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Information and Notices

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[1] Text with EEA relevance

(Continued overleaf)

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[1] Text with EEA relevance

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Authorisation for State aid pursuant to Articles 107 and 108 of the TFEU

Cases where the Commission raises no objections

(Text with EEA relevance)

(2013/C 206/01)

Date of adoption of the decision	6.6.2013	
Reference number of State Aid	SA.35027 (12/N)	
Member State	Poland	
Region	Podlaskie	—
Title (and/or name of the beneficiary)	Budowa szerokopasmowej sieci dystrybucyjnej z publicznymi punktami dostępu do Internetu na terenie gmin: Mońki, Knyszyn, Goniądz i Jaświły	
Legal basis	1) Ustawa o zasadach prowadzenia polityki rozwoju 2) Ustawa o wspieraniu rozwoju usług i sieci telekomunikacyjnych 3) Ustawa o postępowaniu w sprawach dotyczących pomocy publicznej 4) Uchwała Rady Ministrów w sprawie zakresu i warunków dofinansowania Regionalnego Programu Operacyjnego Województwa Podlaskiego na lata 2007–2013, przyjętego decyzją Komisji nr K(2007) 5085	
Type of measure	Individual aid	—
Objective	Sectoral development, Regional development	
Form of aid	Direct grant	
Budget	Overall budget: PLN 7,60 million	
Intensity	—	
Duration (period)	From 6.6.2013	
Economic sectors	Wired telecommunications activities, Wireless telecommunications activities	

Name and address of the granting authority	Gmina Mońki (lider porozumienia gmin) ul. Słowackiego 5a 19-100 Mońki POLSKA/POLAND Zarząd Województwa Podlaskiego ul. Kardynała Stefana Wyszyńskiego 1 15-888 Białystok POLSKA/POLAND
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

http://ec.europa.eu/competition/elojade/isef/index.cfm

Date of adoption of the decision	6.6.2013	
Reference number of State Aid	SA.35028 (12/N)	
Member State	Poland	
Region	Podlaskie	—
Title (and/or name of the beneficiary)	Budowa bezprzewodowej sieci internetowej obsługującej teren gminy Bakałarzewo	
Legal basis	1) Ustawa o zasadach prowadzenia polityki rozwoju 2) Ustawa o wspieraniu rozwoju usług i sieci telekomunikacyjnych 3) Ustawa o postępowaniu w sprawach dotyczących pomocy publicznej 4) Uchwała Rady Ministrów w sprawie zakresu i warunków dofinansowania Regionalnego Programu Operacyjnego Województwa Podlaskiego na lata 2007–2013, przyjętego decyzją Komisji nr K(2007) 5085	
Type of measure	Individual aid	—
Objective	Sectoral development, Regional development	
Form of aid	Direct grant	
Budget	Overall budget: PLN 2,80 million	
Intensity	—	
Duration (period)	From 6.6.2013	
Economic sectors	Wired telecommunications activities, Wireless telecommunications activities	
Name and address of the granting authority	Gmina Bakałarzewo ul. Rynek 3 16-423 Bakałarzewo POLSKA/POLAND Zarząd Województwa Podlaskiego ul. Kardynała Stefana Wyszyńskiego 1 15-888 Białystok POLSKA/POLAND	
Other information	—	

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

http://ec.europa.eu/competition/elojade/isef/index.cfm

Date of adoption of the decision	6.6.2013	
Reference number of State Aid	SA.35029 (12/N)	
Member State	Poland	
Region	Podlaskie	—
Title (and/or name of the beneficiary)	Budowa nadbużańskiej szerokopasmowej sieci dystrybucyjnej	
Legal basis	1) Ustawa o zasadach prowadzenia polityki rozwoju 2) Ustawa o wspieraniu rozwoju usług i sieci telekomunikacyjnych 3) Ustawa o postępowaniu w sprawach dotyczących pomocy publicznej 4) Uchwała Rady Ministrów w sprawie zakresu i warunków dofinansowania Regionalnego Programu Operacyjnego Województwa Podlaskiego na lata 2007–2013, przyjętego decyzją Komisji nr K(2007) 5085	
Type of measure	Individual aid	—
Objective	Sectoral development, Regional development	
Form of aid	Direct grant	
Budget	Overall budget: PLN 39,50 million	
Intensity	—	
Duration (period)	From 6.6.2013	
Economic sectors	Wired telecommunications activities, Wireless telecommunications activities	
Name and address of the granting authority	Gmina Drohiczyn (lider projektu) ul. Kraszewskiego 5 17-312 Drohiczyn POLSKA/POLAND Zarząd Województwa Podlaskiego ul. Kardynała Stefana Wyszyńskiego 1 15-888 Białystok POLSKA/POLAND	
Other information	—	

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

http://ec.europa.eu/competition/elojade/isef/index.cfm

Non-opposition to a notified concentration

(Case COMP/M.6938 — MAHLE/Behr KG)

(Text with EEA relevance)

(2013/C 206/02)

On 16 July 2013, the Commission decided not to oppose the above notified concentration and to declare it compatible with the common market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004. The full text of the decision is available only in German and will be made public after it is cleared of any business secrets it may contain. It will be available:

— in the merger section of the Competition website of the Commission (http://ec.europa.eu/competition/mergers/cases/). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,

— in electronic form on the EUR-Lex website (http://eur-lex.europa.eu/en/index.htm) under document number 32013M6938. EUR-Lex is the on-line access to the European law.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Euro exchange rates [1]

19 July 2013

(2013/C 206/03)

1 euro =

Currency		Exchange rate	Currency		Exchange rate
USD	US dollar	1,3123	AUD	Australian dollar	1,4240
JPY	Japanese yen	131,67	CAD	Canadian dollar	1,3618
DKK	Danish krone	7,4573	HKD	Hong Kong dollar	10,1804
GBP	Pound sterling	0,85995	NZD	New Zealand dollar	1,6471
SEK	Swedish krona	8,5933	SGD	Singapore dollar	1,6591
CHF	Swiss franc	1,2361	KRW	South Korean won	1 471,58
ISK	Iceland króna		ZAR	South African rand	12,9325
NOK	Norwegian krone	7,8560	CNY	Chinese yuan renminbi	8,0548
BGN	Bulgarian lev	1,9558	HRK	Croatian kuna	7,5165
CZK	Czech koruna	25,931	IDR	Indonesian rupiah	13 224,81
HUF	Hungarian forint	295,58	MYR	Malaysian ringgit	4,1915
LTL	Lithuanian litas	3,4528	PHP	Philippine peso	56,922
LVL	Latvian lats	0,7025	RUB	Russian rouble	42,4580
PLN	Polish zloty	4,2468	THB	Thai baht	40,724
RON	Romanian leu	4,4258	BRL	Brazilian real	2,9173
TRY	Turkish lira	2,5227	MXN	Mexican peso	16,3913
			INR	Indian rupee	78,0880

[1] *Source*: reference exchange rate published by the ECB.

Opinion of the Advisory Committee on Mergers given at its meeting of 28 March 2012 regarding a draft decision relating to Case COMP/M.6266 — Johnson & Johnson/Synthes

Rapporteur: Czech Republic

(2013/C 206/04)

1. The Advisory Committee agrees with the Commission that the notified operation constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

2. The Advisory Committee agrees with the Commission that the notified transaction has a Union dimension pursuant to Article 1 of the Merger Regulation.

3. The Advisory Committee agrees with the Commission's definitions of the relevant product and geographic markets as stated in the draft decision.

4. The Advisory Committee agrees with the Commission's assessment that the notified transaction would not lead to a significant impediment of effective competition in the markets concerned in the areas of: (1) spine devices; (2) shoulder devices; (3) cranio-maxillofacial devices; and (4) power tools.

5. The Advisory Committee agrees with the Commission's assessment that the notified transaction, as originally proposed by the notifying parties, would lead to a significant impediment of effective competition in the following markets:

   — non-anatomic plating systems in Denmark, Norway, Slovenia, Sweden and the UK,

   — anatomic wrist plating systems in Norway, Portugal, Spain, Sweden and the UK,

   — anatomic shoulder plating systems in Portugal, Sweden and the UK,

   — anatomic ankle plating systems in France, Germany, Portugal and the UK,

   — anatomic knee plating systems in the Czech Republic, Portugal and Slovenia,

   — anatomic elbow plating systems in Portugal, and

   — cannulated screws (irrespective of whether cancellous cannulated screws are considered being a separate market or not) in Austria, Belgium, Estonia, France, Latvia, Luxembourg, the Netherlands, Slovenia, Spain and the UK.

6. The Advisory Committee agrees with the Commission that the commitments offered by the notifying party on 21 February 2012 and as modified on 13 March 2012 address the competition concerns identified by the Commission and will eliminate the significant impediment to effective competition resulting from the notified transaction.

7. The Advisory Committee agrees with the Commission that the notified transaction must therefore be declared compatible with the common market and the functioning of the EEA Agreement.

Final Report of the Hearing Officer [1]

Johnson & Johnson/Synthes

(COMP/M.6266)

(2013/C 206/05)

(1) On 27 September 2011, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation [2] by which Johnson & Johnson ('notifying party') would acquire control, within the meaning of Article 3(1)(b) of the Merger Regulation, of the whole of Synthes Inc. ('Synthes'), by way of purchase of shares (the notifying party and Synthes are referred to as the 'parties').

I. WRITTEN PROCEDURE

(2) On 3 November 2011, the Commission initiated proceedings pursuant to Article 6(1)(c) of the Merger Regulation. A statement of objections ('SO') was subsequently sent to the notifying party on 25 January 2012 for which the deadline to reply was 8 February 2012.

(3) In the SO, the Commission's preliminary findings indicated that the notified concentration would significantly impede effective competition in various national markets for eight spine devices and various national markets for eight trauma devices.

(4) Noticeable in this case is the fact that there did not seem to exist any reliable market share data for the markets affected by the transaction. Hence, the Commission carried out an extensive market reconstruction exercise, which resulted in the creation of a model, producing market share data for a considerable number of competitors, per product and geographic market. The Commission then used the market share of the parties and their competitors as a criteria to identify problematic markets from a competition viewpoint, notably by categorising markets by reference to the market share of the strongest party to the transaction and the increment in market share resulting from it.

(5) The notifying party submitted its reply to the SO (the 'reply') on 8 February 2012. The reply focused on the spine devices markets, since the notifying party had already decided to divest J&J's trauma business.

Access to file

(6) The notifying party was granted access to the file on 26 January, subsequently to which the notifying party submitted several request for further access.

(7) First, the notifying party requested to be given access to market shares for all affected markets. In response, DG Competition granted access to market shares for certain markets in non-confidential form, i.e. market shares were provided in ranges and competitors' names were not disclosed. The notifying party submitted a reasoned submission explaining why such access was insufficient in light of the potential usefulness of the requested information to respond to the objections. As a result, DG Competition agreed to organise a data room in which market shares (in ranges) of the parties and their competitors for all affected markets would be disclosed to the notifying party's legal and economic advisers under strict confidentiality obligations.

(8) Second, the notifying party requested access to 22 specific documents. DG Competition granted access, where possible, to non-confidential versions of those documents and provided explanations for the confidential nature of those documents that could not be disclosed.

(9) Third, the notifying party requested to have access to the model referred to in paragraph 4 above. Already before the SO was sent and access to file granted, the notifying party had lodged formal requests to DG Competition to have access to the model and the data underlying the model, as well as all relevant correspondence with third parties that provided the data. DG Competition rejected these

[1] Pursuant to Articles 16 and 17 of Decision 2011/695/EU of the President of the European Commission of 13 October 2011 on the function and terms of reference of the hearing officer in certain competition proceedings (OJ L 275, 20.10.2011, p. 29), (the 'terms of reference').

[2] Council Regulation (EC) No 139/2004 of 20 January 2004 (OJ L 24, 29.1.2004, p. 1).

requests but indicated that the notifying party would have access to a non-confidential version of the model consisting of all consolidated Excel spreadsheets, including the formulae as well as the allocation of the brands/devices to the product markets, as provided by the competitors. The competitors' sales data was, however, for reasons of confidentiality, deleted in this non-confidential version of the model. In addition, DG Competition indicated that the parties would be granted access to all other information or documents that were necessary to verify the accuracy of the model, notably communications with the data providers. For all these documents the standard access to file procedure was to apply. Finally, the notifying party was informed that it would be granted access to its own market share ranges, as well as those of its competitors, for all markets in the SO.

(10) As soon as access to file was granted, the notifying party brought the matter formally to my attention by means of a reasoned request. Specifically, the notifying party requested that its legal and economic advisors be granted full access, for markets in the SO, to the actual raw sales data provided by third parties and the cumulative total market sizes, as well as access to documents which have been identified as being relevant to the market reconstruction exercise (notably correspondence between third parties and DG Competition). I responded by decision of 3 February, as follows:

— First, I found that the notifying party had not demonstrated that access to confidential sales data submitted by its competitors was indispensable for the exercise of its rights of defence. To justify its request, the notifying party had mostly put forward the risk that DG Competition may have made errors as regards the methodology underpinning the market reconstruction or as regards the handling, manipulation and analysis of the raw data itself (i.e. that errors may have been made in the process of transferring the raw data to the model).

In respect of the methodology used in the market reconstruction, I noted that the notifying party had been granted access to the market reconstruction model itself, by way of a copy of the Excel file stripped from any business secrets but including all underlying formulae. I concluded that this placed the notifying party in a position to check and comment on the methodology of the analysis that had been conducted.

In respect of the handling, manipulation and analysis of the data, I noted that the mere theoretical possibility of clerical errors could not, in and by itself, justify the disclosure of confidential information at the risk of undermining completely the special protection it is afforded under EU law. I nevertheless informed the notifying party that I could consider disclosure of the actual raw sales data in a restricted manner as provided in Article 8(4) of the terms of reference if there were concrete and credible indicia that DG Competition has made mistakes in the reconstruction exercise. No such indicia had been provided thus far [1].

— Second, I found that certain documents requested by the notifying party, namely communications between the Commission and third parties in the context of the market reconstruction exercise, had not been made accessible at all. I did not see any reason for such full confidential treatment, and asked DG Competition to grant access to non-confidential versions of these documents, which was done on 1 February 2012.

(11) On 5 February 2012, the notifying party reiterated its request for full access to the model on the basis of certain alleged anomalies in the model and inconsistencies between their market intelligence and the findings of the market reconstruction exercise. I responded to the request on 7 February 2012, as set out below.

[1] The notifying party however provided arguments that findings in the SO concerning two companies, based on the market reconstruction exercise, seemed contradicted by market intelligence. In order for the notifying party to be able to comment in full in such findings, I asked DG Competition to obtain from these two companies the permission to disclose further confidential information to the notifying party's legal advisers. The companies agreed, and further information was disclosed for one company on 6 February 2012, and for the other company on 10 February 2012. At this occasion, the second company acknowledged some mistakes in its data, and submitted revised sales data, which had an impact on the market shares found by the Commission in the SO for two spine devices markets.

— First, the notifying party had pointed out three specific errors in connection with, on the one hand, some formulae in the model and, on the other hand, the handling of the parties' sales data for some spine products (i.e. errors in the transfer process of the raw data to the model). DG Competition acknowledged the errors, which had no impact on the markets shares set out in the SO, and indicated to me that it was willing to provide the notifying party with updated market share tables, containing corrected information as regards the specific points raised, which I communicated to the notifying party.

— Second, the notifying party made comments on two points in the SO in relation to VCF product markets. The comments were not, however, of a procedural nature and had no connection with the question of access to the model. I nevertheless provided the notifying party with some explanations after having asked DG Competition to comment on the issues.

— Third, the notifying party expressed doubts as to the result of the market reconstruction exercise in relation to a number of important VCF suppliers which allegedly should have been present in certain markets. Having reviewed the notifying party's individual claims, I decided that the notifying party should be given access to redacted versions of certain third party submissions to demonstrate that their respective data had been reported accurately in the SO. In respect of one supplier, which had submitted after the SO revised figures having an impact on market shares in one market, the notifying party was given access to revised market shares for such market via the data room procedure organised on 6 and 7 February.

(12) On 8 February, the notifying party submitted its reply together with a memorandum on the access to the data room ([1]). Both documents contained further arguments casting doubts on the validity of the Commission's market reconstruction exercise. The memorandum highlighted in total around 100 items allegedly wrongly reported from the model to the SO (mostly market shares inaccuracies ([2]) or omitted competitors). In its reply, the notifying party also referred to other elements, such as market intelligence, which appeared to cast doubts over the validity of the market reconstruction. As regards the alleged errors, DG Competition informed me that some competitors had indeed been omitted since they have only a *de minimis* market share and that some of the errors spotted by the notifying party were in fact due to errors in the material made available in the data room. However, DG Competition also recognised that some errors had been made in manually transferring data from the model into the SO.

(13) In light of these elements, I considered that it was necessary to review my decision of 3 February and give the notifying party access to the requested information. Indeed, the number and scope of the mistakes ([3]) made it difficult to exclude that other mistakes had not been made, in particular when inserting raw sales data into the model. In addition, given the importance of the market share analysis in this case, and the adverse nature of such evidence for the notifying party ([4]), mistakes of that kind, if made, could have had an impact on the outcome of the case. Finally, it had to be taken into account that the notifying party could only to a limited extent put forward further concrete and credible indicia that mistakes had been made.

(14) Consequently, I decided to grant further access to the notifying party to: (i) documents containing data and information which the Commission used to compute market shares for the markets for spine devices for which concerns were identified in the SO (i.e. to address concerns relating to the process of transferring the raw data to the model); and (ii) the market reconstruction model with respect to those same markets in order to allow the notifying party to verify the validity of the data used for the SO (i.e. to address concerns relating to the process of transferring the data from the model to the SO).

([1]) About this data room procedure, see paragraph 7 above.
([2]) For example, the market share of one party was overstated in one market ((40-50 %) in the SO instead of (30-40 %) in the model) and, in the same market, the share of one competitor understated ((10-20 %) in the SO instead of (20-30 %) in the model).
([3]) In particular errors in transferring data from the model to the SO.
([4]) See, in this regard, Case T-210/01 *General Electric* v *Commission* [2005] ECR II-5596, paragraph 660.

(15) My decision was notified to the notifying party on 10 February, i.e. one (working) day before the hearing. However, after the oral hearing, DG Competition informed the notifying party of its intention not to maintain the objections in relation to spine devices markets, following which the notifying party withdrew its request for access to the model and underlying data. As a result, my decision of 10 February was not implemented, i.e. the confidential information was not disclosed to the notifying party's advisers.

Interested third person

(16) On 15 February 2012, I accepted a request from Spinal Kinetics Inc. to be heard as interested third person pursuant to Article 16(1) of Regulation (EC) No 802/2004 [1]. I received no additional request from Spinal Kinetics Inc.

II. **ORAL PROCEDURE**

(17) The oral hearing was held on 13 February 2012 and was attended by the notifying party, and its advisors, the Commission services and representatives from ten NCAs, i.e. the Belgian, German, Spanish, French, Irish, Italian, Polish, Finnish, Swedish and British competition authorities.

(18) No incident occurred during the oral hearing.

III. **THE DRAFT DECISION**

(19) Pursuant to Article 16 of the terms of reference, I have examined whether the draft decision deals only with objections in respect of which the parties have been afforded the opportunity of making known their views, and I have come to a positive conclusion.

(20) In the draft decision, the objections contained in the SO in relation to the spine devices markets have been dropped.

IV. **CONCLUDING REMARKS**

(21) Overall, I conclude that all participants in the proceedings have been able to effectively exercise their procedural rights in this case.

Brussels, 3 April 2012.

Michael ALBERS

[1] Commission Regulation (EC) No 802/2004 of 7 April 2004 (OJ L 133, 30.4.2004, p. 1).

Summary of Commission Decision

of 18 April 2012

declaring a concentration compatible with the internal market and the functioning of the EEA Agreement

(Case COMP/M.6266 — J&J/Synthes)

(notified under document C(2012) 2424 final)

(Only the English version is authentic)

(Text with EEA relevance)

(2013/C 206/06)

On 18 April 2012 the Commission adopted a Decision in a merger case under Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings [1]*, and in particular Article 8(2) of that Regulation. A non-confidential version of the full Decision can be found in the authentic language of the case on the website of the Directorate-General for Competition, at the following address:*

http://ec.europa.eu/comm/competition/index_en.html

I. THE PARTIES

(1) J&J is the ultimate parent company of a global group of companies whose activities are divided into three business segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics. Within the latter segment J&J is active through its subsidiary DePuy in the field of trauma and spine devices and shoulder implants, and through its subsidiary Codman and Shurtleff in CMF and power tools.

(2) Synthes is a global medical device group of companies active in the supply of a wide range of medical devices, instruments, implants and biomaterials used for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.

II. THE OPERATION

(3) On 27 September 2011, the European Commission received the notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 (the 'Merger Regulation') by which Johnson & Johnson ('J&J', USA) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of Synthes Inc. ('Synthes', USA), by way of purchase of shares. (J&J is hereinafter referred to as 'the notifying party', J&J and Synthes as 'the parties').

(4) After examination of the notification and a market investigation, the Commission has concluded that the operation falls within the scope of the Merger Regulation and raises serious doubts as to its compatibility with the internal market and with the EEA Agreement. Therefore, the Commission adopted a decision to initiate proceedings pursuant to Article 6(1)(c) of the Merger Regulation on 3 November 2011.

(5) While the decision to open the in-depth investigation identified serious doubts in all five broad areas concerned by the transaction (trauma devices, spinal devices, cranio-maxillofacial devices ('CMF'), shoulder implants and power tools), the second phase market investigation pointed to competition concerns only with respect to various markets for spine and trauma devices.

(6) On 25 January 2012 a Statement of Objections ('SO') pursuant to Article 18 of the Merger Regulation was addressed to the notifying party. The notifying party replied to the SO on 8 February 2012. An Oral Hearing took place on 13 February 2012. No third parties attended the Oral Hearing.

(7) In a State of Play Meeting on 17 February 2012, the Commission informed the parties that based on new evidence collected after the adoption of the SO it would not maintain concerns for spine devices. In order to address competition concerns maintained in the field of trauma devices the notifying party submitted commitments on 21 February 2012. The Commission launched a market test of those commitments on 23 February 2012.

III. THE RELEVANT MARKETS

(8) The proposed transaction has an impact on a number of markets or groups of markets in the area of orthopaedic medical devices, more particularly (i) Trauma devices, which are used to treat bone fractures throughout the upper and lower extremities of the body and pelvis; (ii) Spine devices, which are used to correct various conditions of the spine caused by degenerative disorders, trauma, tumours and deformities; (iii) Shoulder replacement devices, which are used to reconstruct shoulder joints;

[1] OJ L 24, 29.1.2004, p. 1.

(iv) CMF devices, which are used for the treatment of facial and skull fractures; and (v) Power tools, which are surgical tools such as drill systems, drill bits, reamers and saws. The Commission has not examined the orthopaedic medical devices affected by the proposed transaction in prior merger cases.

(9) As a starting point of its investigation the Commission used the above five broad categories of devices. Within each category the Commission has investigated whether the different types of devices belong to separate product markets and whether devices for different anatomies constitute separate product markets.

3.1. **Trauma**

(10) In case of multiple or non-aligned fractures, surgeons apply internal and external fixation devices, which are hereafter referred to as 'trauma devices'. Internal fixation is the surgical application of devices/implants that physically hold a broken bone together, requiring invasive surgical operation. The range of internal fixation devices is broad. Industry reports covering internal fixation devices generally identify the following product categories: (i) plating systems (plates and screws), (ii) Intra-medullary ('IM') nails, (iii) cannulated screws, (iv) compression hip screws, (v) IM hip screws, and (vi) ancillary devices. External fixation devices are minimally invasive appliances used for a wide range of indications, including fracture fixation, limb lengthening and osteotomy.

(11) The majority of the customers and key opinion leaders consider that the different categories of trauma devices are by reasons of product characteristics and their intended use not or only to a certain degree mutually substitutable. Although there seem to be several trauma devices eligible to treat fractures of a specific anatomy, the degree of substitutability between these trauma devices is generally limited. It varies from anatomy to anatomy, and depends on the kind of fracture. As a result, the trauma market does not seem to form one product market only, but needs to be further sub-divided. The significant price differences between different trauma devices also support this view. Furthermore, the results of the market investigation suggest that most of these categories should be further sub-segmented following the devices' anatomic use.

(12) The flexibility of the supply side to switch production is not high enough to define wider markets due to supply side substitution as competitors cannot switch production in the short term (they rather need between 12 months and three years depending on where they are already active), and this cannot be done without significant investment. Therefore, the possibilities to switch production from the supply side rather have to be considered as potential competition.

(13) The results of the market investigation showed that the plating system market is to be further sub-segmented into at least (i) standard (straight) plating systems (of different sizes) and (ii) anatomically shaped plating systems (meant for different anatomies such as shoulder, wrist, elbow, knee, ankle, etc.) each anatomy constituting a different market.

(14) IM nails are long solid or hollow nails made from stainless steel or titanium inserted into the medullary canal of the treated bone. They are primarily used to treat long bone fractures. IM nails for different anatomies can normally not be substituted. In absence of concerns, the market definition (IM nails overall or different anatomies) can be left open in the present case.

(15) A compression hip screw is a specialised form of plating system, designed for the treatment of hip fractures including a screw barrel that penetrates the femoral neck and a plate to which it connects, which stabilises the fracture, and constitutes an own product market.

(16) IM hip screws are also designed for the treatment of hip fractures. They consist of a screw which penetrates the femoral neck and an IM nail to which it connects being inserted into the femur. Unlike compression hip screws, rather than being anchored by a plate external to the shaft of the bone, they are anchored in an IM nail being inside the medullary cavity. They constitute an own product market.

(17) Cannulated screws have a hollowed central shaft enabling them to be inserted over a guide wire or guide pin. Cannulated screws come in various sizes and are used in the fixation of a variety of fractures. The market investigation showed that cannulated screws can further be subdivided into (i) cortical and (ii) cancellous screws as they serve quite different purposes and, therefore, cannot normally be substituted by each other. As even on the broader level the Commission concluded that the proposed transaction creates a significant impediment to effective competition, the exact market definition can be left open for the purposes of this decision.

(18) Characteristics of ancillary devices, namely pins, wires, cables, screws, staples, differ both from the demand side and supply side. However, since the proposed transaction does not raise competition concern under any alternative market definition, it can be left open for the purposes of this decision.

(19) As regards external fixation devices, the market investigation confirmed that universal and specialised external fixation devices cannot be substituted or can be substituted only to a certain degree. In absence of competition concerns, the market definition can be left open.

3.2. **Spine**

(20) There are essentially three types of spine surgical devices, notably (i) fusion devices, (ii) non-fusion (or motion) devices and (iii) Vertebral Compression Fractures ('VCF') systems. The market investigation confirmed that fusion, non-fusion and VCF devices are in general not substitutable due to their product characteristics and intended uses, although the distinction among certain fusion and non-fusion devices is not very clear cut [1].

(21) Fusion devices are used to permanently fuse together vertebrae to stabilise the spine and prevent painful movement. It was confirmed in the investigation that from a demand-side substitution a further segmentation would be appropriate, taking into account the part of spine (thoracolumbar or cervical), the type of device (pedicle screw and rod system, plating system, interbody cage, or corpectomy cage), and the surgical approach (anterior, posterior, transforaminal, or lateral).

(22) The flexibility of the supply-side to switch products and start marketing other product is not high enough to define wider markets due to supply side substitution as competitors cannot switch the production and start marketing them in the short-term. The respondents to the market investigation estimated that this can take up to two years or even longer for complex or innovative products (this includes the time needed for R&D, production, regulatory approvals and putting products on the market).

(23) Based on the market investigation, thoracolumbar (or cervical, in case of cervical devices) pedicle screw and rod-based systems and plating systems are not typically substitutable due to different surgical approaches. Pedicle screw-based systems are inserted through posterior approach, while plating systems are generally inserted through anterior approach. Also, there are differences in spine indications that can be treated with plates and pedicle screws. In the absence of concerns, it can be left open whether thoracolumbar (or cervical) pedicle screw/rod fixation systems and plating systems belong to the same product market.

(24) Interbody cages are meant to replace the intervertebral discs [2]. Cervical interbody devices and lumbar devices are typically not interchangeable, given differences in indications and product characteristics, and constitute separate markets. For lumbar cages, the majority of the respondents considered that there is very limited substitutability between cages for different surgical approaches, i.e. ALIF, TLIF, PLIF, LLIFs, due to different surgical philosophies. However, in the absence of concerns it can be left open whether ALIF, TLIF, PLIF and LLIF devices constitute separate markets.

(25) It can also be left open whether certain 'hybrid' devices, such as cages with inherent screw fixation and/or plate and cage devices constitute separate product markets or rather belong to a broader product markets (e.g. comprising cervical plates and/or cervical interbody cages), as the parties do not overlap with respect to such stand-alone devices and concerns do not arise under any market definition.

(26) Corpectomy cages are intended for the replacement of vertebral bodies and can be of three types: trimmable mesh, stackable/monoblocks, and expandable cages. The devices designed for cervical and for thoracolumbar spine regions are typically not substitutable. As regards the distinction between trimmable mesh, stackable and expandable devices, while there are some differences in their product characteristics (leading to different degrees of ease of use), they all serve the same clinical purpose typically compete in the same product market.

(27) Non-fusion devices are generally used to treat similar pathologies to fusion devices, but instead seek to preserve the natural motion of the spine. The two main segments of non-fusion implants are (a) dynamic stabilisation systems (pedicle-screw-based posterior dynamic stabilisation systems and interspinous stabilisation devices) and (b) artificial discs for lumbar and cervical spine. It can be left open whether non-fusion devices belong to the same relevant product market or whether they should be sub-segmented as concerns do not arise under any market definition.

(28) Vertebral compression fracture (VCF) devices are used in the (minimally invasive) 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 devices are vertebroplasty and vertebral augmentation (VA) products (the latter including the

[1] E.g., interbody cages (fusion) and artificial discs, or traditional pedicle screw/rod fixation systems (fusion) and posterior dynamic stabilisation systems (non-fusion). For the purposes of the present decision it can be left open whether such products belong to separate product markets, as concerns do not arise under any market definition.

[2] They are generally filled with bone graft and have a porous nature to allow for natural bone growth through the device to achieve a stronger fusion.

presently most common technique, kyphoplasty), both involving the injection of cement into the site of the fracture.

(29) Whilst it is true that all VCF treatments have the same patient base (people suffering from VCFs), there are significant differentiating factors between the use of the products, including in particular the devices and skill-set and the price, which, together with physician loyalty, significantly limit the demand-side substitution of vertebroplasty with kyphoplasty. The evidence of the market investigation points to a distinct demand for vertebroplasty products. In addition, there are no apparent commercial incentives to support an argument for wide-spread supply-side substitutability that would justify the delineation of a wider market. This notwithstanding, there appears to be a certain overlap in use and a degree of competition between these products. Further convergence is expected in terms of prices, marketing and product characteristics. Whether there is a distinct market for vertebroplasty on the one hand and kyphoplasty/VA on the other or whether VCF treatments belong to the same relevant market can be left open as the transaction does not raise competition concerns on the basis of either the narrower or the wider market definition.

3.3. **Shoulder replacement**

(30) Shoulder implants are meant for shoulder joint reconstruction and can be classified by pathology, namely — fracture, degenerative or reverse. They can either be necessary for trauma related reasons (fracture shoulder implants), or for degenerative related reasons, such as arthritis (degenerative shoulder implants). There is also procedure whereby parts of the shoulder are reversed compared to the standard shoulder prosthesis (reverse shoulder replacement).

(31) The market investigation showed that competition takes place at the level of the three different pathologies (degenerative, fracture, reverse). It did not indicate that further sub-segmentation according to the level of the intervention (total, stemless, partial, resurfacing or revision) inside each of these three categories by pathology is plausible.

(32) Since the proposed transaction does not raise concerns neither on the basis of a hypothetical overall nor the narrower shoulder implants markets, the market definition can be left open.

3.4. **CMF**

(33) The market investigation showed that (i) cranial stock fixation implants and (ii) custom-made implants have to be considered as two separate markets as the products are not regarded as substitutes by the customers. Also the respective suppliers differ and could not enter the market in a timely manner and without significant investment. Finally, the observed price differences are considerable.

3.5. **Power tools**

(34) Power tools are used by surgeons in a variety of surgical procedures, including trauma, spine, CMF, neurosurgery as well as orthopaedic joint reconstruction. There are essentially three types of power tools: large bone, small bone and high-speed. The market investigation confirmed that the three types of devices are used for different types of operations and cannot be substituted. Furthermore, within high speed power tool, it supported a further segmentation into two categories, high speed power tools (capital equipment and consumables with the exclusion of cranial perforators) and cranial perforators.

3.6. **Relevant geographic market**

(35) The notifying party argues that from a demand-side perspective there are some industry characteristics suggesting that the relevant geographic markets for the medical devices affected by the proposed transaction are national, in particular due to (i) national reimbursement regimes; (ii) national scale of purchasing patterns by hospitals; (iii) national sales organisations of competitors and national price level differences. At the same time, according to the notifying party, from a supply-side perspective there are several factors indicating that the relevant geographic market could also be EEA-wide in particular due to (i) low regulatory barriers (CE Mark); (ii) pan-European (or worldwide) production and R&D and low transport costs; and (iii) the scope of public tenders not being limited to national suppliers.

(36) The market investigation broadly confirmed the points mentioned by the parties. The Commission found that the market structure varies from country to country. There are regional players which are active only in one or some countries. Furthermore, similarly to other medical sectors, the presence of public reimbursement systems in most Member States has partitioned the markets at national level resulting in significant price differences. Hospitals' purchasing behaviour differs from one country to another. Finally, service (training and assistance from the suppliers; quick delivery; presence of sales force) is regarded as essential by hospitals when choosing their suppliers.

(37) In view of the above, the product markets in the present decision are — as in prior cases for medical devices [1] — considered as being national.

IV. **ASSESSMENT**

(38) The decision focuses on the assessment of unilateral effects, despite concentrated markets in some spinal markets, where the merged entity and Medtronic would together have considerable markets shares. The Commission did not find any evidence which would support a theory of harm based on coordinated effects. In particular, the (i) purchasing patterns in the market,

[1] See e.g. Commission Decision of 27 May 2003 in case COMP/M.3146 Smith & Nephew/Centerpulse; Commission Decision of 28 October 1998 in case COMP/M.1286 Johnson & Johnson/DePuy; Commission Decision of 25 August 2005 in case COMP/M.3687 Johnson & Johnson/Guidant.

(ii) the heterogeneity of products (differentiated product markets), (iii) a lack of transparency as regards market shares, contracts won and prices, (iv) the fact that a number of credible competitors are remaining, (v) strong evidence of recent entry, and finally (vi) the absence of any indication of past coordination speak against such a theory.

(39) Moreover, due to lack of evidence the Commission did not maintain competition concerns based on conglomerate effects. Some concerns were raised in the market investigation that the merged entity might start bundling trauma devices with other orthopaedic devices such as joint reconstruction or prostheses. Before the merger, Synthes has been the leading trauma devices supplier in many EEA countries, while J&J is said to be strong in joint reconstruction, so that post-merger J&J might have a leading position in several orthopaedic implant markets. However, the market investigation showed that trauma and prosthetic/joint replacement are not very frequently bought together nor offered together as a package by the manufacturers. In addition, it also appeared that other suppliers would be able to offer packages for trauma and joint replacement devices as they have a similarly broad portfolio.

(40) There were also concerns that the merged entity could expand the scope of the AO Foundation ('AOF'), with which Synthes has an exclusive partnership and which is considered as very important in the field of trauma, to other markets such as joint reconstruction or prosthetics. However, the Commission conclude that this was not a likely scenario. The current cooperation agreement between Synthes and the AOF is not open to other manufacturers and is independent of the question who owns Synthes. The agreement, therefore, is not extended automatically to J&J's products. The Commission also obtained evidence that the expansion of the AOF into new fields (such as spine and CMF) has not proven successful in the past.

(41) Some of the participants in the market investigation have shown concerns about the enlarged product portfolio in spine devices of the merger entity. However, the Commission has found that in spite of its enlarged product portfolio the merged entity will not acquire as a result of the concentration the ability to foreclose its competitors and that a theory based on foreclosure leading to higher prices as a result of exit of some firms is difficult to sustain.

4.1. **Trauma**

(42) The trauma area overall is more consolidated and mature than the spine area. As confirmed by the parties, there have been fewer new entrants in recent times and the level of innovation is in general lower. Accordingly market shares are more informative for the purposes of carrying out the competitive assessment of the proposed transaction in the area of trauma than in the area of spine.

(43) As regards closeness of competition the Commission concludes, based on the results of the market investigation, that in general the parties are not seen as each other's closest competitor and that Stryker is seen as closest competitor to Synthes, while J&J, Smith & Nephew, Zimmer and Königsee are seen as close competitors. However, in some countries, such as Portugal, Spain and the UK, where J&J maintains a strong sales force or has a historically strong foothold, J&J was more often mentioned as closest competitor to Synthes and as exercising a high competitive constraint on Synthes.

(44) In addition to these larger companies there are smaller regional players which focus on certain Member States or groups of Member States. Next to the regional players there are smaller 'niche' players which focus on particular segments, such as plating systems for particular anatomies. These competitors are seen as credible competitors in their region or in their product segment. Hospitals list them as their main or a secondary supplier. However, in the markets where the transaction leads to a significant impediment to effective competition these other competitors are either not present or achieve very limited sales.

(45) Significant barriers to entry and/or expansion exist in the trauma area. The main barriers are the reputation of the brand, and the need to continuously provide training and education to the surgeons, which leads to a high degree of loyalty of surgeons vis-à-vis a certain supplier. Surgeons typically receive training with implants early in their careers and often remain loyal to the same supplier.

(46) Synthes is particularly strong in the training of surgeons in the trauma area in particular as the company cooperates closely with the AOF on the basis of a cooperation agreement. The AOF is funded by Synthes to a significant extent. The founding principles of the AOF include research and development of products and techniques and continuous education and training of surgeons in new surgical procedures. The AOF emphasizes that the training it provides is different from similar organisations because the main emphasis is given to the clinical needs of surgeons. During the practical sessions only Synthes' devices are used.

(47) Furthermore, the AOF fosters an extensive network of surgeons, operating room personnel and scientists. The AOF attracts key opinion leaders, membership in the AOF and participation in the seminars organised by it is seen as very prestigious amongst surgeons. The prestige

and camaraderie associated with AOF further creates strong preferences for the AOF-certified Synthes' products and presents an additional hurdle to switch from Synthes' products to products of another manufacturer.

(48) In addition to the large training capacity, surgeon loyalty to Synthes' products can also be explained by the fact that these products have been developed through the AOF and Synthes with the support of key opinion leaders with clinical needs in mind, and that they have been carefully checked for usability and are reliable. Regarding R&D, the AOF serves as a platform for new product development which satisfies the clinical needs of surgeons. In particular, the AOF has its own quality certification system which is exclusive to Synthes products. AOF-affiliated surgeons decide which R&D will be carried out based on clinical needs, but also Synthes has a right to propose areas of clinical needs and ideas for product development and it has done so on a regular basis.

(49) The proposed transaction further reinforces the training capabilities of Synthes which are unmatched in terms of prestige and size. Synthes also benefits as regards product development from the relationship with the AOF. The Commission concludes that this is likely to make the entry and expansion of competitors more difficult.

(50) The loyalty of surgeons vis-à-vis the AOF and Synthes is a barrier to entry or expansion in the trauma area because surgeons play an important role in the procurement process and in general choose together with (or sometimes against) the procurement department the suppliers of the medical devices. Across all countries the majority of hospitals consider the surgeons' preference for a particular supplier an important, very important or sometimes the most important criterion in purchase decisions. It seems — however to a differing extent — that the procurement departments in hospitals are rarely able to decide against the will of the surgeons. Instead, in most cases the surgeons are involved to some extent and a change of supplier without the backing of the surgeons seems difficult.

(51) In sum, the loyalty of surgeons to a particular supplier with whom they have trained and their reluctance to switch is a high barrier to entry and limits expansion by alternative suppliers.

(52) Consequently, and also due to the fact that trauma is a more mature area, with less innovation taking place, the level of entry overall is low in the trauma markets. To the extent that innovation is happening, it is rather incremental innovation, i.e. the improvement of existing devices. It is in this context of a much lower level of innovation (compared to spine) that also the previously mentioned characteristics of the trauma markets (strong surgeons' loyalty and their influence on purchasing, important role of AOF in training and education, high reputation of Synthes, strong sales force) need to be seen.

(53) In an environment where product innovation does not act as a considerable incentive for surgeons to switch suppliers (in particular to potential new entrants) the above mentioned barriers to entry gain further weight and make switching more difficult and unlikely. The market reconstruction showed that companies which entered a particular market do not capture a significant share (usually less than 5 %) even after several years.

(54) On the basis of the market reconstruction there are overall 112 group 1 markets spread over 23 countries [1]. The market reconstruction showed that markets are highly concentrated. Synthes has a very strong position in the markets for trauma devices with market shares in the different sub-segments of up to 90 %. Synthes also has the largest product portfolio and the widest geographic footprint. J&J is one of several competitors and has in many instances moderate market shares (in most countries and segments below 5 %).

(55) The market investigation confirmed that in a large number of group 1 trauma markets a number of credible competitors remain post transaction and that the changes to the market structure resulting from the merger can be considered limited in most cases.

(56) However, in a number of markets not only the market shares are high, but also the increment added by J&J is significant. In product terms this applies to a number of countries in particular for (cancellous) cannulated screws, wrist plating systems and non-anatomic plating systems.

(57) The Commission concludes that the transaction would not raise competition concerns in trauma markets where at least two other competitors would remain post-transaction both (i) with a market share at least comparable to the increment or (ii) with a significant market share. The decision identifies 33 markets where these conditions are not met and there are no other circumstances (such as overall size of the market being very small and market shares thus not necessarily appropriately reflecting market power or favourable conditions for potential competition from neighbouring countries, etc.) which would remove competition concerns.

(58) No competition concerns were identified in the case of ancillary devices as the hospitals' purchasing patterns do not suggest that any separate demand exists for such devices. Those products are rather purchased with the main (plates) supplier to save transaction costs and to get higher rebates on the overall trauma volume. Competition concerns in regard of IM nails were not maintained because the combined market shares are

[1] Group 1 markets are markets with a combined market share of the parties of at least 35 % and an increment of at least 1 %. In line with case precedents in the field of pharmaceuticals and medical devices the Commission's investigation focused on the group 1 markets.

generally much lower and IM nails do not belong to the core competence of the parties. Two other strong competitors exist, namely Stryker and Smith & Nephew, which are specialised in IM nails and present in all of the group 1 markets.

(59) The decision finds that the notified transaction results into a significant impediment of effective competition due to horizontal unilateral effects in the following markets:

— Non-anatomic plating systems in Norway, Denmark, Slovenia, Sweden, and the UK,

— Anatomic wrist plating systems in Norway, Portugal, Spain, Sweden, and the UK,

— Anatomic shoulder plating systems in Sweden, Portugal and the UK,

— Anatomic ankle plating systems in France, Germany, Portugal and the UK,

— Anatomic knee plating systems in the Czech Republic, Slovenia, and Portugal,

— Anatomic elbow plating systems in Portugal,

— Cannulated screws (irrespective of whether cancellous cannulated screws are considered being a separate market or not) in Luxembourg, Latvia, Slovenia, Estonia, the Netherlands, Austria, Belgium, Poland, France, the UK, Spain and Slovakia.

4.2. **Spine**

(60) Compared to trauma, spine markets are more dynamic and innovative. The European market for spinal implants is growing steadily due to a growing elderly population and a number of product segments drive innovation, such as minimally invasive surgical approaches, products for the aging spine, non-fusion technologies, interbody cages with inherent fixation, and navigation and image guided surgery technologies.

4.2.1. *Spinal fusion*

(61) The overall spinal fusion market is characterised by several leading players (Medtronic (20-30) %, J&J, Synthes and Stryker with (10-20) % each), followed by a large number of other international players, local/regional players and relatively recent US-based entrants. The level of new entry is a key distinguishing feature between spine and trauma markets. Over the last years, a number of entries by US-based international innovative companies, i.e. K2M, Nuvasive, Globus, Alphatec and Biomet, have taken place. Typically new entrants would enter through large markets (UK or Germany) and then expand into other countries. Some of these new entrants have already demonstrated a significant growth in their fields of expertise (e.g. K2M or Nuvasive). The expansion of regional European players into the neighbouring countries can also be observed.

(62) Despite preliminary concerns in the SO, following further investigation and case file analysis, the Commission concluded that post-merger the merged entity would be constrained in particularly by the global spine market leader, Medtronic. The Commission's further investigation showed that even in hypothetical cases where only two suppliers are retained by hospitals, in all group 1 markets Medtronic and J&J/Synthes would not be the only credible suppliers capable of playing a role of the 'main' and 'secondary' supplier (Aesculap, Stryker, Zimmer and others were also considered by hospitals as credible). The Commission has also found that in cases where hospitals source from several suppliers, the differences in volume between the main supplier and secondary supplier can be as high as 60 %. Therefore, Medtronic and J&J/Synthes would still have incentives to compete with each other for the position of the main supplier with the greatest share of volume, rather than 'settle for the second best'. Typically the selection of suppliers does not guarantee volumes and it can be expected that suppliers continue to compete to maximise purchase orders.

(63) In addition to Medtronic, a number of other competitors, including established companies (Stryker, Zimmer, Aesculap, Biomet), new aggressive and innovative entrants (K2M, Alphatec, Nuvasive, Globus) and strong regional companies (e.g., Ulrich, Spine Art) continue to innovate and invest in new products. Following up on the SO, the Commission carried out a further investigation and reconstructed for the spine markets covered by the SO the market share data for 2009 and 2011. The new data showed that the analysis of static historic data for 2010 was in the dynamic spine fusion market not an accurate proxy to measure the ability and incentives of 'smaller' players to compete vigorously, and that market shares of J&J, Synthes and Medtronic are contestable. Some of the existing established 'smaller' players as well as new innovative companies have been able to gain meaningful market shares in the last years in a number of countries concerned by the SO. The investigation has also confirmed further entry plans for a number of markets. In view of this information, the Commission concluded that 'smaller' competitors are credible competitors in their areas of activity and capable of effectively restraining the merged entity.

(64) Although the barriers to entry and expansion is spine fusion are lower compared to trauma (as evidenced by numerous recent entries), the Commission acknowledges that a number of factors may constitute competitive advantages and in some cases may create entry barriers for brand new entrants. These factors include the need to establish surgeon training infrastructures, build a qualified sales force (either direct or through qualified distributors), invest in R&D for new products and establish reputation among leading surgeons.

(65) The need for manufacturers to offer a sufficient level of surgeon training and education in their devices is also a typical feature of spine markets. However, in spine, the AOF has a much more limited reach than in trauma [1]. In the area of spine Medtronic has the largest training capacity in terms of number of surgeons trained and a historic reputation in the area of spine. For other players, the Commission has found that the quality of training and the level of service are not determined by the size of a manufacturer. A number of players are already present across the EEA and offer trainings of comparable quality and efficacy.

(66) As in other surgical device markets, the surgeons play an important role in the selection of surgical devices. However, based on the results of the market investigation surgeons' preferences are in only one of several other important criteria in selection of spinal implant suppliers. Along with surgeons' preferences, respondents more often considered product specifications, service levels, reputation, level of innovation and prices as important, very important or the most important criterion in the purchasing decisions. Unlike in trauma, surgeons' preferences for spine devices are not exclusively focused on Synthes (or J&J) and can vary depending on the surgeons' training and experience with a product.

(67) However, for all group 1 markets concerned by the decision any barriers to entry are of less importance, given that a number of players are either already present in a given market (with comparable and/or innovative products and effective trainings) and/or have sufficiently concrete entry plans.

(68) On the basis of the market reconstruction (2010 data) there are overall 90 group 1 markets in spine fusion, spread over 19 countries [2]. For a vast majority of group 1 markets, the 2010 market reconstruction data has shown that a number of credible competitors would remain post-transaction that can effectively constrain the merged entity. In particular, for those markets the data has demonstrated that at least two other credible competitors would remain, in the majority of cases having a significant market share (i.e. above (10-20) %) or a market share equal or higher than the increment.

(69) For the remaining markets, the Commission has further reconstructed the market share evolution for the years 2009 and 2011, which ultimately confirmed the parties' view that 2010 data alone was not an accurate proxy for measuring the competitive constraint exercised by other players in the innovative spine markets. On the contrary, the market shares of J&J and Synthes in the area of spine proved to be contestable not only by established players, such as Medtronic, but also by new aggressive entrants, such as K2M, Nuvasive. As regards the small markets, the new data showed that market shares can be highly volatile, especially given overall high prices for spine surgical procedures and a relatively small number thereof in those markets.

(70) Further qualitative evidence has also shown that various players continue to innovate and compete on a number of parameters, including product specifications, service levels, reputation, level of innovation and prices. Finally, the vast majority of customer replies confirmed that products of Medtronic and so-called 'smaller' players are credible alternatives to the products of the merging parties and hospitals consider them as capable of meeting significant hospital's demand for spine devices

(71) Against this background, no competition concerns were identified in any of the group 1 markets in spine fusion.

[1] When the AOF was founded, it originally focused on trauma, while it entered spine only later, and did not achieve there the same outstanding position that it achieved in the field of trauma.

[2] Thoracolumbar pedicle screw/rod based fixation devices in Austria, UK, Italy, Germany, Ireland, Netherlands, Estonia, Latvia, Slovenia, Slovakia, Hungary, Finland, Sweden, and Norway; Cervical pedicle screw/rod based fixation devices in Austria, UK, Italy, Germany, Ireland, Netherlands, Spain, Portugal, Estonia, Slovenia, Slovakia, Hungary, Sweden, and Norway; Cervical plating systems in Austria, UK, Germany, Ireland, Netherlands, Estonia, Latvia, Slovenia, Hungary, Denmark, and Luxembourg; ALIF devices in the UK, Germany, the Netherlands, Denmark, Sweden and Estonia; TLIF devices in Austria, Germany, the UK, Denmark, Sweden, Norway, Italy, Spain, Latvia and Hungary; PLIF devices in Austria, Italy, Portugal, and Norway; ACIF devices in Austria, UK, Ireland, Sweden, Portugal, Italy, the Netherlands, Hungary, Estonia, and Slovenia; thoracolumbar corpectomy devices in Norway, Ireland, Hungary, Austria, Portugal, Spain and the UK; cervical corpectomy devices in Austria, Germany, Hungary, Latvia, Poland, Slovakia, Slovenia, Spain, and the UK.

4.2.2. *Non-fusion*

(72) The transaction leads to group 1 markets only in artificial discs in seven countries [1] (overall category and/or sub-segments of cervical and/or lumbar). In general, the recent and successful entry of a specialised supplier of a new innovative product, Spinal Kinetics, into several (including key) national markets shows that market shares in artificial disc markets are in general contestable even in large markets. In four of the seven countries the parties achieve only moderate combined market shares and/or only a small increment and at least two other significant credible competitors remain to constrain the merged entity. In three countries (Sweden, Slovenia, Luxembourg), the transaction would lead to combined market shares of between 50 % and 100 %, but always with a very small increment of < 1 %. In light of the small value of the markets, general indications of possible entry in this product segment and the competitive constraint stemming from other, significant competitors (including Medtronic) in the same and neighbouring countries, concerns can be excluded in these countries as well.

4.2.3. *VCF*

(73) The main overlap of the parties is in vertebroplasty [2]. Based on the Commission's market reconstruction, the transaction would lead to nine group 1 markets in overall VCF and 17 group 1 markets in vertebroplasty. In nine [3] of these countries competition concerns could be excluded prior to the SO. In each of these countries a sufficient number of existing credible competitors would remain to constrain the merged entity. These competitors are often comparable or more significant than the smaller of the merging parties. In some countries (e.g. Estonia, Norway, Sweden), the small size of the market makes it relatively easier to replicate the competitive constraint stemming from the smaller of the merging parties.

(74) In the SO, the Commission preliminarily concluded that the proposed merger would result in a significant impediment of effective competition in relation to vertebroplasty products in eight countries [4]. The competitive pressure stemming from much smaller remaining competitors and the threat of entry by other competitors was on a preliminary basis not considered sufficient to constrain the merged entity due to indications of barriers to entry and expansion. The market investigation following the SO showed, however, that barriers to entry and expansion (mostly training and distribution capabilities) are in VCF in general not so significant as to prevent competitors from challenging the parties' combined positions. In addition, the market investigation and an extended market reconstruction provided, in several countries, concrete examples of successful entry and plans to enter. This, together with the indications of the presence of a sufficient number of vertebroplasty competitors remaining in group 1 countries, as also indicated by hospital replies, led to the conclusion that the parties would continue to be constrained significantly following the merger.

(75) Also, whilst the parties can in general be considered as close competitors in vertebroplasty, J&J's key product is significantly differentiated from other vertebroplasty products (in terms of product characteristics and price) and there is evidence that it also competes with kyphoplasty/VA products, especially in Member States where kyphoplasty is more wide-spread (e.g. Austria). The merged entity will therefore also be constrained to some degree by premium-priced innovative kyphoplasty/VA products.

(76) In the countries where the transaction would lead to group 1 markets even on the wider VCF market, concerns can also be excluded. This is because in addition to the competitive constraints in vertebroplasty markets, the parties would face competition from Medtronic (which still has a dominant position in kyphoplasty/VA in the EEA) and other competitors.

(77) The decision therefore concludes that the transaction does not raise concerns in relation to VCF markets, including the sub-segments of vertebroplasty and kyphoplasty/VA products.

4.3. **Shoulder replacement**

(78) On an EEA basis, J&J is market leader for shoulder implants overall, followed by a number of other internationally active competitors, such as Biomet, Tornier, Zimmer, Lima and Arthrex. Synthes is number 7 at the EEA level, followed by a number of smaller or regional competitors.

[1] Austria, Finland, France, Hungary, Luxembourg, Slovenia, Sweden.

[2] In kyphoplasty, the issue is only one of potential competition from J&J. Whilst J&J has a kyphoplasty pipeline, the market investigation did not indicate that J&J would present a stronger potential competitive constraint on synthes in kyphoplasty/VA than other existing and potential competitors, and, in particular, the market leader, Medtronic.

[3] Belgium, Estonia, Finland, Germany, Greece, Italy, Norway, Spain, UK.

[4] Austria, Czech Republic, Denmark, Hungary, Latvia, Poland, Portugal, Slovakia.

(79) J&J, Biomet, Tornier and Zimmer provide different products specific for each of the three shoulder replacement segments. All are leading and successful global orthopaedics companies, with a particular focus on shoulder implants, are present in the seven biggest national markets in the EEA (Germany, France, the UK, Italy, Spain, the Netherlands and Belgium) and vigorously competing between themselves. Lima, Arthrex and Synthes provide only one product, which however can be used for more than one condition.

(80) To a very large extent J&J and Synthes are not perceived as being each other's closest competitors, neither by competitors nor by hospitals. Also in the internal documents of the parties no indication was found that they would compete closely. Surgeons' preferences were not ranked as a very important selection criterion for procurement by hospitals, neither by competitors nor by the hospitals themselves. The AOF is not active in shoulder implants. Training is provided by the manufacturers themselves (or their suppliers).As a general remark, neither hospitals nor competitors voiced particular concerns about the transaction in the area of shoulder replacements.

(81) On the supply side, the majority of the international market players have confirmed that they could expand output and could enter a national market within one to two years in the event of an increased demand due for example to a price increase by the merged entity, especially if they were already active in neighbouring countries. There is widespread evidence that there have been recent entries in a number of national markets. On the demand side, hospitals have confirmed that their surgeons would accept switching suppliers in the event of a price increase. All of the suppliers active in their respective countries were listed as credible competitors to the parties and also as participating in the purchasing procedures.

(82) On the basis of the market reconstruction, there are 12 group 1 markets for overall shoulder implants (Poland, Austria, Portugal, Finland, Hungary, Belgium, Sweden, Germany, the UK, Luxembourg, Spain and Norway), eight group 1 markets for degenerative shoulder implants (Poland, Finland, Portugal Austria, Denmark, the UK, Hungary and Sweden) and six group 1 markets for fracture shoulder implants are (Poland Finland, Norway, the UK, Sweden and Luxembourg). In most markets at least two competitors remain with market shares above or around the increment brought by the transaction. In six markets this is not the case, but there is always at least one strong competitor remaining, the markets are partly very small, so that the award of a tender to a different supplier would change the market shares which thus do not adequately reflect the actual market strength, and partly recent entry was confirmed. Taking also into account the general characteristics described above, the Commission concludes that the transaction does not raise concerns in these markets.

(83) Synthes is currently not active in the reverse shoulder implant market, but intends to launch a product in 2013. J&J is market leader at the EEA level and in most national markets. There are a number of strong competitors in this product market. No competitor said in the market investigation to be concerned about the impact of the transaction on this segment, even taking into account a hypothetical entry of Synthes with an own product. Based on this the Commission concludes that the transaction does not raise concerns for reverse shoulder implants.

4.4. **CMF**

(84) (…) of J&J's CMF sales are focused on the cranial region. J&J is not a major player in the overall CMF business. Synthes manufactures and sells a full range of CMF implants, with maxillofacial devices representing the majority of its sales.

(85) Cranial stock implants are largely commoditised. Procurement is typically entrusted to the hospital administrations which are focused on price, given the highly substitutable nature of competing products. The replies of competitors and hospitals in the context of the market investigation show that the tender selection criteria 'price' has a significant weight (between 50 % and 100 %) and is considered to become more important in the next years.

(86) Custom-made implants are significantly more expensive than cranial or maxillofacial stock implants and a market price does not exist. Hospitals do not typically organise tenders for the purchase of custom-made implants as the surgeon will generally decide in each individual case whether the patient needs a custom-made implant. Hospitals therefore usually make few requests for custom-made implants. Prices are determined on the basis of criteria like material, weight and complexity.

(87) Given the presence of a high number of global and niche players both markets are highly competitive and price sensitive. At the same time local sales forces and contact points with the hospitals are required. As a consequence, these markets became less attractive for the well established players (i.e. Medtronic has quit the cranial stock and custom-made implant markets in the last years, J&J's sales in the overall growing cranial stock implant market are decreasing).

(88) Barriers to entry are low in the CMF device market. A high number of the competitors either have recently entered or have plans to enter a new national market. In addition,

low cost suppliers from Turkey, India, Korea and China have also entered the market, first targeting Eastern-European countries, mainly in the maxillofacial area.

(89) According to the data submitted by the notifying party, there are in total six group 1 markets [1]. In most cases either Synthes or J&J is already market leader and the merger reinforces this position. In each market at least four to six competitors are present (of which always three to four have market shares above 5 %). No competitor or customer has expressed concerns that the merged entity will be able to constrain competition, nor claimed in a substantiated way that there will be any negative effect on competition and prices. Based on these considerations the Commission concludes that the transaction does not raise concerns in the area of CMF implants.

4.5. **Power tools**

(90) J&J's presence in the market for high speed power tools (capital equipment and consumables with the exclusion of cranial perforators) is rather low (less than EUR 1 million). For technical compatibility reasons, Synthes' cranial perforator is actually not competing with J&J's cranial perforators. Synthes' market presence is almost immaterial. It can therefore be accepted that the cranial perforators market is not an affected market.

(91) According to the data submitted by the notifying party, there is only one group 1 market, Italy. Synthes is already market leader and the merger reinforces this position. The increment added by J&J is small, and there are at least three other well-established competitors with considerably higher market shares than J&J, so that the merger will not change the competitive pressure on the market leader. Based on these considerations the Commission concludes that the transaction does not raise concerns in the area of power tools.

4.6. **Conclusion on the competitive assessment**

(92) On the basis of the analysis outlined above, the Commission concluded that the notified transaction would significantly impede effective competition in a substantial part of the internal market within the meaning of Article 2 of the Merger Regulation for the trauma markets identified above. Therefore, the Commission has come to the conclusion that the notified transaction is incompatible with the internal market and the functioning of the EEA Agreement.

4.7. **Undertakings submitted by the parties**

(93) In order to address the aforementioned competition concerns in some of the trauma markets, J&J offered to divest its trauma business currently operated by J&J's subsidiary DePuy in the EEA. The commitment will be implemented by way of an asset sale, most likely as part of a divestiture of DePuy's worldwide trauma business.

(94) The business to be divested ('the Divestment Business') essentially includes — all relating directly and predominantly to J&J's trauma products — DePuy's R&D facility, rights to develop and produce trauma devices, main production facility or the production equipment if requested, inventory, the rights to market and sell trauma devices in the EEA, sales and marketing personnel in the EEA and rights under customer contracts in the EEA.

(95) The divestment business covers all overlaps between the parties in the trauma area so that the commitment proposal remedies the possible adverse impact on competition that the concentration would bring in the above mentioned markets. The market test confirmed the viability of the divestment business. It also showed that the transitional agreements submitted are sufficient to ensure a successful take over.

(96) In its decision, the Commission has, therefore, reached the conclusion that, on the basis of J&J's commitment to divest its trauma business, the notified concentration will not lead to a significant impediment of effective competition in any of the trauma markets concerned.

V. **CONCLUSION**

(97) The decision concludes that, subject to full compliance with the commitment submitted by the Parties, the proposed concentration would not significantly impede effective competition in the internal market or in a substantial part of it. Consequently, this suggests declaring the concentration compatible with the internal market and the EEA Agreement, in accordance with Article 2(2) and Article 8(2) of the Merger Regulation and Article 57 of the EEA Agreement.

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[1] Due to the existence of a high number of local or regional players it was not possible for the Commission to reconstruct the market.

V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case COMP/M.6956 — Telefónica/CaixaBank/Banco Santander/JV)

(Text with EEA relevance)

(2013/C 206/07)

1. On 11 July 2013, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 [1] by which the undertakings Telefónica, SA ('Telefónica', Spain), CaixaBank, SA ('CaixaBank', Spain), controlled by La Caixa, Caja de Ahorros ('La Caixa', Spain) and Banco Santander, SA ('Banco Santander', Spain) acquire within the meaning of Article 3(1)(b) of the Merger Regulation joint control of the undertaking Newco (Spain) by way of purchase of shares in a newly created company constituting a joint venture.

2. The business activities of the undertakings concerned are:

— for Telefónica: international group active in the telecommunications sector that provides communication, information and entertainment solutions in a number of EU Member States as well as in a number of countries in Latin America,

— for CaixaBank: financial institution,

— for La Caixa: integrated financial group with banking, insurance, pension and investment fund activities, mainly in Spain,

— for Banco Santander: international banking and financial group active in retail banking, asset management, corporate and investment banking, treasury and insurance,

— for Newco: provision of a variety of services to businesses and consumers, such as advertising services to small and medium size merchants, communication of discounts, vouchers, offers and coupon redemption services to consumers, digital wallet services, and peer-to-peer payment services to consumers.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope the EC Merger Regulation. However, the final decision on this point is reserved.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

[1] OJ L 24, 29.1.2004, p. 1 (the 'EC Merger Regulation').

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by e-mail to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number COMP/M.6956 — Telefónica/CaixaBank/Banco Santander/JV, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

CORRIGENDA

Corrigendum to Commission communication in the framework of the implementation of Commission Regulation (EU) No 1016/2010 of 10 November 2010 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household dishwashers and of Commission Delegated Regulation (EU) No 1059/2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household dishwashers

(Official Journal of the European Union C 169 of 14 June 2013)

(2013/C 206/08)

On page 1:

for:

'ESO ([1])	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1	First publication OJ
(1)	(2)	(3)	(4)	(5)
Cenelec	EN 50242:2008 Electric dishwashers for household use - Methods for measuring the performance IEC 60436:2004 (Modified)			This is the first publication
	EN 50242:2008/A11:2012 IEC 60436:2004/A1:2009 (Modified) + IEC 60436:2004/A2:2012 (Modified)	Note 3	6.8.2013	This is the first publication'

read:

'ESO ([1])	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1	First publication OJ
(1)	(2)	(3)	(4)	(5)
Cenelec	EN 50242:2008 Electric dishwashers for household use - Methods for measuring the performance IEC 60436:2004 (Modified)			This is the first publication
	EN 50242:2008/A11:2012 IEC 60436:2004/A1:2009 (Modified) + IEC 60436:2004/A2:2012 (Modified)	Note 3	6.8.2013	This is the first publication

Clause Z2 on tolerances and control procedures is not part of the present citation.'

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