Competition Commission SINGAPORE

Section 57 of the Competition Act (Cap. 50B)

Grounds of Decision issued by the Competition Commission of Singapore

In relation to the notification for decision of the proposed acquisition by Johnson & Johnson of Synthes, Inc. pursuant to section 57 of the Competition Act

5 January 2012

Case number: CCS 400/009/11

Competition Commission of Singapore
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I. Introduction

The notification

1. On 11 November 2011, CCS accepted the filing of a joint notification under section 57 of the Competition Act ("the Act") made by Johnson & Johnson ("J&J") and Synthes, Inc. ("Synthes")(collectively "the Parties"), applying for a decision by the Competition Commission of Singapore ("CCS") as to whether the acquisition by J&J of all the voting securities in Synthes will infringe the section 54 prohibition of the Act ("the Transaction").

2. CCS has sought the views of 4[1] competitors, 6[2] customers and 4[3] suppliers in the markets for the supply of spine devices, the supply of trauma devices, and the supply of bone graft substitutes. Due to the range of products supplied by manufacturers in these markets, there is significant overlap in the competitors and the customers of the products in these markets. There were also a number of third parties who indicated that they had no comments or declined to comment on the notified Transaction.

3. At the end of the consultation process and after evaluating all the submissions, CCS has concluded that the Transaction will not infringe section 54 of the Act (Cap. 50B).

II. The Parties

Johnson & Johnson

4. 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.[4] The Transaction involves J&J's Medical Devices & Diagnostics ("MD&D") segment. J&J is active in this area, both globally and in Singapore, in the field of orthopaedic medical devices through its DePuy family of companies, including DePuy Orthopaedics, Inc., DePuy Spine, Inc., DePuy Mitek, Inc. and Codman & Shurtleff, Inc. (collectively referred to as "Depuy").[5]

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[1] [✂]
[2] [✂]
[3] [✂]
[4] Paragraph 2.2.2 of Form M1
[5] Paragraph 3.1.17 of Form M1

5. The Singapore turnover of J&J's MD&D segment was [✂] and the worldwide turnover for J&J's MD&D business was US$24.6 billion in the financial year ended 2 January 2011.[6]

Synthes

6. Synthes is a global medical device company, which, through its six product groups (Trauma, Spine, Cranio-Maxillofacial, Biomaterials, Power Tools and Veterinary) develops, produces and markets instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.[7]

7. The Singapore turnover of Synthes was [✂] and the worldwide turnover of Synthes was US$3.7 billion in the financial year ended 31 December 2010.[8]

III. The Transaction

8. The notified Transaction will result in J&J acquiring sole control of Synthes by acquiring all the voting securities in Synthes.[9] At the time of the notification, it had not been completed. Apart from this notification to the CCS, the Transaction has been notified in the European Union on 27 September 2011, the United States where it was re-filed on 7 July 2011, Australia on 18 October 2011, [✂].[10] Completion of the Transaction is subject to obtaining the approvals of the European Commission, the Federal Trade Commission of the United States and the national competition authorities of [✂]. [11]

9. The Parties have submitted that they expect a combined Synthes and DePuy would be better positioned to address significant market trends in Singapore. These include an aging population, patient desire to remain active, increasing

[6] Paragraph 3.1.8 of Form M1
[7] Paragraph 3.1.9 of Form M1
[8] Paragraph 3.1.10 of Form M1 and Page CG11 of Synthes' Annual Report of 2010. The number of Synthes, Inc. shares held by all members of the Board of Directors and the Group Management Committee, including parties closely linked to such persons, is 57,801,959 (including shares held by the Wyss family trusts, for which Amy Wyss is a beneficiary). "Persons closely linked to them" are: (i) their spouse, (ii) their children under age 18, (iii) any legal entities that they own or otherwise control, or (iv) any legal or natural person who is acting as their fiduciary. The total number of shares held by the nine non-executive members of the Board of Directors and parties closely linked to such persons amounted to 9,977,179 (including shares held by the Wyss family trusts).
[9] Paragraphs 3.1.2 and 3.1.3 of Form M1. As a result of the merger, each share of issued and outstanding common stock in Synthes will be converted into the right to receive approximately 35% and 65% of the value of the share in cash and J&J common stock respectively. No public tender offer will take place.
[10] Paragraph 1.5.1 of Form M1
[11] Paragraph 3.1.21 of Form M1

rates of obesity and the resulting impact on joint disease, growing treatment demands in emerging markets and a movement towards earlier intervention.[12]

10. Specifically, the Parties expect to bring together product development capabilities and pipelines from the two organizations, global reach to bring a broader portfolio of orthopaedic solutions, and expertise in professional education.[13]

11. The Parties [✂].[14]

12. Based on the Parties' submission that the Transaction is an acquisition of sole control by J&J over Synthes, the Transaction constitutes a merger pursuant to s 54(2)(b) of the Act[15].

IV. Competition Issues

13. As set out in the CCS Guidelines on the Substantive Assessment of Mergers, CCS is generally of the view that competition concerns are unlikely to arise in a merger situation unless the merged entity will have a market share of 40% or more or the merged entity will have a market share of more than 20% with the post-merger CR3[16] at 70% or more[17].

14. For this transaction, the Parties have submitted that the Parties overlap in the supply for three categories of devices: spine devices, trauma devices and bone graft substitutes ("BGS"). The market share estimates submitted by the parties in the markets for spine devices and trauma devices exceed the indicative thresholds set out in the CCS Guidelines. Although the market share estimates of the Parties in the market for the supply of BGS do not exceed the indicative threshold, CCS has nonetheless sought the views of third parties to ascertain the potential impact of the Transaction in this market.

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[12] Paragraph 3.2.1 of Form M1
[13] Paragraph 3.2.1 of Form M1
[14] Response from Allen & Gledhill received via email on 6th December 2011.
[15] Section 54(2)(b) provides that a merger occurs if one or more persons or other undertakings acquire direct or indirect control of the whole or part of one or more other undertakings.
[16] Paragraph 5.14 of *CCS Guidelines on the Substantive Assessment of Mergers*. CR3 refers to the combined market shares of the three largest firms.
[17] Paragraph 5.15 of *CCS Guidelines on the Substantive Assessment of Mergers*

15. In evaluating the potential impact of the Transaction, CCS has considered whether the Transaction will lead to coordinated and non-coordinated effects that would substantially lessen competition in these markets.

V. Relevant Markets

(a) Product markets

16. The Parties have submitted that the relevant product markets for the purposes of this notification are[18]:

(a) the market for the supply of spine devices in Singapore;
(b) the market for the supply of trauma devices in Singapore; and,
(c) the market for the supply of BGS in Singapore.

17. The identified product markets correspond to the statement of the European Commission ("EC") in *Johnson & Johnson/DePuy* where the EC had delineated the segments relating to the orthopaedic industry in the same product categories.[19]

Description of Product

(1) Spine Devices

18. Spine devices are used to correct various conditions of the spine caused by degenerative disorders, trauma, tumours and deformities. Spinal implants and instruments made by the parties are designed to assist in the treatment of spine pathologies. Depending on the severity of the situation, physicians may employ a number of different treatment options ranging from conservative treatments such as physiotherapy and exercise to surgery. As a general rule, conservative treatments would be considered as first options with surgery only envisaged at a later stage or in cases of emergency.[20]

19. The devices have been categorized into their intended applications, for instance, to achieve fusion, plates, rods, screws and interbody devices are typically used by a surgeon[21]. Non-fusion devices are used to treat similar pathologies to fusion devices, but instead seek to preserve the natural motion of the spine. Non-fusion devices include dynamic stabilization systems,

[18] Paragraph 3.13 of Form M1
[19] *Johnson & Johnson/De Puy*, Case No. IV/M.1286, Paragraphs 7 and 8.
[20] Paragraphs 1.1.1 and 1.1.6 of Annex A of Form M1
[21] Paragraph 1.1.7 of Annex A of Form M1

interspinous devices and artificial discs. Implants and procedures are being developed to replace only part of the disc or vertebra[22].

20. From a demand perspective, the Parties have submitted that hospital and buying groups view spine products as a class of products separate to other orthopaedic devices where purchasing is concerned[23]. Feedback received from third parties verify this and CCS has not received feedback to the contrary.[24]

21. From a supply perspective, the Parties submitted that all the major suppliers offer various spine devices and components for the various treatment options.[25] The Parties have further submitted that even where global competitors may not currently supply certain spine devices in Singapore, the products are part of the global portfolio of the suppliers and can be imported into Singapore, without significant difficulty, in response to customer demand[26]. Feedback received from competitors indicates that global manufacturers have in their global portfolio ranges of products that are wider than that which are currently sold in Singapore[27].

(2) Trauma Devices

22. Trauma devices are used to treat bone fractures throughout the appendicular skeleton, i.e. the upper extremities (including hand and wrist), the lower extremities (including foot and ankle), the shoulder girdle and the pelvic girdle. Their main purpose is to keep the bone in place and support during the healing process, while still allowing stress on the bone as this helps the bone to heal.[28]

23. Devices are utilized using internal or external fixation techniques. Internal fixation is the surgical application of devices or implants that physically hold broken bone together from within the body.[29] External fixation devices are minimally invasive appliances used for a wide range of indications, including fracture fixation, limb lengthening and osteotomy.[30] While the principal uses of these devices differ, for instance external fixation devices are primarily

[22] Paragraph 1.1.10 of Annex A of Form M1
[23] Paragraph 1.2.4 of Annex A of Form M1
[24] See Notes of teleconference between CCS and [✂] on 7 December 2011.
[25] Paragraph 1.2.5 of Annex A of Form M1
[26] Paragraphs 1.2.5 and 1.2.6 of Annex A of Form M1
[27] See Notes of meeting between CCS and [✂] on 28 November 2011 and notes of meeting between CCS, [✂] dated 5 December 2011
[28] Paragraph 1.1.1 of Annex B of Form M1
[29] Paragraph 1.1.3 of Annex B of Form M1
[30] Paragraph 1.1.4 of Annex B of Form M1

used for lengthening bones, transporting segments of long bones or preliminary fixation of fractures before further treatment. In many cases, surgeons will be able to choose between external and internal fixation when treating a fracture.[31]

24. From a demand perspective, the Parties have submitted that customers will tender or negotiate contracts for a wide range of trauma devices. Within the range of products procured, customers typically identify tender lots or conclude contracts comprising of types of products, such as "plating systems", "cannulated screws" or "IM nails."[32] CCS understands from the responses of customers that when tendering for medical devices, including trauma devices, they will seek to arrange for the supply of as extensive a range of products as possible.[33] CCS further understands that the range of products will depend on the type of application and the patient's needs but it is fairly typical that such tenders will involve a range of products that will anticipate a variety of needs specific to the type of application, be it for trauma cases or spinal operations.[34]

25. From a supply-side perspective, the Parties have submitted that all the major suppliers of trauma devices supply a variety of trauma devices, comprising plating systems, IM nail systems, cannulated screws, IM hip screws, compression hip screws, and external fixation devices.[35] The Parties have further submitted that manufacturing technology and designs for trauma services are fairly generic and readily available.[36] In addition, the Parties have also submitted that there have been several instances where trauma device suppliers have launched new product lines by copying competitors' devices.[37] Feedback received from suppliers of inputs to the Parties have indicated that in the production of trauma medical services, there is no practical difference between the production of generic devices and those belonging to Parties.[38] In relation to the latter statement by the Parties, CCS has received feedback from a third party that there are manufacturers who replicate similar products, but not entirely identical products, to patented products.[39]

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[31] Paragraph 1.1.5 of Annex B of Form M1
[32] Paragraph 1.2.5 of Annex B of Form M1
[33] See Notes of meeting between CCS and [✂] on 28 November 2011and notes of meeting between CCS, [✂]dated 5 December 2011
[34] See Notes of meeting between CCS and [✂] on 28 November 2011and notes of meeting between CCS, [✂] dated 5 December 2011
[35] Paragraph 1.2.6 of Annex B of Form M1
[36] Paragraph 1.2.7 of Annex B of Form M1
[37] Paragraph 1.2.8 of Annex B of Form M1
[38] Feedback received from [✂] dated 26 November 2011 and [✂] dated 6 December 2011.
[39] See Notes of meeting between CCS and [✂] on 28 November 2011

(3) Bone Graft Substitutes

26. BGS is a type of orthopaedic biomaterial that is used in certain trauma, spine, cranio-maximillo facial and joint reconstruction procedures.[40] BGS can be used in a variety of applications. Some examples provided by the Parties about the usage of BGS includes the usage of BGS along with a fixation device in spinal fusion procedures, with a plate or screw to repair a tibia fracture, to fill voids between the bone and joint implant during joint revision and reconstruction surgery or to support surgical implants during cranio-maxillofacial surgery.[41]

27. From a demand perspective, the Parties have submitted that surgeons are generally able to use different types of BGS interchangeably for all treatments where BGS are required. Consultation carried out by CCS has not found information to the contrary.[42]

28. From a supply-side perspective, the Parties have submitted that the major global suppliers of BGS supply a range of different types of BGS on a global basis. CCS is aware from the feedback received from competitors that they have BGS in their global portfolio[43]. Customers have also indicated that there are several suppliers of BGS in Singapore and they are able to obtain the range of BGS that they require.[44]

29. In light of the foregoing, CCS agrees with the Parties' submissions on the definition of the relevant product markets.

(b) Geographic Market

(i) Parties' Submissions

30. The Parties submitted that the relevant geographic market for the three identified markets above is Singapore in respect of the specific licenses required from the Health Sciences Authority ("HSA").[45]

(ii) CCS' assessment

[40] Paragraph 1.1.1 of Annex C of Form M1
[41] Paragraph 1.1.3 of Annex C of Form M1
[42] See notes of meeting between CCS, [✂] dated 5 December 2011.
[43] See Notes of meeting between CCS and [✂] on 28 November 2011
[44] See notes of meeting between CCS, [✂] dated 5 December 2011.
[45] Paragraph 1.4.1 of Annex A of Form M1, Paragraph 1.3.1 of Annex B of Form M1 and Paragraph 1.4.1 of Annex C of Form M1.

31. Based on the submissions and research carried out by CCS, CCS is in agreement with the geographic market definition provided by the Parties.

VI. Market Structure

Process for the Supply of Medical Devices into Singapore

Product Launch

32. New medical devices are usually launched first in the United States and Europe before entering into the Asian market, with Singapore being the first few countries in Asia where the products are launched. Depending on the regulatory process in the different countries, this will affect the timeline for the new product launches [46].

33. To enter the market in Singapore, a new entrant carrying out direct sales to customers in Singapore[47] would typically need to invest in setting up operations in Singapore. This would include, amongst other considerations, the costs of registering a range of products with the relevant regulatory body, HSA, engaging a team of staff and the leasing of physical premises for their operations[48]. The approximate time required for entry has been estimated to be one year where the medical devices to be imported into Singapore have already been approved by regulators in other jurisdictions[49].

Registration

34. HSA is the regulatory body in Singapore which licenses the manufacture, import and wholesale of medical devices[50]. Depending on the nature of the business, any of the following licenses may be required: (i) a manufacturer's license for any person who manufactures medical devices in Singapore; (ii) an importer's license for any person who imports medical devices to Singapore and (iii) a wholesaler's license for any person who supplies medical devices for wholesale (which includes export) in Singapore.

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[46] See Notes of meeting between CCS and [✂] on 28 November 2011.
[47] An alternative method of bringing in products into Singapore is via a third party distributor.
[48] See Notes of teleconversation with [✂] on 23 December 2011.
[49] See Notes of teleconversation with [✂on 23 December 2011.
[50] http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_framework.html

35. As medical devices in the relevant markets fall within the definition of health products[51] in the Health Products Act, new medical devices must comply with requirements imposed by HSA and be approved for listing in the Singapore Medical Device Register[52]. [✂], CCS understands the turnaround approval times for medical devices which require registration with HSA are as follows and are comparable to HSA's overseas regulatory counterparts.

Risk Classification[53]	**Turnaround Time for Abridged Evaluation**	**Turnaround Time for Full Evaluation**
A	60 working days	
B	100 working days	160 working days
C	160 working days	220 working days
D	220 working days	310 working days
Combination Products	310 working days	

36. The medical devices identified in the relevant markets would fall within the Class C or Class D categories. In order to avoid duplication of scientific assessment, HSA takes into account the decisions of overseas regulatory counterparts and recognized reference agencies during the abridged evaluation process. Based on feedback received from competitors and the Parties[54], CCS understands that the majority, i.e. more than [✂] of the medical devices imported into Singapore would have received regulatory approval in other jurisdictions prior to entering the Singapore market and would thus benefit from the abridged evaluation procedures in order to shorten the application process. From the Parties' feedback on their own experience, this would usually entail a shorter approval period of about [✂][55].

37. Feedback obtained from third parties has indicated that the normal approval process may take up to 2 years. Alternatively, medical devices and

[51] Section 2 and First Schedule of the Health Products Act, Cap. 122D.
[52] Section 15 of the Health Products Act, Cap. 122D, prohibits the supply of unregistered health products save in prescribed circumstances. The Singapore Medical Device Register (SMDR) is a comprehensive database of medical devices for human use in Singapore that have been given marketing clearance for local commerce by HSA. http://www.hsa.gov.sg/publish/hsaportal/en/services/medics/smdr.html
[53] Devices falling within Class A and Class B categories are lower risk devices such as bandages or contact lenses. Devices falling within Class C and Class D categories are more complex and higher risk devices such as sophisticated diagnostic imaging equipment or cardiac stents.
[54] See Notes of meeting between CCS and the Parties on 13 December 2011
[55] See Notes of meeting between CCS and the Parties on 13 December 2011.

instruments can also be brought into Singapore through an authorization route. This is usually done by individual patients or health care institutions, where doctors assume the full responsibility for the usage of the medical device on their patients. It entails a lower application cost, and the license would last for six months. It would take typically about 14 days for HSA to approve an application through the authorisation route[56].

38. The Parties submitted that the time required for registration in Singapore is not prohibitive and is in line with the timeline of the other major overseas jurisdictions with mandatory registration programs[57].

Procurement Process

39. The Parties have submitted that the customers of the orthopaedic medical devices and orthopaedic biomaterials such as BGS are almost always hospitals. For public restructured hospitals in Singapore, the hospital administration would usually procure the devices whilst relying on inputs from surgeons and operating theatre management who use the devices in the therapies that they provide. In the case of private hospitals in Singapore, surgeons would usually decide on the spine or trauma devices to procure[58].

40. The public hospitals in Singapore generally purchase the medical devices by way of competitive tender (i.e. Request for Proposal or RFP) and all suppliers are generally invited to submit tenders or proposals for the products required. Public hospitals in Singapore are clustered into two groups, Singapore Health Services[59] ("SingHealth") and the National Healthcare Group ("NHG")[60], and through the respective Group Purchasing Offices ("GPO") of the two healthcare groups, they are able to collectively procure products through competitive tender processes.[61]

41. To illustrate the tendering process, based on feedback obtained from third parties, tenders for spine and trauma devices are often conducted in response to requests for specific devices by surgeons. Tenderers are expected to submit a binding price list for specified products under the tender. The

[56] See Notes of meeting between CCS and [✂] on 28 November 2011.
[57] See Notes of meeting between CCS and the Parties on 13 December 2011.
[58] Paragraph 3.2.36 of Form M1
[59] Singhealth GPO procures for Changi General Hospital, Singapore General Hospital and KK Women's and Children's Hospital.
[60] National Health Group GPO procures for Tan Tock Seng Hospital.
[61] See notes of meeting between CCS, [✂] dated 5 December 2011

hospitals would assess and shortlist the suppliers for the award of tenders based on a number of factors such as the suitability of the products, price, product quality and performance, reputation, supply track record, customer support (i.e. educational programmes, trainings, logistics, reliable product delivery and customer relationship programmes) and hospital clinical service delivery (i.e. ease of use, consistency of outcomes across surgeons of different levels of experience and case load, and impact on the hospital's efficiency of care provision). Hospitals would only pay for the products that they eventually consume.

42. CCS notes that the hospitals frequently award the right to supply at the tendered price to more than one supplier pursuant to the tenders. As and when specific products are required, the hospital will approach the suppliers to procure the volume and combination of spine or trauma products required at the specified prices. For instance[62], in an operation where a supplier's representative prepares different kits for use by the surgeon, the hospital only pays for the specific products selected and consumed during the surgery; they do not purchase the medical products in advance as the surgeon may have to adapt to the patient's condition during the surgery, e.g. the length of screw to be used. Further, the tender provided to the hospitals would typically include 'ala carte' prices of implants and a range of other spinal devices as well as package pricing for complementary products such as bone graft substitutes and spinal devices.

43. CCS notes that there are no penalties for terminating these contracts and also no volume commitments are made by the hospitals. CCS notes that it is possible that even if an award is made to a specific tenderer, not every product in that list of may be ultimately purchased during the validity of the contract. The Parties submitted that the hospitals may procure the majority of their requirements from the supplier with the lowest tendered prices, with the other suppliers awarded contracts as back-up suppliers in the event that the primary supplier does not have sufficient stocks of spine or trauma devices of a certain size or specification.

44. According to [✂], they might choose to enter into a contract with just one supplier for supply of non-critical products. On the other hand, for the supply of critical products, [✂] would have contracts with at least two different suppliers to ensure stability of supply. Another possible reason for a selection of multiple suppliers is to have a more comprehensive range of products and

[62] See Notes of meeting between CCS and [✂] on 28 November 2011.

services as not all suppliers offer the same width of products and level of customer support[63].

45. Tenders are generally called and awarded for two years. During the contracted period, suppliers will not be able to revise the price list for the products tendered, regardless of any increase in costs of production or distribution. Hospitals will also have the option for the contract to be extended for a further one year period. The Parties submitted that the hospitals are accordingly able to lock-in suppliers' tendered prices for duration of two to three years at a time, with the suppliers bearing the risk of any rise in costs.

46. In the case of private hospitals, the procurement is usually done by the surgeons on an individual basis[64]. The process of procurement by surgeons in private practice is also done on a consignment basis where the surgeons would choose a supplier based on a price list of products offered. Payment will be based on the volume of the products consumed by each surgeon. Although feedback from third parties indicates that surgeons in private practice do not generally procure through a central purchasing unit and each surgeon will choose their own supplier who can best meet their requirements[65], the Parties have submitted that [✂] procures products centrally for its cluster of [✂] private hospitals[66].

(i) Market shares and market concentration

Market for the supply of Spine Devices

(i) Parties' Submissions

47. The Parties have submitted that the estimated market shares of the Parties in the market for the supply of spine devices, based on internal estimations, will be [40-50%] post-Transaction with a CR3 of [90-100%].

[63] See answer to question 15 of the questionnaire provided by [✂] dated 28 November 2011.
[64] See Notes of teleconference between CCS and [✂] on 7 December 2011.
[65] See Notes of teleconference between CCS and [✂] on 7 December 2011.
[66] See Notes of meeting between CCS and the Parties on 13 December 2011. The [✂] private hospitals are [✂].

Estimates of market shares (by value) in the Reportable Market for the supply of spine devices in Singapore from 2008 to 2010, based on J&J's and Synthes' actual sales, and an adjustment factor of [✂]. Applied to other competitors' sales[67], based on J&J's internal market share estimates for 2008 and 2009 and [a market study] for 2010[68]

		Supply of spine devices in Singapore		
		2008	2009	2010
J&J	Actual sales value	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])
	Adjusted market share estimates	[45-55%]	[45-55%]	[25-35%]
Synthes	Actual sales value	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])
	Adjusted market share estimates	[10-20%]	[10-20%]	[10-20%]
Merged entity	Adjusted market share estimates	[60-70%]	[60-70%]	[45-50%]
Medtronic	Adjusted sales value estimates	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])
	Adjusted market share estimates	[25-35%]	[24-35%]	[40-50%]
Zimmer	Adjusted sales value estimates	[✂]	[✂] ([✂]	[✂]
	Adjusted market share estimates	[0-10%]	[0-10%]	[0-10%]
Stryker	Adjusted sales value estimates	[✂] ([✂])	[✂]	[✂]
	Adjusted market share estimates	[0-10%]	[0-10%]	[0-10%]
NuVasive	Adjusted sales value estimates	[✂]	[✂]	[✂] ([✂])
	Adjusted market share	[0-10%]	[0-10%]	[0-10%]

[67] [✂]
[68] Table 2 of Form M1

		Supply of spine devices in Singapore		
		2008	2009	2010
	estimates			
Others69	Adjusted sales value estimates	[✂]	[✂]	[✂] ([✂])
	Adjusted market share estimates	[0-10%]	[0-10%]	[0-10%]
Total size of the market	Adjusted sales value estimates	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])

48. The Parties have submitted that despite the estimated market shares of the merged entity and the CR3 that has exceeded the indicative thresholds set out in the CCS Guidelines, [✂] following [✂]'s expansion of portfolio of spine devices in Singapore. The Parties submit that this is illustrative of the significance of [✂] as a competitor in the market post-Transaction and also indicates that the closest competitor to J&J is [✂], and not Synthes.

49. Based on the feedback received by customers, while CCS is cognizant of the high CR3 of the relevant market, CCS understands that there are several alternatives to the Parties for the potential supply of spinal products, which can provide a competitive constraint on the Parties post-Transaction. Further, CCS has received feedback that apart from the Parties and [✂], other suppliers such as [✂] are currently active in the market and are providing such devices concurrently to customers of the Parties[70].

Market for the supply of Trauma Devices

50. The Parties submitted that the estimated market shares of the Parties in the market for the supply of trauma devices, based on internal estimations, will be [80-90%] post-Transaction with a CR3 of [90-100%].

Market share estimates (by value) in the Reportable Market for the supply of trauma devices in Singapore in 2008 to 2010

		Supply of trauma devices in Singapore		
		2008	2009	2010
J&J	Actual sales	[✂] ([✂])	[✂]	[✂]

[69] This would include suppliers such as B.Braun Singapore Pte Ltd and Scient'x-Alphatec Spine Asia-Pacific Pte Ltd which is distributed by Opto Systems (S) Pte Ltd.
[70] See Notes of meeting between CCS, [✂] dated 5 December 2011

		Supply of trauma devices in Singapore		
		2008	**2009**	**2010**
	value		([✂])	([✂])
	Estimated market shares	[0-10%]	[0-10%]	[0-10%]
Synthes	Actual sales value	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])
	Estimated market shares	[75-85%]	[75-85%]	[80-90%]
Merged entity	Estimated market shares	[75-85%]	[75-85%]	[80-90%]
Zimmer	Estimated market shares	[10-20%]	[10-20%]	[10-20%]
Small Bone Innovations, Inc. ("Small Bone Innovations")71	Estimated market shares	[0-10%]	[0-10%]	[0-10%]
Stryker	Estimated market shares	[0-10%]	[0-10%]	[0-10%]
Total size of the market	Estimated sales value	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])

Source: Synthes' internal market share estimates for the market for trauma devices in Singapore. The market share estimates are based on [✂].

51. The Parties have submitted that the estimated market share of J&J/DePuy in the market for the supply of trauma devices is negligible.[72] As such, the incremental market share is marginal.[73]

52. CCS has considered the market shares of the merged entity and the CR3 post-Transaction relative to the market shares pre-Transaction and is of the

[71] The Parties had submitted that Small Bone Innovations had entered the Reportable Market for trauma devices in 2010.
[72] Paragraph 3.2.11 of Form M1
[73] Paragraph 3.2.16 of Form M1

view that although these cross the indicative thresholds, the increment in the market shares of the merged entity is marginal as J&J/De Puy does not have a significant presence in the market for trauma devices. As such, the resulting market shares post-Transaction is not a consequence of the Transaction. Feedback received by CCS supports the Parties' submissions about the current state of the competition in the market.[74] CCS further notes that due to the structure of the supply of the market, market share estimates of the competitors in the market may fluctuate from time to time due to the award of tenders by hospitals. According to [✂], if a company loses market share in a particular tender, it is likely to lower its prices in the next tender to gain back market share.[75] Therefore, tender prices and market shares would always change across the different medical devices companies based on competition in the market.

Market for the supply of Bone Graft Substitutes

53. For the BGS market, the Parties submitted that the estimated market shares of the merged entity is likely to be [15-25%] and the CR3 is likely to [90-100%].

Market share estimates (by value) in the Reportable Market for the supply of BGS in Singapore from 2008 to 2010[76]

		Supply of BGS in Singapore		
		2008	**2009**	**2010**
J&J/DePuy	Actual sales value	[✂]	[✂]	[✂]
	Estimated market shares	[0-10%]	[0-10%]	[0-10%]
Synthes	Actual sales value	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])
	Estimated market shares	[10-20%]	[10-20%]	[10-20%]

[74] See Response provided by [✂] dated 28 November 2011, notes of meeting between CCS, [✂] dated 5 December 2011 and notes of meeting between CCS and [✂] on 28 November 2011.
[75] See telephone note with [✂] dated 19 December 2011
[76] Table 5 of Form M1

		Supply of BGS in Singapore		
		2008	**2009**	**2010**
Merged entity	Estimated market shares	[10-20%]	[10-20%]	[15-25%]
Medtronic	Estimated market shares	[45-55%]	[70-80%]	[70-80%]
NuVasive	Estimated market shares	[0-10%]	[0-10%]	[0-10%]
Total size of market	Estimated sales value	[✂] ([✂])	[✂] ([✂])	[✂] ([✂])

Source: Parties' internal estimates based on observations of the market, and the Parties' actual sales revenues for BGS

54. The Parties have submitted that in the market for BGS, the estimated market shares of the merged entity is expected to be less than 20% post-Transaction, thus falling under the indicative market share thresholds set out in the CCS Guidelines[77].

55. CCS' consultation with third parties have indicated that there are several suppliers of BGS in Singapore currently, and post-Transaction, customers will continue to have a choice of alternative suppliers.[78] In light of the feedback received and estimated market shares of the Parties, CCS is of the view that the increased market shares do not raise concerns of excessive market power held by the merged entity in this market.

Barriers to entry and expansion

56. Entry by new competitors or expansion by existing competitors may be sufficient in likelihood, scope and time to deter or defeat any attempt by the merger parties or their competitors to exploit the reduction in rivalry flowing from the Transaction (whether through coordinated or non-coordinated strategies)[79].

(i) The Parties' submission

[77] Paragraph 5.15 of *CCS Guidelines on Substantive Assessment of Mergers*.
[78] See notes of meeting between CCS, [✂] dated 5 December 2011
[79] Paragraph 7.2 of *CCS Guidelines on Substantive Assessment of Mergers*.

57. The Parties submitted that there are no prohibitive barriers to entry in the relevant markets as the cost of entry is not prohibitively high[80], regulatory requirements are not prohibitive[81], there are no patents that may act as a material entry barrier[82] and there are no likely barriers in terms of economics of scale[83].

58. In terms of expansion, the Parties submitted that the expected market growth [✂] is likely to spur new entry and expansion[84]. The Parties have submitted that in view of the structure of supply, spine and trauma device manufacturers are generally able to readily expand their product lines within and/or between the product types, given that there are limited differences in the respective manufacturing processes.[85] In respect of the market for the supply of BGS, the Parties consider that most suppliers are generally able to readily expand their product line and there are limited significant capacity constraints at the manufacturing level.[86]

59. The Parties have submitted that besides the Parties, the following competing suppliers and manufacturers have a local presence in the respective relevant markets:

Name	Spine Devices	Trauma Devices	BGS
Acumed		√	
Aseculap (B. Braun)	√	√	
Alphatec Spine	√		
Biomet	√	√	
Medtronic	√		√
NuVasive	√		√
Orthofix	√	√	
Small Bone Innovations		√	
Smith & Nephew		√	
Stryker	√	√	

[80] Paragraphs 3.2.68 and 3.2.69 of Form M1.
[81] Paragraphs 3.2.70, 3.2.71 and 3.2.72 of Form M1.
[82] Paragraphs 3.2.73, 3.2.74 and 3.2.75 of Form M1.
[83] Paragraphs 3.2.76, 3.2.77 and 3.2.78 of Form M1.
[84] Paragraphs 3.2.79 of Form M1.
[85] Paragraph 3.2.58 of Form M1
[86] Paragraph 3.2.60 of Form M1

Zimmer	√	√	

60. The Parties have also submitted a list of companies who are either active in the US or EU markets for the relevant products, There are 94 companies in the spine devices market, 63 companies in the trauma devices markets and 28 companies for the supply of BGS all of which may be potential entrants into Singapore.

(ii) Feedback from third parties

61. The views of third parties sought by CCS seem to suggest that there may be some barriers to entry given the relatively high market shares of Synthes in the trauma devices market and the relative lack of new entrants in the spine and trauma markets in recent years.

62. The reasons commonly cited by third parties for the relative lack of new entrants in the relevant markets include the high initial capital and labour investment for the manufacture and marketing of medical devices, significant regulatory costs and lag time in getting medical devices approved for use in Singapore and inertia in gaining wide acceptance by surgeons.

63. A third party has commented that extensive customer support, which includes training for the surgeons, customer service to handle queries about the medical products and other services including the presence of representatives at complicated operations, are considerations for surgeons in deciding which supplier to procure from. Many surgeons would strongly prefer to use a supplier who can provide the required support[87]. Regulatory costs for approval of spinal, trauma devices and bone graft substitutes by HSA typically range from about $3,500 to $11,800 per device [88]. It may also take up to two years for HSA to evaluate the devices and grant an approval, although [✂] the general total turnaround time for evaluation under the abridged route would take about 160 to 220 working days and the Parties have submitted that approval via the abridged evaluation route would usually be granted in [✂]. In relation to the point on surgeons' acceptance, third parties have submitted that, amongst other factors, surgeons' familiarity with the devices, consistency of outcomes and positive empirical clinical evidence are factors taken into consideration by surgeons[89]. The factors, taken together, seem to suggest some lead time is needed for a device to gain a certain level of acceptance by surgeons.

[87] See notes of meeting between CCS and [✂] dated 28 November 2011.
[88] See Response from [✂] received via email on 17 December 2011. The estimated fees are for abridged applications.
[89] See notes of meeting between CCS, [✂] dated 5 December 2011.

64. Submissions by third parties have indicated the entry of only one company in the spine devices market[90] and none in the trauma devices market in the last three years[91]. Even then, a third party commented that the new entrant in the spine devices market has not been able to provide a comprehensive range of products to compete effectively and impose a significant constraint on the players already present in the market[92].

65. However, third parties have also indicated that existing multinational global manufacturers and suppliers would be the most likely entrants to enter or expand in the Singapore market for the supply of spinal and trauma devices. These global manufacturers may currently have a limited range of product offerings in Singapore but have the ability to expand its portfolio of products (albeit at some cost) if demand for these products justifies it. CCS understands that several manufacturers with a global presence would have a comprehensive range of products in the relevant markets similar to the Parties' offerings, but for commercial reasons, have chosen not to replicate the range in Singapore[93]. However, feedback received from a competitor indicated that given Singapore's strategic location and strong government support in areas pertaining to protection of intellectual property, clinical trials, training and education, Singapore is an attractive base for its operations. [✂][94] [✂][95]

(iii) CCS' Assessment

66. CCS notes the differences between the views expressed by the Parties and by third parties relating to the perceived barriers to entry. While the Parties submitted that there are no prohibitive barriers to entry in the relevant markets, views from third parties and the lack of recent entrants seem to indicate some barriers to entry and expansion in Singapore. However, CCS notes the possibility of potential entry by the many global manufacturers and suppliers active in the relevant markets. The global manufacturers and suppliers, who are the likely entrants into the Singapore market, face a lower barrier to entry as compared to a completely new entrant given the already sunk investments and comprehensive range of products offered globally. [✂].[96] Further, CCS understands that HSA's approval process is generally in line with overseas jurisdictions and the timeline for approval is usually

[90] [✂]
[91] See answer to question 11 of the questionnaire provided by [✂] dated 28 November 2011.
[92] See notes of meeting between CCS and [✂] dated 28 November 2011.
[93] See notes of meeting between CCS, [✂] dated 5 December 2011.
[94] See Notes of teleconference between CCS and [✂] on 7 December 2011.
[95] See [✂] responses to CCS' questions dated 28 November 2011; response to Question 1.
[96] See Notes of teleconference between CCS and [✂] on 7 December 2011.

factored into a company's business plans for launching a product in Singapore or when deciding to enter the local markets. The approval process may also be shortened through an authorization route which allows hospitals or surgeons to bring in devices not formally approved within a relatively short period of 14 days and at a lower cost of $500. This route is open to and preferred by smaller manufacturers who may bring in limited quantity of devices each time at a lower cost[97].

67. CCS has also considered feedback from third parties[98] which have estimated the costs of entry to be approximately [✂]. This estimate takes into account various factors including fees for registering the medical devices with HSA, operational costs such as leases and annual licence fees, and the employment of staff. In assessing the costs of entry relative to the turnover of a new entrant[99], CCS is of the view that the cost of entry is not prohibitive.

68. CCS is of the view that the barriers to entry into the 3 product markets are moderate. From the regulatory perspective, the registration fees for seeking approval from HSA is not prohibitively high[100] for these global competitors while the time period required for registration is likely to be less than a year in most instances[101]. CCS is of the view that potential entry by these global competitors would be sufficient in likelihood, scope and time to deter or constrain any attempt by the Parties or their competitors to exploit the reduction in rivalry post-merger.

(ii) Countervailing buyer power

(i) Parties' Submission

69. Parties have submitted that customers in the relevant markets have significant countervailing power due to the collective procurement process carried out by the GPOs by way of competitive tenders. Upon the award of the tender, suppliers are required to maintain the tendered prices and

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[97] See Notes of meeting between CCS and [✂] dated 28 November 2011.
[98] See Notes of teleconference between CCS and [✂] dated 23 December 2011 and answer to question 5 of the questionnaire provided by [✂] dated 28 November 2011.
[99] [✂]
[100] Registration fees are between $3,500 to $11,800 per device depending on the class of the device for the purposes of registration.
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/fees_and_charges0.html
[101] Most medical devices imported into Singapore would have been approved by another regulatory authority, hence they would qualify for the abridged evaluation route which would typically take between 8 to 12 months.

hospitals are able to further exert buyer power by exercising an option of extending the contracted period by another year.

70. Apart from the ability to lock in the supplier's tendered prices for a period of two to three years with suppliers bearing the risk of rising costs, hospitals also do not face obligations to purchase determined volumes in order to enjoy the tendered price. Accordingly, at the point of submitting a tender, suppliers face significant pressure to quote competitively. Hospitals do not generally renegotiate for lower prices with any supplier on the basis of prices tendered by other suppliers and given that prices are locked in for two years, the pressure for suppliers to quote competitively is heightened, in order not to lose the customer for the next two years.

71. Further, as there are no volume commitments by the hospitals, the actual volume of devices sold by the suppliers (if at all) will be determined by the prices tendered.

72. The Parties had further submitted that switching costs, if any, are minimal for hospitals to switch between suppliers of spine and trauma devices. Contracts are typically awarded to more than one supplier and hospitals can easily switch between suppliers of spine or trauma devices on a surgery to surgery basis. In addition, any switching cost in respect of any new training needed to learn how to use a different set of instruments and devices are generally low and not prohibitive. Sale representatives of the suppliers would generally be present in surgeries to guide surgeons on the use of the device, which facilitates the surgeons' familiarization with the devices.

73. The manner in which trauma and spine devices are delivered to hospitals also positively reduces any switching costs as hospitals and surgeons do not keep inventory of spine and trauma devices or instruments. Suppliers are required by customers either to supply devices and instruments to customers on an on-call and as-required, basis, or to consign the devices and instruments free of charge with the hospital making payment only when a device is used. In respect of BGS, there are no switching costs involved if a customer decides to switch to another supplier for BGS. Long term supply agreements are not common which further facilitates the ability customers to switch to other suppliers of BGS.

(ii) Feedback from industry stakeholders

74. CCS understands from the feedback received from customers that the procurement of medical devices and instruments are collectively carried out

through the [✂], which helps to keep the purchase prices of the medical devices at an affordable level.[102]

75. With respect to the ease of switching suppliers, one of the customers' feedback indicated that it is not prohibitive to switch suppliers for spine devices and BGS given the availability of alternative suppliers. However for trauma products, due to the limited number of suppliers in Singapore that can offer a comprehensive range of products, it is difficult for them to switch[103]. CCS notes that while one of the customers managed to switch suppliers for the trauma devices, they had to switch back to the original supplier when the price of the competitor's products increased. [✂[104]]. CCS also notes that while there are other usable substitutes which are manufactured by less reputable manufacturers, they are not viable alternatives to the products supplied by the more established global manufacturers due to the lack of reputation and empirical clinical evidence concerning the performance and quality of the products. It usually takes a few years for these alternative devices to gain acceptance by the surgeons, by way of empirical clinical evidence as well as reputational gains[105].

(iii) CCS' Assessment

76. CCS is of the view that customers generally do not have trouble switching suppliers for the spine devices and BGS. They may face some difficulties in switching suppliers for trauma devices due to limited alternatives that are able to provide a comprehensive range of products, notwithstanding that there are currently 8 suppliers of trauma devices[106]in the Singapore market. The potential difficulty in switching for trauma devices is a prevailing market condition, and not a consequence of the proposed Transaction. This difficulty is mitigated by the ability of global manufacturers and suppliers to expand their portfolio of products in Singapore when the demand increases. CCS had received feedback during the period of consultation that global manufacturers would consider entering the market in Singapore in the event of an increase in demand for trauma devices[107]. Further, the ability of public hospitals to procure the medical devices and instruments as a group also puts them in a strong buyer position. This is also the case for some private healthcare groups like [✂] who also may procure centrally for its cluster of private hospitals. Although surgeons with individual private practices often

[102] See notes of meeting between CCS, [✂] dated 5 December 2011
[103] See notes of meeting between CCS, [✂] dated 5 December 2011.
[104] See Notes of meeting between CCS and [✂] on 28 November 2011.
[105] See Notes of meeting between CCS, [✂] dated 5 December 2011.
[106] See Response received from M/s Allen & Gledhill on 15 December 2011.
[107] See Notes of meeting between CCS and [✂] dated 28 November 2011.

do not have the same level of bargaining power as public hospitals due to their smaller procurement volumes, this is mitigated by the availability of alternative suppliers. On balance, the customers are likely to be able to exercise strong countervailing power to keep the prices of the medical devices at competitive level.

VII. Competition Assessment

(a) Non-coordinated effects

77. Non-coordinated effects may arise where, as a result of the Transaction, the merged entity finds it profitable to raise prices (or reduce output or quality) because of the loss of competition between the merged entities[108]. Other firms in the market may also find it profitable to raise their prices because the higher prices of the merged entity's product will cause some customers to switch to rival products, thereby increasing demand for the rivals' products[109].

78. CCS is of the view that post-Transaction, non-coordinated effects are not likely to arise because of the limited overlap between the Parties in the relevant product markets for the supply of trauma devices[110] and BGS[111]. While the estimated market shares of the Parties in the spinal market indicate that the Parties are likely to have a market share of approximately [40-50%] post-Transaction[112], feedback received during the consultation period indicates that there are several suppliers in this market with potential new entrants that are likely to constrain any exercise of market power by the Parties.[113] CCS further notes that the market shares of the parties fluctuate, with J&J losing market share from [45-55%] to [25-35%] in 2009 and 2010 respectively. This is suggestive of the fairly rampant competition in this market where buyers are able to switch suppliers with ease due to the availability of viable alternatives and low costs associated with switching.

79. As outlined above, the notified Transaction is unlikely to result in any incremental market shares in each of the relevant markets as the Parties have different levels of participations and presence in the relevant markets. CCS has taken into account the high CR3s in the relevant markets and is of the

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[108] Paragraph 6.3 of *CCS Guidelines on the Substantive Assessment of Mergers*.
[109] Ibid.
[110] In the market for the supply of trauma devices, the estimated market share of J&J is [0-10%] while the estimated market share of Synthes is [80-90%]. See Table 3 of Form M1.
[111] In the market for the supply of BGS, the estimated market share of J&J is [0-10%] while the estimated market share of Synthes is [10-20%]. See Table 5 of Form M1.
[112] Table 2 of Form M1 with a post merger CR3 of [90-100%].
[113] See notes of meeting between CCS, [✂] dated 5 December 2011

view that this may not necessarily be indicative of sustainable market power due to other considerations such as the ease of entry, countervailing buyer power and the availability of alternative suppliers. As such, the Parties are unlikely to find it profitable to raise prices or reduce output post-transaction as they will be sufficiently constrained.

(b) Coordinated effects

80. A merger may also lessen competition substantially by increasing the possibility that, post-merger, firms in the same market may coordinate their behaviour to raise prices, or reduce quality or output. Given certain market conditions, and without any express agreement, tacit collusion may arise merely from an understanding that it will be in the firms' mutual interests to coordinate their decisions. Coordinated effects may also arise where a merger reduces competitive constraints in a market, thus increasing the probability that competitors will collude or strengthen a tendency to do so[114]. Vertical mergers may facilitate coordination, for example by increasing market transparency. Integration may afford the merged entity better knowledge of selling prices in the upstream or downstream market, thereby facilitating collusion in either of those markets[115].

81. On the available evidence, CCS concludes that the structural change brought about by the Transaction in the context of the characteristics of the markets under consideration is not such as to raise concerns about coordinated effects as the products supplied are sufficiently differentiated and the relevant product markets are marked by intense competition between the suppliers due to the structure of supply where suppliers enter into fixed contracts for a minimum of two years and the method of procurement via competitive tenders. Further, in respect of the relevant product markets, CCS also notes that competition within these markets is usually not based on price but on other factors such as customer service and the clinical track record of the products.

VIII. Efficiencies

82. The Parties have submitted that the merged entity is expected to achieve synergies in product development capabilities and pipelines from the two organizations, as well as provides the potential for technology convergence across J&J. The Parties have also submitted that together, the Parties would

[114] Paragraph 6.7 of *CCS Guidelines on Substantive Assessment of Mergers*.
[115] Paragraph 8.8 of *CCS Guidelines on Substantive Assessment of Mergers*.

increase their global reach to bring a broader portfolio of orthapaedics solutions to developed and emerging markets as well as leadership and expertise in professional education to the medical community[116].

83. CCS is unable to comment on the likely savings in time and costs as this information was not provided by the Parties.

IX. Conclusion

84. For the reasons above and based on the information available, CCS assesses that the Transaction is unlikely to infringe the section 54 prohibition.

Yena Lim
Chief Executive
Competition Commission of Singapore

[116] Paragraph 3.2.1 of Form M1