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;
(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 subdivided. 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 Fracture (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,

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.

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.

There were also concerns that the merged entity could expand the scope of the AO Foundation (‘AOF’), 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.

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

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

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.

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.

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.

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.

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.

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.

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.

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 %).

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.

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.

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.

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

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(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 Nuasive). 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.
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.

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. 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.

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.

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.

On the basis of the market reconstruction (2010 data) there are overall 90 group 1 markets in spine fusion.

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.

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.

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

(1) 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.
(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 are 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 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.