence of Zimmer on the market for bone cement is not important at the moment⁷¹¹ and

⁷⁰⁷ The Notifying Party was not able to provide reliable market shares for Lithuania.

⁷⁰⁸ Source: Form CO, (estimates of the Parties).

⁷⁰⁹ Response to the Article 6(1)(c) Decision, paragraph 1025.

⁷¹⁰ Response to the Article 6(1)(c) Decision, paragraph 1028.

⁷¹¹ Non-confidential minutes of the conference call with Heraeus of 22.09.2014.

Biomet's bone cement products are much more used than those of Zimmer's, especially in countries such as the United Kingdom or Scandinavia.⁷¹²

- (1632) According to some respondents to the market investigation, Heraeus is currently Biomet's most competitive constraint and that is mainly because Biomet is producing copycat products of Heraeus. This has led to a patent litigation between Heraeus and Biomet following which Biomet was precluded from selling its bone cement products in Germany, one of the biggest markets in Europe. This statement is supported by several of Biomet's internal documents that compare Biomet's bone cement products mainly with that of Heraeus, and less with other suppliers.⁷¹³
- (1633) In view of the arguments set out in this section, it can be concluded that Zimmer does not exert a significant competitive constraint on Biomet with respect to bone cement products.

8.10.1.5. Country-specific Competitive Assessment

Belgium (including Luxembourg)

- (1634) In Belgium (including Luxembourg), the total value of the overall bone cement market is EUR [1-50]* million, representing [0-5]*% of total bone cement sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1635) Over the 2011-2013 period Zimmer's market share increased from [0-5]*% to [5-10]*%, while Biomet's increased from [30-40]*% to [30-40]*%.
- (1636) The Parties have a combined market share of [40-50]*% with Zimmer contributing an increment of [5-10]*%. Post-merger, there will be two other competitors left with market shares significantly bigger than the increment, namely Heraeus ([20-30]*%) and Stryker ([20-30]*%), as well J&J/DePuy ([5-10]*%) and Mathys ([5-10]*%).
- (1637) The market reconstruction however shows a different picture as the total market size of the bone cement is bigger than what the Parties have estimated. In this case, the combined market shares of the Parties do not lead to an affected Group 1 national market and it will be in the range of [20-30]*%.

Conclusion

- (1638) Given the presence of other strong competitors in the market, and that none of the hospitals in Belgium (including Luxembourg) raised concerns about the merger⁷¹⁴ in relation to bone cement, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in Belgium (including Luxembourg).

Czech Republic

- (1639) In the Czech Republic, the total value of the overall bone cement market is EUR [1-50]* million, representing [0-5]*% of total bone cement sales in the

⁷¹² Non-confidential minutes of the conference call with Dr Robertsson from Lund University Hospital of 25.06.2014 and Non-confidential minutes of the conference call with Bradford Hospital of 14.10.2014.

⁷¹³ See Biomet's internal document "*Heraeus Medical vs Biomet CT*" of 17.02.2015.

⁷¹⁴ One customer indicated that the effect of the merger will probably be the rationalisation of product portfolio by the merged entity.

EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.

- (1640) Over the 2011-2013 period, Zimmer's market share increased from [0-5] to [5-10], while Biomet's increased from [30-40] to [30-40].
- (1641) The Parties have a combined market share of [40-50] with Zimmer contributing an increment of [5-10]. Post-merger, there will be three other competitors with market shares bigger than the increment, namely Heraeus ([30-40]), J&J/DePuy ([10-20]) and Stryker ([10-20]), as well as Lima with a market share of [5-10].

Conclusion

- (1642) Given the presence of other strong competitors in the market, and that none of the hospitals in the Czech Republic raised concerns about the merger in relation to bone cement, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in the Czech Republic.

Greece

- (1643) In Greece, the total value of the overall bone cement market is very small, amounting to only EUR [less than 1] million and representing [0-5] of total bone cement sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1644) Over the 2011-2013 period, Zimmer's market share decreased from [0-5] to [0-5], while Biomet's increased from [40-50] to [40-50].
- (1645) The Parties have a combined market share of [40-50] with Zimmer contributing a small increment of only [0-5]. There will be three other competitors left with market shares significantly bigger than the increment. These are Heraeus ([40-50]), J&J/DePuy ([10-20]) and Tecres ([10-20]).
- (1646) The market reconstruction data shows however a different picture as the value of the market for bone cement in Greece is bigger than the Parties' estimates. In this case, the combined market shares of the Parties do not lead to an affected Group 1 national market and it will be in the range of [20-30].

Conclusion

- (1647) Given the presence of other strong competitors in the market, the limited increment, and that none of the hospitals in Greece raised concerns about the merger in relation to bone cement, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in Greece.

Italy

- (1648) In Italy, the total value of the overall bone cement market is EUR [1-50] million, representing [5-10] of total bone cement sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1649) Over the 2011-2013 period, Zimmer's market share increased from [5-10] to [10-20], while Biomet's increased from [30-40] to [30-40].
- (1650) The Parties have a combined market share of [40-50] with Zimmer contributing an increment of [10-20]. There will be two other competitors with market shares bigger than the increment. These are Heraeus ([20-30])

and Tecres ([10-20]*%), as well as smaller competitors such as Stryker ([10-20]*%) and J&J/DePuy ([5-10]*%).

- (1651) The market reconstruction data shows however a different picture as the value of the market for bone cement in Italy is bigger than the Parties' estimates. In this case, although the combined market shares of the Parties still lead to an affected Group 1 national market, it is smaller than the Parties' estimates and in the range of [30-40]*%. [...]*.⁷¹⁵ Furthermore, the market investigation indicated that the main competitors in Italy are Heraeus, Stryker and Technimed.⁷¹⁶

Conclusion

- (1652) Given the presence of other strong competitors in the market, taking into account that Zimmer's main product will be phased out in 2015, and that none of the hospitals in Italy raised serious concerns⁷¹⁷ about the merger in relation to bone cement, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in Italy.

Lithuania

- (1653) In Lithuania, the total value of the overall bone cement market is very small, amounting to EUR [less than 1]* million and representing [0-5]*% of total bone cement sales in the EEA. The Parties' sales amount to EUR [...]* for Zimmer and EUR 0.4 million for Biomet.
- (1654) The Parties have very high combined market share with Zimmer contributing a small increment of [0-5]*%. However, based on Zimmer's data there will be four other competitors left with market shares bigger than the increment. These are Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%) and Tecres ([5-10]*%).
- (1655) Approximately 80% of the demand for bone cement in Lithuania is purchased by the Central Purchase Organisation ("CPO") through nation-wide tenders. Following a tender in 2011, Heraeus was selected as the main supplier of bone cement to Lithuanian hospitals. Biomet was selected as the main supplier in 2013. Zimmer has never been declared a successful bidder in tenders for bone cement in Lithuania.
- (1656) The high volatility of market shares in the Lithuanian market for bone cement is well illustrated by the position of Biomet which as a result of the successful tender increased massively from below [10-20]*% in 2012 to close to [90-100]*% in 2013. As a result of the tender, the market share of Heraeus, selected the successful supplier in the previous tender, rapidly decreased. As such, the current market shares only reflect the outcome of the last CPO tender and not actual market power.

Conclusion

- (1657) Given the presence of other strong competitors in the market, the small size of the market, the volatility of market shares and the small increment brought

⁷¹⁵ Reply to the Article 6(1)(c) Decision, paragraph 1038.

⁷¹⁶ Non-confidential minutes of the conference call with Tecres of 7.10.2014.

⁷¹⁷ One hospital in Italy indicated a possible price increase, one indicated a reduction in the quantity offered and one indicated a possible rationalisation of the product portfolio.

about Zimmer, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in Lithuania.

Portugal

- (1658) In Portugal, the total value of the overall bone cement market is very small, amounting to EUR [less than 1]* million and representing [0-5]*% of total bone cement sales in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1659) Over the 2011-2013 period, Zimmer's market share decreased from [5-10]*% to [5-10]*%, while Biomet's increased from [30-40]*% to [40-50]*%.
- (1660) The Parties have a combined market share of [40-50]*% with Zimmer contributing an increment of [5-10]*%. There will be four other competitors left with market shares above 5%. These are Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%) and Tecres ([5-10]*%). In addition, there are several other competitors present in the market, including MBA and Artur Salgado.
- (1661) The market reconstruction data shows however a different picture as the value of the market for bone cement in Portugal is bigger than what the Parties have estimated. In this case, although the combined market shares of the Parties still lead to an affected Group 1 national market, it is smaller than the Parties' estimates and in the range of [30-40]*%, with a small increment from Zimmer.

Conclusion

- (1662) Given the presence of other strong competitors in the market, the small increment brought about the merger, and that none of the hospitals in Portugal raised concerns about the merger in relation to bone cement, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in Portugal.

8.10.1.6. Conclusion – Bone Cement

- (1663) The Commission concludes that the proposed merger does not significantly impede effective competition in relation to bone cement market in any of the Group 1 national markets.

8.10.2. Bone Cement Accessories

8.10.2.1. Overview of the market for bone cement accessories

- (1664) Bone cement accessories market is a commoditized market where price is the primary selection criterion and where surgeons do not have a preference for a specific supplier. Being a commoditized market, all accessories can be easily reproduced by potential market entrants. Furthermore, no specific training is required for the OR staff.
- (1665) The Notifying Party submits that for bone cement accessories, there is only the requirement for the quality assessment process to obtain the CE mark. The process is straightforward as it consists in the provision of supporting documentation to a competent body. Typically it takes no longer than one month to obtain a CE mark.
- (1666) The Notifying Party submits that barriers to entry and expansion are particularly low given the presence of OEM supply options available to potential entrants. In particular, aap Implantate, Teknimed, Tecres and Summit Medical provide a broad portfolio to interested distributors.

8.10.2.2.The Parties and their competitor's products

- (1667) Both Zimmer and Biomet are active in the supply of bone cement accessories. Zimmer's product range include, inter alia, the Power Mix Vacuum Cement Mixing System, the 3-Dose Compact Vacuum Cement Mixing Systems (allows for up to three doses (3x40g) of bone cement), the Vacuum Foot Pump II line and the Miller line. Biomet's product range include the Optipac line ([...]*), the Optivac and the OptiLavage line.
- (1668) The Notifying Party submits that although accessories are typically purchased separately and not pre-packed together with bone cement, the trend is to manufacture pre-packed cement mixing systems. For example, Biomet's Optipac, and Heraeus' Palacos Pro are exceptionally sold as "pre-packed" bone cement mixing systems.

8.10.2.3.Structure of the bone cement accessories market

- (1669) According to the Parties' estimates, total EEA sales for all bone cement accessories were EUR [50-100]* million in 2013. That same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.

Table 107: All bone cement accessories – Group 1 countries – Market shares by value in 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁷¹⁸	Competitors
<i>AT</i>	[5-10]*%	[40-50]*%	[40-50]*%	[less than 1]*	Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Stryker ([5-10]*%)
<i>CZ</i>	[5-10]*%	[30-40]*%	[30-40]*%	[less than 1]*	Heraeus ([30-40]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%), Lima ([5-10]*%)
<i>FI</i>	[5-10]*%	[20-30]*%	[30-40]*%	[1-50]*	Heraeus ([30-40]*%), Stryker ([5-10]*%)
<i>DE</i>	[20-30]*%	[20-30]*%	[40-50]*%	[1-50]*	Heraeus ([30-40]*%)
<i>LT</i>	[5-10]*%	[30-40]*%	[30-40]*%	[less than 1]*	Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Stryker ([10-20]*%)
<i>NL</i>	[10-20]*%	[20-30]*%	[40-50]*%	[1-50]*	J&J/DePuy ([10-20]*%), Heraeus ([10-20]*%), Stryker ([5-10]*%)
<i>NO</i>	[5-10]*%	[20-30]*%	[30-40]*%	[less than 1]*	Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Tecres ([5-10]*%), Stryker ([5-10]*%)
<i>SE</i>	[0-5]*%	[30-40]*%	[30-40]*%	[1-50]*	Heraeus ([30-40]*%)
<i>EEA</i>	[5-10]*%	[10-20]*%	[20-30]*%	[1-50]*	Heraeus ([10-20]*%), J&J/DePuy ([10-20]*%), Summit ([10-20]*%), Stryker ([5-10]*%)

Source: Reply to 6(1)c, Table 16 and Form CO and Annex 6.2(b)

8.10.2.4. General Competitive Assessment

- (1670) The Notifying Party notes that Zimmer is only a number four player at the EEA level and offers a limited portfolio of delivery and mixing systems consisting of Easymix, MixiGun, Quick-Vac, Non-vacuum cement mixer and non-branded open bowls and spatulas. On the other hand, Biomet is the market leader offering broader portfolio of mixing and delivery systems, including pre-filled mixing systems. Accordingly, the competitive pressure exerted by Zimmer on Biomet is not significant.⁷¹⁹
- (1671) Furthermore, while the majority of Biomet's sales of mixing and delivery systems is generated by sales of pre-filled mixer and vacuum mixers, majority of Zimmer's sales are generated by sales of much less advanced products such as open bowls and spatulas.⁷²⁰
- (1672) Zimmer does not produce bone cement accessories but sources them from three suppliers (Promixa AB, aap Biomaterials and Summit Medical). As the

⁷¹⁸ Source: Zimmer estimates of sales sizes, reply to 6(1)c.

⁷¹⁹ Reply to the Article 6(1)(c) Decision, paragraph 1120.

⁷²⁰ Reply to the Article 6(1)(c) Decision, paragraph 1122.

exclusivity clause in the distribution agreement with aap Biomaterials with respect to Easymix has recently expired, currently Zimmer does not have exclusive distribution rights over any of its accessories other than MixiGun. The Notifying Party submits that the dependence on third-party suppliers further limits competitive pressure exerted by Zimmer on Biomet. In particular, Zimmer cannot independently react to price decreases proposed by companies such as Biomet and Heraeus and it cannot independently increase output.⁷²¹

- (1673) In view of the arguments set out in this section, it can be concluded that Zimmer does not exert a significant constraint on Biomet with respect to bone cement accessories.

8.10.2.5. Country-specific Competitive Assessment

Austria

- (1674) In Austria, the total value of the market for bone cement accessories is EUR [less than 1]* million, representing [0-5]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet. Over [50-60]*% of Zimmer's sales of mixing and delivery systems in Austria are generated by the sales of non-branded open bowls and spatulas which are offered by a number of competitors.⁷²²
- (1675) The Parties have a combined market share of [40-50]*% with Zimmer contributing an increment of [5-10]*%. Post-merger, there will be three other competitors with market shares above 5% post-merger. These are Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%) and Stryker ([5-10]*%).

Conclusion

- (1676) Given the presence of other strong competitors in the market and that none of the hospitals in Austria raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement in Austria.

Czech Republic

- (1677) In the Czech Republic, the total value of the market for bone cement accessories is EUR [less than 1]* million, representing [0-5]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet. All of Zimmer's sales in the segment for mixing and delivery systems in the Czech Republic were generated by sales of non-branded open bowls and spatulas.
- (1678) The Parties have a combined market share of [30-40]*% with Zimmer contributing an increment of [5-10]*%. Post-merger, there will be three other competitors with market shares above the increment, namely Heraeus ([30-40]*%), J&J/DePuy ([10-20]*%) and Stryker ([10-20]*%), as well as smaller ones such as Lima ([5-10]*%).
- (1679) Evidence suggests that entry and expansion into the Czech market is relatively easy as supported by the recent example of Mathys which entered the Czech bone cement accessories market in 2014.

⁷²¹ Reply to the Article 6(1)(c) Decision, paragraph 1121.

⁷²² Reply to the Article 6(1)(c) Decision, paragraph 1148.

Conclusion

- (1680) Given the presence of other strong competitors in the market, and that none of the hospitals in the Czech Republic raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in the Czech Republic.

Finland

- (1681) In Finland, the total value of the market for bone cement accessories is EUR [1-50]* million, representing [0-5]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1682) The Parties have a combined market share of [30-40]*%, with Zimmer contributing an increment of [5-10]*%. Post-merger, there will be two other competitors left with market shares above the increment, namely Heraeus ([30-40]*%) and Stryker ([5-10]*%).

Conclusion

- (1683) Given the presence of other strong competitors in the market, and that none of the hospitals in Finland raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in Finland.

Germany

- (1684) In Germany, the total value of the market for bone cement accessories is EUR [1-50]* million, representing [10-20]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet. Over [40-50]*% of Zimmer's sales in Germany were generated by non-branded open bowls and spatulas.
- (1685) The Parties have a combined market share of [40-50]*% with Zimmer contributing an increment of [20-30]*%. Post-merger, Heraeus will be the main competitor of the merged entity with a market share amounting to [30-40]*%.
- (1686) However, recent developments have led to a significant erosion of Biomet's competitive position in the market for bone cement accessories. Specifically, a court judgment has prevented Biomet from selling bone cement in Germany. As a result, Biomet stopped selling all of its bone cement, including its bestselling bone cement accessory, a pre-filled mixing system, in Germany on 24 August 2014. With Germany accounting for approximately [10-20]*% of bone cement accessories sales in the EEA (EUR [1-50]* million out of EUR [1-50]* million in 2013), this development has significantly weakened Biomet's presence in market for bone cement accessories at EEA level.⁷²³
- (1687) According to the Notifying Party, barriers to enter the German market for bone cement accessories are particularly low as shown by the recent example of Tornier which entered the market in 2009. The ease of entry is also well illustrated by the presence of a significant number of local players.

⁷²³ Reply to the Article 6(1)(c) Decision, paragraph 1164.

Conclusion

- (1688) Given Biomet's weakened presence in the market for bone cement accessories and that none of the hospitals in Germany raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in Germany.

Lithuania

- (1689) In Lithuania, the total value of the market for bone cement accessories is EUR [less than 1]* million, representing [0-5]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1690) The Parties have a combined market share of [30-40]*% with Zimmer contributing an increment of [5-10]*%. Post-merger, there will be three other competitors with market shares bigger than the increment, namely Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%) and Stryker ([10-20]*%).

Conclusion

- (1691) Given the presence of other strong competitors in the market, and that none of the hospitals in Lithuania raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in Lithuania.

The Netherlands

- (1692) In the Netherlands, the total value of the market for bone cement accessories is EUR [1-50]* million, representing [5-10]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1693) The Parties have a combined market share of [40-50]*% with Zimmer contributing an increment of [10-20]*%. There will be three other competitors with market shares above 5% post-merger. These are J&J/DePuy ([10-20]*%), Heraeus ([10-20]*%) and Stryker ([5-10]*%).
- (1694) Entry is possible in the Dutch market for bone cement accessories as illustrated by the success of Zimmer which entered the market in 2010 and rapidly gained a market share of [10-20]*%.

Conclusion

- (1695) Given the presence of other strong competitors in the market, and that none of the hospitals in the Netherlands raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in the Netherlands.

Norway

- (1696) In Norway, the total value of the market for bone cement accessories is EUR [less than 1]* million, representing [0-5]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1697) The Parties have a combined market share of [30-40]*% with Zimmer contributing an increment of [5-10]*%. There will be four other competitors

with market shares above 5% post-merger. These are Heraeus ([20-30]*%), J&J/DePuy ([10-20]*%), Tecres ([5-10]*%) and Stryker ([5-10]*%).

Conclusion

- (1698) Given the presence of other strong competitors in the market, and that none of the hospitals in Norway raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in Norway.

Sweden

- (1699) In Sweden, the total value of the market for bone cement accessories is EUR [1-50]* million, representing [0-5]*% of total sales of bone cement accessories in the EEA. The Parties' sales amount to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1700) The Parties have a combined market share of [30-40]*% with Zimmer contributing an increment of [0-5]*%. Post-merger, Heraeus will be the strongest competitor after the merged entity with a market share amounting to [30-40]*%. In addition, there will be a number of smaller competitors which will continue exerting competitive pressure on the Parties post-merger, including Implantcast, Pulse Lavage, S&N, Stryker and Tecres.
- (1701) Entry is feasible in the Swedish market as illustrated by the recent example of Pulse Lavage which entered the Swedish market for bone cement accessories in 2012 and the entry of Tecres in 2008.

Conclusion

- (1702) Given the presence of other strong competitors in the market, the limited increment, and that none of the hospitals in Sweden raised concerns about the merger in relation to bone cement accessories, it can be concluded that the merger is not likely to significantly impede effective competition in the market for bone cement accessories in Sweden.

8.10.2.6. Conclusion – Bone Cement Accessories

- (1703) The Commission concludes that the proposed merger does not significantly impede effective competition in relation to bone cement accessories market in any of the Group 1 national markets.

8.10.3. Surgical Tools (*Pulsed Lavage*)

8.10.3.1. Overview of the market for Pulsed Lavage

- (1704) Pulsed Lavage is a commoditised product. In the EEA, the market pulsed lavage amounted to approximately EUR [1-50]* million in 2013.
- (1705) According to the Notifying Party, at EEA level, two global American suppliers play a major role in this market, that is, Zimmer and Stryker. In addition, a number of small- to medium-sized suppliers are present in specific national markets, generally with their own versions of pulsed lavage devices.

Table 108: EEA market shares – pulsed lavage

Competitor	EEA Market Share
Zimmer	[30-40]*%

Competitor	EEA Market Share
Stryker	[30-40]*%
Biomet	[0-5]*%
S&N	[0-5]*%
Microaire	[0-5]*%
Heraeus	[0-5]*%
Samsun	[0-5]*%
Orthomedicor	[0-5]*%
Orthoinnovation	[0-5]*%
Equalityortho	[0-5]*%
Wright	[0-5]*%
Euroset	[0-5]*%

Source: Form CO

(1706) Table 109 below exhibits the presence of each competitor in the 8 Group 1 national markets identified for pulsed lavage devices at national level.

Table 109: Suppliers presence in Group 1 markets

Competitor	Product	AT	BE	FR	DE	LT	NL	SL	SV
Stryker	Interpulse	x	x	x	x	x	x	x	x
Aap Implantate	MicroAire Pulse Lavage System				x				x
Heraeus	Palavage	x	x		x		x	x	x
S&N	Powerpulse	x	x	x	x	x	x	x	x
Microport Orthopedics (China)	Right Pulse	x	x	x	x	x		x	x
Exactech	Ortholavage		x	x					
Oudshoorn	Euro-Pulse						x		
Corin	Solomax	x	x	x	x	x		x	
Sevika	Equality Pulse Lavage System	x	x	x	x	x		x	
Orthopedic Innovation Ltd (China)	Smartpulse	x	x	x	x	x		x	
	Smartpulse II								

Source: Response to 6(1)(c) Decision, Table 18

- (1707) The use of pulsed lavage does not require any training or familiarity with the product. Suppliers only organise product demonstrations and workshops for marketing purposes, rather than to teach techniques related to the use of their products. They also do not provide additional services typical for orthopaedic implants. Non-Union suppliers often market their products via third-party distributors as the sales of pulsed lavage do not require a specialized sales force.

8.10.3.2. The Parties and their competitor's products

- (1708) Zimmer offers one brand of fully disposable wound debridement system, Pulsavac365. Pulsavac is available in three different main configurations offering solutions for orthopaedic and trauma surgery (battery-powered Pulsavac Plus and electric-cord-powered Pulsavac Plus AC, both high pressure) as well as lower pressure lavage for wound cleaning therapies (Pulsavac Plus LP). Copies of Zimmer products are offered by many competitors, including Orthopedic Innovation (SmartPulse), Equality Orthopedics (PulseLavage), OrthoMedicor (Jet Lavage), Samsun Surgical (PulseLavage), Corin Group (Solomax), S&N (Euro-Pulse), MicroAire (ApexPulse) and MicroPort/Wright Medical (Right Pulse).
- (1709) Biomet offers a technologically less advanced, reusable wound debridement system, marketed under the brand OptiLavage. The OptiLavage system is designed for use in orthopaedic and trauma interventions. In early 2013, Biomet introduced a new single-use high pressure pulsed lavage system, E-5. Biomet does not manufacture its branded products, but simply packages and distributes them.

8.10.3.3. Structure of the pulsed lavage market

- (1710) According to the Parties' estimates,⁷²⁴ total EEA sales for pulsed lavage devices were EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet. In a market encompassing all pulsed lavage, the merged entity would have a market share of approximately [40-50]*%⁷²⁵ at EEA level.
- (1711) There are 8 Group 1 national markets identified at national level: Austria, Belgium (including Luxembourg), France, Germany, Lithuania, the Netherlands, Slovenia, and Sweden. In 2013, the total value of the Group 1 national markets was EUR [1-50]* million, and the Parties' sales in these markets amounted to EUR [...] for Zimmer and EUR [...] for Biomet.⁷²⁶ The Parties have combined market shares in these markets ranging from approximately [30-40]*% to [60-70]*% and the increment ranges between approximately [0-5]*% and [60-70]*%.⁷²⁷

⁷²⁴ Form CO, annex 6.1(a).

⁷²⁵ Form CO, annex 6.1(a), page 208.

⁷²⁶ Form CO, paragraph 927.

⁷²⁷ Form CO, paragraph 928.

Table 110: All pulsed lavage – Group 1 markets – Market shares by value, 2013

Country	Zimmer	Biomet	Combined	Market size (EUR million) ⁷²⁸	Competitors
<i>AT</i>	[20-30]*%	[10-20]*%	[30-40]*%	[less than 1]*	Stryker ([50-60]*%), Euroset ([5-10]*%), others ([5-10]*%)
<i>BE</i>	[40-50]*%	[10-20]*%	[50-60]*%	[1-50]*	Stryker ([30-40]*%), others ([10-20]*%)
<i>FR</i>	[40-50]*%	[0-5]*%	[40-50]*%	[1-50]*	Stryker ([20-30]*%), others ([20-30]*%)
<i>DE</i>	[40-50]*%	[0-5]*%	[40-50]*%	[1-50]*	Stryker ([30-40]*%), Heraeus ([5-10]*%), others ([10-20]*%)
<i>LT</i>	[20-30]*%	[20-30]*%	[40-50]*%	[less than 1]*	Stryker ([50-60]*%), others ([5-10]*%)
<i>NL</i>	[50-60]*%	[5-10]*%	[60-70]*%	[1-50]*	Stryker ([10-20]*%), Heraeus ([5-10]*%), others ([10-20]*%)
<i>SL</i>	[10-20]*%	[10-20]*%	[30-40]*%	[less than 1]*	Stryker ([30-40]*%), others ([20-30]*%)
<i>SE</i>	[50-60]*%	[10-20]*%	[60-70]*%	[1-50]*	Stryker ([30-40]*%), Microaire ([5-10]*%)
<i>EEA</i>	[30-40]*%	[0-5]*%	[40-50]*%	[1-50]*	Stryker ([30-40]*%)

Source: Form CO

(1712) At EEA level, the merged entity would become number one player in the market for all pulsed lavage devices, followed by Stryker with [30-40]*% market share. In Belgium (including Luxembourg), France, Germany, the Netherlands, Slovenia and Sweden, the merged entity would become number one player, with increments ranging between approximately [0-5]*% and [20-30]*%. In Austria and Lithuania, the merged entity would become the number two player in the market for all pulsed lavage.

(1713) The Notifying Party submits that the competitive situation in these markets is dynamic enough to counteract any potential lessening of competition.

8.10.3.4. General Competitive Assessment

(1714) As seen below in section 8.10.3.5 below, the merger would give rise to 8 Group 1 national markets in pulsed lavage. In 6 of these Group 1 national markets, the merged entity would become the new market leader, with significant increments ranging from [0-5]*% (in France) to [10-20]*% (in Slovenia). In 6 of these Group 1 national markets, the merged entity would have a market share of above [40-50]*%. In 3 of these Group 1 national markets, the merged entity would have a market share of above [50-60]*%.

⁷²⁸ Source: Form CO, (estimates of the Parties).

- (1715) There are a number of competitors for pulsed lavage in the EEA. These include the major orthopaedic implants providers, such as S&N and Stryker which are active across the EEA, some companies from Asia (for example Oudshoorn, Columbus Medical, Microport Orthopedics and Orthopedic Innovation Ltd), as well as a number of smaller competitors which are active in some EEA countries, such as Heraeus, Exatech and Corin.
- (1716) The Parties combined market share in the EEA would be similar to the market share of Stryker, which is currently the number 3 competitor in the EEA. In addition, the Commission notes that Biomet's market share is very small on an EEA-wide level and therefore, the increment arising from the merger is so small that it is unlikely to impact the competitive conditions in the EEA overall.
- (1717) The market investigation indicated some examples of customer switching suppliers of pulsed lavage.⁷²⁹

8.10.3.5. Country-specific Competitive Assessment

Austria

- (1718) According to the Notifying Party, in Austria, the total value of the pulsed lavage market was EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1719) The Parties have combined market shares of approximately [40-50]*% in the pulsed lavage market, with Biomet contributing an increment of approximately [10-20]*%. Post-merger, there would be one competitor (Stryker) bigger than the merged entity, as well as Euroset with market share over [5-10]*%.
- (1720) Over the 2011-2013 period, Zimmer's position increased from [20-30]*% to [20-30]*%, while Biomet's position decreased from [10-20]*% to [10-20]*%.
- (1721) In terms of market entry, the Notifying Party claims that the entry of MST (distributor of KMT JetLavage) in March 2014 shows that entry into the Austrian market for pulsed lavage is feasible.⁷³⁰

Conclusion

- (1722) The Commission concludes that in the Austrian market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker, which would remain number one competitor and that new, aggressive entrants would continue to constrain the merged entity post-merger.

Belgium (including Luxembourg)

- (1723) According to the Notifying Party, in Belgium (including Luxembourg), the total value of the pulsed lavage market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1724) The Parties' combined market share threshold exceeds [50-60]*% in this market, with the merged entity holding market share of approximately [50-60]*% in the pulsed lavage market, with Biomet contributing an increment of

⁷²⁹ Responses to Questionnaire Q31 to hospitals, question 137.

⁷³⁰ Response to the Article 6(1)(c) Decision, paragraph 1245.

[10-20]*%. Post-merger, apart from residual competitors, there would be one competitor left (Stryker) with market share over 5%.

- (1725) Over the 2011-2013 period, Zimmer's position increased from [30-40]*% to [40-50]*%, while Biomet's position remained essentially the same, moving from [10-20]*% to [10-20]*%.

Conclusion

- (1726) The Commission concludes that in the Belgian market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker would remain number two competitor and would continue to constrain the merged entity post-merger.

France

- (1727) According to the Notifying Party, in France, the total value of the pulsed lavage market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.

- (1728) The Parties have combined market shares of approximately [40-50]*% in the pulsed lavage market, with Biomet contributing an increment of approximately [0-5]*%. Post-merger, apart from residual competitors, there would be one competitor left (Stryker) with market share over 5%.

- (1729) Over the 2011-2013 period, Zimmer's position increased from [40-50]*% to [40-50]*%, while Biomet's position remained essentially the same, moving from [0-5]*% to [0-5]*%.

- (1730) The Notifying Party identified [...] instances that where customers switched to another supplier of pulsed lavage devices, indicating that switching is a common phenomenon in the Dutch market for pulsed lavage.⁷³¹

- (1731) In terms of market entry, the Notifying Party claims that the entry of Exactech in 2010 and MicroPort in 2013, as well as Biotech (Apex Pulse) and aap Implantate in the past five years shows that entry into the French market for pulsed lavage is feasible.⁷³²

Conclusion

- (1732) The Commission concludes that in the French market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker, which would remain number two competitor, as well as new aggressive entrants, would continue to constrain the merged entity post-merger.

Germany

- (1733) According to the Notifying Party, in Germany, the total value of the pulsed lavage market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.

- (1734) The Parties have combined market shares of approximately [40-50]*% in the pulsed lavage market, with an increment of approximately [0-5]*% from Biomet. Post-merger, apart from residual competitors, there would be two

⁷³¹ Response to the Article 6(1)(c) Decision, paragraph 1255, and Response to the RFI Q16 of 8 October 2014 - Switching Events.

⁷³² Response to the Article 6(1)(c) Decision, paragraph 1256, and Form CO, paragraph 2573.

competitors left with market share over 5%, namely Stryker and Heraeus. Biomet is only a marginal player in the pulsed lavage market in Germany.

- (1735) Over the 2011-2013 period, Zimmer's position increased from [30-40]*% to [40-50]*%, while Biomet's position decreased from [5-10]*% to [0-5]*%.
- (1736) In terms of market entry, the Notifying Party claims that the entry of OrthoMedicor in 2013 shows that entry into the German market for pulsed lavage is feasible.⁷³³ The market investigation also indicated that Helios Kliniken recently switched suppliers of pulsed lavage.⁷³⁴

Conclusion

- (1737) The Commission concludes that in the German market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker and Heraeus, which would remain number two and three competitors respectively, as well as new aggressive entrants, would continue to constrain the merged entity post-merger.

Lithuania

- (1738) According to the Notifying Party, in Lithuania, the total value of the pulsed lavage market was EUR [less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1739) The Parties have combined market shares of approximately [40-50]*% in the pulsed lavage market, with an increment of approximately [20-30]*% from Biomet. Post-merger, apart from residual competitors, there would be one competitor left (Stryker) with market share over 5%.
- (1740) Over the 2011-2013 period, Zimmer's position increased from [0-5]*% to [20-30]*% and Biomet's position increased from [10-20]*% to [20-30]*%.

Conclusion

- (1741) The Commission concludes that in the Lithuanian market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker, which would remain number one competitor, would continue to constrain the merged entity post-merger.

The Netherlands

- (1742) According to the Notifying Party, in the Netherlands, the total value of the pulsed lavage market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1743) The Parties' combined market share threshold exceeds [50-60]*% in this market, with the merged entity holding market share of approximately [60-70]*% in the pulsed lavage market, with an increment of approximately [5-10]*% from Biomet. Post-merger, apart from residual competitors, there would be two competitors left with market share over 5%, namely Stryker and Heraeus.
- (1744) Over the 2011-2013 period, Zimmer's position decreased from [60-70]*% to [50-60]*%, and Biomet's position decreased from [5-10]*% to [5-10]*%.

⁷³³ Response to the Article 6(1)(c) Decision, paragraph 1261.

⁷³⁴ Responses to Questionnaire Q31 to hospitals, question 137.

- (1745) The Notifying Party identified that recently [...]*, in [...]* switched to Biomet from Stryker, indicating that switching is a common phenomenon in the Dutch market for pulsed lavage.⁷³⁵
- (1746) In terms of market entry, the Notifying Party claims that the entry of Heraeus in 2010 and Columbus Medical and Microaire in 2011 shows that entry into the Dutch market for pulsed lavage is feasible.⁷³⁶ In addition, according to the Notifying Party, a number of Asian competitors are present in the Dutch market via local distributors Oudshoorn and Columbus Medical and offer low-cost copies of Zimmer's Pulsavac.⁷³⁷

Conclusion

- (1747) The Commission concludes that in the Dutch market for pulsed lavage, it is likely that the established players as well as new aggressive entrants would continue to constrain the merged entity post-merger.

Slovenia

- (1748) According to the Notifying Party, in Slovenia, the total value of the pulsed lavage market was EUR[less than 1]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1749) The Parties have combined market shares of [30-40]*% in the pulsed lavage market, with an increment of approximately [10-20]*% from Biomet. Post-merger, apart from residual competitors, there would be one competitor left (Stryker) with market share over 5%.
- (1750) Over the 2011-2013 period, Zimmer's position increased from [5-10]*% to [10-20]*% and Biomet's position increased from [0-5]*% to [10-20]*%.

Conclusion

- (1751) The Commission concludes that in the Lithuanian market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker, which would have market share similar to that of the merged entity, would continue to constrain the merged entity post-merger.

Sweden

- (1752) According to the Notifying Party, in Sweden, the total value of the pulsed lavage market was EUR [1-50]* million in 2013. In the same year, the Parties' sales amounted to EUR [...]* for Zimmer and EUR [...]* for Biomet.
- (1753) The Parties' combined market share threshold exceeds [50-60]*% in this market, with the merged entity holding market share of approximately [60-70]*% in the pulsed lavage market, with Biomet contributing an increment of approximately [10-20]*%. Post-merger, there would be two competitors left with market share over 5%, namely Stryker and Microaire.
- (1754) Over the 2011-2013 period, Zimmer's position decreased from [40-50]*% to [10-20]*%, while Biomet's position increased from [10-20]*% to [10-20]*%.

⁷³⁵ Response to the Article 6(1)(c) Decision, paragraph 1272.

⁷³⁶ Response to the Article 6(1)(c) Decision, paragraph 1273.

⁷³⁷ Form CO, paragraph 2590.

- (1755) In terms of market entry, the Notifying Party claims that the entry of Pulsed Lavage in 2012 as well as entry of several Asian companies show that entry into the Swedish market for pulsed lavage is feasible.⁷³⁸

Conclusion

- (1756) The Commission concludes that in the Swedish market for pulsed lavage, the proposed merger would not significantly impede effective competition, since it is likely that Stryker and Microaire, which would remain number two and three competitors respectively, as well as new aggressive entrants, would continue to constrain the merged entity post-merger.

8.10.3.6. Conclusion – Pulsed Lavage

- (1757) The Commission considers that barriers to entry and expansion in pulsed lavage are not significant enough to prevent remaining and potential competitors from efficiently constraining the merged entity.
- (1758) On this basis, the Commission concludes that the proposed merger does not significantly impede effective competition in relation to pulsed lavage market in any of the Group 1 national markets.

8.10.4. Spine Devices

8.10.4.1. Overview of the market for Spine Devices

- (1759) Spine devices are used in surgical procedures to repair vertebrae and intervertebral discs in the spinal column.
- (1760) The spine sector is fragmented among many suppliers, with Zimmer and Biomet facing competition from a large number of significant competitors, including J&J/DePuy, Medtronic and Stryker. The Parties represent only a small part of the market. Where the Parties do overlap, the increment to the larger party's existing position is generally very small.
- (1761) As discussed in section 7.1.5.4, following the *J&J/Synthes* Decision, the Commission will assess the overall spine devices market and the plausible sub-segmentation into (a) fusion devices, (b) non-fusion devices and (c) VCF devices.
- (1762) The Commission has consider possible further sub-segmentations:
- (a) Within fusion devices: (i) pedicle screw / rod based fixation devices, (ii) plating systems, (iii) inter-body cages and (iv) corpectomy cages. Some of these segments are further divided between cervical and thoracolumbar devices.
 - (b) Within non-fusion devices: (i) dynamic stabilisation devices and (ii) artificial disks.
 - (c) Within VCF devices: (i) vertebroplasty and (ii) vertebral augmentation.

8.10.4.2. The Parties and their competitor's products

- (1763) The Parties supply a number of spine implants and devices. The Parties are active in all three sub-segments. However, in non-fusion devices and in VCF devices, the Parties sales are minimal.

⁷³⁸ Response to the Article 6(1)(c) Decision, paragraph 1282, and Form CO, paragraph 2607.

- (1764) In relation to fusion devices, in pedicle screw / rod based fixation devices, Zimmer supplies a portfolio of Pedicle / screw rod based devices, which includes the Sequoia Pedicle Screw System, the ST360° Spinal Fixation System, the Universal Clamp™ Spinal Fixation System, the Instinct Java pedicle screw System, and the Nex-Link Spinal Fixation System and Nex-Link OCT® Occipital Cervical Plating System. Biomet supplies the following pedicle screw/rod based fixation systems; the Polaris 5.5 and 6.35 Spinal Systems, the Array spinal system, the Omega 21 LPSC, the Silverton and Silverton-D, Lineum OCT System, and the ALTIUS-MINI OCT System.
- (1765) In relation to fusion devices, in plating systems, Zimmer supplies various plating systems, namely; the V2F Anterior Fixation System, the InViZia Anterior Cervical Plate System, the ThinLine Anterior Cervical Plate, and the Trinica and Trinica Select Anterior Cervical Plate System. Biomet supplies the following plating systems; OMEGA 21 LP Plating System, MaxAn Ant Cervical Plate, VueLock Ant Cervical Plate and SnowCap Anterior Cervical Plate.
- (1766) In relation to fusion devices, in interbody cages, both Parties supply a wide array of interbody cages, designed for different surgical accesses, namely anterior and posterior. The Parties offer stand-alone devices as well as devices that are designed to be used in conjunction with other implants.
- (1767) Finally, in relation to fusion devices for corpectomy, the corpectomy product range of Zimmer includes VBR-L for lumbar. Zimmer's VBR-L corpectomy cage is composed of Trabecular Metal technology. This metal has an advanced fixation surface with a high coefficient of friction (0.98), the material also enhances the potential for bone growth, and is highly corrosion-resistant. On the other hand, Biomet is only present in this subsegment through the sales of Co-Ligne's stackable cages.

8.10.4.3. Structure of the spine devices market

Overall Spine Devices

- (1768) Based on 2013 Zimmer market size and market share estimates, the total size of the EEA market for spine devices was EUR [700-800]* million, and the Parties accounted for [5-10]*% of those sales EUR [...] (EUR [...] for Zimmer and EUR [...] for Biomet).
- (1769) In the market for overall spine devices the Parties' combined market shares range from [0-5]*% to [10-20]*% and the increment ranges between [0-5]*% and [5-10]*%.

Fusion Spine Devices

- (1770) Based on 2013 Zimmer market size and market share estimates, the total size of the EEA market for the overall fusion devices was EUR [500-600]* million, and the Parties sales in this segment account for [5-10]*%.
- (1771) In the overall fusion devices segment, Zimmer and Biomet have combined market shares ranging from [0-5]*% to [20-30]*% and the increment is between [0-5]*% and [5-10]*%. The Parties have a combined market share of [10-20]*% across the EEA.

Non-fusion Spine Devices

- (1772) Based on 2013 Zimmer market size and market share estimates, the total size of the EEA market for the overall non-fusion devices was EUR [50-100]* million, and the Parties sales in this segment account for EUR [...]*
- (1773) Biomet has very limited presence in the overall non-fusion devices segment. It only supplied these devices to Spain and Poland in 2013. In these two sub-segments, the Parties' combined share never exceeds [10-20]*% and the increment is, at its maximum, below [0-5]*%.

VCF Devices

- (1774) Based on 2013 Zimmer market size and market share estimates, the total size of the EEA market for the overall VCF devices was EUR [100-200]* million, and the Parties sales in this segment account for EUR [...]*

8.10.4.4. Competitive Assessment

- (1775) There are no affected or Group 1 national markets on the overall spine implants market.
- (1776) Moreover, there are no affected or Group 1 national markets in the non-fusion and VFC devices segments or any of their sub-segmentations.
- (1777) In relation to the fusion devices segment, there are no Group 1 national markets. However, if the Commission sub-segments the market further, then there are three Group 1 national markets.
- (1778) These are the sub-segments for:
 - (a) Fusion devices, overall plating systems, in Belgium (including Luxembourg);
 - (b) Fusion devices, plating systems – cervical, in Belgium (including Luxembourg); and
 - (c) Corpectomy cages stackable / monoblock, in Italy.

General Competitive Assessment

- (1779) The Parties market shares in all spine sub-segments are generally very low. On all plausible sub-segments, only three Group 1 national markets were identified.
- (1780) In addition, a number of strong competitors would continue to exert significant competitive constraint on the merged entity. J&J/DePuy and Medtronic are market leaders for spine implants. They are followed by a number of other companies, including Stryker and Aesculap.
- (1781) The spine devices market is dynamic, with new entrants recorded in the EEA in the past 3-5 years.

Fusion devices, overall plating systems and plating systems – cervical (Belgium (including Luxembourg))

- (1782) In the overall plating systems sub-segment in Belgium (including Luxembourg), the total value of the fusion plating sub-segment is EUR [1-50]* million, which represents [5-10]*% of total sales in the EEA EUR [1-50]* million. The Parties' combined sales are EUR [...] (EUR [...] for Zimmer and EUR [...] for Biomet). Their combined market share is [40-50]*% with Biomet contributing an increment of [10-20]*%. Other competitors already present in this market include Medtronic, J&J/DePuy, Globus and Stryker.

There are accordingly a number of competitors able to constrain the merged entity post-merger.

- (1783) In the narrower even sub-segment for plating systems – cervical in Belgium (including Luxembourg), the total value of the fusion plating cervical sub-segment is EUR [1-50]* million, which represents [5-10]*% of total sales in the EEA EUR [...]*. The Parties' combined sales are EUR (EUR [...]* for Zimmer and EUR [...]* for Biomet). Their combined market share is [50-60]*% with Biomet contributing an increment of [10-20]*%. Other competitors already present in this market include Medtronic, J&J/DePuy, Globus and Stryker. There are accordingly a number of competitors able to constrain the merged entity post-merger.
- (1784) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the potential markets for overall plating systems and for cervical plating systems in Belgium (including Luxembourg).

Corpectomy cages stackable / monoblock (Italy)

- (1785) In Italy, the total value of the fusion corpectomy cages stackable/monoblock sub-segment is EUR [less than 1]* million, which represents [10-20]*% of total sales in the EEA EUR [1-50]* million. The Parties' combined sales are EUR [...]* (EUR [...]* for Zimmer and EUR [...]* for Biomet).
- (1786) Their combined market share is [50-60]*% with Zimmer contributing an increment of [5-10]*%. Other competitors already present in this market include J&J/DePuy, Medtronic, Stryker, Nuvasive and Globus. There are accordingly a number of competitors able to constrain the merged entity post-merger.
- (1787) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the potential market for stackable / monoblock corpectomy cages in Italy.

8.10.4.5. Conclusion – Spine Devices

- (1788) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the national market for the provision of spine devices or in any of its potential sub-markets.

8.10.5. Trauma Devices

8.10.5.1. Overview of the market for Trauma Devices

- (1789) Trauma devices are used to treat bone fractures throughout the upper and lower extremities (including foot and ankle), the shoulder girdle and the pelvic girdle.
- (1790) Surgeons apply trauma devices either as internal or as external fixation devices. Internal fixation devices date back to the mid-19th century whilst external fixation devices were developed in the 1950's.
- (1791) The trauma devices sector is fragmented among many competitors, with Zimmer and Biomet facing competition from a large number of suppliers including J&J/DePuy, S&N, Stryker and a large number of smaller suppliers.

8.10.5.2. The Parties' products

- (1792) Zimmer categorises its products as plates & screws, intramedullary systems, and external fixation. Plates & screws covers locking plates and screws designed using cutting edge technology for reducing the stiffness of locking

plate constructs and improving patient outcomes. Intramedullary Systems pertain to nails characterised by their anatomic shape, with the design to help restore the shape of the fractured bone to its natural, pre-injured state. External Fixation refers to the XTRAFIX system used during orthopaedic surgery, which allows surgeons to build rigid constructs with fewer components in less time.

- (1793) Biomet categorises its products as orthopaedic trauma, implantable stimulation foot and ankle, paediatric and reconstruction, and upper extremity. Orthopaedic trauma refers to locking plates, screws and nails. Implantable Stimulation covers implants providing electrical stimulation for bone growth. Foot and ankle products are plates, screws, nails, grafts and wedges designed to heal foot and ankle injuries. The paediatrics and reconstruction category contains adjustments systems aimed at young patients and adults. Upper extremity products are platings, screws and nails used above-waist.

8.10.5.3. Structure of the trauma devices market

- (1794) Based on 2013 Zimmer market size and market share estimates, the total size of the EEA market for all trauma devices was EUR [800-900]* million. That same year, the Parties' sales amounted to EUR [...] for Zimmer and EUR [...] for Biomet.
- (1795) J&J/DePuy is the market leader with a market share of [30-40]*%, followed by Stryker with a market share of [20-30]*%. S&N is in 3rd position with a share of [10-20]*%. Together these top three players account for more than [70-80]*% of the market. Biomet and Zimmer are jointly in 4th position each with a share of [5-10]*%. Aesculap has a strong national presence in countries including Slovakia, Slovenia, Latvia and the Czech Republic. There are also a number of other market players in trauma, which account for [10-20]*% of the market (including Wright /Microport).

8.10.5.4. Competitive Assessment

- (1796) The Parties' market shares in each country show no Group 1 national markets for overall trauma. Zimmer and Biomet have combined market shares in these markets ranging from [0-5]*% to [20-30]*% and the increment is between [0-5]*% and [10-20]*% in all markets.
- (1797) The Commission has also assessed the effects of the proposed merger in the different product markets of the overall trauma sector, namely (a) internal fixation devices and its sub-segments (i) plating systems (non-anatomic and anatomically shaped plates and screws), (ii) intramedullary ("IM") nails and IM hip screws, (iii) cannulated screws, (iv) compression hip screws, and (v) ancillary devices; and (b) external fixation devices and its sub-segments (i) universal external fixation and (ii) specialised external fixation.
- (1798) The Parties' market shares show no Group 1 national markets for the external fixation devices market and any of its potential sub-segments.
- (1799) In relation to the potential sub-markets relating to internal fixation devices, there are only 2 Group 1 markets:
- (a) Internal fixation devices, cannulated screws in Belgium (including Luxembourg); and
 - (b) Internal fixation devices, plating systems in the United Kingdom.

Internal fixation devices, cannulated screws (Belgium (including Luxembourg))

- (1800) In Belgium (including Luxembourg), the total value of the cannulated screws market is EUR [1-50]* million, which represents only [0-5]*% of total sales in the EEA EUR [100-200]* million, according to the Notifying Party. The Parties' combined sales are EUR [...] (EUR [...] for Zimmer and EUR [...] for Biomet). Their combined market share is [40-50]*% with Zimmer contributing an increment of [0-5]*%. Other competitors already present on this market include J&J/DePuy, Stryker, and S&N. There are accordingly a number of competitors able to constrain the merged entity post-merger.
- (1801) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of cannulated screws (internal fixation devices) in Belgium (including Luxembourg).

Internal fixation devices, plating systems (United Kingdom)

- (1802) In the UK, the total value of the trauma plating systems market is EUR [1-50]* million, which represents only [10-20]*% of total sales in the EEA EUR [...] million. The Parties' combined sales are EUR [...] (EUR [...] for Zimmer and EUR [...] for Biomet). Their combined market share is [40-50]*% with Zimmer contributing an increment of [5-10]*%. Other competitors already present on this market include J&J/DePuy, S&N and Stryker. There are accordingly a number of competitors able to constrain the Merged Entity post-merger.
- (1803) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the market for the provision of trauma plating systems (internal fixation devices) in the United Kingdom.

8.10.5.5. Conclusion – Trauma Devices

- (1804) On this basis, the Commission concludes that the proposed merger would not significantly impede effective competition on the national market for the provision of trauma devices or in any of its sub-markets.

9. COMMITMENTS

- (1805) On 3 December 2014 the Notifying Party formally submitted commitments pursuant to Article 8(2) of the Merger Regulation, purporting to address the Commission's concerns regarding the proposed merger (the "Commitments of 3 December 2014") in relation to the national unicondylar knee, elbow and total (primary and revision)_ knee implants markets of concern. The Commission subjected these commitments to a market test. The market test indicated that the commitments were insufficient to entirely eliminate the concerns raised by the proposed merger. The Commission communicated the results of the market test to the Notifying Party on 18 December 2014.
- (1806) In order to address the issues raised in the market test, the Notifying Party informally submitted revised commitments on 24 January 2015. The Commission consulted various market participants on a number of aspects of these informal revisions.
- (1807) Subsequently, the Notifying Party formally submitted a revised second set of commitments on 9 February 2015 (the "Final Commitments").

9.1. Remedies principles

- (1808) The following principles from the Commission's notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004⁷³⁹ (the "Remedies Notice") apply where parties to a merger choose to offer commitments in order to restore effective competition.
- (1809) Where a concentration raises competition concerns in that it could significantly impede effective competition, in particular as a result of the creation or strengthening of a dominant position, the parties may seek to modify the concentration in order to resolve the competition concerns and thereby gain clearance of their merger.⁷⁴⁰
- (1810) The Commission only has power to accept commitments that are capable of rendering the concentration compatible with the internal market in that they will prevent a significant impediment to effective competition in all relevant markets where competition concerns were identified.⁷⁴¹ To that end, the commitments have to eliminate the competition concerns entirely⁷⁴² and have to be comprehensive and effective from all points of view.⁷⁴³
- (1811) In assessing whether proposed commitments are likely to eliminate its competition concerns, the Commission considers all relevant factors including *inter alia* the type, scale and scope of the commitments, judged by reference to the structure and particular characteristics of the market in which those concerns arise, including the position of the parties and other participants on the market.⁷⁴⁴ Moreover, commitments must be capable of being implemented effectively within a short period of time.⁷⁴⁵
- (1812) Where a proposed concentration threatens to significantly impede effective competition the most effective way to maintain effective competition, apart from prohibition, is to create the conditions for the emergence of a new competitive entity or for the strengthening of existing competitors via divestiture by the merging parties.⁷⁴⁶
- (1813) The divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern. The business must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness and all personnel which are currently

⁷³⁹ OJ 2008/C 267/01.

⁷⁴⁰ Remedies Notice, paragraph 5.

⁷⁴¹ Remedies Notice, paragraph 9.

⁷⁴² Case C-202/06 *P Cementbouw Handel & Industrie v Commission* [2007] ECR 2007 I-12129, paragraph 54: "*it is necessary, when reviewing the proportionality of conditions or obligations which the Commission may, by virtue of Article 8(2) of Regulation No 4064/89, impose on the parties to a concentration, not to determine whether the concentration still has a Community dimension after those conditions or obligations have been complied with, but to be satisfied that those conditions and those obligations are proportionate to and would entirely eliminate the competition problem that has been identified*".

⁷⁴³ Remedies Notice, paragraph 9 and 61.

⁷⁴⁴ Remedies Notice, paragraph 12.

⁷⁴⁵ Remedies Notice, paragraph 9.

⁷⁴⁶ Remedies Notice, paragraph 22.

employed or which are necessary to ensure the business' viability and competitiveness.⁷⁴⁷

- (1814) Personnel and assets which are currently shared between the business to be divested and other businesses of the parties, but which contribute to the operation of the business or which are necessary to ensure its viability and competitiveness, must also be included. Otherwise, the viability and competitiveness of the business to be divested would be endangered. Therefore, the divested business must contain the personnel providing essential functions for the business such as, for instance, group R&D and information technology staff even where such personnel are currently employed by another business unit of the parties —at least in a sufficient proportion to meet the on-going needs of the divested business.⁷⁴⁸
- (1815) Normally, a viable business is a business that can operate on a stand-alone-basis, which means independently of the merging parties as regards the supply of input materials or other forms of cooperation other than during a transitory period.⁷⁴⁹
- (1816) The intended effect of the divestiture will only be achieved if and once the business is transferred to a suitable purchaser in whose hands it will become an active competitive force in the market. The potential of a business to attract a suitable purchaser is an important element already of the Commission's assessment of the appropriateness of the proposed commitment. In order to ensure that the business is divested to a suitable purchaser, the commitments must include criteria to define the suitability of potential purchasers. This will allow the Commission to conclude that the divestiture of the business to such a purchaser will likely remove the competition concerns identified.⁷⁵⁰
- (1817) There are cases where only the proposal of an up-front buyer will allow the Commission to conclude with the requisite degree of certainty that the business will be effectively divested to a suitable purchaser. The parties to such merger cases must undertake in the commitments that they are not going to complete the notified operation before having entered into a binding agreement with a purchaser for the divested business, approved by the Commission.⁷⁵¹

9.2. Description of the proposed commitments

9.2.1. The Commitments of 3 December 2014

9.2.1.1. Substance of the proposal

- (1818) The Commitments of 3 December 2014 consisted of the proposed divestment to one or several suitable purchasers of specified businesses (the "Divestment Businesses"), as described below in recital (1819) onwards and in more detail in the Schedule to the Commitments of 3 December 2014.
- (1819) The Divestment Businesses contained within the Commitments of 3 December 2014 related to the following products:

⁷⁴⁷ Remedies Notice, paragraph 23-25.

⁷⁴⁸ Remedies Notice, paragraph 26.

⁷⁴⁹ Remedies Notice, paragraph 32.

⁷⁵⁰ Remedies Notice, paragraph 47.

⁷⁵¹ Remedies Notice, paragraph 53.

- (a) Zimmer Unicompartmental High-Flex Knee System (the "ZUK", Zimmer's unicondylar knee implant) and, if necessary to strengthen the viability of the ZUK Divestment Business, the AGC Knee (the "AGC Knee", a Biomet total knee implant);
 - (b) Biomet Discovery Elbow system (the "Discovery Elbow", a Biomet elbow implant system); and
 - (c) Vanguard Knee (the "Vanguard Knee", a Biomet total knee system, including primary and revision products).
- (1820) The geographic scope of the different Divestment Businesses varied. Whereas the proposed ZUK (and the related AGC Knee) and Discovery Elbow Divestment Businesses were EEA-wide in scope, the Vanguard Knee Divestment Business related to Denmark and Sweden only.
- (1821) The Divestment Businesses proposed in the Commitments of 3 December 2014 included, in particular:
- (a) tangible assets for use exclusively in the geographic boundaries described in the preceding recital. These tangible assets included implant inventory, instrumentation inventory, copies of design history files, copies of all proprietary testing and clinical data, marketing materials and training materials;
 - (b) intangible assets for use exclusively in the geographic boundaries described in the preceding recital. These intangible assets included the transfer of intellectual property rights used exclusively for the products of the Divestment Businesses, and fully paid-up non-exclusive licences⁷⁵² to other intellectual property rights that are necessary for the manufacturing, marketing or sale of the divested product, as specified in the Schedule of the Commitments of 3 December 2014;⁷⁵³
 - (c) transfer of, or if not legally possible, access to all licences, permits and authorisations issued by any governmental organisation necessary to develop, manufacture and market the products of the Divestment Businesses;
 - (d) transfer of, or if not legally possible, access to CE marks;
 - (e) customer contracts, leases, commitments and customer orders of the Divestment Businesses or, if not legally possible in exceptional instances, the continued supply of the products by the Merged Entity while ensuring a commission on those sales for the purchaser(s);
 - (f) customer records, credit records and other records of the Divestment Businesses (including list of existing and past customers and copies of customer records); and
 - (g) Key Personnel related to the particular Divestment Business.
- (1822) The Notifying Party was also prepared, at the option of the purchaser(s) to offer the following additional items:

⁷⁵² All licences are perpetual, subject to termination in exceptional circumstances, such as breach or insolvency.

⁷⁵³ Where, in exceptional circumstances, consent by third parties may be required, the Merged Entity undertook to take all reasonable efforts to obtain such consent.

- (a) transitory, non-exclusive supply or manufacturing arrangements for the products of the Divestment Businesses, for a transitional period of up to 24 months, with the possibility of an additional extension of 12 months if the Monitoring Trustee deems necessary;⁷⁵⁴
 - (b) technical assistance for a transitional period of up to 24 months in order to enable the purchaser(s) to assume responsibility for the manufacture, marketing and sale of the products of the Divestment Businesses in the relevant territory, with the possibility of an additional extension of 12 months if the Monitoring Trustee deems necessary;⁷⁵⁵
 - (c) to provide training on the products of the Divestment Business as well as technical training;
 - (d) to provide assistance in selling the products of the Divestment Businesses until the relevant regulatory authorisations, permits and licenses are obtained by the purchaser(s);
 - (e) in relation to the ZUK Divestment Business: long-term supply or manufacturing services on an at cost basis to allow the purchaser continued access to the PPMA pre-coat process and/or Vivacit-E polyethylene;
 - (f) in relation to the Discovery Elbow Divestment Business, long-term supply or manufacturing services on an at cost basis to allow the purchaser continued access to the ARCOM polyethylene; and
 - (g) in relation to the AGC Knee Divestment Business and the Vanguard Knee Divestment Business, long-term supply or manufacturing services on an at cost basis to allow the purchaser continued access to the E1 and/or ARCOM polyethylene.
- (1823) The proposed commitments excluded, in particular, any facilities or manufacturing equipment.
- (1824) According to the Notifying Party, the purchaser(s) would obtain well recognised, established products with solid track records, together with growth potential and immediate access to the markets in which the products are sold.
- (1825) The Notifying Party argued that the products in the Divestment Businesses are not complex to manufacture for any company active in the orthopaedics sector. The Notifying Party was therefore confident that there would be purchaser(s) capable of manufacturing and marketing each of the products in the Divestment Businesses viably and effectively.
- (1826) The Commitments of 3 December 2014 however contained reinforced purchaser suitability criteria. In this regard, the proposed commitments provided that the purchaser(s) shall have experience of and capability to

⁷⁵⁴ The said transitional arrangements would be offered on terms and conditions that are equivalent to those at present afforded to the Divestment Businesses. The Notifying Party has confirmed that the above means that supply / service arrangements will be offered on terms and conditions that are reasonable and customary and at the same quality level at which the Divestment Businesses are currently supplied with by the Notifying Party.

⁷⁵⁵ The said transitional arrangements would be offered on terms and conditions that are equivalent to those at present afforded to the Divestment Businesses. The Notifying Party has confirmed that the above means that supply / service arrangements will be offered on terms and conditions that are reasonable and customary and at the same quality level as those currently supplied to the Divestment Businesses by the Notifying Party.

manufacture, market and supply products that are marketed in the orthopaedics implant sector; and the purchaser(s) shall currently offer orthopaedic implants in the EEA. The Commitments of 3 December 2014 included an upfront buyer clause pursuant to which the Parties undertook that they would not complete the notified merger before having entered into a binding agreement with a purchaser(s) for all the Divested Businesses, approved by the Commission.

- (1827) The Notifying Party anticipated that there would be no unnecessary delay in purchasers being able to offer each of the products in the Divestment Businesses on the market and to successfully integrate them within their own organisations. In addition, the Notifying Party considered that the Divestment Businesses constituted an attractive investment that would allow a purchaser(s) to enter or expand in the segments concerned, and operate as a strong, viable competitor.

9.2.1.2. The market test and the Commission's assessment

- (1828) The Commission conducted a market test of the Commitments of 3 December 2014. The Commission sent out e-questionnaires to competitors and customers (including hospitals and purchasing groups) and followed up with conference calls to a number of leading competitors, potential purchasers and regulatory experts. In addition, J&J/DePuy submitted a memorandum as a follow up of its submissions regarding the remedies market test.⁷⁵⁶
- (1829) The results of the market test of the Commitments of 3 December 2014 were mixed, with a number of positive responses but also with a number of concerns in relation to the scope and the viability of the commitments offered.

Suitability of the scope of the Divestment Business

A. Unicondylar knee implants - The ZUK Divestment Business and the AGC Divestment Business

i. Tangible and intangible assets

The ZUK Divestment Business

- (1830) The majority of respondents to the market test indicated that the unicondylar knee products offered as part of the ZUK Divestment Business consisted of a range of products which were well-regarded by the orthopaedic community.⁷⁵⁷ Indeed, the ZUK is considered as a good, proven implant with good clinical results.⁷⁵⁸
- (1831) The ZUK is advertised and promoted as being based on the Miller Gallante System (M/G).⁷⁵⁹ Indeed, the ZUK is based on the established implant design of Zimmer's - M/G unicompartamental Knee System. Whilst the M/G is no longer marketed, the M/G II is still sold.
- (1832) The ZUK is advertised and promoted as being based on the M/G System. Indeed, the ZUK is based on the established implant design of Zimmer's

⁷⁵⁶ J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁵⁷ Non-confidential minutes of conference calls with S&N, 17.12. 2014, 14.01.2015, 22.02.2015, 2.02. 2015 and 3.02. 2015.

⁷⁵⁸ Non-confidential minutes of conference calls with Lima, 16.12.2014, 14.01.2015 and 2.02.2015 and Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 3; Responses to Remedies Market Test, Q36 – Questionnaire to Customers, question 6.

⁷⁵⁹ Miller Gallante is an older knee system manufactured by Zimmer.

Miller-Galante (M/G) unicompartamental Knee System. Whilst the M/G product is no longer marketed, the M/G II is still sold.

- (1833) Some respondents considered that the assets (tangible and intangible) included in the ZUK Divestment Business were sufficient for the purchaser to develop the ZUK Divestment Business and become as competitive as Zimmer currently is in the EEA in relation to unicondylar knee implants. However, a number of respondents to the market test submitted that a number of additional elements would, in their view, need to be included in the ZUK Divestment Business.
- (1834) **Instrumentation.** The market investigation established that instrumentation is a strong differentiating factor for implant manufacturers and that the ZUK instrumentation is particularly well regarded. The Commitments of 3 December only included instrumentation that is used exclusively for the ZUK Divestment Business. Some respondents to the market test indicated the need for the Divestment Business to include all surgical instruments used for the implantation, even if these are common to other Zimmer knee products and are not used exclusively for the ZUK.⁷⁶⁰ Some respondents to the market investigation claimed that the ZUK divestment business may have certain instrumentation common with other Zimmer product lines. On this basis, there were concerns that these instruments would not be covered by the proposed commitments, as they were not used exclusively for the ZUK.
- (1835) The Commission considered these arguments and took the view that all necessary instrumentation should be included in the scope of the ZUK Divestment Business to ensure its viability, even if the instrumentation was not exclusive to the ZUK, but was used for implantation of the ZUK.
- (1836) **Neighbouring implants.** In addition, one competitor, J&J/DePuy, submitted that the ZUK Divestment Business should also include a patello-femoral implant as part of the divested assets. J&J/DePuy⁷⁶¹ indicated that a supplier's inability to offer a patello-femoral implant which is compatible with the ZUK implant could dissuade the surgeon from performing a unicondylar knee procedure and thus reduce the competitiveness of the ZUK Divestment Business.
- (1837) The Commission examined whether the non-inclusion of a patello-femoral implant would negatively impact the competitiveness and viability of the ZUK Divestment Business.
- (1838) In its the PFJ/ZUK Note, the Notifying Party sought to demonstrate that the inclusion of patello-femoral implant was not necessary for the viability of the remedy. The Notifying Party explained that patello-femoral implants are used as an add-on to unicondylar implants only on rare occasions.⁷⁶²
- (1839) This aspect was confirmed by the market investigation. If a condyle is affected, as well as the patella cap, the surgeon theoretically has a choice between using a total knee implant or a unicondylar and a patello-femoral implant. However,

⁷⁶⁰ JJ/DePuy follow up on the remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁶¹ JJ/DePuy follow up on the remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁶² Notifying Party, White Paper, Patello-Femoral Joint Replacement and ZUK, 7.01.2015.

as indicated in recital (53), such bi-compartmental surgical procedure takes place in an insignificant proportion of partial knee procedures.⁷⁶³

- (1840) Furthermore, the Notifying Party indicated that patello-femoral implants from competitors can easily be used with the ZUK implant. Thus, even in the rare cases in which a bi-compartmental operation takes place, patello-femoral implants offered by competitors may be used together with the ZUK implant.
- (1841) In this regard, the Commission's investigation showed that various suppliers have patello-femoral implant offerings in the market, including: S&N (Journey PFJ), J&J/DePuy (LCS PFJ), Stryker (AVON patello-femoral), Arthrex (iBalance PFJ System), Wright/Microport (Femoro Patella Vialli - FPV) and Arthosurface (Patello-femoral HemiCap).
- (1842) Moreover, the instrumentation of the ZUK and the patello-femoral implants differ. Zimmer's internal document "Knee Profiler" shows that the surgery techniques for its patello-femoral implant and ZUK are different and that each of the two implants benefits from its own set of instruments.⁷⁶⁴
- (1843) Therefore no efficiency gains would be had for the customer in relation to instrumentation as the customer would still need to acquire a different set of instruments for the patello-femoral implant.
- (1844) On this basis, the Commission considered that a patello-femoral implant was not necessary to ensure the competitiveness and/or viability of the ZUK Divestment Business.

The AGC Divestment Business

- (1845) The majority of respondents to the market test were critical about the AGC total knee as a supportive element to the ZUK Divestment Business to ensure the viability of the unicondylar remedy. Indeed, the respondents to the market test did not consider that a total knee system would be needed as part of the unicondylar implant remedy to support the viability of the unicondylar remedy and that the ZUK was sufficient.
- (1846) Besides this, a number of competitors described the AGC product range as a well-established but old generation of technology.⁷⁶⁵ The market test indicated that the AGC is indeed an old asset, the phase out of which is already in progress.⁷⁶⁶ It was introduced in the 1980s, with very low sales in the EEA. According to respondents, the AGC is an outdated (first generation) product. Its technology is now old and its instruments have not been significantly updated in more than 20 years. According to respondents, the AGC will likely bring no advantages to the purchaser of the ZUK Divestment Business.⁷⁶⁷ For instance, in this regard J&J/DePuy submitted that the AGC Knee is an older product that would not be suitable to include as part of any remedy in this case.⁷⁶⁸ Indeed, in the 2014 United Kingdom national joint registry report, the

⁷⁶³ <https://aoanjrr.dmac.adelaide.edu.au/documents/10180/172286/Annual%20Report%202014>, page 128.

⁷⁶⁴ Zimmer's internal documents, "Knee profiler", September 2012, pages 22 and 34, ID 278.

⁷⁶⁵ Non-confidential minutes of conference calls with Lima, 16.12.2014, 14.01.2015 and 2.02 2015; Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 6.

⁷⁶⁶ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 6.

⁷⁶⁷ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 23 and 32.

⁷⁶⁸ J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

AGC is described as a product which has lost momentum and did not even feature amongst the top 5 most implanted knees (from amongst the knee surgery procedures reported to the NJR).

- (1847) Furthermore, the AGC is a primary knee system only and has no revision capabilities. That would mean that if an AGC knee needs revisiting, then all components may need to be replaced with a different brand. This would be a concern for surgeons.⁷⁶⁹
- (1848) Finally, the clinical outcomes for the AGC are not as favourable in comparison to second or third generation knee systems.⁷⁷⁰
- (1849) The respondents indicated that in so far as the purchaser has experience in the orthopaedic implants markets and may be considered as reliable and experienced in terms of customer service and logistical and sales service,⁷⁷¹ a total knee range was not needed. In other words, the purchaser suitability criteria would be sufficient to avoid viability risks.⁷⁷²
- (1850) On this basis, the Commission considers that the inclusion of the AGC total knee range is not necessary, nor appropriate, to ensure the viability of the ZUK Divestment Business.

ii. Key Personnel

- (1851) The Commitments of 3 December 2014 did not specify the details of the Key Personnel in terms of number of personnel and positions. The majority of respondents to the market investigation emphasised the importance of key personnel in order to maintain the established relationship between a producer and a customer. One respondent stressed that it was important to include additional R&D, marketing and sales personnel as Key Personnel.⁷⁷³
- (1852) On this basis, the Commission considered that the proposed commitments were not sufficient, as they were drafted in too vague terms. The Commission considered that the Key Personnel needed to include personnel responsible for the product / marketing as well as sales representatives at country level.

iii. Transitional supply arrangements for common platform technologies

- (1853) As indicated above in recital (1822), the Commitments of 3 December provided for "long-term supply or manufacturing services" at the purchaser's option to allow continued access for the purchaser to the PMMA pre-coat process and/or the Vivacit-E polyethylene.
- (1854) These common platform technologies (most commonly coatings and polyethylene plastics) are used for a wide range of implants, including the ZUK Divestment Businesses. They form part of the design file of the relevant implant and may impact its track record.

⁷⁶⁹ J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁷⁰ J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁷¹ Responses to Remedies Market Test, Q36 – Questionnaire to Customers, question 8.

⁷⁷² Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 20.

⁷⁷³ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 11; J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

- (1855) The market test indicated that the purchaser would need to have access to the manufacturing know-how for all common platform technologies used for the manufacture of the ZUK product range, rather than a long term supply agreement. A number of respondents indicated that a long term supply agreement would link the purchaser to Zimmer's supply chain and render the purchaser dependent on Zimmer, impacting also the viability of the Divestment Business.⁷⁷⁴
- (1856) The Notifying Party argued that a long term supply agreement would not create a relationship of dependency, as the cost of the common technologies was a very low proportion of the average selling price of the entire implant (approximately [0-5]*% for the PMMA and [0-5]*% for the ViVacit-E). In addition, these common platform technologies are highly proprietary to the merging parties and are also used in other products, not included in the Divestment Businesses. Finally, the Notifying Party argued that the purchaser would prefer to be supplied with such technologies, rather than being obliged to manufacture those itself.⁷⁷⁵
- (1857) Moreover, the Notifying Party argued that many common platform technologies are only used for a small subset of the volumes sold. For example, [...]*. This is examined in recitals (1917) to (1929) below.
- (1858) The Commission took account of its Remedies Notice,⁷⁷⁶ and in particular the reference to the arrangements for the supply of products and services by the merged entity to the divested business (or vice versa). Such an on-going relationship will only be accepted on a transitional basis and in so far as it does not affect the independence of the divested business from the parties.
- (1859) On this basis, the Commission concluded that a long term supply of the common platform technologies (in so far these were required) would not be appropriate, as this would create a long term dependency between the purchaser and the merged entity.

iv. Conclusion

- (1860) On this basis, the Commission considered that the Commitments of 3 December in relation to the ZUK Divestment Business were not sufficient to remedy the competition concerns.

B. Elbow Implants - the Discovery Elbow Divestment Business

i. Tangible and intangible assets

- (1861) The Discovery Elbow is the flagship elbow implant of Biomet. [...]*.⁷⁷⁷ One market respondent stated that it considers the Discovery Elbow as a potentially attractive asset.⁷⁷⁸

⁷⁷⁴ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 9-11; Non-confidential minutes of conference calls with J&J, 17.12. 2014, 14.01 2015, 2.02.2015 and 3.02. 2015; J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁷⁵ Notifying Party, White Paper on Platform Technologies, 19.01.2015.

⁷⁷⁶ Paragraph 28.

⁷⁷⁷ Response to RFI14 - Internal documents production - ID 376 - Elbow Sales Aid rev5(UK) Jul14, slide 6.

⁷⁷⁸ Non-confidential minutes of conference calls with J&J, 17.12.2014, 14.01.2015, 02.02 2015 and 03.02.2015

- (1862) Some respondents considered that the assets (tangible and intangible) included in the Discovery Elbow Divestment Business were sufficient for the purchaser to develop the Discovery Elbow Divestment Business and become as competitive as Biomet currently is in the EEA in relation to elbow implants.⁷⁷⁹ However, a number of respondents to the market test submitted that a number of additional elements would, in their view, need to be included in the Discovery Elbow Divestment Business.
- (1863) **Instrumentation.** The same arguments were made as in relation to the ZUK Divestment Business (see recitals (1834) and (1835) above), in relation to the need to include non-exclusive instrumentation that is used for the Discovery Elbow Divestment Business.
- (1864) The Commission took the view that in principle, all necessary instrumentation should be included in the scope of the Discovery Elbow Divestment Business to ensure its viability, even in case the instrumentation was not exclusive to the Discovery Elbow Divestment Business.
- (1865) On this basis, the Commission considered that the Commitments of 3 December, as drafted only to include instrumentation that is used exclusively for the Discovery Divestment Business were not sufficient.
- ii. Key Personnel*
- (1866) The Commitments of 3 December 2014 did not specify the details of the Key Personnel in terms of number of personnel and positions. On this basis, the Commission considered that the proposed commitments were not sufficient, as they were drafted in too vague terms. The Commission considered that the Key Personnel needed to include personnel responsible for the product / marketing as well as sales representatives at country level.
- iii. Transitional supply arrangements for common platform technologies*
- (1867) As indicated above in recital (1822), the Commitments of 3 December provided for "long-term supply or manufacturing services" at the purchaser's option to allow continued access for the purchaser to the ARCOM polyethylene, which is used for the production of the Discovery Elbow.
- (1868) The market test indicated that the purchaser would need to have access to the manufacturing know-how for all common platform technologies used for the manufacture of the Discovery Elbow product range, rather than a long term supply agreement. A number of respondents indicated that a long term supply agreement would link the purchaser to Zimmer's supply chain and render the purchaser dependent on Zimmer, impacting also the viability of the Divestment Business.⁷⁸⁰
- (1869) The Notifying Party made the same arguments in relation to the cost of the ARCOM (1900H) as a proportion of the Discovery Elbow entire implant

⁷⁷⁹ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 40-41.

⁷⁸⁰ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 9-11; Non-confidential minutes of conference calls with J&J, 17.12. 2014, 14.01 2015, 02.02.2015 and 3.02.2015; J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

(approximately [10-20]*%) as those submitted regarding the platform technologies for the ZUK.⁷⁸¹

(1870) As discussed in recitals (1813) to (1817), the Commission took account of its Remedies Notice,⁷⁸² and in particular the reference to the arrangements for the supply of products and services by the merged entity to the divested business (or vice versa). Such an on-going relationship will only be accepted on a transitional basis and in so far as it does not affect the independence of the divested business from the parties.

(1871) On this basis, the Commission considered that a long term supply of the ARCOM common platform technology would not be appropriate, as this would create a long term dependency between the purchaser and the merged entity.

iv. Conclusion

(1872) On this basis, the Commission considered that the Commitments of 3 December in relation to the Discovery Elbow Divestment Business were not sufficient to remedy the competition concerns.

C. Total (Primary and Revision) Knee Implants - Vanguard Divestment Business

i. Tangible and intangible assets

(1873) A number of respondents to the market investigation submitted that Biomet's Vanguard is a competitive product.⁷⁸³

(1874) However, the overwhelming majority of respondents expressed their concerns about the viability of the divestiture in so far as it is limited only to Denmark and Sweden.⁷⁸⁴ Indeed the market test indicated that in order to ensure that effective competition is maintained in Denmark and Sweden, the scope of the proposed divestiture would need to be extended to cover at least the EEA.⁷⁸⁵

(1875) This restriction of the Divestment Business to Denmark and Sweden appears to give rise to serious viability issues for the proposed Divestment Business, throughout the value chain, from R&D to manufacturing as well as marketing and sales. A purchaser would not be able to develop economies of scale and rely on its ability to sell the Vanguard on an international scale.

(1876) Manufacturing the Vanguard for only Denmark and Sweden would disproportionately increase the cost of production for the relatively small volumes (currently less than [...]*) and would render the business uncompetitive. The respondents to the market investigation clearly indicated that it would not be feasible to produce an implant to be sold in only Denmark and Sweden⁷⁸⁶ and that the purchaser of the Vanguard Divestment Business would not have the incentives to develop the product line only for two

⁷⁸¹ Notifying Party, White Paper on Platform Technologies, 19.01.2015.

⁷⁸² Paragraph 28.

⁷⁸³ Non-confidential minutes of conference calls with J&J, 17.12. 2014, 14.01 2015, 02.02.2015 and 3.02.2015; Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 82.

⁷⁸⁴ Non-confidential minutes of conference calls with S&N, 17.12.2014, 14.01 2015, 22.01. 2015, 02.02 2015 and 03.02 2015.

⁷⁸⁵ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 82.

⁷⁸⁶ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 58 and 60 and J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

countries.⁷⁸⁷ In this regard, the market test indicated that the expected unit volumes in Denmark and Sweden will not generate enough sales to compensate for the fixed costs and the investments making it difficult to establish a profitable business.⁷⁸⁸ Moreover, according to the respondents to the market investigation "*the geographic limitation also excludes the opportunity to really grow or develop the Vanguard into other and more interesting [geographic] markets*".⁷⁸⁹ In addition to the arguments in recitals (1873) to (1877) in relation to the geographic scope of the Vanguard Divestment business, a number of respondents to the market test submitted that a number of additional elements would, in their view, need to be included in the Vanguard Divestment Business.⁷⁹⁰

- (1877) The Commission took the view that the Commitments of 3 December, as drafted only to include Denmark and Sweden in the scope of the Vanguard Divestment business, were not sufficient.
- (1878) **Instrumentation.** The same arguments were made as in relation to the ZUK Divestment Business (see recitals (1834) and (1835) above), in relation to the need to include non-exclusive instrumentation that is used for the Vanguard Divestment Business.
- (1879) For similar reasons as explained in recitals (1834) and (1835) above, the Commission took the view that in principle, all necessary instrumentation should be included in the scope of the Vanguard Divestment Business to ensure its viability, even in case the instrumentation was not exclusive to the Vanguard Divestment Business.
- (1880) On this basis, the Commission considered that the Commitments of 3 December regarding the Vanguard Divestment Business were not sufficient.
 - ii. *Key Personnel*
 - (1881) The Commitments of 3 December 2014 did not specify the details of the Key Personnel in terms of number of personnel and positions. On this basis, the Commission considered that the proposed commitments were not sufficient, as they were drafted in too vague terms. The Commission considered that the Key Personnel needed to include personnel responsible for the product / marketing as well as sales representatives at country level.
 - iii. *Transitional supply arrangements for common platform technologies*
 - (1882) As indicated above in recital (1822), the Commitments of 3 December provided for "long-term supply or manufacturing services" at the purchaser's option to allow continued access for the purchaser to the ARCOM polyethylene, the E1 polyethylene, and the Regenerex porous titanium construct, which are used for the production of the Vanguard knee.
 - (1883) The market test indicated that the purchaser would need to have access to the manufacturing know-how for all common platform technologies used for the manufacture of the Vanguard product range, rather than a long term supply agreement. A number of respondents indicated that a long term supply

⁷⁸⁷ Non-confidential minutes of conference calls with Lima, 16.12. 2014, 14.01. 2015 and 02,02.2015.
⁷⁸⁸ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 59.
⁷⁸⁹ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 60.
⁷⁹⁰ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 60.

agreement would link the purchaser to Zimmer's supply chain and render the purchaser dependent on Zimmer, impacting also the viability of the Divestment Business.⁷⁹¹

- (1884) The Notifying Party made the same arguments - as those submitted regarding the platform technologies for the Discovery Elbow - in relation to the cost of the common technologies as a proportion of the average selling price of the Vanguard as a whole:[...]* for the ARCOM (non-1900H),[...]* for the Regenerex and[...]* for the E1.⁷⁹²
- (1885) Moreover, the Notifying Party argued that many common platform technologies are only used for a small subset of the volumes sold. For example, the Regenerex is only used for [0-5]*% of the Vanguard implants sold in Denmark and Sweden, while the E1 is only used for [5-10]*%. This is examined in recitals (1917) to (1929) below.
- (1886) As discussed in recital (1858), the Commission took account of its Remedies Notice,⁷⁹³ and in particular the reference to the arrangements for the supply of products and services by the merged entity to the divested business (or vice versa). Such an on-going relationship will only be accepted on a transitional basis and in so far as it does not affect the independence of the divested business from the parties.
- (1887) On this basis, the Commission concluded that a long term supply of the common platform technologies (in so far as these were required) would not be appropriate, as this would create a long term dependency between the purchaser and the merged entity.

iv. Conclusion

- (1888) On this basis, the Commission considered that the Commitments of 3 December in relation to the Vanguard Divestment Business were not sufficient to remedy the competition concerns.

Purchaser Suitability

- (1889) The majority of respondents to the market investigation also argued that experience in orthopaedic implants would be necessary and that experience in the relevant implant market would be more advantageous. Understanding the market dynamics and the indications is essential in selling implants. Orthopaedic implants are a specialised market and it takes years to build up the necessary experience. Experience is required to establish its own manufacturing processes, set up sales teams and channels and to properly support surgeon needs and the technical issues / questions that they raise.⁷⁹⁴
- (1890) On the other hand, some respondents considered that the importance of prior experience could be partially mitigated by the experience of the Key Personnel transferred.

⁷⁹¹ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 9-11; Non-confidential minutes of conference calls with J&J, 17.12. 2014, 14.01 2015, 2.02.2015 and 3.02. 2015; J&J/DePuy follow up on remedies market test, Memorandum for the European Commission (Non-confidential version), 17.12.2014.

⁷⁹² Notifying Party, White Paper on Platform Technologies, 19.01.2015.

⁷⁹³ Paragraph 28.

⁷⁹⁴ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 19, 54 and 77.

- (1891) In addition, almost all respondents argued that a suitable purchaser of the Divestment Businesses needed to have experience in the EEA markets. According to the respondents, the European market has many facets. Experience in the EEA markets is mandatory, due to the market differences (indications, workflows, budgets, reimbursements, sales channels, legal environment, regulatory aspects, etc). In addition, the patients and their specific needs differ depending on countries and regions and vary significantly in the EEA. As a consequence, experience and knowledge of implants, indications and techniques within the EEA are important requirements to be successful in the EEA.⁷⁹⁵
- (1892) Some respondents highlighted the importance to have a wide EEA presence. According to them, it simply would not be credible to a player without any presence in these markets in the EEA to enter all the different countries where the Commission has identified competition concerns with a single (or at least limited) product line only. There are fundamental differences in the individual countries and detailed know-how is required in order to be successful.

The Commission's overall conclusions regarding the suitability of the Commitments of 3 December 2014 to remove the identified concerns

- (1893) On the basis of the responses of the market test, the Commission considered that the Commitments of 3 December 2014 were insufficient to eliminate entirely the concerns raised by the Commission.
- (1894) As regards the Vanguard Divestment Business, as the assessment in recital (1873) onwards indicates, the scope of the divestment business was not such as to effectively remedy the competition concerns in Denmark and Sweden since greater scale (beyond the volumes for Denmark and Sweden) was required both for the implant to be viably manufactured by the purchaser and sold in Denmark and Sweden as well as for the development of the implant by the purchaser in these two countries where the Commission has identified concerns. Indeed, the commitments failed in this respect to allow for the emergence or strengthening of a competitor that could replace the constraint that Biomet exerts on Zimmer today in Denmark and Sweden.
- (1895) As explained in the assessment in recital (1853) onwards, another particularly serious concern of the Commission regarding these commitments related to the arrangements provided for in relation to common platform technologies. In this regard, the Commitments of the 3 December 2014 provided for longstanding dependence of the purchaser of the Divestment Businesses on the merged entity and excluded access to technologies intrinsic to retain CE marks and track record. This is examined in more detail in recitals (1917) to (1929) below.

9.2.2. *The Final Commitments of 9 February 2015*

- (1896) In order to address the issues raised in the market test, the Notifying Party informally submitted revised commitments on 24 January 2015. The Commission consulted various market participants on a number of aspects of these informal revisions.

⁷⁹⁵ Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, questions 20, 55 and 78.

(1897) On 9 February 2015, the Notifying Party formally submitted a revised, final set of commitments.

9.2.2.1. Substance of the proposal

(1898) The Divestment Businesses consist of:

- (a) the divestiture of the ZUK Divestment Business (as described in Schedule 1 to the Final Commitments) in the EEA;
- (b) the divestiture of the Discovery Elbow Divestment Business (as described in Schedule 2 to the Final Commitments) in the EEA; and
- (c) the divestiture of the Vanguard Knee Divestment Business (as described in Schedule 3 to the Commitments) in Denmark and Sweden and, in order to ensure the viability of the Vanguard Knee Divestment Business in Denmark and Sweden, an EEA-wide licence to the rights and know-how which are currently used and are needed for the manufacturing of an exact copy of the Vanguard Knee Product Line, under a different brand name, for the EEA and for the development of the pipeline projects as defined at the time of the transfer of the legal title to the respective purchaser ("Closing") (the "Vanguard Knee EEA Licence").

(1899) The ZUK, Discovery Elbow and Vanguard Knee Divestment Businesses include in particular the following key tangible and intangible assets:

- (a) tangible assets relating to the Divestment Businesses for use exclusively in the geographic boundaries described in the preceding recital. These tangible assets include implant and instrumentation inventory, copies of design history files, demonstration models, testing and clinical evaluation reports and marketing-related materials and supporting materials for training purposes);⁷⁹⁶
- (b) intangible assets for use exclusively in the geographic boundaries described in the preceding recital. These intangible assets include: (i) the transfer of intellectual property rights used exclusively for the products of the Divestment Businesses; (ii) fully paid-up non-exclusive licences to other intellectual property rights that are used and needed for the manufacturing, marketing or sale of the products of the Divestment Businesses as at the time of Closing; (iii) the transfer of technical and manufacturing know-how, trade secrets and designs; (iv) as regards the Vanguard Divestment Business in Denmark and Sweden, a fully paid-up and royalty-free, non-exclusive licence to the IP and know-how necessary for the manufacturing and marketing or sale of ARCOM polyethylene (including any rights/assistance required to manufacture ARCOM as well as reasonable assistance to access raw materials); (v) as regards the ZUK Divestment Business, a fully paid-up and royalty-free, non-exclusive licence to the IP and know-how necessary for the manufacturing and marketing or sale of the PMMA pre-coat process; and (vi) as regards the Discovery Divestment Business, a fully paid-up and royalty-free, non-exclusive licence to the IP and know-how necessary for the manufacturing and marketing or sale of ARCOM polyethylene (including any rights/assistance required to manufacture ARCOM as well as reasonable assistance to access raw materials);

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In case of a global divestiture, certain tooling and fixtures for the ZUK and the Discovery will also be offered. No such tooling and fixtures are offered for the Vanguard Knee as the Notifying Party will continue manufacturing the product.

- (c) transfer of, or if not legally possible, access to all licences, permits and authorisations issued by any governmental organisation needed to develop, manufacture and market the products of the Divestment Businesses (including CE marks);
 - (d) licence of rights under sub-contracting agreements and supply agreements or, where not possible, transitional back-to-back supply agreements for the devices and input materials relevant to the Divestment Businesses, as well as rights under consultancy or development agreements with key opinion leaders.;
 - (e) customer contracts, commitments and customer orders of the Divestment Businesses or, if not legally possible, the continued supply of the products by Zimmer while ensuring a commission on those sales for the purchaser(s);⁷⁹⁷
 - (f) customer lists, customer credit and other customer records of the Divestment Businesses, as well as other business records; and
 - (g) Key Personnel.
- (1900) The Notifying Party has described the intangible assets in the Annexes to the Final Commitments. Annex 3 to the Final Commitments lists patents and patent applications that are used exclusively for the Divestment Business, whereas Annex 6 lists patents and patent applications that are not exclusive to the Divestment Business but which are necessary for the manufacturing of the products (the former will be transferred to the purchaser and the latter will be provided under a non-exclusive licence). Annex 4 to the Final Commitments lists three Community trademarks that are being used in connection with the Vanguard Knee Divestment Business, but that are not exclusive to the Vanguard Knee Divestment Business.
- (1901) The Notifying Party submits that the full list of the tangible and intangible assets relating to the Divestment Businesses is provided with the Final Commitments. Therefore, the Final Commitments are comprehensive of all tangible and intangible assets required to enable the purchaser(s) to manufacture and market the products of the Divestment Businesses, as applicable, and as at the time of Closing.
- (1902) Zimmer has also offered the following additional arrangements with regard to the ZUK, Discovery Elbow and Vanguard Knee Divestment Businesses (on a reasonable cost-plus basis):⁷⁹⁸
- (a) to provide transitory, non-exclusive supply or manufacturing arrangements for the products of the Divestment Businesses and relevant technologies, for a transitional period of up to 24 months from Closing, with the possibility of an additional extension of 12 months if the Monitoring Trustee deems necessary;
 - (b) to provide reasonable technical assistance for a transitional period of up to 24 months from Closing, in order to enable the purchaser(s) to assume responsibility for the manufacture, marketing and sale of the products of the Divestment Businesses and the relevant technologies, with the possibility of an

⁷⁹⁷ Where consent by third parties may be required, the Notifying Party will take all reasonable efforts to obtain such consent.

⁷⁹⁸ The said transitional arrangements will be offered on a reasonable cost-plus basis.

additional extension of 12 months if the Monitoring Trustee deems necessary;⁷⁹⁹

- (c) to provide training on the products of the Divestment Business and the relevant technologies on a reasonable cost-plus basis as well as technical training; and
 - (d) to provide a transitional supply or manufacturing arrangement for certain common platform technologies for up to two years, commencing once the purchaser has started manufacturing the relevant product line of each Divestment Business, on a reasonable cost plus basis, to allow the purchaser continued access to the relevant common technologies. This period may be extended by the Monitoring Trustee for a further period of 12 months if the Monitoring Trustee deems it necessary.
- (1903) The Vanguard Knee EEA Licence provisions of the Commitments include in particular: (i) tangible assets for use exclusively in the EEA, including copies of design history files and copies of publicly available testing and clinical data and market research reports as at the time of Closing; and (ii) intangible assets, such as a non-exclusive licence to intellectual property rights applicable (exclusively and not exclusively) to the Vanguard product line in the EEA and which are necessary for the manufacturing, marketing or sale of the copy product subject to the Vanguard EEA licence in the EEA; a non-exclusive licence to all technical and manufacturing know-how, trade secrets and designs which are used exclusively for the Vanguard product line in the EEA; a non-exclusive licence to the intellectual property rights which are necessary for the manufacturing, marketing or sale of ARCOM polyethylene, for copies of the Vanguard product line in the EEA; and a non-exclusive licence to the intellectual property rights and know-how necessary for the manufacturing, marketing or sale of instruments that are used in connection with, but are not exclusive to, the copy of the Vanguard product line in the EEA.
- (1904) The Vanguard Knee EEA Licence provisions also include the following transitional supply arrangements: an up to two year transitional supply or manufacturing agreement, once the purchaser has started manufacturing the Vanguard copy for the EEA, on a reasonable at cost plus basis, to allow the purchaser continued access to the ARCOM polyethylene, the Regenerex Porous Titanium Construct and the E1, in relation to the production of copies of the Vanguard product line in the EEA.

9.2.2.2. Further testing of the Final Commitments and the Commission's assessment

- (1905) The Commission consulted market participants regarding a revised informal commitments proposal submitted by the Notifying Party on the 24 January, which led to the Final Commitments (of 9 February 2015). The Commission conducted conference calls with a number of market participants, including competitors, potential purchasers, industry experts and registry officials.
- (1906) The information collected indicated that significant improvements had been made to the Commitments of 3 December 2015 and that the informal revised commitments would, subject to some limited revisions, be suitable to remedy

⁷⁹⁹ Such assistance may include assisting the purchaser to establish manufacturing processes, inventory management, warehousing and distribution, billing and collections, supplier management and regulatory support.

the Commission's competition concerns, if they were offered formally by the Notifying Party.

The Vanguard EEA Licence

- (1907) A number of market participants considered that the addition of the Vanguard EEA Licence to the Vanguard Knee Divestment Business provides the needed scale for the purchaser to manufacture, sell and develop the Vanguard Knee in Denmark and Sweden in a viable manner.
- (1908) S&N considered, on a hypothetical basis, that the larger volume could justify an investment in setting up manufacturing operations and commercial channels.⁸⁰⁰
- (1909) According to Lima, selling a copy of the Vanguard knee implant under a different brand name throughout the EEA without the track record of the original product does not pose difficulties. The success of selling such a product relies mainly on the credibility of the company and its relationship with surgeons. There are a number of successful implants which have been copied by every large orthopaedic implants manufacturer. Examples of these are the Zweimueller and the Corail stem. These copies rely on the design of the original product but also on the clinical data of each supplier. The importance of registry track records for the purpose of achieving successful sales varies from country to country. Although Denmark and Sweden are countries where it is more difficult to enter with a new product (without track record), other countries such as Germany (the biggest EEA market), Italy, France and Spain are more open to new implants.⁸⁰¹
- (1910) In relation to intangible assets, the Vanguard Knee EEA Licence is an EEA-wide non-exclusive licence, bearing a fair, reasonable, non-discriminatory royalty, to the rights (in particular patents and know how) that are used and needed for the manufacturing, marketing and sale of an exact copy of the Vanguard Knee (including instruments, any improvements and pipeline projects at the time of Closing associated with the products being divested) under a different name in the EEA.
- (1911) No transfer of patents or patent applications can take place under the Vanguard Knee EEA License. There are 26 patents (including pending patent applications) that will be licensed to the Purchaser on a non-exclusive basis for the sole purpose of manufacturing and marketing or sale in the EEA of copies of the Vanguard Knee Product Line. These are set out in Annex 6 of the Commitments. One of these patents is co-owned, (Stabilised Knee Prosthesis With Rotatable Tibial Bearing), however Biomet has the right to license the patent under the co-ownership agreement.

Instrumentation

- (1912) As explained in recitals (1834) and (1835) a number of competitors argued that all instruments should be included in the scope of the Divestment Businesses, even if these were not exclusive to the Divestment Business. The Notifying Party has clarified in the commitments that all instrumentation

⁸⁰⁰ Non-confidential minutes of conference calls with S&N, 17.12.2014, 14.01.2015, 22.01. 2015, 02.02. 2015 and 03.02. 2015.

⁸⁰¹ Non-confidential minutes of conference calls with Lima, 16.12.2014, 14.01. 2015 and 02.02 2015.

(exclusive and non-exclusive) associated with the Divestment Businesses are included within the scope of the Divestment Businesses. This includes a licence for instrumentation in relation to the Vanguard EEA licence.

- (1913) Instrumentation is bought on a purchase order basis rather than a contractual basis, hence, according to the Notifying Party, it will not be difficult for a purchaser to secure a supply of the necessary instruments either through internal sourcing or outsourcing to a third party manufacturer.
- (1914) The purchaser will be provided with all the required assets to manufacture the instrumentation required for the Divestment Businesses. This is accomplished by offering all design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory control standards, and regulatory records that are related to the Divestment Businesses product lines and the necessary instrumentation. Furthermore, the Notifying Party offers transitional technical assistance to the purchaser for the manufacturing of said instrumentation.
- (1915) According to the Notifying Party, there are no intellectual property rights or know-how linked to the instrumentation, which further facilitates the transfer of the instrumentation to the purchaser. Nevertheless, in order to be exhaustive, the Commitments also provide for a non-exclusive licence to instrumentation that is used in connection with, but not exclusive to the Divestment Businesses.
- (1916) The Commission considers that the non-exclusive licence to all instrumentation that is used in connection with, but not exclusive to the Divestment Businesses is sufficient to remedy the competition concerns.

Common platform technologies

- (1917) In line with submissions by respondents to the market test, the Notifying Party has included certain common platform technologies within the scope of the Divestment Businesses.
- (1918) As indicated in recitals (1899) and (1904) above, the Final Commitments offer to the purchaser(s) a fully paid-up and royalty-free non-exclusive licence to the intellectual property rights which are necessary for the manufacturing and marketing or sale of certain common platform technologies used widely in relation to the Divestment Businesses in the EEA. These licences relate to the PMMA pre-coat process for the ZUK; the ARCOM (1900H) polyethylene for the Discovery Elbow; and the ARCOM (non-1900H) polyethylene for the Vanguard Knee in Denmark and Sweden and for the Vanguard Knee EEA Licence in the EEA.
- (1919) In addition, the Final Commitments also provide a transitional supply or manufacturing agreement for up to two years, once the purchaser has started manufacturing the relevant products of the Divestment Businesses on a cost-plus reasonable basis in relation to the common processes.
- (1920) The Commission discussed in detail the characteristics of the relevant platform technologies with potential purchasers, hospitals and industry experts. Moreover, the Notifying Party submitted a White Paper on Platform Technologies on 19 January 2015, which set out in detail the characteristics of each relevant platform technology.

- (1921) Market participants confirmed that coatings can impact the track record of an implant.⁸⁰² The PMMA pre-coat and the ARCOM polyethylene are used for the vast majority of the implants in relation to the respective Divestment Businesses and for part of the track record of these implants. The PMMA pre-coat is used for [90-100]*% of the ZUK Divestment Business. The ARCOM (1900H) polyethylene is used for [...] of the Discovery Elbow Divestment Business and the ARCOM (non 1900H) for [...] of the Vanguard in Denmark and Sweden.⁸⁰³ As far as the track record is concerned, the platform technologies where the usage is 90-100% are included in the EEA track record.⁸⁰⁴
- (1922) On the other hand, certain other platform technologies are only used for a small subset of the overall volumes sold. There are currently no sales of the Vivacit-E and the E1 technologies in relation to the ZUK Divestment Business in the EEA. Similarly, in relation to the Vanguard Product Line in Denmark and Sweden, only [0-5]*% uses the Regenerex Porous Titanium Construct ("Regenerex") and only [5-10]*% uses the E1 vitamin polyethylene.⁸⁰⁵
- (1923) As far as the track record is concerned, the platform technologies where the usage is minimal are not included in the EEA track record. Accordingly, Vivacit-E, E1 and Regenerex have very limited or no impact in relation to the track record of the Divestment Businesses.
- (1924) The Commission investigated whether it was necessary for these technologies to be included in the scope of the Divestment Businesses.
- (1925) **Vivacit-E for the ZUK.** [...] However, S&N argued that this technology has experienced a significant growth in the US between Q1 2013 and the end of 2014. The Vivacit-E enhanced ZUK implants have reached 25% of the total US partial knee market, despite a price premium of about 10-15%. Thus S&N argued that a supply agreement of two years would be needed to allow the purchaser to transition towards its own coating for the ZUK.⁸⁰⁶
- (1926) **E1 for the Vanguard.** In relation to the E1, the Commission discussed with hospitals in Denmark which have in the past procured products from the Vanguard product line with the E1 vitamin polyethylene (the E1 is not sold in Sweden).⁸⁰⁷ All hospitals confirmed that the use of the E1 polyethylene is reserved for exceptional cases, where the patient is particularly young. If the E1 technology was no longer available for the Vanguard product line, the hospital would not switch away from the Vanguard but would probably use the standard polyethylene. The advantages of the Vanguard will not be jeopardised

⁸⁰² Non-confidential minutes of a conference call with ODEP, 28.01.2015; Non-confidential minutes of a conference call with Professor Blunn, 02.02.2015; Non-confidential minutes of a conference call with NJR, 30.01.2015

⁸⁰³ Zimmer, White Paper on Platform Technologies, 19.01.2015, Annex I.

⁸⁰⁴ Zimmer, White Paper on Platform Technologies, 19.01.2015.

⁸⁰⁵ Zimmer, White Paper on Platform Technologies, 19.01.2015, Annex I.

⁸⁰⁶ Non-confidential minutes of conference calls with S&N, 17.12.2014, 14.01.2015, 22.01.2015, 02.02.2015 and 03.02.2015.

⁸⁰⁷ Non-confidential minutes of a conference call with Farso Sygehus (Denmark), 29.01.2015; Non-confidential minutes of a conference call with Velje Sygehus (Denmark), 29.01.2015; Non-confidential minutes of a conference call with CFR Hospitaler (Denmark), 28.01.2015; Non-confidential minutes of a conference call with Hvidovre Hospital (Denmark), 30.01.2015; Non-confidential minutes of a conference call with Frederiksberg Hospital (Denmark), 30.01.2015.

by the lack of availability of the E1 technology. The E1 technology has no significant track record but has mainly been tried on the basis of laboratory tests. S&N submitted that E1 technology is a "nice to have" rather than a "must have".⁸⁰⁸

- (1927) **Regenerex for the Vanguard.** Market participants made similar remarks regarding the Regenerex. It is better for the hospitals if the technologies are available as these solutions are superior to the alternative solutions. However, the technology can be replaced. It must be emphasised that the Regenerex is used rarely and that each surgeon assesses on a case-by-case basis when the medical case at hand merits the use of the Regenerex.⁸⁰⁹
- (1928) On the basis of the arguments set out in this section, the Commission concludes that in relation to the platform technologies that are rarely used with the Divestment Businesses in the EEA, a licence is not necessary, especially as it does not impact the track record of the Divestment Businesses, nor the ultimate choice of implant.
- (1929) In line with the conclusion in recital (1928), the Notifying Party has offered a transitional supply or manufacturing agreement for up to two years in relation to the Vivacit-E, the Regenerex and the E1.

Purchaser suitability

- (1930) Following the responses to the market test, the Commission considers that it was essential to ensure that the proposed purchaser has the relevant product market and geographic market experience to become a viable purchaser and compete with the merged entity.
- (1931) On this basis, the Notifying Party included additional purchaser criteria in the Final Commitments. Besides indicating that the purchaser shall have "*sufficient experience of and capability to manufacture, market and supply products that are marketed in the orthopaedics implant sector*", the Final Commitments now also require that the purchaser shall currently offer "*or have the proven ability to offer orthopaedic implants in a significant proportion of those EEA Member States where the Divestment Businesses are currently active*".
- (1932) The Commission considers that these additional criteria are necessary and appropriate to ensure that a suitable purchaser is selected by the Notifying Party.

The AGC Divestment Business

- (1933) In line with the results of the market test of the Commitments of 3 December 2014, the Final Commitments no longer contained the AGC Divestment Business from the Divestment Business related to unicondylar knee implants.

Conclusion

- (1934) The Commission concludes, on the basis of the market test, that the additional purchaser criteria are sufficient to ensure the viability of the purchaser and that the inclusion of a total knee product range within the scope of the ZUK Divestment Business is not necessary.

⁸⁰⁸ Non-confidential minutes of conference calls with S&N, 17.12.2014, 14.01. 2015, 22.01. 2015, 02.02. 2015 and 03.02. 2015.

⁸⁰⁹ Non-confidential minutes of the conference call with Velje Sygehus, 29.01.2015.

9.3. The Commission's overall assessment of the Final Commitments

9.3.1. *The Final Commitments are suitable to remove the significant impediment to effective competition*

- (1935) The Commission has assessed the suitability of the Final Commitments to fully eliminate the concerns identified in relation to:
- (a) the market for unicondylar knee implants in Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden and the United Kingdom (section 8.6.8).
 - (b) the market for elbows implants in Austria, Belgium (including Luxembourg), the Czech Republic, Denmark, France, Germany, Italy, Norway, Portugal, Spain, Sweden and the United Kingdom (section 8.7).
 - (c) the market for total knee implants in Denmark (primary and revision) and Sweden (primary) (sections 8.6.2, 8.6.3 and 8.6.4).
- (1936) The Notifying Party considers that the Final Commitments will essentially eliminate the overlap resulting from the merger and thus any risk that the proposed merger will significantly impede effective competition.⁸¹⁰ In the Notifying Party's view, the Final Commitments eliminate the Commission's competition concerns entirely, they are comprehensive and effective, and are capable of being implemented effectively within a short period of time. The Commission's conclusions are set out in recital (1968) below.⁸¹¹

9.3.1.1. The ZUK Divestment Business

- (1937) In relation to the ZUK Divestment Business, the Final Commitments ensure that the purchaser will acquire the position that Zimmer currently holds in the unicondylar knee implants market.
- (1938) Through divesting the ZUK Divestment Business the market share overlap in the Group 1 countries is essentially removed. Namely, the 2013 sales of ZUK unicondylar knees amount to [80-90]*% of Zimmer's sales of partial knees in Group 1 countries. Furthermore, in 12 of the 17 Group 1 unicondylar knee national markets identified by the Notifying Party, the ZUK accounted for more than [80-90]*% of Zimmer's sales in the national markets in question. Thus, any potential competition law concerns are effectively remedied.⁸¹²

9.3.1.2. The Discovery Elbow Divestment Business

- (1939) Similarly, in relation to the Discovery Elbow Divestment Business, the Final Commitments ensure that the purchaser will acquire the position that Biomet currently holds in the elbow implants market.
- (1940) The sales of Discovery Elbows amount to [90-100]*% of Biomet's sales of elbows in relation to the Group 1 national markets. In 10 of the 12 Group 1 elbow national markets, the Discovery Elbow accounted for more than [90-100]*% of Biomet's elbow sales in the national market in question (in the

⁸¹⁰ Notifying Party, Form RM of Annex IV of the Implementing Regulation (Form RM), 09.02.2015.

⁸¹¹ Remedies notice, paragraph 9.

⁸¹² The remaining sales in the partial knee segment are allocated to Zimmer patello-femoral knee and Allegretto.

remaining 2 Group 1 national markets it accounts for [80-90]*% and [90-100]*%). Hence, the overlap is effectively removed.⁸¹³

9.3.1.3. The Vanguard Divestment Business

- (1941) The Vanguard Knee is Biomet's best-selling knee implant in Denmark and Sweden, with more than [...] units sold, representing [60-70]*% of its sales in Denmark and [90-100]*% of its sales in Sweden.⁸¹⁴ Thus, the proposed remedy will substantially reduce Zimmer's post-merger market share in this market in these two countries, transferring the largest part of Biomet's share to a competitor, thereby remedying any competition concerns in these two countries.⁸¹⁵
- (1942) The Commission had expressed concerns that the existence of knee registries in both Denmark and Sweden may make it more difficult for new entrants with knee offerings that are not on these registries to effectively compete in these two countries. To remedy this concern, the Final Commitments include one of the most successful total knee system (including primary and revision products) sold in Denmark and Sweden, namely the Vanguard Knee. The Vanguard Knee is listed in both the Danish and the Swedish registries and has very good performance records. For example, according to the 2013 Danish knee registry, the Vanguard CR had the highest survival rate among equivalent products after 10 years following the surgery.⁸¹⁶
- (1943) On this basis, the Commission considers that the Final Commitments are suitable to remove the significant impediment to effective competition.

9.3.2. *The Final Commitments are viable, comprehensive and effective*

- (1944) The Notifying Party argues that the proposed Commitments constitute a viable, comprehensive and effective solution.⁸¹⁷
- (1945) The Commission finds that the remedies for the ZUK and Discovery Elbow are not only directed towards Group 1 national markets but are EEA-wide in scope. With the assignment and licensing of the relevant intellectual property, there will be a clean break and therefore no scope for any customer confusion or other impediments to the ability of the purchaser(s) to have full control over the ZUK and Discovery Elbow Divestment Businesses. Further, the key exclusive rights transferred to the purchaser(s) of the products of the ZUK and Discovery Elbow Divestment Business will not be on a temporary basis; rather, Zimmer and Biomet will permanently sever their ability to manufacture or market the said products and, as such, the proposal represents a viable solution.
- (1946) The Notifying Party regards these remedies as straightforward from an execution perspective. In particular, since the principal rights involved for the ZUK and Discovery Elbow Divestment Businesses are transferred for the whole of the EEA there is no difficulty in separating ownership in specific EEA countries. A number of respondents to the market test agree that the ZUK

⁸¹³ Notifying Party, Form RM, 09.02. 2015.

⁸¹⁴ The remainder of Biomet's share in Denmark and Sweden relates to the AGC Knee, which as indicated in recitals (1845) to (1848) above, is currently being phased-out and is largely considered as a product with past generation technology.

⁸¹⁵ Notifying Party, Form RM, 09.02.2015.

⁸¹⁶ See: https://www.knee.dk/groups/dkr/pdf/DKR_2013.pdf, page 82.

⁸¹⁷ Notifying Party, Form RM, 09.02.2015.

and the Discovery Elbow Divestment Businesses in the Final Commitments include the assets required to ensure that the purchaser will be an effective competitor in the relevant markets.

- (1947) The Notifying Party argues that the Vanguard remedy in Denmark and Sweden is also straightforward to execute, since it effectively amounts to a full divestment in Denmark and Sweden. The Notifying Party argues that the Divestment Businesses consist of all rights which are used and needed for the effective production of the products of the Divestment Businesses. Based on the evidence in the file, the Commission notes that the inclusion of revision products in Sweden is necessary to ensure the viability of the primary line of products in this market. This is because, when choosing a primary knee implant, surgeons will consider the availability of revision products belonging to the same product family.
- (1948) In addition, the Vanguard Knee EEA Licence comprises all the rights and know-how required to manufacture, market and/or sell an exact copy in the EEA and as such, it is a comprehensive, EEA-wide viability remedy to the Vanguard Knee Business. It also ensures that the purchaser will be in a position to improve the product going forward in Denmark and Sweden. This is confirmed by a number of respondents to the market test; they agree that the Vanguard Divestment Business in the Final Commitments include the assets required (and in particular the Vanguard Knee EEA Licence) to ensure that the purchaser will be an effective competitor in the relevant markets.
- (1949) In particular, the Commission notes that the divestments are permanent, and that the package includes everything that could be required to effectively transfer the Divestment Businesses to the purchaser(s) and to ensure that the purchaser(s) can swiftly and effectively step into the shoes of Zimmer/Biomet (such as a transitional supply or manufacturing arrangements, technical assistance, training and assistance on the divested product, and even Key Personnel related to the products of the Divestment Businesses).
- (1950) The Notifying Party submits that the ZUK, Discovery Elbow and Vanguard Knee Divestment Businesses offered constitute a solution that allows a new entrant to compete effectively in the markets the Commission has expressed concern on.
- (1951) The Commission considers that with the Final Commitments, hospitals, procurement authorities and patients will be able to rely on a competing supplier that can replace the constraint that Zimmer exerts on Biomet today and vice versa. The purchasers of the Divestment Businesses will have the necessary assets to credibly and effectively bid for their orthopaedic implants needs in relation to unicondylar knees, elbows or total (primary and revision) knees implants. Customers can choose to procure implants from the purchaser of the Divestment Business or use the presence of such a player to obtain competitive offers from the merged entity.
- (1952) On this basis, the Commission concludes that the Final Commitments are suitable to remove the significant impediment to effective competition that would have been likely to result from the proposed merger, and adequately address all the comments of the respondents to the market test.

9.3.3. *The Final Commitments are capable of being implemented effectively within a short period of time*

- (1953) The Notifying Party is offering interim assistance to ensure the timely and effective transfer of the Divestment Businesses to the purchaser(s). The remedies can be easily and rapidly implemented and are as a result workable for the Commission and any monitoring trustee.
- (1954) The main ongoing links will be transitional and intended to enable the purchaser(s) to quickly develop, manufacture and supply its own products. These transitional links include transitional supply or manufacturing arrangements, technical assistance and training in the divested products as well as transitional supply of some platform technologies, the majority of which are not used often in the divested products.⁸¹⁸ They will last for a period of 24 months with the possibility of an additional extension of 12 months if the Trustee deems necessary.
- (1955) The Notifying Party considers that the Divestment Businesses are commercially attractive and will generate significant interest in the market. The ZUK unicondylar knee, Discovery elbow and Vanguard total knee systems they represent a significant share of their respective segments.⁸¹⁹ This is further demonstrated by the number of interested buyers and in any event this is covered by the upfront buyer requirement.
- (1956) Furthermore, the unicondylar knee and elbow markets are growing. For instance elbow sales are expected to grow at [5-10]*% (CAGR) from 2013 to 2023 with growth rates as high as [5-10]*% in the early years of the forecast. Therefore, the Divestment Businesses will be profitable in their current form for the foreseeable future, while they also offer opportunities for investment and growth. In relation to the Vanguard Knee, the offering also encompasses a significant part of the sales of total knee implants in the relatively conservative markets of Denmark and Sweden, namely [10-20]*% and [10-20]*% respectively, illustrating the commercial appeal of the remedy for these jurisdictions; furthermore the Vanguard Knee EEA Licence offers potential for significant sales of the copy product across the whole EEA.⁸²⁰
- (1957) The Notifying Party submits that there are several potential purchasers who have a genuine interest in adding these products to their product portfolios, all of whom have the financial resources, expertise and incentives to maintain and develop the Divestment Businesses as a viable competitor in the marketplace. The Commission has market tested the interest of potential competitors and has identified some interest in the Divestment Businesses. Given the commitment of the Notifying Party not to complete the merger until the Divestment Businesses are divested, the interest of potential purchasers can be assessed during the upfront buyer approval process.
- (1958) The Commission considers that the transitional arrangements, in combination with the additional purchaser criteria will ensure that the purchaser will be able to enter the relevant markets swiftly and compete effectively with the merged entity.

⁸¹⁸ Notifying Party, White Paper on Platform Technologies, 19.01.2015.

⁸¹⁹ Notifying Party, Form RM, 09.02.2015.

⁸²⁰ Notifying Party, Form RM, 09.02.2015.

- (1959) On this basis, the Commission considers that the Final Commitments are capable of being implemented effectively within a short period of time

9.3.4. *The need to include additional purchaser criteria*

- (1960) Overall, the Commission considers that the strict purchaser criteria in the Final Commitments will enable finding a sufficiently experienced purchaser with the capability to manufacture, market and supply products that are marketed in the orthopaedic implant sector in a significant proportion of those EEA countries where the Divestment Businesses are currently active.
- (1961) Finally, some respondents to the market test considered that the Divestment Businesses would only be viable if the purchaser was already active in the field of orthopaedic implants in the EEA. The Final Commitments now specify that any purchaser of the Divestment Business must demonstrate its capability in orthopaedic implants and its presence or willingness to expand its presence in a significant proportion of the EEA countries where the Divestment Businesses are currently active. As the Commission approves the purchaser and the terms of sale of the Divestment Business, it will certify that the purchaser does, indeed, have the assets and personnel to expand its geographic presence in this manner.
- (1962) On this basis, the Commission considers that the purchaser criteria in the Final Commitments are appropriate to ensure the suitability of the proposed purchasers.

9.3.5. *The need for the upfront buyer clause*

- (1963) In order to address the significant risk in the effective implementation of the commitments the Notifying Party included an upfront buyer clause. Pursuant to that clause, the Notifying Party cannot complete the acquisition of Biomet until it has signed a binding sales and purchase agreement for the Divestment Businesses with a suitable purchaser for each Divestment Business. The suitable purchaser needs to meet the strict purchaser criteria listed in the commitments, and the Commission needs to approve both the purchaser and the terms of sale of the Divestment Business.
- (1964) The Commission considers that the inclusion of an upfront buyer clause⁸²¹ is an adequate and necessary solution to address significant risks regarding the effective implementation of the commitments and to ensure the effective transfer of the Divestment Business to a suitable purchaser.
- (1965) First, the additional purchaser requirements that are needed in this case can ultimately reduce the pool of suitable purchasers of the Divestment Business. The respondents to the market test argued that an upfront buyer clause was necessary, as the remedy would only be effective if transferred to a competitor with an established business in orthopaedic implants.⁸²² The Commission notes that the pool of potential purchasers is very limited.
- (1966) Second, the Commission considers that there would have been considerable risks involved in preserving the competitiveness and saleability of the Divestment Business in the interim period until divestiture.

⁸²¹ Remedies Notice, paragraphs 54 and 55.

⁸²² Responses to Remedies Market Test, Q35 – Questionnaire to Competitors, question 18.

- (1967) On this basis, the Commission can conclude with the requisite degree of certainty that the Final Commitments will be fully implemented and will maintain effective competition on the relevant markets.

9.4. Conclusion

- (1968) In light of the findings in section 9.3 above, the Commission concludes that the Final Commitments fully address the competition concerns identified by the Commission on the markets for unicondylar knee implants, elbow implants and total (primary and revision) knee implants.

9.5. Conditions and Obligations

- (1969) Pursuant to the second subparagraph of Article 8(2) of the Merger Regulation, the Commission may attach to its Decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the internal market.
- (1970) The fulfilment of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve that result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's Decision declaring the concentration compatible with the internal market is no longer applicable. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance Decision in accordance with Article 8(6) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.
- (1971) In accordance with the basic distinction described in recital (1970) as regards conditions and obligations, this Decision should be made conditional on compliance by the Notifying Party with sections B (including Schedules 1 to 4 and Annexes 1 to 13 to the Schedules) of the Final Commitments submitted by the Notifying Party on 9 February 2015 and all other sections should be obligations within the meaning of Article 8(2) of the Merger Regulation. The full text of the commitments is attached in the Annex to this Decision.

HAS ADOPTED THIS DECISION:

Article 1

The notified operation whereby Zimmer Holdings, Inc. (United States) acquires sole control of Biomet, Inc. (United States) within the meaning of Article 3(1)(b) of Regulation (EC) No 139/2004 is hereby declared compatible with the internal market and the EEA Agreement, subject to compliance with the conditions set out in section B of the Annex to this Decision.

Article 2

Zimmer Holdings, Inc. shall comply with the obligations set out in sections C, D, E and F of the Annex to this Decision.

Article 3

This Decision is addressed to: Zimmer Holdings, Inc., 1800 West Center St., IN 46581-0708
Warsaw United States of America

Done at Brussels, 30.3.2015

For the Commission

(signed)

Margrethe VESTAGER

Member of the Commission

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Articles 8(2) and 10(2) of Council Regulation (EC) No 139/2004 (the "**Merger Regulation**"), Zimmer hereby enters into the following Commitments (the "**Commitments**") vis-à-vis the European Commission (the "**Commission**") with a view to rendering the acquisition of Biomet, Inc. (the "**Concentration**") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 8(2) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "**Decision**"), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "**Remedies Notice**").

Section A - Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "*Consolidated Jurisdictional Notice*").

Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Businesses as indicated in Section B, paragraph 6(a), (b) and (c) and described more in detail in the Schedule.

Biomet: incorporated under the laws of Indiana (US), with its registered office at 56 East Bell Drive / P.O. Box 587, Warsaw, Indiana 46581-0587, U.S. and registered with the Commercial/Company Register at Indiana Secretary of State under number 197711-684.

Closing: the transfer of the legal title to the relevant Divestment Business to the respective Purchaser(s).

Closing Period: the period of [...] from the approval of the Purchaser(s) and the terms of sale by the Commission.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divestment Business(es): the business or businesses as defined in Section B and in the Schedules which Zimmer commits to divest.

Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Zimmer and who has/have received from Zimmer the exclusive Trustee Mandate to sell the Divestment Businesses to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of [...] from the Effective Date.

Global Divestment: the scenario whereby Zimmer does not retain the Divestment Businesses in any jurisdiction, or does not sell it to any other party than the Purchaser of the Divestment Business in any other jurisdiction than the one(s) specified in the Commitments.

Hold Separate Manager: the person appointed by Zimmer for the Divestment Businesses to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Businesses, as defined in the Schedule, points 2(g), including the Hold-Separate Manager.

Merged Entity: the entity resulting from the acquisition of Biomet by Zimmer. Any obligation referring to the Merged Entity shall be understood as obligation of Zimmer.

Monitoring Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Zimmer, and who has/have the duty to monitor

Zimmer's compliance with the conditions and obligations attached to the Decision.

Parties: the Notifying Party, herein Zimmer, and the undertaking that is the target of the concentration, herein Biomet.

Personnel: all staff currently employed by the Divestment Businesses, including staff seconded to the Divestment Businesses, shared personnel as well as the Key Personnel defined in the Schedule, points 2(g).

Purchaser(s): the entity or entities approved by the Commission as acquirer(s) of the Divestment Businesses in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 17 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule(s): the schedule to these Commitments describing more in detail the Divestment Businesses.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

Trustee Divestiture Period: the period of [...] from the end of the First Divestiture Period.

Zimmer: incorporated under the laws of Delaware (US), with its registered office at 1800 West Center St. / P.O. Box 708, Warsaw, Indiana 46581-0708, U.S. and registered with the Commercial/Company Register at Delaware Divisions of Corporations under number 3343799. Zimmer should be understood as the Merged Entity when referring to the post- closing period of the Zimmer/ Biomet Transaction.

Section B - The commitment to divest and the Divestment Businesses

2.1 Commitment to divest

2. In order to maintain effective competition, Zimmer commits to divest, or procure the divestiture of the Divestment Businesses by the end of the Trustee Divestiture Period as a going concern to a Purchaser(s) and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, Zimmer commits to find a Purchaser(s) and to enter into a final binding sale and purchase agreement(s) for the sale of each of the Divestment Businesses within the First Divestiture Period. If Zimmer have not entered into such an agreement(s) at the end of the First Divestiture Period, Zimmer shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Businesses in accordance with the procedure described in paragraph 30 in the Trustee Divestiture Period.
3. The proposed concentration shall not be implemented before Zimmer or the Divestiture Trustee have entered into a final binding sale and purchase agreement for the sale of each of the Divestment Businesses (and the Vanguard Knee EEA License) and the Commission has approved the Purchaser(s) and the terms of sale in accordance with paragraph 18.
4. Zimmer shall be deemed to have complied with this commitment if:
 - (a) by the end of the Trustee Divestiture Period, the Parties or the Divestiture Trustee has entered into a final binding sale and purchase agreement in relation to each of the Divestment Businesses and the Commission approves the proposed Purchaser(s) and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 18; and
 - (b) the Closing of the sale of each of the Divestment Businesses to the Purchaser(s) takes place within the Closing Period.
5. In order to maintain the structural effect of the Commitments, Zimmer shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of any of the Divestment Businesses, unless, following the submission of a reasoned request from Zimmer showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Businesses is no longer necessary to render the proposed concentration compatible with the internal market.

2.2 Structure and definition of the Divestment Businesses

6. The Divestment Businesses consist of:
 - (a) the divestiture of the ZUK Divestment Business, as described in Schedule 1, in the EEA;
 - (b) the divestiture of the Discovery Elbow Divestment Business, as described in Schedule 2, in the EEA; and
 - (c) the divestiture of the Vanguard Knee Divestment Business, as described in Schedule 3, in Denmark and Sweden and an EEA-wide license to the rights and know-how which are currently used and are needed for the manufacturing of an exact copy of the Vanguard Knee Product Line for the EEA and/or for the development of the pipeline projects as defined at the time of Closing (the "Vanguard Knee EEA License") as described in Schedule 4, in order to ensure the viability of the Vanguard Knee Divestment Business in Denmark and

Sweden.

7. The legal and functional structure of the Divestment Businesses as operated to date is described in the Schedule. The Divestment Businesses (except the Vanguard Knee EEA License), described in more detail in the Schedule, includes all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Businesses, in particular:
 - (a) all tangible assets relating to the Divestment Businesses listed in Schedule, point 2(a) (including implant and instrumentation inventory, copies of design history files and marketing materials, supporting materials for training purposes);
 - (b) all intangible assets, such as intellectual property rights used exclusively for the products of the Divestment Businesses and fully paid-up licenses to other intellectual property rights which are currently used and are needed for the manufacturing, marketing or sale of the products of the Divestment Businesses and/or for the development of the pipeline projects of the Divestment Businesses as defined at the time of Closing;
 - (c) transfer of, or if not legally possible, access to all licenses, permits and authorisations issued by any governmental organisation necessary to develop, manufacture and market the products of the Divestment Businesses;
 - (d) all customer contracts, leases, commitments and customer orders of the Divestment Businesses or, if not legally possible, the continued supply of the products by Zimmer whilst ensuring a commission on those sales for the Purchaser(s);
 - (e) all customer, credit and other records of the Divestment Businesses (including list of existing and past customers and copies of customer records); and
 - (f) the Key Personnel.
8. In addition, the Divestment Businesses (except the Vanguard Knee EEA License) include the benefit, for a transitional period of up to 24 months after Closing, with the possibility of an additional extension of 12 months if the Monitoring Trustee deems necessary, and on terms and conditions equivalent to those at present afforded to the Divestment Businesses, of arrangements under which the Parties or their Affiliated Undertakings supply products or services to the Divestment Businesses, as detailed in the Schedule. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside the relevant business unit/division providing the relevant product/service operations.

Section C - Related commitments

- 3.1 Preservation of viability, marketability and competitiveness
9. From the Effective Date until Closing of the sale of each of the Divestment Businesses, Zimmer shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Businesses. In particular Zimmer undertakes:
- (a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Businesses or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Businesses;
 - (b) to make available, or procure to make available, sufficient resources for the development of the Divestment Businesses, on the basis and continuation of the existing business plans;
 - (c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Businesses and not to solicit or move any Key Personnel to Zimmer's remaining businesses. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Businesses, Zimmer shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Zimmer must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.
- 3.2 Hold-separate obligations
10. Zimmer commit(s), from the Effective Date until Closing of the sale of each of the Divestment Businesses (except the Vanguard Knee EEA License), to procure that the Divestment Businesses are kept separate from the business(es) that Zimmer will be retaining and, after closing of the Concentration to keep the Divestment Businesses separate from the business that Zimmer is retaining and to ensure that unless explicitly permitted under these Commitments: (i) management and staff of the business(es) retained by Zimmer have no involvement in the Divestment Business; and (ii) the Key Personnel of the Divestment Business have no involvement in any business retained by Zimmer and do not report to any individual outside the Divestment Business.
11. Until Closing of the sale of each of the Divestment Businesses (except the Vanguard Knee EEA License), Zimmer shall assist the Monitoring Trustee in ensuring that the Divestment Businesses are managed as distinct and saleable entities separate from the business(es) which Zimmer is retaining. Immediately after the adoption of the Decision, Zimmer shall appoint a Hold Separate Manager. The Hold Separate Manager, who shall be part of the Key Personnel, shall manage the Divestment Businesses independently and in the best interest of the businesses with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by Zimmer. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 9(c) of these Commitments. The Commission may, after having heard Zimmer, require Zimmer to replace the Hold Separate Manager.

3.3 Ring-fencing

12. Zimmer shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Businesses and that any such Confidential Information obtained by Zimmer before the Effective Date will be eliminated and not be used by Zimmer. In particular, the participation of the Divestment Businesses in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Businesses. Zimmer may obtain or keep information relating to the Divestment Businesses which is reasonably necessary for the divestiture of the Divestment Businesses or the disclosure of which to Zimmer is required by law.

3.4 Non-solicitation clause

13. Zimmer undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel made available to the Purchaser(s) with the Divestment Businesses for a period of 10 years after Closing of the sale of each of the Divestment Businesses.

3.5 Due diligence

14. In order to enable potential Purchaser(s) to carry out a reasonable due diligence of the Divestment Businesses, Zimmer shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:
 - (c) provide to potential Purchaser(s) sufficient information as regards the Divestment Businesses; and
 - (d) provide to potential Purchaser(s) sufficient information relating to the Key Personnel and allow them reasonable access to the Key Personnel.

3.6 Reporting

15. Zimmer shall submit written reports in English on potential Purchaser(s) of the Divestment Businesses and developments in the negotiations with such potential Purchaser(s) to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request). Zimmer shall submit a list of all potential Purchaser(s) having expressed interest in acquiring the Divestment Businesses to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.
16. Zimmer shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential Purchaser(s).

Section D - The Purchaser(s)

17. In order to be approved by the Commission, the Purchaser(s) must fulfil the following criteria:
- (a) The Purchaser(s) shall have sufficient experience of and capability to manufacture, market and supply products that are marketed in the orthopaedics implant sector.
 - (b) The Purchaser shall currently offer or have the proven ability to offer orthopaedic implants in a significant proportion of those EEA Member States where the Divestment Businesses are currently active.
 - (c) The Purchaser(s) shall be independent of and unconnected to Zimmer and its Affiliated Undertakings (this being assessed having regard to the situation following the divestiture).
 - (d) The Purchaser(s) shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Businesses as a viable and active competitive force in competition with the Merged Entity and other competitors.
 - (e) The acquisition of the Divestment Businesses by the Purchaser(s) must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser(s) must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Businesses.
18. The final binding sale and purchase agreement(s) (as well as ancillary agreements) relating to the divestment of the Divestment Businesses shall be conditional on the Commission's approval. When Zimmer has reached an agreement with a Purchaser(s), it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. Zimmer must be able to demonstrate to the Commission that the Purchaser(s) fulfils the Purchaser Criteria and that the Divestment Businesses are being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the Purchaser(s) fulfils the Purchaser Criteria and that the Divestment Businesses are being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Businesses without one or more Assets or parts of the Key Personnel, or by substituting one or more Assets or parts of the Key Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Businesses after the sale, taking account of the proposed Purchaser(s).

Section E - Trustee

5.1 Appointment procedure

19. Zimmer shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. Zimmer commits not to close the Concentration before the appointment of a Monitoring Trustee.
20. If Zimmer has not entered into a binding sale and purchase agreement(s) regarding the Divestment Businesses one month before the end of the First Divestiture Period or if the Commission has rejected the Purchaser(s) proposed by Zimmer at that time or thereafter, Zimmer shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.
21. The Trustee shall :
 - (f) at the time of appointment, be independent of Zimmer and its Affiliated Undertakings;
 - (g) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and
 - (h) neither have nor become exposed to a Conflict of Interest.
22. The Trustee shall be remunerated by Zimmer in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Businesses, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

5.2 Proposal by Zimmer

23. No later than two weeks after the Effective Date, Zimmer shall submit the name or names of one or more natural or legal persons whom Zimmer proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period or on request by the Commission, Zimmer shall submit a list of one or more persons whom Zimmer proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 and shall include:
 - (i) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;
 - (j) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and
 - (k) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

5.2.1 Approval or rejection by the Commission

24. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Zimmer shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Zimmer shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

5.2.2 New proposal by Zimmer

25. If all the proposed Trustees are rejected, Zimmer shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 24 of these Commitments.

5.2.3 Trustee nominated by the Commission

26. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Zimmer shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

5.3 Functions of the Trustee

27. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Zimmer, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

5.3.1 Duties and obligations of the Monitoring Trustee

28. The Monitoring Trustee shall:
 - (a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.
 - (b) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Businesses (except the Vanguard Knee EEA license) with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Zimmer with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:
 - (i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses, and the keeping separate of the Divestment Businesses from the business retained by the Parties, in accordance with paragraphs 9 and 10 of these Commitments;
 - (ii) supervise the management of the Divestment Businesses as a distinct and saleable entity, in accordance with paragraph 11 of these Commitments;
 - (c) with respect to Confidential Information:
 - (i) determine all necessary measures to ensure that Zimmer does not after the Effective Date obtain any Confidential Information relating to the Divestment Businesses,
 - (ii) in particular strive for the severing of the Divestment Businesses' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Businesses,
 - (iii) make sure that any Confidential Information relating to the Divestment Businesses obtained by Zimmer before the Effective Date is eliminated and will not be used by Zimmer, and
 - (iv) decide whether such information may be disclosed to or kept by Zimmer as the disclosure is reasonably necessary to allow Zimmer to carry out the divestiture or as the disclosure is required by law;
 - (d) monitor the splitting of assets and the allocation of Key Personnel between the

Divestment Businesses and Zimmer or Affiliated Undertakings;

- (i) propose to Zimmer such measures as the Monitoring Trustee considers necessary to ensure Zimmer's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Businesses, the holding separate of the Divestment Businesses and the non-disclosure of competitively sensitive information;
 - (ii) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:
 - potential Purchasers receive sufficient and correct information relating to the Divestment Businesses and the Key Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and
 - potential Purchasers are granted reasonable access to the Key Personnel;
 - (iii) act as a contact point for any requests by third parties, in particular potential Purchasers, in relation to the Commitments;
 - (iv) provide to the Commission, sending Zimmer a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Businesses as well as the splitting of assets and the allocation of Key Personnel so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential Purchasers;
 - (v) promptly report in writing to the Commission, sending Zimmer a non-confidential copy at the same time, if it concludes on reasonable grounds that Zimmer is failing to comply with these Commitments;
 - (vi) within one week after receipt of the documented proposal referred to in paragraph 18 of these Commitments, submit to the Commission, sending Zimmer a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed Purchaser(s) and the viability of the Divestment Businesses after the sale(s) and as to whether the Divestment Businesses are sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sales of the Divestment Businesses without one or more Assets or not all of the Key Personnel affects the viability of the Divestment Businesses after the sale, taking account of the proposed Purchaser(s);
 - (vii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.
29. If the Monitoring and Divestiture Trustee are not the same legal persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

5.3.2 Duties and obligations of the Divestiture Trustee

30. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Businesses to the Purchaser(s), provided that the

Commission has approved both the Purchaser(s) and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 17 and 18 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement(s) (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement(s) such customary representations and warranties and indemnities as are reasonably required to effect the sale(s). The Divestiture Trustee shall protect the legitimate financial interests of Zimmer, subject to the Merged Entity's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

31. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non- confidential copy to the Merged Entity.

5.4 Duties and obligations of the Parties

32. Zimmer shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Zimmer's or the Divestment Businesses' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Zimmer and the Divestment Businesses shall provide the Trustee upon request with copies of any document. Zimmer and the Divestment Businesses shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
33. Zimmer shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Businesses. This shall include all administrative support functions relating to the Divestment Businesses which are currently carried out at headquarters level. Zimmer shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential Purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. Zimmer shall inform the Monitoring Trustee on possible Purchasers, submit lists of potential Purchasers at each stage of the selection process, including the offers made by potential Purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.
34. Zimmer shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sales (including ancillary agreements), the Closings and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sales and the Closings, including the appointment of advisors to assist with the sale processes. Upon request of the Divestiture Trustee, Zimmer shall cause the documents required for effecting the sales and the Closings to be duly executed.
35. Zimmer shall indemnify the Trustee and its employees and agents (each an "**Indemnified Party** ") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Zimmer for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

36. At the expense of Zimmer, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Zimmer's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Zimmer refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Zimmer. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Zimmer during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.
37. Zimmer agrees that the Commission may share Confidential Information proprietary to Zimmer with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.
38. Zimmer agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.
39. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.
- 5.5 Replacement, discharge and reappointment of the Trustee
40. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:
- (a) the Commission may, after hearing the Trustee and Zimmer, require Zimmer to replace the Trustee; or
 - (b) Zimmer may, with the prior approval of the Commission, replace the Trustee.
41. If the Trustee is removed according to paragraph 40 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19-26 of these Commitments.
42. Unless removed according to paragraph 40 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee, if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F - The review clause

43. The Commission may extend the time periods foreseen in the Commitments in response to a request from Zimmer or, in appropriate cases, on its own initiative. Where Zimmer requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a nonconfidential copy of the report to Zimmer. Only in exceptional circumstances shall Zimmer be entitled to request an extension within the last month of any period.
44. The Commission may further, in response to a reasoned request from Zimmer showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Zimmer. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G - Entry into force

45. The Commitments shall take effect upon the date of adoption of the Decision.

(signed)

duly authorised for and on behalf of
Zimmer
Brussels, 9 February 2015

SCHEDULES

Schedule 1. The ZUK Divestment Business

- (1) This Divestment Business consists of the rights, title and interests in the partial knee currently marketed under the brand name Zimmer® Unicompartmental High Flex Knee System (the "**ZUK**") including instrumentation, any improvements at the time of Closing and the pipeline projects at the time of Closing, also set out in **Annex 1** (together the "**ZUK Product Line**"), including the right to develop, manufacture and use with a view to its marketing and sale in the EEA (the "**ZUK Divestment Business**").
- (2) The ZUK Divestment Business includes:
 - (a) the following main **tangible assets** at the time of Closing for use exclusively in the EEA:
 - (i) existing ZUK **implant inventory** for the EEA market (excluding implant inventory necessary to accommodate existing non-transferrable contractual obligations, if any);
 - (ii) **instrumentation inventory** for the ZUK for the EEA market (excluding instrumentation inventory necessary to accommodate existing non-transferrable contractual obligations, if any);
 - (iii) available ZUK Product Line **advertising, marketing and promotional materials** for the EEA, subject to reprinting with the Purchaser's name;
 - (iv) copies of any and all **design history files**, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records related to and necessary for the ZUK Divestment Business;
 - (v) proprietary **demonstration models**, prototypes, samples, instruments, and supporting equipment utilized predominantly in connection with the ZUK Divestment Business for **training purposes** in the EEA and copies of any and all **training materials** that are used for training that is specific to the proper use of the ZUK Product Line and designed for use in the EEA;
 - (vi) copies of any and all proprietary **testing and clinical data**, market research reports, marketing plans and other **marketing-related information and materials** that are used in connection with the ZUK Product Line and are necessary for the ZUK Divestment Business in the EEA; and
 - (vii) in case of a global divestiture, certain **tooling and fixtures** used exclusively to manufacture the ZUK Product Line, as described in **Annex 2**;
 - (b) the following main **intangible assets** at the time of Closing for use exclusively in the EEA:
 - (i) the transfer of any **patents** (including patent applications) which are owned by the Merged Entity used **exclusively** for the ZUK Product Line in the EEA, including but not necessarily limited to those listed in **Annex 3**;
 - (ii) any **trademarks** listed in **Annex 4**;
 - (iii) the transfer of all technical and manufacturing **know-how, trade**

- secrets and designs** which are used exclusively for the ZUK Product Line in the EEA and are owned by the Merged Entity, and contribute to the current operation of or are necessary to ensure the viability and the competitiveness of the ZUK Divestment Business and which are not subject to the provisions of 2(b)(iv)- (x) below;
- (iv) any **copyrights** owned by the Merged Entity in the Merged Entity's marketing materials and support documents exclusively used in connection with the ZUK Divestment Business which are not subject to the provisions of 2(b)(x);
 - (v) the transfer of (either directly or by means of withdrawal and reregistration) any **internet domain names** relating exclusively to the ZUK Divestment Business as listed in **Annex 5**;
 - (vi) a **fully paid-up and royalty-free, non-exclusive license** for the sole purpose of manufacturing and marketing or sale of the ZUK Product Line in the EEA **to any intellectual property rights that are not exclusive to the ZUK Product Line**, but which are necessary for the manufacturing, marketing or sale of the ZUK Product Line, as listed in **Annex 6** and excluding intellectual property rights with respect to components or materials as contemplated in 2(b)(vii)-(viii) and excluding intellectual property rights with respect to PSI guides which shall be subject to 2(b)(ix);
 - (vii) a fully paid-up and royalty-free, non-exclusive license to the intellectual property rights and know-how which are owned by the Merged Entity and are necessary for the manufacturing and marketing or sale of the PMMA pre-coat process for the ZUK Product Line in the EEA;
 - (viii) an up to two-year transitional supply or manufacturing agreement, once the Purchaser has started manufacturing the ZUK Product Line, on a reasonable cost plus basis, to allow the Purchaser continued access to the PMMA pre-coat process and/or the Vivacit-E® polyethylene, in relation to the ZUK Divestment Business in the EEA. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary;
 - (ix) the Merged Entity undertakes to make all reasonable efforts to facilitate the entering into a contract between third-party providers and the Purchaser in relation to the **PSI Guide** for the ZUK Divestment Business, or in the event that such arrangements cannot be made, to sublicense any relevant rights, subject to third party consent, notwithstanding all reasonable efforts by the Merged Entity to obtain such consent; and
 - (x) agreement not to assert against the Purchaser any restriction to the use of the name "ZUK", other than the use of the stylised Z for Zimmer®, and agreement not to use the name "ZUK" by the Merged Entity for any products included in the retained businesses or any future products in the EEA. The Merged Entity also undertakes to take reasonable steps to make publicly known that the ZUK brand has been divested to the Purchaser;
 - (xi) a fully paid-up and royalty-free, non-exclusive license to the intellectual property rights and know-how which are owned by the Merged Entity and are necessary for the manufacturing and marketing or sale of instruments that are used in connection with,

but are not exclusive to, the ZUK Product Line in the EEA, for the sole purpose of manufacturing and marketing or sale of the ZUK Product Line in the EEA.

- (c) in relation to **licenses, permits and authorisations:**
- (i) the transfer of, or if not legally possible, access to, as appropriate, all licenses, permits and authorisations issued by any governmental organization and held by the Merged Entity, to the extent necessary to develop, manufacture and market or sell the ZUK Product Line in the EEA, including all relevant dossiers to the current and/or pending authorisations held or sought by the Merged Entity relating exclusively to the ZUK Divestment Business, and, where necessary, reasonable assistance (which shall not require the Merged Entity to conduct or pay for any trial or study) related to the transfer to the Purchaser of such licenses, permits and authorizations, and providing reasonable technical assistance (which shall not require the Merged Entity to conduct or pay for any trial or study) to the Purchaser, if necessary, to make any regulatory filings and obtain any authorisations that are necessary for the development and/or manufacture of the ZUK Divestment Business and/or its marketing and/or sale in the EEA; and
 - (ii) the transfer of, or if not legally possible, access to all current and pending **CE marks** relating to the ZUK Divestment Business, as listed in **Annex 7**, which are held by the Merged Entity, including all relevant dossiers to the current and/or pending CE marks held or sought by the Merged Entity relating exclusively to the ZUK Divestment Business and, where necessary, reasonable assistance to the Purchaser (which shall not require the Merged Entity to conduct or pay for any trial or study) for obtaining any necessary authorisations within the EEA for product registration and CE-marking of the ZUK Product Line under the Purchaser's brand names; the Merged Entity retains the right to reference the above material in its own dossiers for its own future products;
 - (iii) the certification, at the request of the Purchaser, to the competent authorities in the EEA that the Merged Entity has transferred to the Purchaser the files which are currently used and are needed to obtain any authorisations within the EEA.
- (d) the following main **contracts, agreements, commitments and understandings:**
- (i) to the extent legally possible, license of those **rights under sub-contracting agreements** to the extent such rights relate to the manufacture of ZUK Divestment Business (**Annex 8**). In the event that such arrangements cannot be made, the Merged Entity will conclude back-to-back supply agreements with the Purchaser to make the relevant devices available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months, once the Purchaser has started manufacturing the ZUK Product Line. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell the ZUK Divestment Business in an EEA country;
 - (ii) to the extent legally possible, license of those **rights under the supply agreements** to the extent such rights relate to the ZUK Divestment Business (**Annex 8**). In the event that such arrangements

cannot be made, the Merged Entity is willing to conclude back-to-back supply agreements with the Purchaser to make the relevant input materials available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months, once the Purchaser has started manufacturing the ZUK Product Line. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell the ZUK Divestment Business in an EEA country; and

- (iii) to the extent legally possible, those **rights under the consultancy or development agreements concluded with key opinion leaders ("KOLs")** to the extent such rights relate exclusively to the ZUK Divestment Business used or sold in the EEA, as listed in **Annex 9**;
- (e) the following **customer contracts** as described in **Annex 10**:
- (i) the Merged Entity undertakes to transfer all **customer contracts, commitments and customer orders** of the ZUK Product Line, to the extent legally transferable, as well as to provide assistance to transition customers to the Purchaser;
 - (ii) where **third-party consent is required** for customer contracts to be transferred, the Merged Entity undertakes to make all reasonable efforts to obtain such consent; and
 - (iii) for contracts that are **not legally transferable** as well as for customer contracts that cover more products than the ZUK Product Line and where the ZUK Product Line part is not severable and transferable, the Merged Entity undertakes, on the basis of licensed back rights for the sale and marketing of the ZUK Product Line to the Merged Entity by the Purchaser, to **continue the supply of the ZUK Product Line until the expiry of the contracts** in question and ensure that the Purchaser receives a reasonable and customary commission on the sales;
- (f) the following **customer, credit and other records**:
- (i) a **list of existing and past customers** of the ZUK Divestment Business in the EEA, provided, however, that the Merged Entity may continue to use such lists to the extent they relate to its retained businesses; and provided further, that any parts of such customer lists that do not relate to the ZUK Divestment Business may be redacted from the lists delivered to the Purchaser. A customer list is attached as **Annex 11**;
 - (ii) customer credit and other **customer records** relating to the ZUK Divestment Business, provided, however, that the Merged Entity may continue to use such records to the extent they relate to its retained business; and provided further, that any parts of such customer records that do not relate to the ZUK Divestment Business may be redacted from the lists delivered to the Purchaser. To the extent that the Merged Entity is obliged to retain copies of such documents in support of legal obligations, the Merged Entity shall be entitled to do so;
 - (iii) copies of all books, ledgers and other **business records** to the extent that they relate predominantly to the ZUK Divestment Business, save that any parts thereof that do not relate to the ZUK Divestment Business may be redacted from such copies; and
 - (iv) clinical, regulatory, and customer sales databases supporting the

ZUK Divestment Business that are incorporated into the Merged Entity reporting systems, provided, however, that the Merged Entity may continue to use such databases to the extent they relate to its retained businesses; and provided further, that any parts of such databases that do not relate to the ZUK Divestment Business may be redacted from the databases delivered to the Purchaser;

- (g) the Merged Entity undertakes to incentivize (in accordance with normal business practices) **Key Personnel** located in the EEA and related to the ZUK Divestment Business, as listed in **Annex 12**, to transfer with the ZUK Divestment Business, to the extent that such personnel is necessary to maintain the viability and competitiveness of the ZUK Divestment Business;
 - (h) in order to help facilitate a smooth transition, the Merged Entity also undertakes, as described in **Annex 13** and to the extent legally possible as applicable:
 - (i) to provide transitory, non-exclusive **supply or manufacturing arrangements** for the ZUK Product Line (including PMMA coating required for the manufacturing of the ZUK Product Line), on a reasonable cost plus basis, for a transitional period of up to 24 months from Closing of the ZUK Divestment Business. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary;
 - (ii) to provide reasonable **technical assistance** for a transitional period of up to 24 months from Closing of the ZUK Divestment Business, in order to enable the Purchaser to assume responsibility for the manufacture, marketing and sale of the ZUK Product Line in the EEA on a reasonable cost plus basis. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary. Such assistance may include assisting the Purchaser to establish manufacturing processes for the ZUK (including PMMA), access to raw materials, inventory management, warehousing and distribution, billing and collections, supplier management and regulatory support; and
 - (iii) to provide, on a reasonable cost plus basis, **training** on the ZUK Product Line, if requested by the Purchaser.
- (3) The ZUK Divestment Business **shall not include:**
- (a) any facilities used by the ZUK Divestment Business or any manufacturing equipment, except the tooling and fixtures listed in 2(a)(vii);
 - (b) any trademarks not exclusively used for the ZUK Divestment Business, including, without limitation, Zimmer®, notwithstanding the undertaking under point 2(b)(ii);
 - (c) any other intellectual property rights or technology not captured by 2(b)(i) and 2(b)(iii)-2(b)(xi);
 - (d) any right to actively or passively use the ZUK brand, products, materials, intellectual property rights, etc. in any country outside the EEA (except if the Purchaser were to acquire the global ZUK Divestment Business);
 - (e) any right to actively or passively sell and distribute the ZUK Product Line in any country outside the EEA (except if the Purchaser were to acquire the global ZUK Divestment Business);
 - (f) information management systems, software and hardware;

- (g) any distribution or agency network or any related assets; and
 - (h) any customer contracts not captured by 2(e).
- (4) If there is any asset or personnel which is not covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the ZUK Divestment Business and necessary for the continued viability and competitiveness of the ZUK Divestment Business, that asset or adequate substitute will be offered to potential Purchaser. If the Merged Entity and the Purchaser are unable to agree, the issue will be submitted to the Monitoring Trustee who will discuss those matters with both sides and report to the Commission.
- (5) In order to maintain the structural effect of the Commitments, the Merged Entity shall, for a period of 10 years after Closing of the ZUK Divestment Business, not acquire, whether directly or indirectly, the possibility of exercising influence over the whole or part of the ZUK Divestment Business, unless, following the submission of a reasoned request from the Merged Entity showing good cause and accompanied by a report from the Monitoring Trustee, the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the ZUK Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.
- (6) The proposed Concentration shall not be implemented before Zimmer or the Divestiture Trustee has entered into a final binding sale and purchase agreement for the sale of the ZUK Divestment Business and the Commission has approved the Purchaser and the terms of sale.

Schedule 2. The Discovery Elbow Divestment Business

- (1) This Divestment Business consists of the rights, title and interests in the elbow system currently marketed under the brand name Discovery® Elbow, including instrumentation, any improvements at the time of Closing and the pipeline projects at the time of Closing, also set out in **Annex 1** (together the "**Discovery Elbow Product Line**"), including the right to develop, manufacture and use with a view to its marketing and sale in the EEA (the "**Discovery Elbow Divestment Business**").
- (2) The Discovery Elbow Divestment Business includes:
 - (a) the following main **tangible assets** at the time of Closing for use exclusively in the EEA:
 - (i) existing Discovery Elbow **implant inventory** for the EEA market (excluding implant inventory necessary to accommodate existing non-transferrable contractual obligations, if any);
 - (ii) **instrumentation inventory** for the Discovery Elbow for the EEA market (excluding instrumentation inventory necessary to accommodate existing non-transferrable contractual obligations, if any);
 - (iii) available Discovery Elbow Product Line **advertising, marketing and promotional materials** for the EEA, subject to reprinting with the Purchaser's name;
 - (iv) copies of any and all **design history files**, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records related to and necessary for the Discovery Elbow Divestment Business;
 - (v) proprietary **demonstration models**, prototypes, samples, instruments, and supporting equipment utilized predominantly in connection with the Discovery Elbow Divestment Business for **training purposes** in the EEA and copies of any and all **training materials** that are used for training that is specific to the proper use of the Discovery Elbow and designed for use in the EEA;
 - (vi) copies of any and all proprietary **testing and clinical data**, market research reports, marketing plans and other **marketing-related information and materials** that are used in connection with the Discovery Elbow Product Line and are necessary for the Discovery Elbow Divestment Business in the EEA; and
 - (vii) in case of a global divestiture, certain **tooling and fixtures** used exclusively to manufacture the Discovery Elbow Product Line, as described in Annex 2.
 - (b) the following main **intangible assets**, at the time of Closing, for use exclusively in the EEA:
 - (i) the transfer of any **patents** (including patent applications) which are owned by the Merged Entity used exclusively for the Discovery Elbow Product Line in the EEA, including but not necessarily limited to those listed in **Annex 3**;
 - (ii) the **trademarks** listed in **Annex 4**;
 - (iii) the transfer, subject to payment of pass-through royalties to third parties, as applicable, of all technical and manufacturing know-how, trade secrets and designs which are used exclusively for the

Discovery Elbow Product Line in the EEA and are owned by the Merged Entity, and contribute to the current operation of or are necessary to ensure the viability and the competitiveness of the Discovery Elbow Divestment Business and which are not subject to the provisions of 2(b)(iv)-(ix) below;

- (iv) any **copyrights** owned by the Merged Entity **in the Merged Entity's marketing materials and support documents** exclusively used in connection with the Discovery Elbow Divestment Business which are not subject to the provisions of 2(b)(ix);
 - (v) the transfer of (either directly or by means of withdrawal and reregistration) the **internet domain names** relating exclusively to the Discovery Elbow Divestment Business as listed in **Annex 5**;
 - (vi) the right to a **fully paid-up and royalty-free, non-exclusive** license for the sole purpose of manufacturing and marketing or sale of the Discovery Elbow Product Line in the EEA **to intellectual property rights that are not exclusive** to the Discovery Elbow Product Line, but which are necessary for the manufacturing, marketing or sale of the Discovery Elbow Product Line, as listed in **Annex 6** and excluding intellectual property rights with respect to components or materials to be manufactured by the Merged Entity as contemplated in 2(b)(vii)-(viii);
 - (vii) a fully paid-up and royalty-free, non-exclusive license to intellectual property rights and know-how which are owned by the Merged Entity and are necessary for the manufacturing, marketing or sale of the ARCOM® polyethylene for the Discovery Elbow Product Line in the EEA, including any rights or assistance required for the manufacturing of ARCOM® as well as reasonable assistance to access raw materials;
 - (viii) an up to two-year transitional supply or manufacturing agreement, once the Purchaser has started manufacturing the Discovery Elbow Product Line, on a reasonable cost plus basis, to allow the Purchaser continued access to the ARCOM® polyethylene, in relation to the Discovery Elbow Divestment Business. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary; and
 - (ix) agreement not to assert against the Purchaser any restriction to the use of the name "Discovery" and agreement not to use the name "Discovery" by the Merged Entity for any products included in the retained businesses or any future products in the EEA. The Merged Entity also undertakes to take reasonable steps to make publicly known that the Discovery brand has been divested to the Purchaser.
 - (x) a fully paid-up and royalty-free, non-exclusive license to the intellectual property rights and know-how which are owned by the Merged Entity and are necessary for the manufacturing and marketing or sale of instruments that are used in connection with, but are not exclusive to, the Discovery Elbow Product Line in the EEA, for the sole purpose of manufacturing and marketing or sale of the Discovery Elbow Product Line in the EEA.
- (c) in relation to **licenses, permits and authorisations**:
- (i) the transfer of, or if not legally possible, access to, as appropriate, all **licenses, permits and authorisations** issued by any governmental organization and held by the Merged Entity, to the extent necessary to develop, manufacture and market or sell the Discovery Elbow Product Line in the EEA, including all relevant dossiers to the current and/or pending authorisations held or sought by the Merged Entity relating exclusively to the Discovery Elbow Divestment Business, and, where necessary, reasonable assistance (which shall not require the Merged Entity to conduct or pay for any trial or study) related to the transfer to the Purchaser of such licenses,

permits and authorizations, and providing reasonable technical assistance (which shall not require the Merged Entity to conduct or pay for any trial or study), if necessary, to make any regulatory filings and obtain any authorisations that are necessary for the development and/or manufacture of the Discovery Elbow Divestment Business and/or its marketing and/or sale in the EEA;

- (ii) the transfer of, or if not legally possible, access to all current and pending **CE marks** relating to the Discovery Elbow Divestment Business, as listed in **Annex 7**, which are held by the Merged Entity, including all relevant dossiers to the current and/or pending CE marks held or sought by the Merged Entity relating exclusively to the Discovery Elbow Divestment Business and, where necessary, reasonable assistance to the Purchaser (which shall not require the Merged Entity to conduct or pay for any trial or study) for obtaining any necessary authorisations within the EEA for product registration and CE- marking of the Discovery Elbow Product Line under the Purchaser's brand names; the Merged Entity retains the right to reference the above material in its own dossiers for its own future products;
- (iii) the certification, at the request of the Purchaser, to the competent authorities in the EEA that the Merged Entity has transferred to the Purchaser the files which are currently used and are needed to obtain any authorisations within the EEA.

(d) the following main **contracts, agreements, commitments and understandings**:

- (i) to the extent legally possible, license to those **rights under sub-contracting agreements** to the extent such rights relate to the manufacture of Discovery Elbow Divestment Business (**Annex 8**). In the event that such arrangements cannot be made, the Merged Entity will conclude back-to-back supply agreements with the Purchaser to make the relevant devices available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months, once the Purchaser has started manufacturing the Discovery Elbow Product Line. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell the Discovery Elbow Divestment Business in an EEA country;
- (ii) to the extent legally possible, license to those **rights under the supply agreements** to the extent such rights relate to the Discovery Elbow Divestment Business (**Annex 8**). In the event that such arrangements cannot be made, the Merged Entity is willing to conclude back-to-back supply agreements with the Purchaser to make the relevant input materials available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months, once the Purchaser has started manufacturing the Discovery Elbow Product Line. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell the Discovery Elbow Divestment Business in an EEA country;
- (iii) to the extent legally transferrable, those **rights under the consultancy or development agreements concluded with key opinion leaders ("KOLs")** to the extent such rights relate exclusively to the Discovery Elbow Divestment Business used or sold in the EEA, as listed in **Annex 9**;

- (e) the following **customer contracts** as described in **Annex 10**:
- (i) the Merged Entity undertakes to transfer all **customer contracts, commitments and customer orders** of the Discovery Elbow Product Line, to the extent legally transferable, as well as to provide assistance to transition customers to the Purchaser;
 - (ii) where **third-party consent is required** for customer contracts to be transferred, the Merged Entity undertakes to make all reasonable efforts to obtain such consent; and
 - (iii) for customer contracts that are **not legally transferable** as well as for customer contracts that cover more products than the Discovery Elbow Product Line and where the Discovery Elbow Product Line part is not severable and transferable, the Merged Entity undertakes, on the basis of licensed back rights for the sale and marketing of the Discovery Elbow Product Line to the Merged Entity by the Purchaser, to **continue the supply of the Discovery Elbow until the expiry of the contracts** in question and ensure that the Purchaser receives a reasonable and customary commission on the sales;
- (f) the following **customer, credit and other records**:
- (i) **a list of existing and past customers** of the Discovery Elbow Divestment Business in the EEA, provided, however, that the Merged Entity may continue to use such lists to the extent they relate to its retained businesses; and provided further, that any parts of such customer lists that do not relate to the Discovery Elbow Divestment Business may be redacted from the lists delivered to the Purchaser. A customer list is attached as **Annex 11**;
 - (ii) Customer credit and other **customer records** relating to the Discovery Elbow Divestment Business, provided, however, that the Merged Entity may continue to use such records to the extent they relate to its retained business; and provided further, that any parts of such customer records that do not relate to the Discovery Elbow Divestment Business may be redacted from the lists delivered to the Purchaser. To the extent that the Merged Entity is obliged to retain copies of such documents in support of legal obligations, the Merged Entity shall be entitled to do so;
 - (iii) Copies of all books, ledgers and other **business records** to the extent that they relate predominantly to the Discovery Elbow Divestment Business, save that any parts thereof that do not relate to the Discovery Elbow Divestment Business may be redacted from such copies; and
 - (iv) Clinical, regulatory, and customer sales **databases** supporting the Discovery Elbow Divestment Business that are incorporated into the Merged Entity's reporting systems, provided, however, that the Merged Entity may continue to use such databases to the extent they relate to its retained businesses; and provided further, that any parts of such databases that do not relate to the Discovery Elbow Divestment Business may be redacted from the databases delivered to the Purchaser;
- (g) the Merged Entity undertakes to incentivize (in accordance with normal business practices) **Key Personnel** located in the EEA and related to the Discovery Elbow Divestment Business, as listed in **Annex 12**, to transfer with the Discovery Elbow Divestment Business, to the extent that such

personnel is necessary to maintain the viability and competitiveness of the Discovery Divestment Business;

- (h) in order to help facilitate a smooth transition, the Merged Entity also undertakes, as described in **Annex 13** and to the extent legally possible:
 - (i) to provide transitory, non-exclusive **supply or manufacturing arrangements** for the Discovery Elbow Product Line (including ARCOM® polyethylene required for the manufacturing of the Discovery Elbow Product Line) on a reasonable cost plus basis, for a transitional period of up to 24 months from Closing of the Discovery Elbow Divestment Business. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems it necessary;
 - (ii) to provide reasonable **technical assistance** for a transitional period of up to 24 months from Closing of the Discovery Elbow Divestment Business in order to enable the Purchaser to assume responsibility for the manufacture, marketing and sale of the Discovery Elbow in the EEA on a reasonable cost plus basis. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems it necessary. Such assistance may include assisting the Purchaser to establish manufacturing processes for the Discovery Elbow Product Line (including ARCOM®), access to raw materials, inventory management, warehousing and distribution, billing and collections, supplier management and regulatory support; and
 - (iii) to provide on a reasonable cost plus basis **training** on the Discovery Elbow Product Line, if requested by the Purchaser.
- (3) The Discovery Elbow Divestment Business **shall not include**:
 - (a) any facilities used by the Discovery Elbow Divestment Business or any manufacturing equipment, except the tooling and fixtures listed in 2(a)(vii) ;
 - (b) any trademarks not exclusively used for the Discovery Elbow Divestment Business, including, without limitation, Biomet® and LVB Acquisitions®;
 - (c) any other intellectual property rights or technology not captured by 2(b)(i)-2(b)(x);
 - (d) any right to actively or passively use the Discovery Elbow brand, products, materials, intellectual property rights, etc. in any country outside the EEA (except if the Purchaser were to acquire the global Discovery Elbow Divestment Business);
 - (e) any right to actively or passively sell and distribute the Discovery Elbow Product Line in any country outside the EEA (except if the Purchaser were to acquire the global Discovery Elbow Divestment Business);
 - (f) information management systems, software and hardware;
 - (g) any distribution or agency network or any related assets; and
 - (h) any customer contracts not captured by 2(e).
- (4) If there is any asset or personnel which is not covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Discovery Elbow Divestment Business and necessary for the continued viability and competitiveness of the Discovery Elbow Divestment Business, that asset or adequate substitute will be offered to potential Purchaser. If the Merged Entity and the Purchaser are unable to agree, the issue will be submitted to the Monitoring Trustee who will discuss those

matters with both sides and report to the Commission.

- (5) In order to maintain the structural effect of the Commitments, the Merged Entity shall, for a period of 10 years after Closing of the Discovery Elbow Divestment Business, not acquire, whether directly or indirectly, the possibility of exercising influence over the whole or part of the Discovery Elbow Divestment Business, unless, following the submission of a reasoned request from the Merged Entity showing good cause and accompanied by a report from the Monitoring Trustee, the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Discovery Elbow Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.
- (6) The proposed Concentration shall not be implemented before Zimmer or the Divestiture Trustee has entered into a final binding sale and purchase agreement for the sale of the Discovery Elbow Divestment Business and the Commission has approved the Purchaser and the terms of sale.

Schedule 3. The Vanguard Knee Divestment Business (Denmark and Sweden)

- (1) This Divestment Business consists of the rights, title and interests in the total knee system currently marketed under the brand name Vanguard® in Denmark and Sweden ("**Vanguard Knee**"), including instrumentation, any improvements at the time of Closing and the pipeline projects at the time of Closing, also set out in **Annex 1** (together the "**Vanguard Knee Product Line**") including the right to develop, manufacture and use with a view to its marketing and sale in Denmark and Sweden only (the "**Vanguard Knee Divestment Business**").
- (2) The Vanguard Knee Divestment Business includes:
 - (a) the following main **tangible assets at the time of Closing for use** exclusively in Denmark and Sweden only:
 - (i) existing Vanguard Knee **implant inventory** for marketing and sale in Denmark and Sweden (excluding implant inventory necessary to accommodate existing non-transferrable contractual obligations, if any);
 - (ii) **instrumentation inventory** for the Vanguard Knee for marketing and sale in Denmark and Sweden (excluding instrumentation inventory necessary to accommodate existing non-transferrable contractual obligations, if any);
 - (iii) available Vanguard Knee Product Line **advertising, marketing and promotional materials** for use in Denmark and Sweden;
 - (iv) copies of any and all **design history files**, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records related to and necessary for the Vanguard Knee Divestment Business in Denmark and Sweden;
 - (v) proprietary **demonstration models**, prototypes, samples, instruments, and supporting equipment utilized predominantly in connection with the Vanguard Knee Divestment Business for **training purposes** in Denmark and Sweden and copies of any and all **training materials** that are used for training that is specific to the proper use of the Vanguard Knee Product Line and designed for use in Denmark and Sweden; and
 - (vi) copies of any and all proprietary **testing and clinical evaluation reports**, market research reports, marketing plans and other **marketing-related information and materials** that are used in connection with the Vanguard Knee Product Line and are necessary for the Vanguard Knee Divestment Business in Denmark and Sweden;
 - (b) the following main **intangible assets** at the time of Closing for use exclusively in Denmark and Sweden only:
 - (i) the transfer of any patents (including patent applications) which are owned by the Merged Entity used exclusively for the Vanguard Knee Product Line in Denmark and Sweden, including but not necessarily limited to those listed in Annex 3;
 - (ii) the trademarks listed in Annex 4;
 - (iii) the transfer, subject to payment of pass-through royalties to third parties, as applicable, of all technical and manufacturing know-how, trade secrets and designs which are used exclusively for the Vanguard Knee Product Line in Denmark and Sweden and are owned by the Merged Entity, and contribute to the current operation of or are necessary to ensure the viability and the competitiveness of the Vanguard Divestment Business in

Denmark and Sweden and which are not subject to the provisions of 2(b)(iv)-(x);

- (iv) any copyrights owned by the Merged Entity in the Merged Entity's marketing materials and support documents exclusively used in connection with the Vanguard Divestment Business in Denmark and Sweden which are not subject to the provisions of 2(b)(x);
- (v) the transfer of (either directly or by means of withdrawal and reregistration) the internet domain names relating exclusively to the Vanguard Divestment Business in Denmark and Sweden as listed in Annex 5;
- (vi) a fully paid-up and royalty-free (but subject to payment of pass-through royalties to third parties, as applicable), non-exclusive license for the sole purpose of manufacturing and marketing or sale of the Vanguard Knee Product Line in Denmark and Sweden to intellectual property rights that are not exclusive to the Vanguard Knee Line in Denmark and Sweden, but which are necessary for the manufacturing, marketing or sale of the Vanguard Knee Product Line in Denmark and Sweden, as listed in Annex 6, subject to third party consent where required, notwithstanding all reasonable efforts by the Merged Entity to obtain such consent, and excluding intellectual property rights with respect to components or materials to be manufactured as contemplated in 2(b)(vii)-2(b)(viii) and excluding intellectual property rights with respect to Signature™ system which shall be subject to 2(ix);
- (vii) a fully paid-up and royalty-free, non-exclusive license to the intellectual property rights and know-how owned by the Merged Entity which are necessary for the manufacturing and marketing or sale of ARCOM® polyethylene for the Vanguard Knee Product Line in Denmark and Sweden, including any rights or assistance required for the manufacturing of ARCOM®, as well as reasonable assistance to access raw materials, subject to third party consent where required, notwithstanding all reasonable efforts by the Merged Entity to obtain such consent;
- (viii) an up to two-year transitional supply or manufacturing agreement, once the Purchaser has started manufacturing the Vanguard Knee Product Line, on a reasonable cost plus basis, to allow the Purchaser continued access to the ARCOM® polyethylene, the Regenerex® Porous Titanium Construct and the E1®, in relation to the Vanguard Knee Divestment Business in Denmark and Sweden This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary;
- (ix) the Merged Entity undertakes to make all reasonable efforts to facilitate the entering into a contract between third-party providers and the Purchaser in relation to the Signature™ system for the Vanguard Knee Divestment Business in Denmark and Sweden, or in the event that such arrangements cannot be made, to sublicense any relevant rights, subject to third party consent;
- (x) agreement not to assert against the Purchaser any restriction to the use of the name "Vanguard" in Denmark and Sweden and agreement not to use the name "Vanguard" by the Merged Entity in Denmark and Sweden for any products included in the retained businesses or any future products. The Merged Entity also undertakes to take reasonable steps to make publicly known that the Vanguard brand has been divested to the Purchaser in Denmark and Sweden. Purchaser commits that it will not, directly or through entering into any license, distribution or similar

arrangement, use the name Vanguard, or any similar name, as a business name, or promote, distribute, actively sell or offer for sale, or otherwise in relation to, any product (including any copy product) under the name Vanguard, or any similar name, outside of Denmark and Sweden. The Merged Entity commits that it will not, directly or through entering into any license, distribution or similar arrangement, use the name Vanguard as a business name, or actively promote, distribute, sell or offer for sale, or otherwise in relation to, any copy of the Vanguard Product Line or any product under the name Vanguard, or any similar name, in Denmark and Sweden, without prejudice to the transitional agreements under 2(h)(i).

- (xi) a fully paid-up and royalty-free, non-exclusive license to the intellectual property rights and know-how which are owned by the Merged Entity and are necessary for the manufacturing and marketing or sale of instruments that are used in connection with, but are not exclusive to, the Vanguard Knee Product Line in Denmark and Sweden, for the sole purpose of manufacturing and marketing or sale of the Vanguard Knee Product Line in Denmark and Sweden.
- (c) **in relation to** licenses, permits and authorisations:
- (i) the transfer of, or if not legally possible, access to, as appropriate, all **licenses, permits and authorisations** issued by any governmental organisation and held by the Merged Entity, to the extent necessary to develop, manufacture and market or sell the Vanguard Knee Product Line in Denmark and Sweden, including all relevant dossiers to the current and/or pending authorisations held or sought by the Merged Entity relating exclusively to the Vanguard Knee Divestment Business in Denmark and Sweden, and, where necessary, reasonable assistance (which shall not require the Merged Entity to conduct or pay for any trial or study) related to the transfer to the Purchaser of such licenses, permits and authorizations, and providing reasonable technical assistance (which shall not require the Merged Entity to conduct or pay for any trial or study) to the Purchaser, if necessary, to make any regulatory filings and obtain any authorisations that are necessary for the development and/or manufacture of the Vanguard Knee Divestment Business in Denmark and Sweden and/or its marketing and/or sale in Denmark and Sweden; and
 - (ii) access to all current and pending **CE marks** relating to the Vanguard Knee Divestment Business as listed in **Annex 7** which are held by the Merged Entity, including all relevant dossiers to the current and/or pending CE marks held or sought by the Merged Entity relating exclusively to the Vanguard Knee Divestment Business in Denmark and Sweden, and, where necessary, reasonable assistance to the Purchaser (which shall not require the Merged Entity to conduct or pay for any trial or study) for obtaining any necessary authorisations within Denmark and Sweden for product registration and CE- marking of the Vanguard Knee Product Line under the Purchaser's brand names; the Merged Entity retains the right to reference the above material in its own dossiers for its own future products;
 - (iii) the certification, at the request of the Purchaser, to the competent authorities in Denmark and Sweden that the Merged Entity has transferred to the Purchaser the files which are currently used and are needed to obtain any authorisations in Denmark and Sweden.
- (d) the following main **contracts, agreements, commitments and understandings** for use exclusively in Denmark and Sweden only:
- (i) to the extent legally possible, license of those **rights under sub-contracting agreements** to the extent such rights relate to the

manufacture of the Vanguard Knee Divestment Business in Denmark and Sweden (**Annex 8**). In the event that such arrangements cannot be made, the Merged Entity will conclude back-to-back supply agreements with the Purchaser to make the relevant devices available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months, once the Purchaser has started manufacturing the Vanguard Product Line for sale in Denmark and Sweden. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell the Vanguard Knee Divestment Business in Denmark and Sweden;

- (ii) to the extent legally possible, license of those **rights under the supply agreements** to the extent such rights relate to the Vanguard Knee Divestment Business in Denmark and Sweden (**Annex 8**). In the event that such arrangements cannot be made, the Merged Entity is willing to conclude back-to-back supply agreements with the Purchaser to make the relevant input materials available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months, once the Purchaser has started manufacturing the Vanguard Product Line for sale in Denmark and Sweden. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell the Vanguard Knee Divestment Business in Denmark and Sweden; and
- (iii) to the extent legally possible, and subject to payment of pass-through royalties to third parties, as applicable, sublicense of those **rights under the consultancy or development agreements** concluded with key opinion leaders ("KOLs") to the extent such rights relate exclusively to the Vanguard Knee Divestment Business used or sold in Denmark and Sweden, as listed in **Annex 9**;
- (e) the following **customer contracts** as described in **Annex 10** for use exclusively in Denmark and Sweden only:
 - (iv) the Merged Entity undertakes to transfer all **customer contracts, commitments and customer orders** of the Vanguard Knee Product Line in Denmark and Sweden to the extent legally transferable, as well as to provide assistance to transition customers to the Purchaser;
 - (v) where **third-party consent is required** for customer contracts to be transferred, the Merged Entity undertakes to make all reasonable efforts to obtain such consent; and
 - (vi) for customer contracts in Denmark and Sweden that are **not legally transferable** as well as for customer contracts that cover more products than the Vanguard Knee Product Line and where the Vanguard Knee Product Line part is not severable and transferable, the Merged Entity undertakes, on the basis of licensed back rights for the sale and marketing of the Vanguard Knee Product Line to the Merged Entity by the Purchaser, to **continue the supply of the Vanguard Knee Product Line** in Denmark and Sweden **until the expiry of the contracts** in question and ensure that the Purchaser receives a reasonable and customary commission on the sales;
- (f) the following **customer, credit and other records** for use exclusively in Denmark and Sweden only:
 - (i) a **list of existing and past customers** of the Vanguard Knee Divestment Business (i.e. customers in Denmark and Sweden), provided, however, that the Merged Entity may continue to use such lists to the extent they relate to its retained businesses; and provided further, that any parts of

such customer lists that do not relate to the Vanguard Knee Divestment Business in Denmark and Sweden may be redacted from the lists delivered to the Purchaser. A customer list is attached as **Annex 11**;

- (ii) customer credit and other **customer records** relating to the Vanguard Knee Divestment Business in Denmark and Sweden, provided, however, that the Merged Entity may continue to use such records to the extent they relate to its retained business; and provided further, that any parts of such customer records that do not relate to the Vanguard Knee Divestment Business in Denmark and Sweden may be redacted from the lists delivered to the Purchaser. To the extent that the Merged Entity is obliged to retain copies of such documents in support of legal obligations, the Merged Entity shall be entitled to do so;
 - (iii) copies of all books, ledgers and other **business records** to the extent that they relate predominantly to the Vanguard Knee Divestment Business in Denmark and Sweden, save that any parts thereof that do not relate to the Vanguard Knee Divestment Business in Denmark and Sweden may be redacted from such copies;
 - (iv) clinical, regulatory, and customer sales **databases** supporting the Vanguard Knee Divestment Business in Denmark and Sweden that are incorporated into the Merged Entity's reporting systems, provided, however, that the Merged Entity may continue to use such databases to the extent they relate to its retained businesses; and provided further, that any parts of such databases that do not relate to the Vanguard Knee Divestment Business in Denmark and Sweden may be redacted from the databases delivered to the Purchaser;
- (g) the Merged Entity undertakes to incentivize (in accordance with normal business practices) **Key Personnel** located in Denmark and Sweden and related to the Vanguard Knee Divestment Business as listed in **Annex 12**, to transfer with the Vanguard Divestment Business, to the extent that such personnel is necessary to maintain the viability and competitiveness of the Vanguard Divestment Business in Denmark and Sweden;
- (h) in order to help facilitate a smooth transition, the Merged Entity also undertakes, as described in **Annex 13**, and to the extent legally possible, and only with respect to marketing and sale in Denmark and Sweden:
- (i) to provide transitory, non-exclusive **supply or manufacturing arrangements** for the Vanguard Knee Product Line in Denmark and Sweden (including ARCOM® polyethylene, the Regenerex® Porous Titanium Construct and the E1® required for the manufacturing of the Vanguard Knee Product Line in Denmark and Sweden) on a reasonable cost plus basis, for a transitional period of up to 24 months from Closing of the Vanguard Knee Divestment Business. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems it necessary;
 - (ii) to provide reasonable **technical assistance** for a transitional period of up to 24 months from Closing of the Vanguard Knee Divestment Business in order to enable the Purchaser to assume responsibility for the manufacture, marketing and sale of the Vanguard Knee Product Line in Denmark and Sweden on a reasonable cost plus basis. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems it necessary. Such assistance may include assisting the Purchaser to establish manufacturing processes for the Vanguard Knee in Denmark and Sweden (including ARCOM®) s access to raw materials, inventory management, warehousing and distribution, billing and collections, supplier management and regulatory

support; and

(iii) to provide, on a reasonable cost plus basis, **training** on the Vanguard Knee for the sale and marketing in Denmark and Sweden, if requested by the Purchaser.

(3) The Vanguard Knee Divestment Business **shall not include:**

- (a) any facilities used by the Vanguard Knee Divestment Business or any manufacturing equipment;
- (b) any trademarks not exclusively used for the Vanguard Knee Divestment Business in Denmark and Sweden, including, without limitation, Biomet® and LVB Acquisitions®;
- (c) any other intellectual property rights or technology not captured by 2(b)(i)-2(b)(xi);
- (d) any other right to use the Vanguard Knee brand, products, materials, intellectual property rights including the trademarks listed in Annex 6, or to use the name Vanguard, or any similar name, as a business name, or to promote, distribute, sell or offer for sale, or otherwise in relation to, any product (including any copy product) under the name Vanguard, or any similar name, in any country other than Denmark and Sweden;
- (e) any right to actively sell and distribute the Vanguard Knee Product Line in any country other than Denmark and Sweden;
- (f) information management systems, software and hardware;
- (g) any distribution or agency network or any related assets; and
- (h) any customer contracts not captured by 2(e).

(4) If there is any asset or personnel which is not covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Vanguard Knee Divestment Business and necessary for the continued viability and competitiveness of the Vanguard Knee Divestment Business, that asset or adequate substitute will be offered to potential Purchaser. If the Merged Entity and the Purchaser are unable to agree, the issue will be submitted to the Monitoring Trustee who will discuss those matters with both sides and report to the Commission.

(5) In order to maintain the structural effect of the commitment, the Merged Entity shall for a period of 10 years after Closing of the Vanguard Knee Divestment Business, not acquire, whether directly or indirectly, the possibility of exercising influence over the whole or part of the Vanguard Knee Divestment Business in Sweden and Denmark, unless, following the submission of a reasoned request from the Merged Entity showing good cause and accompanied by a report from the Monitoring Trustee, the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Vanguard Knee Divestment Business in Sweden and Denmark is no longer necessary to render the proposed concentration compatible with the internal market.

(6) The proposed Concentration shall not be implemented before Zimmer or the Divestiture Trustee has entered into a final binding sale and purchase agreement for the sale of the Vanguard Knee Divestment Business in Sweden and Denmark, and the Commission has approved the Purchaser and the terms of sale.

Schedule 4. The Vanguard Knee EEA License as a viability addition to the Vanguard Knee Divestment Business

- (1) This Divestment Business consists of a fair, reasonable and non-discriminatory royalty-bearing non-exclusive license to all rights, other than those set forth in 3(b), necessary for the manufacturing, marketing and sale in the EEA of a copy of the total knee system currently marketed under the brand name Vanguard® ("**Vanguard Knee**"), including instrumentation, any improvements at the time of Closing and the pipeline projects at the time of Closing, also set out in **Annex 1** (together the "**Vanguard Knee Product Line**") (the "**Vanguard Knee EEA License**"). The Vanguard Knee EEA License is offered to the Purchaser of the Vanguard Knee, to ensure the viability of the Vanguard Knee Divestment Business. For the purposes of determining the fair, reasonable and non-discriminatory royalty rate, account should be taken of the fact that such a royalty must not hamper the viability and competitiveness of the Vanguard Knee Divestment Business.
- (2) The Vanguard Knee EEA License includes:
 - (a) the following main **tangible assets** at the time of Closing for use exclusively in the EEA:
 - (i) copies of any and all **design history files**, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records related to and necessary for the Vanguard Knee EEA License;
 - (ii) copies of any and all publicly available **testing and clinical performance reports** and market research reports that are used in connection with the Vanguard Knee Product Line and are necessary for the Vanguard Knee EEA License, so that the Purchaser could rely on the Vanguard Knee track record in the EEA;
 - (b) the following main **intangible assets**, at the time of Closing, for use exclusively in the EEA:
 - (i) subject to payment of pass-through royalties to third parties, as applicable, a **nonexclusive license**, for the sole purpose of manufacturing and marketing or sale in the EEA of copies of the Vanguard Knee Product Line, to **intellectual property rights** applicable (exclusively and not exclusively) to the Vanguard Knee Product Line in the EEA, and which are necessary for the manufacturing, marketing or sale of the copy product subject to the Vanguard Knee EEA License in the EEA, as listed in **Annex 6**, subject to third party consent where required, notwithstanding all reasonable efforts by the Merged Entity to obtain such consent, and excluding intellectual property rights with respect to components or materials as contemplated in 2(b)(iii)-(iv);
 - (ii) a **non-exclusive license**, subject to payment of pass-through royalties to third parties, as applicable, for the sole purpose of manufacturing and marketing or sale in the EEA of copies of the Vanguard Knee Product Line, to all technical and manufacturing **know-how, trade secrets and designs** which are used exclusively for the Vanguard Product Line in the EEA and are owned by the Merged Entity, and contribute to the current operation of and which are required to manufacture copies of the Vanguard Product Line in the EEA;
 - (iii) a **non-exclusive license** to the intellectual property rights which are owned by the Merged Entity and are necessary for the manufacturing and

marketing or sale of **ARCOM® polyethylene**, for copies of the Vanguard Knee Product Line in the EEA subject to third party consent where required, notwithstanding all reasonable efforts by the Merged Entity to obtain such consent;

- (iv) **an up to two-year transitional supply** or manufacturing agreement, once the Purchaser has started manufacturing the Vanguard copy for the EEA, on a reasonable at cost plus basis to allow the Purchaser continued access to the **ARCOM® polyethylene, the Regenerex® Porous Titanium Construct and the E1®**, in relation to the production of copies of the Vanguard Knee Product Line in the EEA. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary;
- (v) Purchaser commits that it will not, directly or through entering into any license, distribution or similar arrangement, use the name Vanguard, or any similar name, as a business name, or promote, distribute, actively sell or offer for sale, or otherwise in relation to, any product (including any copy product) under the name Vanguard, or any similar name, outside of Denmark and Sweden.
- (vi) a fully paid-up and royalty-free, non-exclusive license to the intellectual property rights and know-how which are owned by the Merged Entity and are necessary for the manufacturing and marketing or sale of instruments that are used in connection with, but are not exclusive to, the copy of the Vanguard Knee Product Line in the EEA, for the sole purpose of manufacturing and marketing or sale of a copy of the Vanguard Knee Product Line in the EEA.

(3) The Vanguard Knee EEA License **shall not include:**

- (a) any facilities, manufacturing equipment, or any other tangible assets;
 - (b) any other intellectual property rights or technology not captured by 2(b)(i)-(vi);
 - (c) any licenses, permits and/or authorisations;
 - (d) any current or pending CE marks;
 - (e) any customer contracts;
 - (f) any customer credit and other records;
 - (g) any contracts with third parties;
 - (h) any personnel;
 - (i) information management systems, software and hardware;
 - (j) any distribution or agency network or any related assets; and
 - (k) any transitional agreements for the manufacture and supply, technical assistance and/or training.
- (4) If there is any asset which is not covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Vanguard Knee Divestment Business and necessary for the continued viability and competitiveness of the Vanguard Knee Divestment Business, that asset or adequate substitute will be offered to potential Purchaser. If the Merged Entity and the Purchaser are unable to agree, the issue will be submitted to the Monitoring Trustee who will discuss those matters with both sides and report to the Commission.
- (5) The proposed Concentration shall not be implemented before Zimmer or the

Divestiture Trustee has entered into the non-exclusive Vanguard Knee EEA License, and the Commission has approved the Purchaser and the terms of the license.

ANNEXES TO THE SCHEDULES

Annex 1. The products of the Divestment Business

- (1) The Divestment Business includes the following implants, as listed in the table below marketed in the EEA or Denmark and Sweden, as applicable, as well as associated instrumentation (exclusive and non-exclusive) listed in the following excel file "M.7265- Supplement to Annex 1- Instrumentation ZUK, Discovery Elbow, Vanguard Knee".

Device/Brand	Category
Z1UK	
ZUK	Partial knee implant
Discovery Elbow	
Discovery® Elbow	Total Elbow implant
Vanguard Knee (Denmark and Sweden)	
Vanguard Complete Knee	Total Knee implant
Vanguard 360	Total Knee implant
Vanguard ROCC	Total Knee implant
Vanguard SSK	Total Knee implant
Vanguard Copy Knee (EEA License)	
Vanguard Complete Knee	Total Knee implant
Vanguard 360	Total Knee implant
Vanguard ROCC	Total Knee implant
Vanguard SSK	Total Knee implant

The Divestment Businesses also include the pipeline products listed below. To the extent any pipeline projects are not exclusively used in the ZUK, Discovery or Vanguard, non-exclusive licenses for their application in the ZUK, Discovery or Vanguard, as applicable, will be provided.

Project	Category
Z1UK	
[...]*	[...]*
[...]*	[...]*
Discovery Elbow	
[...]*	[...]*
Vanguard Knee (Denmark and Sweden)	
[...]*	[...]*e
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*

[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
Vanguard Copy Knee (EEA License)	
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*

Annex 2. Tooling transferred

- (1) The table below lists tooling that would be made available for the ZUK. This is the only machinery that would be made available to a Purchaser; considering that there is no other machinery that is dedicated to the ZUK production.

ZUK			
[...]*			
SZ	Item Number	Robot Arbor Number	
[...]*	[...]*	[...]*	
[...]*	[...]*	[...]*	
[...]*	[...]*	[...]*	
[...]*	[...]*	[...]*	
[...]*	[...]*	[...]*	
[...]*	[...]*	[...]*	
[...]*	[...]*	[...]*	
[...]*			
[...]*			
SZ	Item Number	Vice Number	Jaw Number
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*			
Compression Mould Tooling			
SZ	Item Number	Mold Number	Recipe Number
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*			
SZ	Item Number	Vice Number	
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*

Annex 3. Patents

(1) The following patents will be transferred to the Purchaser:

Patent Number	Title	Country	Grant date	Technology category (instruments, implants etc)
ZUK				
[...]*	[...]*	[...]*	[...]*	[...]*
Discovery				
[...]* ¹	[...]*	[...]*	[...]*	[...]*
[...]* ²	[...]*	[...]*	[...]*	[...]*
Vanguard Knee (Denmark and Sweden)				
[...]*	[...]*	[...]*	[...]*	[...]*
Vanguard Copy Knee (EEA)				
[...]*	[...]*	[...]*	[...]*	[...]*

¹[...]*

²[...]*

Annex 4. Trademarks

(1) The following trademarks will be transferred to the Purchaser:

Trademark name	Registration Date	Registration No.	Country/Region	Status
ZI			JK	
[...]*	[...]*	[...]*	[...]*	[...]*
Discovery				
[...]*	[...]*	[...]*	[...]*	[...]*
Vanguard Knee (Denmark and Sweden)				
[...]*	[...]*	[...]*	[...]*	[...]*
Vanguard Copy Knee (EEA)				
[...]*	[...]*	[...]*	[...]*	[...]*

Annex 5. Internet domain names

(1) The following domain names form part of the Divestment Businesses.

- **ZUK:** [...]*.
- **Discovery:** [...]*.
- **Vanguard Knee:** [...]*.

Annex 6. IP rights that are not exclusively used by the Divestment Business

- (1) A non-exclusive, non-transferrable license strictly limited to use with the products in the relevant Divestment Businesses and in the relevant countries (whether EEA or Sweden and Denmark depending on the Divestment Business) will be granted to the Purchaser for the following patents:

Patent Number	Title	Country	Grant date	Technology category
ZUK				
[...]*	[...]*	[...]*	[...]*	[...]*
Discovery.				
[...]*	[...]*	[...]*	[...]*	[...]*
Vanguard Knee (Denmark and Sweden)				
[...]* ³	[...]*	[...]*	[...]*	[...]*
[...]* ⁴	[...]*	[...]*	[...]*	[...]*
[...]* ⁵	[...]*	[...]*	[...]*	[...]*
Vanguard Copy Knee (EEA license)				
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*
[...]* ⁶	[...]*	[...]*	[...]*	[...]*

³[...]*.

⁴[...]*.

⁵[...]*.

⁶[...]*.

[...]*	[...]*	[...]*	[...]*	[...]*
[...]* ⁷	[...]*	[...]*	[...]*	[...]*
[...]* ⁸	[...]*	[...]*	[...]*	[...]*
[...]	[...]	[...]	[...]	[...]
[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*

- (2) A non-exclusive, non-transferrable license strictly limited to use with the products in the relevant Divestment Businesses and in the relevant countries (whether EEA or Sweden and Denmark depending on the Divestment Business) will be granted to the Purchaser for the following trademarks:

Registration No.	Registration Date	Trademark name	Country/Region
ZUK			
[...]*	[...]*	[...]*	[...]*
Discovery			
[...]*	[...]*	[...]*	[...]*
Vanguard Knee (Denmark and Sweden)			
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*
Vanguard Copy Knee (EEA)			
[...]*	[...]*	[...]*	[...]*

⁷[...]*

⁸[...]*

Annex 9. Consultancy and Development Agreements

(1) The following consultancy and development agreements are relevant to the Divestment Businesses:

Product developer	Description	Contract termination	Reason for termination	Transferability (Y/N)	Reason for non-transferability	Royalty rate payable by Purchaser	Territory
ZUK							
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
Discovery							
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
Vanguard Knee (Denmark and Sweden)							
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*	[...]*
Vanguard Copy Knee (EEA)							
N/A							

Annex 10. Customer contracts pertaining to Divestment Business

- (1) For a list of customer contracts please refer to the following excel files:
 - (a) For ZUK Divestment Business: "M.7265 - Annex 10 supplementary - ZUK - customer contracts.xls";and
 - (b) For Discovery and Vanguard Knee (Denmark and Sweden) Divestment Businesses: "M.7265 - Annex 10 supplementary - Discovery, VG - supply contracts.xlsx".
- (2) This includes: (a) customer contact details; (b) type of customer; (c) type of supply contract; and (d) sales to each customer across various segments for the last three years, as appropriate.

Annex 11. Customer List

- (1) For a list of top customers per product of Divestment Business along with the net sales in 2013 to each customer please refer to the following excel files:
 - (a) For ZUK Divestment Business: "M.7265 - Annex 11 supplementary - ZUK - Top customers.xlsx"; and
 - (b) For Discovery and Vanguard Knee (Denmark and Sweden) Divestment Businesses: "M.7265 - Annex 11 supplementary - Discovery, VG- Top customers.xls".

(3) For the Vanguard Knee, the Merged Entity would make available the following number of **sales representatives** who can provide assistance in the Operating Room and training **at country level**:

Vanguard (Denmark and Sweden)	
Country	Total Sales Reps offered
[...]*	[...]*
[...]*	[...]*
[...]*	[...]*

Annex 13. Transitional arrangements

(1) Supply or manufacturing arrangements

Zimmer will provide non-exclusive transitional supply or manufacturing arrangements with respect to products belonging to the following product lines: ZUK Product Line, Discovery Elbow Product Line and Vanguard Knee Product Line in Denmark and Sweden only and listed in **Annex 1**.

The arrangements will be concluded for a transitional period of up to 24 months from Closing. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Monitoring Trustee deems necessary (the "**Transitional Period**").

The supply/service arrangements will be offered on terms and conditions that are equivalent to those at present afforded to the Divestment Businesses (including at the same quality level at which the products are offered at present by the Divestment Businesses) to maintain the viability and competitiveness of the Divestment Businesses.

The supply or manufacturing agreements shall include appropriate provisions with regard to regulatory compliance.

During the Transitional Period, the Relevant Products will be sold to the Purchaser on a reasonable cost-plus margin basis" at a level consistent with standard industry practice.

The Purchaser shall be required to transfer to Zimmer non-binding forecasts of its reasonably expected requirements for the Relevant Product[s] (firm and binding as to the next three months).

The supply agreement shall include appropriate provisions with regard to Zimmer building and keeping an adequate safety stock of products as well as ensuring necessary manufacturing capacity at all times during the duration of the transitional arrangement. The Monitoring Trustee may recommend appropriate safety stock levels to ensure security of supply, or if necessary, such additional supply-related measures as may be reasonably needed to ensure that product is available to the Purchaser.

The Purchaser may terminate the supply agreement at its discretion on six months' notice.

Delivery of the Relevant Products will be made in a timely manner.

Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside the personnel necessary to effectuate the supply or manufacturing arrangements.

(2) Transitional technical assistance

Zimmer will provide transitional technical assistance to enable the Purchaser(s) to assume responsibility for the manufacturing, marketing and sale of the ZUK Product Line, Discovery Elbow Product Line and Vanguard Knee Product Line in Denmark and Sweden only.

Such assistance may include assisting the Purchaser to establish manufacturing processes, inventory management, warehousing and distribution, billing and collections, supplier management and regulatory support.

Technical assistance will be offered for a transitional period of up to 24 months, with the possibility of an additional extension of 12 months if the Monitoring Trustee deems necessary.

Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside the personnel necessary to effectuate the transitional technical assistance.

(3) Training

Zimmer will provide, training on the ZUK Product Line, Discovery Elbow Product Line and Vanguard Knee Product Line in Denmark and Sweden only. The training should include training on manufacturing, marketing and sales promotion on all aspects of the Divestment Businesses.