EN

Case No IV/M.1286 - JOHNSON & JOHNSON / DEPUY

Only the English text is available and authentic.

REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 28/10/1998

Also available in the CELEX database
Document No 398M1286

Office for Official Publications of the European Communities
L-2985 Luxembourg

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.10.1998

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EEC) No 4064/89 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party

Dear Sirs,

Subject: Case No IV/M.1286 – Johnson & Johnson / DePuy
Notification of 15.09.1998 pursuant to Article 4 of Council Regulation N°4064/89

1. On 15/09/1998 the Commission received a notification of a proposed concentration by which Johnson & Johnson (J&J), through its wholly owned subsidiary LIB Acquisition Corp., acquires sole control of DePuy, currently controlled by Roche.

I. THE PARTIES

2. J&J is a global group of companies whose activities may be divided into three business segments: ***i)*** consumer, notably personal care and hygienic products, including baby care products, first aid products and non prescription drugs, sanitary protection products and adult skin &hair products; ***ii)*** pharmaceutical, ***iii)*** professional, which comprise a wide range of products used mainly in professional fields by different customers such as hospitals, laboratories, therapists and doctors; this last segment includes the orthopaedic line of products which constitutes the object of this operation.

3. DePuy is the ultimate parent company of a group active in the development, production and sale of orthopaedic products. DePuy is a public company controlled by Roche Healthcare Limited, a subsidiary of Roche.

II. THE OPERATION

4. The operation consists of a cash tender offer made by J&J for all outstanding DePuy shares. Simultaneously, the main shareholder in DePuy, Roche, has entered into a stockholder agreement with J&J whereby it will sell to J&J, within the framework of the tender offer, its DePuy shares, representing approximately 84% of the outstanding DePuy shares.

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III. CONCENTRATION

5. As the transaction will result in the acquisition of sole control of DePuy by J&J, it constitutes a concentration under the meaning of the Merger Regulation.

IV. COMMUNITY DIMENSION

6. The combined aggregate worldwide turnover of the undertakings concerned exceeds ECU 2,500 million (J&J, ECU 19,954 million; and DePuy ECU 679 million). The aggregate Community-wide turnover of each party exceeds ECU 100 million (J&J ECU […] million; and DePuy ECU […] million). In each of at least three Member States, namely France, Germany and the UK, each of the parties has a turnover in excess of ECU 25 million, and in each of those Member States the parties' combined aggregate turnover exceeds ECU 100 million. The undertakings concerned do not achieve more than two thirds of their turnover in one and the same Member State. The notified operation has therefore a Community dimension, meeting the thresholds of the Merger Regulation.

V. THE RELEVANT MARKET

a) The relevant product markets

7. The proposed concentration involves a number of segments relating to the orthopaedic industry: ***i)*** spinal implants ***ii)*** trauma products, ***iii)*** sport medicines, ***iv)*** arthroscopy, ***v)*** bone stimulation, ***vi)*** orthobiologics, ***vii)*** reconstructive implants.

8. Spinal implants are fixation devices in conjunction with bony fusion designed to treat spinal pain, deformity and disease. Trauma products are devices aimed at the management of fractures. Sport medicines include casting, bracing support and cold therapy products. Arthroscopy relates to devices used to treat disease in a less invasive manner. Bone stimulation involves electrical and ultrasound stimulation devices used to treat problematic fractures. Orthobiologics are materials intended to improve therapy by regenerating bone and other musculoskeletal tissues. Bone substitutes are used as alternative to human bone for bone graft procedures. J&J and DePuy activities in the above mentioned segments are to a large extent complementary. Therefore, it is not necessary to further delineate the relevant product markets because, in all alternative market definitions considered, there are no affected markets and, therefore, following the operation effective competition would not be impeded in the EEA or any substantial part of that area.

9. Conversely, in the segment of reconstructive implants there are significant overlaps. Reconstructive implants are devices and instruments used to replace joints, including hips, knees, shoulders, elbows, etc., which are worn, damaged or diseased. While DePuy manufactures and sells a full line of reconstructive implants, J&J is active only in hip and knee implants and has an insignificant presence in elbow implants. Accordingly, in view of the low market shares of the parties for elbow implants, the only market further assessed concerns hip and knee implants.

Cemented v cementless implants

10. Both hip and knee implants may be further segmented into cemented and cementless implants. Cemented implants are lower cost but require more frequently revision surgery as cement may break down over time. They are usually used for older and less active patients. Cementless implants are biologically fixed. They have a substantial higher cost with potential for longer life of the product. Therefore, these implants are generally used on younger patients. Despite the above mentioned indications, the parties submit that these two segments should be regarded as one product market due to the fact that the demand, constituted by doctors and hospitals, are familiar with both implants and view them as substitutes. In addition, there would be as well a certain price relation between such implants as proven by a recent increase in cemented implants in the US following a price increase of cementless implants. It is also submitted by the parties that, from the supply side, there is a high degree of substitutability as manufacturers can easily switch production with minor changes to the production process and without incurring important costs. In this respect, the market testing has fully confirmed that manufacturers view these products as very close in terms of manufacturing technologies and they all offer both ranges of products. In the light of the above, cemented and cementless implants should be viewed as belonging to the same product market.

Primary versus revision implants

11. Another distinction is made between primary and revision implants. In this respect, where primary implants fail during the patient's life from loosening or wear, a revision implant is required. The features of primary and revision implants are however only slightly different and therefore, there is a very high degree of supply-side substitutability. Again the market testing has confirmed that manufacturers consider these products as extremely close in terms of manufacturing technologies and that they all typically offer both implants. As a consequence, primary and revision implants are to be regarded as one product market.

Hip implants

12. Hip implants might also be differentiated by reference to the surgical design philosophy on which they are based, such as the Charnley or the Müller tradition. Each type of implant utilises different technical instrumentation. The Charnley implant has been particularly successful in the UK, Ireland and the Scandinavian countries. The Müller implant is quite successful in German-speaking countries. Other hip implants with strong credentials are the Exeter and the Stanmore implant, both popular in English-speaking countries. While suppliers normally manufacture hips based on a single surgical design philosophy, most of them contend, in their responses to the market testing, that these products are quite close in terms of manufacturing technology and that a switch from one model to another is envisageable with minor changes to the production process and with no major costs. On the other hand, such products, given their field of use, can be realistically put into market only on the basis of a well established historic clinical record. From the demand side, most hospitals responded that their medical staff was familiar with a number of surgical design philosophies and could be trained to use a new surgical design philosophy in a relatively short time. Nonetheless, a clear preference was

generally expressed in favour of one or the other system, depending on the nationality.

13. All these things considered, in the light, more particularly, of the above described demand-side substitutability, hip implants should be regarded as constituting one single product market, irrespective of the different surgical design philosophies on which they are based.

Fixed-bearing versus mobile-bearing knees

14. With regard only to knee implants, a further distinction is to be made between fixed-bearing knees and mobile-bearing knees. From the demand side these products appear to be different in terms of characteristics, performances and price. Fixed-bearing implants allow less mobility to patients, are easier to implant and have lower cost, whereas mobile-bearing implants are more technically advanced, allow more mobility and are more expensive. The evidence collected through the market testing in this respect was mixed. Some hospitals and doctors expressed doubts as to the proven superiority of mobile-bearing knees. Others clearly viewed these implants as more advanced and having higher performance. Few considered the two models as direct substitutes.

15. From the supply side, the degree of substitutability from fixed to mobile implants appears limited in so far as mobile-bearing implants are protected by patents, which render unlikely an easy entry of fixed-bearing implants manufacturers into the mobile-bearing segment. Conversely, mobile-bearing knee manufacturers can more easily switch to fixed-bearing implants as the latter represent a less sophisticated version of the former and are not protected by patents. On this point, most manufacturers have agreed in their responses to the market testing. In addition, it is worth noting that manufacturers either produce both models, or they are present only in the fixed-bearing knee segment. Accordingly, as substitutability relations appear to be asymmetric, two product markets could be considered for the purpose of the case, notably the fixed-bearing knees plus the mobile-bearing knees market and the mobile-bearing knees market taken on its own.

b) The relevant geographic market

16. The parties submit that the markets are EEA-wide due to a number of factors: ***i)*** within the EEA the regulatory context is now fully harmonised as the medical devices directive has removed intracommunity trade barriers; ***ii)*** the introduction of the Euro is likely to lead to an accelerated price approximation within the EEA; ***iii)*** on the supply side the same players compete throughout the EEA with implants in identical form. In this respect, orthopaedics manufacturers have centralised manufacturing and R&D operations and supply their customers established around the world from few plants. ***iv)*** customers (especially public hospitals) procure these goods through public tenders, which ensure a higher degree of competition and increasingly solicit offers from non-national suppliers.

17. Despite all the above-mentioned factors, there still remain a number of indications militating in favour of national markets. Firstly both prices and market shares of the major players in this sector vary greatly from country to country, with very

pronounced differences even between neighbour countries (like Austria and Germany, or Italy and France).

18. Secondly, and more importantly, it should be noted that in the sector concerned by the transaction both training and assistance from the suppliers are regarded as essential by hospitals and doctors. Accordingly, presence on the ground from the suppliers is to be ensured constantly and this renders unlikely a successful bid from a supplier lacking a presence on a national basis. The evidence collected in the market investigation has confirmed such a view. Hospitals and doctors tend to attach great importance to after-sale support and especially value service quality and product reliability. To further confirm such evidence, trade patterns show that, notwithstanding the existence of public tender procedures, orders are hardly ever awarded to suppliers lacking a presence at national level.

19. Finally, as in other medical sectors, the presence of public reimbursement systems in a large number of EU countries has partitioned off the markets at national level. Some countries exercise a direct influence on prices of such implants by imposing a price cap (France, Belgium and Greece). Others indirectly constrain prices by fixing budgets for the hospitals (Ireland, the UK, Germany and Italy). In all cases, the above described mechanisms appear to influence competitive conditions on national markets, giving rise to strong price variations across European countries.

20. From the above it follows that the geographic markets for the purpose of this case are to be considered as national in scope.

VI. ASSESSMENT

European level

21. The operation will have an important impact at European level, less pronounced in the market for hip implants, and more significant in the market for knee implants. However, these markets will remain competitive because of the presence of several large competitors active in Europe. In particular, with a combined market share in hip implants of [less than 20] % (J&J [less than 5] % and DePuy [between 15 and 25] %), the parties will encounter competition from Sulzer Medica, which is leader of the European market with [more than 25] %, Howmedica ([less than 20] %), Zimmer ([less than 10] %), Stratec ([less than 10] %), Biomet ([less than 10] %), Aesculap ([less than 10] %), Smith & Nephew ([less than 5] %) and Stryker ([less than 5] %). In knee implants, the parties will become the market leader with [between 25 and 35]% (J&J [between 10 and 20]%, DePuy [between 10 and 20]%), but a number of competitors will remain active such as Zimmer ([less than 15] %), Howmedica ([less than 15] %), Sulzer Medica ([less than 15] %), Biomet ([less than 15] %), Smith & Nephew ([less than 10] %), Striker ([less than 5] %), Waldemar Link ([less than 5] %) and Wright Medical ([less than 5] %).

National level

22. The table below shows the EU countries where the parties will have combined market shares (in value) of 40% or more in the segment for hip implants.

Hips	J&J	DePuy	Combined	Howmedica	Sulzer	Biomet	Zimmer
Ireland	[1-10]	[70-80]	[75-85]	[5-15]			[1-10]
UK	[1-10]	[30-40]	[40-50]	[15-25]	[1-10]	[1-10]	[1-10]
Portugal	[5-15]	[25-35]	[40-50]	[1-10]	[5-15]	[25-35]	

23. The operation will have a quite significant impact in a number of countries. With respect to hip implants, the new entity resulting from the transaction will have a very important market share primarily in Ireland with [between 75 and 85]%, but also in the UK with [between 40 and 50]%, and Portugal with [between 40 and 50]%. A number of other EU countries are affected to a lesser degree (Sweden [between 25 and 35]%, France [between 30 and 40]%, Denmark [between 15 and 25]%).

24. The table below shows the EU countries where the parties will have combined market shares (in value) of more than 40% in the segment for knee implants.

Knees	J&J	Depuy	Combined	Howmedica	Sulzer	Biomet	Zimmer	Smith& Nephew
Ireland	[40-50]	[25-35]	[75-85]	[5-15]		[1-10]	[1-10]	
UK	[25-35]	[5-15]	[35-45]	[15-25]	[1-10]	[5-15]	[10-20]	[1-10]
Austria	[1-10]	[30-40]	[35-45]	[10-20]	[1-10]	[1-10]	[15-25]	

25. In the segment of mobile-bearing implants taken by itself there is no overlap between the parties as only DePuy is active in such a segment. Conversely, in the whole segment, composed of fixed-bearing plus mobile-bearing knee implants, there will be a very significant overlap again primarily in Ireland, where the new entity resulting from the merger will have a market share of [between 75 and 85]%, but also in Austria with [between 35 and 45]%, the UK with [beween 35 and 45]%, Portugal with [between 35 and 45]%. A number of other EU countries are affected to a lesser degree (Germany [between 25 and 35]%, Denmark [between 25 and 35]%).

Ireland

26. With respect to Ireland, the merger gives rise to an extremely high concentration in terms of market share in both hip and knee implants. More particularly, in hip implants DePuy is an uncontested market leader while J&J contributes with a small fraction to the combined position. The only competitors left will be Howmedica and Zimmer with market shares between [5-15%] and [1-10%] respectively. In knee implants, J&J and DePuy are the first and the second operator respectively, and the only competitors left, namely Howmedica, Zimmer and Biomet, will have a marginal position with market shares between [5-15%], [1-10%] and [1-10%] respectively. An additional competitive advantage for the merging entity derives from the fact that it will acquire an uncontested leadership in both segments for hip and knee implants.

27. Moreover, unlike other EU countries, still few Irish hospitals procure reconstructive implants through public tenders. While a new Public Entity has been recently set up (Materials Management Implementation Group) to ensure, *inter alia*, that individual hospitals co-ordinate and award certain contracts on a joint basis through public tender procedures, a full implementation of such a policy is realistically foreseeable only within two years time. As a consequence, the still limited use of tendering procedures cannot be viewed, at this stage, as an effective competitive constraint upon suppliers.

28. Ireland, in addition, represents a very small market in terms of value ([less than 0.5]% of the whole European market), and this renders it an even less appealing market for newcomers. In this respect, the minor importance of such a market could keep other potential competitors away. In more general terms, it should also be noted that in these markets products performance and reliability are the key factors behind most buying decisions. Customers, accordingly, tend to show a certain degree of fidelity, which in turn constitutes a further considerable entry barrier for newcomers.

29. In the market investigation conducted by the Commission, Irish customers unanimously raised a number of concerns, in particular pointing out the risk of monopolization of the market by the merging entity, which in turn could cause an increase in price as much as a reduction of the quality of products and services supplied.

30. In the light of all of the above considerations, it follows that the present transaction will give rise to serious competitive concerns in Ireland. In the market for hip implants J&J will add to its small presence DePuy's unopposed dominant position. As a consequence, the operation will give rise to a strenghtening of a dominant position in such a segment as a result of which effective competition would be significantly impeded in Ireland. In the market for knee implants, J&J, being market leader, will acquire the very significant position of DePuy. Consequently, in the latter segment the operation will create a dominant position as a result of which effective competition would be significantly impeded in Ireland.

Other EU countries

31. As to other EU countries mostly affected by the operation, notably the UK for both hip and knee implants, Portugal for hip implants and Austria for knee implants, despite the significant market shares held by the merging entity, the markets appear to remain sufficiently competitive for a number of reasons.

32. First, a number of large competitors are active on these markets with significant market shares. In particular, the new entity will encounter competition from Howmedica, Sulzer, Biomet, and Zimmer, not to mention other operators having a significant localised presence in one or in few EU countries. In particular, some of the competitors are subsidiaries of large pharmaceutical companies, such as Howmedica, which is a division of Pfizer, and Zimmer, which is a division of Bristol Myers. Some others, such as Biomet, are highly successful companies raising their market shares steadily.

33. Second, none of the players present on the market, including the merging entity, has an uncontested leadership in terms of products quality or technology. Rather, they all have substantial financial means, similar technology and the clinical records to compete effectively with the merging entity in the sector at stake. With regard, for instance, to mobile-bearing knee implants, where DePuy is leader, it is worth noting that currently all the other competitors manufacture a mobile-bearing implant. As for hip implants, the parties' competitors manufacture a number of successful models, including those based on the Charnley tradition.

34. Third, this operation will result primarily in an increase of the product range of the merging entity rather than a pure horizontal addition of overlapping products. In this respect, it should be noted that in both markets affected by the operation the parties' products are imperfect substitutes one of the other as they are based on different technologies and surgical traditions. In the hip segment, for instance, DePuy manufactures its models based on the British Charnley tradition while J&J uses the German Müller tradition. Similarly, in knees, DePuy is especially strong in mobile-bearing knee implants while J&J manufactures only fixed-bearing knee implants. These considerations are especially relevant for those countries (e.g. the UK) where preference for a surgical philosophy is very strong.

35. Fourth, on the demand front, customers appear to be sufficiently sophisticated purchasers paying increasing attention to cost efficiencies. In some cases, they jointly manage their purchasing policies, thus acquiring a more significant bargaining power. In the UK, in particular, the National Health Service plays an important role in providing guidance to hospitals in this respect. As a result of such a policy, the UK market appears to be more price sensitive. Furthermore, it appears from the investigation that hospitals generally perform a dual sourcing policy under which they prefer to be supplied by more than one supplier, in order to avoid a dependency relationship. This mechanism allows them to keep a certain competitive pressure on suppliers. For the purpose of this case, it should be noted that such a buying policy should mitigate somehow the market share addition resulting from the merger in favour of other competitors. Indeed, over time the parties are likely to lose sales in those hospitals where they are currently both retained as suppliers. In this respect, it is also worth mentioning that the parties maintain in their notification that they will proceed rapidly to a full integration of their orthopaedic business, in particular

completing the merging process in 6 months/1 year time, at least in the above mentioned countries mostly affected by the transaction.

36. Finally, budgetary constraints imposed on hospitals by Public Authorities (because of national reimbursement systems) are an additional constraint that suppliers are to take into account when fixing price.

VII. MODIFICATION TO THE ORIGINAL CONCENTRATION

37. In order to remove the competitive concerns raised by the operation in relation to the markets for hip and knee implants in Ireland, J&J has submitted some undertakings to the Commission. The text of the undertakings is annexed and forms an integral part of this decision.

38. J&J has undertaken to divest its orthopaedic sale and distribution business in Ireland to a competitor in orthopaedic products. The sale will comprise inventory, all contracts in Ireland, know-how, technical and commercial information and other assets required by the purchaser to promote the marketing and sale of the products in Ireland including […] the maintenance of on the ground support to surgeons and hospital staff. The purchaser of the business will be a competitor in the hip and knee implant sector and will be independent from the parties. Meanwhile, and until the divestiture of the business is completed, J&J will continue to manage the business in the usual way. Should the business not be divested by the end of the given period of time, a trustee will be appointed to sell the business to a purchaser within a further period of time. The undertakings also contain a non-compete clause for J&J which will prevent J&J to take part in any marketing or distribution activities for hip and knee implants in Ireland for a given period running from the conclusion of the divestiture process.

39. The Commission has conducted a market test to verify that these undertakings are sufficient to remove the competitive concerns raised by this operation. No objections have been raised by third parties.

40. The Commission considers that once an effective competitor purchases J&J's business of sales and distribution of the current range of J&J hip and knee joint replacements, effective competition in Ireland will be maintained. In this respect, no overlap between the parties' activities will result from the merger since J&J's sale business will be acquired by a third party competitor. Accordingly, customers will also continue to benefit from competition in the concerned markets. This commitment also assures a continuity in the supply of the products, avoiding any risk of reduction of customers' choice.

41. The Commission thus concludes that the undertakings submitted by J&J are sufficient to address the competition concerns raised by this concentration as far as the markets for hip and knee implants in Ireland are concerned.

VIII. CONCLUSION

42. For the above reasons the Commission decides not to oppose the notified operation and to declare it compatible with the common market and with the functioning of the EEA Agreement. This decision is adopted in application of Article 6 (1)(b) of Council Regulation (EEC) No.4064/89, as amended by Regulation 1310/97, and of Article 57 of the EEA Agreement.

For the Commission,

Annex to Commission decision of 28.10.1998 in case IV/M.1286 – Johnson & Johnson / DePuy

[Non-confidental version]

Johnson & Johnson / DePuy - Case IV/M.1286

Formal proposal for a commitment

Pursuant to Article 6(1a) of Council Regulation (EEC) No. 4064/89 (as amended; the "Regulation"), Johnson & Johnson ("J&J") hereby gives the commitments set out below to the EC Commission with respect to J&J's acquisition of DePuy, Inc. ("DePuy"). These commitments shall take effect on receipt of the EC Commission's decision declaring J&J's acquisition of DePuy compatible with the common market pursuant to Article 6(1)(b) of the Regulation.

1. J&J undertakes, in accordance with the provisions set out below, to divest its existing business of sale and distribution of the current range of J&J's hip and knee joint replacements in Ireland (the "Business"). The current range of J&J's hip and knee joint replacements (the "Products") is listed in the annex hereto.

2. The Business will comprise inventory, all contracts with customers in Ireland (including tenders, offers or estimates awaiting acceptance or rejection) and goodwill relating to the Business. J&J will also make available to the purchaser of the Business know-how, technical and commercial information and other assets required by the purchaser to effectively promote the marketing and sale of the Products in Ireland. In addition, J&J will make available to the purchaser its existing orthopaedic sales personnel in Ireland on an as needed basis. If required by the purchaser, J&J will provide clinical support to surgeons in Ireland in the implantation of the Products.

3. J&J undertakes to use its best efforts for completing the divestiture of the Business within a period of […….] following the notification of the EC Commission's decision under Article 6(1)(b) of the Regulation.

4. J&J undertakes to report, every three months, in writing to the EC Commission on developments in its negotiations with potential purchasers of the Business, subject to the EC Commission agreeing to keep confidential all such information received.

5. The purchaser of the Business will be a viable existing or prospective competitor in the knee and hip implants sector of the orthopaedics market and will be independent from and unconnected to J&J and DePuy, the satisfaction of such conditions being subject to approval by the EC Commission. If the EC Commission has not formally indicated its disagreement to a prospective purchaser within two weeks after receipt of a report identifying such party, the divestiture to such prospective purchaser shall be free to proceed. The EC Commission shall not unreasonably withhold its approval.

6. Pending the divestiture of the Business, J&J shall manage the Business on an ongoing viable basis.

7. As soon as practicable and in any event not later than one month following the notification of the EC Commission's decision under Article 6(1)(b) of the Regulation, J&J

will appoint an independent trustee (the "trustee"), such as an investment bank, subject to the approval of the EC Commission, such approval not to be unreasonably withheld.

The trustee will review that the Business will be continued by J&J on an ongoing viable basis, and that no measures are taken which would have a substantial adverse impact on the Business.

8. In the event that the Business has not been divested by the end of the first […….] period, J&J will give the trustee an irrevocable mandate to find a purchaser for the Business, for the best possible price and other terms, within a period of another […….]. J&J will provide the trustee with all reasonable assistance and information necessary for the execution of such divestment, and shall be kept informed by the trustee of all negotiations regarding finding a purchaser.

The EC Commission may object against a prospective purchaser in accordance with paragraph 5.

9. The […….] periods referred to in paragraphs 3 and 8 may be extended, at J&J's request, in case of *force majeure*.

10. For a period of […….] after the conclusion of a divestiture agreement, J&J will refrain from any direct marketing or distribution of the Products to customers in Ireland.

11. To enable customers in Ireland to use the Products, if they so desire, J&J will enter into a […….] supply contract with the purchaser of the Business to supply the purchaser with its requirements of the Products at transfer prices allowing the purchaser of the Business an adequate margin to set its retail prices at a competitive level.

On behalf of the parties,

(signed)

Koen Platteau

8 October 1998