Results of Investigation on the Transaction Plan of Zimmer and Biomet

March 25th, 2015
Japan Fair Trade Commission

Regarding the Transaction of Zimmer, Inc. (Head Office based in the USA; the corporate group to which the company belongs is hereinafter referred to as “Zimmer”) and Biomet, Inc. (Head Office based in the USA; the corporate group to which the company belongs is hereinafter referred to as “Biomet”, and hereinafter Zimmer and Biomet are collectively referred to as “the Parties”) (hereinafter referred to as “the Transaction”) (Note), the Japan Fair Trade Commission (the JFTC) received a written notification of the plan from the Parties based on the regulations of the Antimonopoly Act, and has undertaken its investigation. As a result, on the premise that the remedy proposed by the Parties would be taken, the JFTC concluded that the Transaction would not substantially restrain competition in any particular fields of trades, and thereby notified the Parties of not issuing a cease and desist order.

The JFTC kept cooperating with the United States Federal Trade Commission (USFTC), the European Commission (EC) which also investigated the same transaction and others also investigate the Transaction.

Note: The Transaction is (1) for a subsidiary company of Zimmer, Inc. and a parent company of Biomet, Inc. to merger with the parent company of Biomet, Inc. to be the surviving company, and (2) for Zimmer, Inc. to acquire all the stocks of the company after the merger.

1. Outline of the Transaction

This aims at consolidating Zimmer and Biomet manufacturing and marketing business of medical devices.

2. Sequence of events

2014	August 4th	Acceptance of a notification of the plan on merger and a notification of the plan on stock acquisition (commencement of the preliminary investigation)
	September 3rd	Request for reports etc. (commencement of the secondary investigation)
	December 25th	Acceptance of all reports and others the JFTC requested. (Deadline of advance notice: March 26th, 2015)
2015	March 25th	Notice of not issuing a cease and desist order

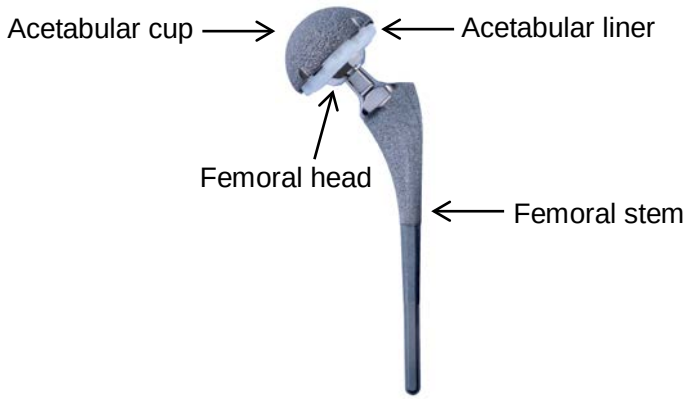
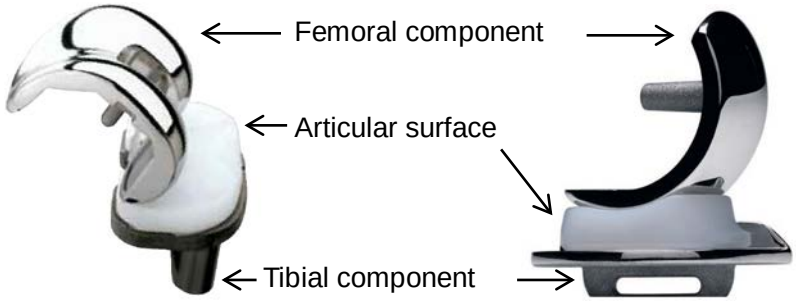
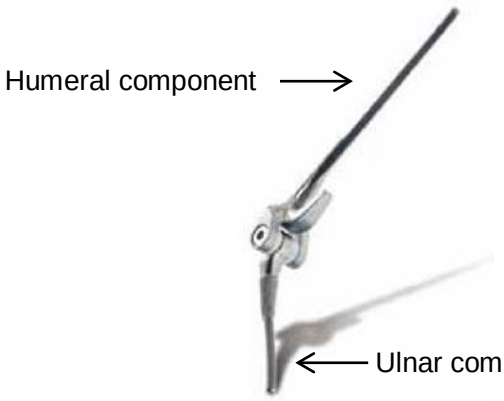
3. Conclusion

On the premise that the remedy on “UKA (one type of artificial knee joints)” and “artificial elbow joints” proposed to the JFTC by the Parties would be taken, the JFTC concluded that the Transaction would not substantially restrain competition in any particular fields of trades (see the Attachment for the detailed results of the investigation on the summary of the products, remedies, etc.).

Inquiries	Mergers and Acquisitions Division, Economic Affairs Bureau, General Secretariat, Japan Fair Trade Commission Phone: +81-3-3581-3719 (Direct line)
Website	http://www.jftc.go.jp/en

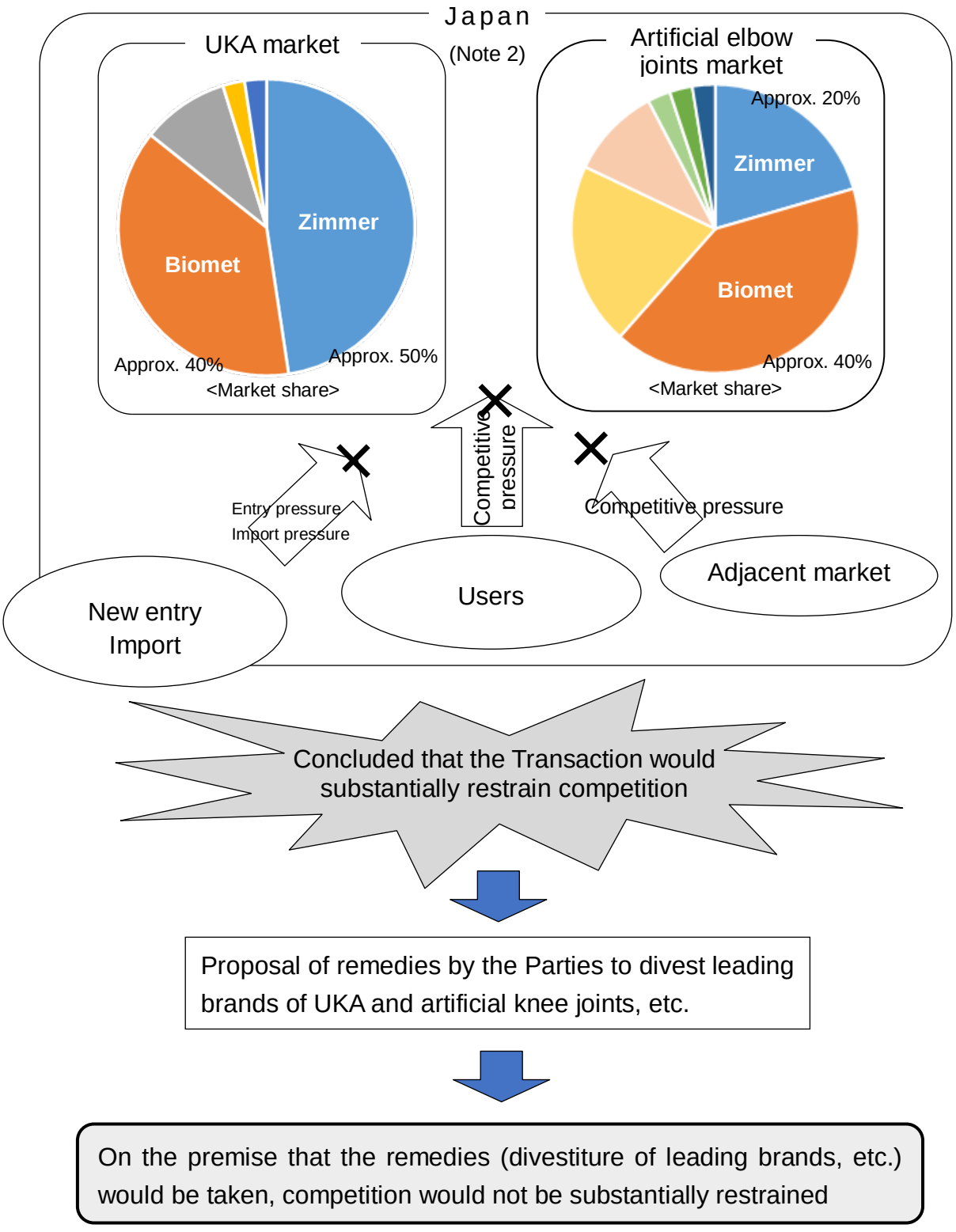
Reference

1. Products subject to this Investigation (main products)

Type of product	Sample image
Artificial hip joints	
Artificial knee joints	
Artificial shoulder joints	
Artificial elbow joints	

(Source: Materials submitted to the JFTC)

2. Brief illustration of this investigation (Note 1)



Note 1: Among the products subject the Investigation (main products) shown in Section 1 above, regarding those other than UKA and artificial knee joints, the JFTC concluded that the Transaction would substantially restrain competition.

Note 2: The geographic scope was defined to be all parts of Japan for both products.

Attachment

Results of Investigation on the Transaction between Zimmer and Biomet

1. The Parties

Zimmer, Inc. (the corporate group to which the company belongs is hereinafter referred to as “Zimmer”) is a company that conducts medical device marketing business, etc.

Biomet, Inc. (the corporate group to which the company belongs is hereinafter referred to as “Biomet”) is a company that conducts medical device marketing business, etc.

Zimmer and Biomet are collectively referred to as “the Parties” hereinafter.

2. Outline and applicable provisions of the Act

The Transaction is (1) for a subsidiary company of Zimmer, Inc. and a parent company of Biomet, Inc. to merger with the parent company of Biomet, Inc. to be the surviving company, and (2) for Zimmer, Inc. to acquire all the stocks of the company after the merger.

Applicable provisions are Articles 10 and 15 of the Antimonopoly Act.

Zimmer, Inc. and Biomet, Inc. are companies that conduct medical device marketing business, and there are a wide range of products marketed by both companies or their subsidiaries that are in horizontal relations[1]. From Section 3 below onward, among such products, investigation was carried out for artificial joints[2] (articifial hip joints, artificial knee joints, artificial shoulder joints and artificial elbow joints; the same shall apply hereinafter), because the Parties have a relatively large market share for them and it was considered that the influence of the Transaction on competition would be relatively significant.

3. Sequence of events and brief summary of the investigation

1. Sequence of events

Since June 2014, the Parties voluntarily submitted written opinions and materials to

[1] Refers to being in competition within the same field of trade.

[2] Regarding artificial joints, medical institutions (physicians) select products and purchase from wholesalers. Artificial joints are covered by the insurance reimbursement system (material price standard system). In the system, insurance reimbursement prices (hereinafter referred to as “reimbursement prices”) are specified by the Ministry of Health, Labour and Welfare (MHLW) for medical materials that constitute each medical device (refers to designated insured medical materials; the same shall apply hereinafter), and medical institutions that performed medical services using artificial joints are uniformly reimbursed of the reimbursement prices from a health insurance society, etc. Reimbursement prices are revised once every two years after investigation by MHLW on the purchase prices of medical devices by medical institutions and selling prices of similar products in overseas. In most cases, medical institutions purchase medical devices at prices cheaper than reimbursement prices by a certain degree, since purchasing at prices higher than the reimbursement prices results in the difference between the reimbursement prices and the purchase prices (including consumption tax) becoming a loss.

the JFTC stating that the Transaction would not substantially restrain competition, and the JFTC held meetings several times with the Parties in response to requests by the Parties. Subsequently, on August 4th , 2014, the JFTC accepted a written notification of the plan of the Transaction submitted by the notifying companies based on the regulations of the Antimonopoly Act, and commenced the preliminary investigation. The JFTC proceeded with the preliminary investigation based on the abovementioned wirtten notification and other documents submitted by the Parties, hearing to users, etc. As a result, the JFTC decided to open the secondary investigation, because of necessity of further investigation on September 3, 2014, the JFTC requested the notifying companies to provide reports etc, made the investigation public, and solicited public comments from third persons .

In the secondary investigation, the JFTC held meetings several time with the Parties in response to requests by the Parties. The JFTC also proceeded with the secondary investigation on the effect of the Transaction on competition, based on the results etc. of hearing from medical institutions, wholesalers and competing rivals, in addition to the reports etc. sequentially submitted by the notifying companies.

Regarding the request for provision of reports etc. to the notifying companies, submission of all reports etc. was completed with the reports etc. submitted on December 25th , 2014.

2. Brief summary of the investigation

In the Transaction, on the premise that the remedy described in Section 7 below on “UKA” and “artificial elbow joints” among artificial joints proposed to the JFTC by the Parties would be taken, the JFTC concluded that the Transaction would not substantially restrain competition in any particular fields of trades, including fields of trade other than the two.

Details of investigation results pertaining to the artificial joints are described in Sections 4 and 5.

4. Particular field of trade

1. Product range

(1) Artificial hip joints

a. Product description

Artificial hip joints are medical devices used as a replacement of hip joints for when the function of the original hip joints is impaired.

Replacement therapy using artificial hip joints is roughly divided into two methods. One is total hip arthroplasty (THA; hereinafter refers to artificial hip joints used for this therapy method) to replace both of the acetabular side (pelvic side)

and the femoral side that constitute hip joints to artificial joints for when damage is identified in both sides. The other is “artificial femoral head (AFH) replacement” to replace the femoral side only to artificial joints for when the neck part of the bone head at the tip of femur is fractured.

THA consists of pelvic side medical materials “acetabular cup” and “acetabular liner” and femoral side medical materials “femoral stem”, “femoral head”, etc., while AFH consists of “femoral stem” and “femoral head” only.

Two types of products are available for THA and AFH. One is “primary” that is used for the first surgery and the other is “revision” that is used for repeat surgery. Further, there are two types of femoral stem or acetabular cup products depending on the joining method with the bone. One is cement-less type that is used for direct fixing by means of bone fusion (property of bone fusing with titanium) and the other is cement type that is used for indirect fixing by means of bone cement.

b. Demand substitutability

Among artificial hip joints, while THA is used for when replacing both the acetabular side and the femoral side, AFH is used for when replacing the femoral side only. Applicable conditions are different between THA and AFH, and thus there is no demand substitutability between the two. Regarding primary and revision, basically primary products are used for the first surgery and revision products are used for repeat surgery, and thus their demand substitutability is limited. Meanwhile, regarding cement-less type products and cement type products, physicians make the selection depending on the condition of the patient, experience, etc., but they share the basic usage and thus there is demand substitutability.

c. Supply substitutability

Medical materials that constitute AFH are basically the same as a part of medical materials that constitute THA, and thus there is supply substitutability between THA and AFH.

Regarding primary and revision, while there are some differences in the form or structure, basically they can be manufactured using the same manufacturing technology and equipment. Further, regarding sales, while sales require approval etc. based on the Pharmaceuticals and Medical Devices (PMD) Act[3] (see Section 2 below) and it usually takes 6-12 months from application to approval, the required

[3] Former Pharmaceutical Affairs Act. The “Act for Partial Amendment of the Pharmaceutical Affairs Act, etc.” came into force on November 25, 2014, and it was renamed to “Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (abbreviation: Pharmaceuticals and Medical Devices Act or PMD Act).

time becomes shortened considerably when similar products are available in the market.

For that reason, it is considered that an enterprise that currently markets primary products only (or revision products only) is able to manufacture and market revision products (or primary products) in a short period of time without bearing a large amount of additional expense. Therefore, there is supply substitutability between primary and revision.

d. Summary

As described above, a certain degree of demand substitutability and supply substitutability is identified among the abovementioned product types, and the JFTC defined the product range to be “artificial hip joints”.

(2) Artificial knee joints

a. Product description

Artificial knee joints are medical devices used as a replacement of knee joints for when the function of the original knee joints is impaired.

Replacement therapy using artificial knee joints is roughly divided into two methods. One is total knee arthroplasty (TKA, which hereinafter refers to artificial knee joints used for this therapy method) to replace both the inner side and the outer side of knee joints to artificial joints for when damage is identified in both sides. The other is “unicompartmental knee arthroplasty” (UKA; hereinafter refers to artificial knee joints used for this therapy method) to replace the inner or outer side of knee joints to artificial joints for when damage is identified in one side only.

While TKA and UKA both consist of medical materials “femoral component” to be attached to the femur, “tibial component” to be attached to the tibia, and “articular surface (bearing insert)” to be attached to the sliding portion, the form etc. of each medical material is different between TKA and UKA.

Similar to artificial hip joints, there are primary products and revision products for TKA, and there are cement-less type and cement type products for each of the abovementioned components of TKA and UKA.

b. Demand substitutability

Among artificial knee joints, while TKA is used for when replacing the whole knee joints, UKA is used for when replacing one side only. Applicable conditions are different between TKA and UKA, and thus there is no demand substitutability between the two. Similar to artificial hip joints, demand substitutability between primary and revision of TKA is limited, and there is demand substitutability between

cement-less type and cement type products.

c. Supply substitutability

While the form etc. of medical materials that constitute TKA and UKA is different, the technology required for manufacturing is similar, and equipment required for manufacturing is almost identical. Further, while sales of TKA and UKA by manufacturers etc. in Japan require approval etc. based on the PMD Act and it usually takes 6-12 months from application to approval, the required time becomes shortened considerably when similar products are available in the market. For that reason, it is considered that an enterprise that currently markets TKA only (or UKA only) is able to manufacture and market UKA (or TKA) in a short period of time without bearing a large amount of additional expense. Therefore, there is supply substitutability between TKA and UKA. Additionally, similar to artificial hip joints, there is supply substitutability between primary and revision of TKA.

d. Summary

As described above, there is no demand substitutability yet there is supply substitutability between TKA and UKA, and there is demand substitutability among abovementioned product types of TKA and UKA. For that, it is possible to define the product range to “artificial knee joints (TKA and UKA)”. However, in addition to the fact that there is no demand substitutability between TKA and UKA due to different applicable conditions, the competition environment (composition of suppliers and the situation of market share) of the TKA market is significantly different from that of the UKA market. Therefore, it is appropriate to consider that TKA and UKA form different markets.

For that reason, the JFTC separately defined the product range to be “TKA” and “UKA”.

(3) Artificial shoulder joints

a. Product discription

Artificial shoulder joints are medical devices used as a replacement of shoulder joints for when the function of the original shoulder joints is impaired.

Replacement therapy using artificial shoulder joints is roughly divided into two methods One is total shoulder arthroplasty (TSA, which hereinafter refers to artificial shoulder joints used for this therapy method) to replace both the humeral side and the scapular side that constitute shoulder joints to artificial joints for when damage is identified in both sides. The other is “artificial humeral head (AHH) replacement” to replace the humeral side only to artificial joints for when damage is

identified only in the bone head at the humeral side of shoulder joints.

TSA consists of medical materials “humeral stem” and “humeral head” to be attached to the humerus and “glenoid” to be attached to the scapula, while AHH consists only of “humeral stem” and “humeral head” on the humeral side.

Similar to artificial hip joints, there are primary products and revision products for artificial shoulder joints, and there are cement-less type and cement type products for humeral stem and glenoid.

In Japan, “reverse type” artificial shoulder joints where the head and glenoid have a reverse structure (head is attached to the scapular side, and glenoid is attached to the humeral side) are marketed since 2014. Reverse type products are applicable to conditions where major damage has occurred to the rotator cuff, which could not be treated with TSA.

b. Demand substitutability

Among artificial shoulder joints, while TSA is used for when replacing both of the humeral side and scapular side, AHH is used for when replacing the humeral side only. Applicable conditions are different between TSA and AHH, and thus there is no demand substitutability between the two. Similar to artificial hip joints, demand substitutability between primary and revision is limited, and there is demand substitutability between cement-less type and cement type products.

Regarding the reverse type goods, the applicable conditions are different from that of TSA and there is no demand substitutability between TSA and reverse type goods.

c. Supply substitutability

Medical materials that constitute AHH are basically the same as a part of medical materials that constitute TSA, and thus there is supply substitutability between AHH and TSA. Additionally, similar to artificial hip joints, there is supply substitutability between primary and revision.

Regarding TSA and reverse type products, applicable conditions are different and the technology required for designing is thus different. Further, reverse type products are new products approved for the first time in Japan in 2014, and it is considered that approval etc. based on the PMD Act takes a longer period of time compared to other existing artificial joints such as TSA. Therefore, it is considered difficult for TSA manufacturers to manufacture and market reverse type products in a short period of time without bearing a large amount of additional expense, and there is no supply substitutability among them.

d. Summary

From the abovementioned understanding, the JFTC defined the product range to be “artificial shoulder joints (excludes reverse type)”[4].

(4) Artificial elbow joints

a. Product discription

Artificial elbow joints are medical devices used as a replacement of elbow joints for when the function of the original elbow joints is impaired.

Replacement therapy using artificial elbow joints is roughly divided into two methods. One is total elbow arthroplasty (TEA, which hereinafter refers to artificial elbow joints used for this therapy method) to replace both the humeral side and the ulnar side of elbow joints to artificial joints for when damage is identified in both sides. The other is “artificial radial head (ARH) replacement” to replace the section near the radial head to artificial joints for when damage is identified in the section.

TEA consists of medical materials “humeral component” to be attached to the humerus and “ulnar component” to be attached to the ulna, while ARH consists of “radial component” to be attached to the radius.

There are linked type (the abovementioned components are completely linked) and non-linked type (the abovementioned components are not completely linked) products for TEA. Basically, applicable conditions are common for the both types, and either of linked type and non-linked type products is used when the collateral ligament functions, and non-linked type products are selectively used in relatively severe exceptional cases where damage is identified in the collateral ligament.

Similar to artificial hip joints, there are primary goods and revision goods for TEA, and there are cement-less type and cement type products for each of the abovementioned components.

b. Demand substitutability

Among artificial elbow joints, while TEA is used for when replacing both of the humeral side and ulnar side, ARH is used for when replacing the radial head. Applicable conditions are different between TEA and ARH, and thus there is no demand substitutability between the two. Regarding the linked type and non-linked type products, while physicians make the selection depending on the condition of the patient, experience, etc., applicable conditions are basically the same for them except some exceptional cases where the collateral ligament is not functioning. Therefore, there is demand substitutability between linked type and non-linked type

[4] One of the Parties does not market reverse type products and reverse type products are not in horizontal relations between the Parties, and thus the market is not separately defined for reserve type products.

products. Additionally, similar to artificial hip joints, demand substitutability between primary and revision of TEA is limited, and there is demand substitutability between cement-less type and cement type products.

c. Supply substitutability

While the form etc. of medical materials that constitute TEA and ARH is different, the technology required for manufacturing is similar, and equipment required for manufacturing is almost identical. Further, while sales of TEA and ARH in Japan require approval etc. based on the PMD Act and it usually takes 6-12 months from application to approval, the required time becomes shortened considerably when similar products are available in the market. For that reason, it is considered that an enterprise that currently markets TEA only (or ARH only) is able to manufacture and market ARH (or TEA) in a short period of time without bearing a large amount of additional expense. Therefore, there is supply substitutability between TEA and ARH. Additionally, similar to artificial hip joints, there is supply substitutability between primary and revision of TEA.

d. Summary

From the abovementioned understanding, the JFTC defined the product range to be “artificial elbow joints”.

2. Geographic range

Regarding artificial hip joints, TKA, UKA, artificial shoulder joints (excludes reverse type) and artificial elbow joints, sales of individual products by domestic manufacturers, Japanese subsidiaries of overseas manufacturer or sole import distributorships require approval etc. based on the PMD Act. Additionally, the current situation is that medical institutions as users purchase the approved goods designed for marketing in Japan via wholesalers.

Therefore, the JFTC defined the geographic range to be “all parts of Japan”.

5. Examination of substantial restrainment of competition

1. Artificial hip joints

By the Transaction, the Herfindahl-Hirschman Index (HHI) will be approximately 1400, the combined market share and ranking of the Parties become approximately 30% and the first place, respectively, and the incremental HHI will be approximately 280. Therefore, the Transaction comes under the safe harbor rules for horizontal business combination.

[Market share of artificial hip joints in FY2012]

Rank	Company name	Market share
1	Zimmer	Approx. 20%
2	Company A	Approx. 20%
3	Company B	Approx. 10%
4	Company C	Approx. 10%
5	Biomet	Approx. 10%
	Others	Approx. 30%
Total		100%

2. TKA

(1) Position of the Parties

By the Transaction, HHI will be approximately 2400, the combined market share and ranking of the Parties become approximately 40% and the first place, respectively, and the incremental HHI will be approximately 720. Therefore, the Transaction does not come under the safe harbor rules for horizontal business combination.

[Market share of TKA in FY2012]

Rank	Company name	Market share
1	Zimmer	Approx. 30%
2	Company D	Approx. 20%
3	Biomet	Approx. 10%
4	Company E	Approx. 10%
5	Company F	Approx. 5%
6	Company G	0-5%
	Others	Approx. 15%
Total		100%

(2) Conditions of competing enterprises

There exist influential competing enterprises, company D with the market share of approximately 20% and company E with the market share of approximately 10%. Additionally, there exist multiple competing enterprises.

Further, it is considered that each company possesses a certain level of excess capacity.

(3) Entry pressure

It is considered that the possibility of frequent new entry into the market in the future is low, for the fact that a majority of influential overseas manufacturers have already entered the Japanese market, the fact that the enterprises newly entered into the market in late years have not acquired a certain level of market share, and there is no sign of the scale of domestic market significantly expanding in a short period of time.

Therefore, it is considered that entry pressure is not acting adequately.

(4) Competitive pressure from adjacent markets

Regarding the treatment methods of diseases pertaining to joints, while there are rheumatism treatment methods using biological preparations or autologous cartilage transplantation, these treatment methods are preventively used during the relatively early stage of disease and rarely applied to patients with advanced conditions where knee replacement arthroplasty becomes applicable. Therefore, it is considered that competitive pressure from adjacent markets is not acting.

(5) Competitive pressure from users

At medical institutions as users, there is a strong tendency where physicians who perform surgery select products depending on the quality of products and experience. In late years, there are some cases observed where prices are taken into account in the selection, such as cases where medical institutions request to lower prices by holding discount negotiations with multiple wholesalers. However, medical institutions (physicians) still have a tendency to set high value on the quality of products and experience. Additionally, while special surgery equipment is used on performing artificial joint replacement, the method of use of such equipment varies depending on the manufacturer, and it is necessary to acquire a certain level of skills to use the equipment. Also from this viewpoint, physicians tend not to change to products from other manufacturers frequently. Therefore, it is considered that such a situation has not come to a state where discount negotiations conducted by medical institutions can be assessed as competitive pressure.

The Parties are claiming that the reimbursement prices are acting as suppression pressure on price increase. As a matter of fact, medical institution almost never purchase artificial joints (e.g., TKA) at prices higher than the reimbursement prices. However, manufacturers compete at the price range that is below the reimbursement prices, and the reimbursement prices themselves are revised once every two years reflecting the actual selling prices. Therefore, it is considered not appropriate to

assess the reimbursement prices as adequate suppression pressure on price increase.

Therefore, it is considered that competitive pressure from users is not acting adequately.

(6) Legal assessment based on the Antimonopoly Act

After the Transaction, the market share of the Parties in the TKA market will become approximately 40%, and the number of companies competing in the market will reduce by one. However, there still exist company D and company E as influential competing enterprises in the market, and there also exist other competing enterprises. Additionally, each competing enterprise possesses a certain level of excess capacity, and there is no circumstance identifiable that will facilitate highly accurate prediction of each other's actions by the enterprises.

Therefore, the JFTC concluded that the Transaction would not substantially restrain competition in the TKA market because of unilateral conduct of the Parties or coordinated conduct with competing enterprises.

3. UKA

(1) Position of the Parties

By the Transaction, HHI will be approximately 7800, the combined market share and ranking of the Parties become approximately 90% and the first place, respectively, and the incremental HHI will be approximately 3800. Therefore, the Transaction does not come under the safe harbor rules for horizontal business combination.

[Market share of UKA in FY2012]

Rank	Company name	Market share
1	Zimmer	Approx. 50%
2	Biomet	Approx. 40%
3	Company H	Approx. 10%
4	Company I	0-5%
	Others	0-5%
Total		100%

(2) Conditions of competing enterprises

While there exists company H that holds the market share of approximately 10% as an influential competing enterprise, the gap from the Parties is large and the market

share of other competing enterprises is extremely small (competing enterprises that are influential in other artificial joints markets do not hold much market share in the UKA market). Additionally, the Parties occupied the market as the first place and the second place with similar market shares of approximately 50% and approximately 40%, recognized each other as a competing enterprise and actively competed in the past. Therefore, it is considered that the influence of the competition between the Parties ceasing to exist on the competition is large.

Additionally, while it is considered that each company possesses a certain level of excess capacity, a majority of enterprises have a small market share and it is not adequate to act as checking power to the Parties.

(3) Entry pressure

While the UKA market is in a trend of gradual expansion, its scale is still small[5], and new entry is not expected. Therefore, it is considered that entry pressure is not acting.

(4) Competitive pressure from adjacent markets

Since the situation is similar to the TKA market, it is considered that competitive pressure from adjacent markets is not acting.

(5) Competitive pressure from users

Since the situation is similar to the TKA market, it is considered that competitive pressure from users is not acting adequately.

(6) Legal assessment based on the Antimonopoly Act

After the Transaction, the market share of the Parties in the UKA market will become approximately 90%, and there will emerge a significant gap from competing enterprises. Additionally, competition previously conducted between the Parties will be lost. Meanwhile, each competitive pressure on the UKA market is limited, and the Transaction would result in creating a situation where the Parties would be able to freely control the prices etc. to a certain degree. Therefore, the JFTC concluded that the Transaction would substantially restrain competition in the UKA market.

4. Artficial shoulder joints (excludes reverse type)

(1) Position of the Parties and conditions of the competitors

By the Transaction, HHI will be approximately 2700, the combined market share

[5] The scale of artificial knee joints (TKA and UKA) market in 2012 was approximately 31 billion yen, and the percentage of UKA in the artificial knee joints market was less than 10% in a quantity basis.

and ranking of the Parties become approximately 30-40% and the second place, respectively, and the incremental HHI will be approximately 600. Therefore, the Transaction does not come under the safe harbor rules for horizontal business combination.

[Market share of artificial shoulder joints (excludes reverse type) in FY2012]

Rank	Company name	Market share
1	Company J	Approx. 40%
2	Zimmer	Approx. 20%
3	Biomet	Approx. 20%
4	Company K	Approx. 10%
5	Company L	5-10%
6	Company M	5-10%
	Others	0-5%
Total		100%

(2) Conditions of competing enterprises

There exist influential competing enterprises, company J with the market share of approximately 40% and company K with the market share of approximately 10%. Additionally, there exist multiple competing enterprises such as company L and company M.

Further, it is considered that each company possesses a certain level of excess capacity.

(3) Entry pressure

While entry of overseas manufacturers is observed in late years, the scale of market is small[6] and the possibility of new entries frequently taking place in the future is considered relatively low.

Therefore, it is considered that entry pressure is not acting adequately.

(4) Competitive pressure from adjacent markets

Since the situation is similar to the TKA market, it is considered that competitive pressure from adjacent markets is not acting.

(5) Competitive pressure from users

Since the situation is similar to the TKA market, it is considered that competitive

[6] While the scale of artificial knee joints (TKA and UKA) market in 2012 was approximately 31 billion yen, the scale of artificial shoulder joints market was approximately 1.1 billion yen.

pressure from users is not acting adequately.

(6) Legal assessment based on the Antimonopoly Act

After the Transaction, the market share of the Parties in the artificial shoulder joints market will become approximately 30-40%, and the number of companies competing in the market will reduce by one. However, there still exist company J and company K as influential competing enterprises in the market, and there also exist other competing enterprises. Additionally, each competing enterprise is considered to possess a certain level of excess capacity, and there is no circumstance identifiable that will facilitate highly accurate prediction of each other's actions by the enterprises.

Therefore, the JFTC concluded that the Transaction would not substantially restrain competition in the artificial shoulder joints market because of unilateral conduct of the Parties or coordinated conduct with competing enterprises.

5. Artificial elbow joints

(1) Position of the Parties and conditions of the competitors

By the Transaction, HHI will be approximately 4600, the combined market share and ranking of the Parties become 60-70% and the first place, respectively, and the increased portion of HHI will be approximately 1900. Therefore, the Transaction does not come under the safe harbor rules for horizontal business combination.

[Market share of artificial elbow joints in FY2012]

Rank	Company name	Market share
1	Biomet	Approx. 40%
2	Zimmer	Approx. 20%
3	Company N	Approx. 20%
4	Company O	Approx. 10%
5	Company P	0-5%
6	Company Q	0-5%
	Others	0-5%
Total		100%

(2) Conditions of competing enterprises

While there exist company N that holds the market share of approximately 20% and company O that holds the market share of approximately 10% as influential competing enterprises, the gap from the Parties will become remarkably large (competing enterprises that are influential in other artificial joints markets do not hold

much market share or has not entered into the artificial elbow joints market). Additionally, the Parties occupied the market as the first place and the second place with market shares of approximately 40% and approximately 20%, recognized each other as a competing enterprise and actively competed in the past. Therefore, it is considered that the influence of the competition between the Parties ceasing to exist on the competition is large.

Additionally, while it is considered that each company possesses a certain level of excess capacity, a majority of enterprises have a small market share and it is not adequate to act as checking power to the Parties.

(3) Entry pressure

The scale of artificial elbow market is small[7], and new entry is not expected. Therefore, it is considered that entry pressure is not acting.

(4) Competitive pressure from adjacent markets

Since the situation is similar to the TKA market, it is considered that competitive pressure from adjacent markets is not acting.

(5) Competitive pressure from users

Since the situation is similar to the TKA market, it is considered that competitive pressure from users is not acting adequately.

(6) Legal assessment based on the Antimonopoly Act

After the Transaction, the market share of the Parties in the artificial elbow joints market will become 60-70%, and there will emerge a significant gap from competing enterprises. Additionally, competition previously conducted between the Parties will be lost. Meanwhile, each competitive pressure on the artificial elbow joints market is limited, and the Transaction would result in creating a situation where the Parties can freely control the prices etc. to a certain degree. Therefore, the JFTC concluded that the Transaction would substantially restrain competition in the artificial elbow joints market.

6. Economic analysis

Expenditures on artificial joints are subject to reimbursement under the national health insurance system. Under this system, regulated reimbursement prices function as de facto ceiling prices when medical institutions purchase artificial joints from

[7] While the scale of artificial knee joints (TKA and UKA) market in 2012 was approximately 31 billion yen, the scale of artificial elbow joints market was approximately 0.4 billion yen.

wholesalers. However, the average selling prices from wholesalers to medical institutions (hereinafter referred to as “wholesale prices”) are below the reimbursement prices by a certain degree, and the average selling prices from manufacturers to wholesalers (hereinafter referred to as “manufacturer prices”) are, in turn, below the wholesale prices. Therefore, it is possible for the Transaction to affect these prices at each distribution stage. Additionally, the reimbursement prices are revised once every two years in accordance with the level of prevailing wholesale prices. Therefore, if competition among manufacturers declines as a result of the Transaction, causing the manufacturer prices and wholesale prices to increase, there is a possibility that future reimbursement prices will remain high.

To address these concerns, the JFTC conducted econometric analysis regarding the relationship between market structure and manufacturer, taking into account the possibility that manufacturer prices affect market structure through new entry. As a result, it was found that higher market concentration is associated with higher manufacturer prices. Based on this result, simulation analysis pertaining to the impact of the Transaction on manufacturer prices and reimbursement prices was carried out. According to the simulation results, if a Transaction similar to the Transaction hypothetically took place in FY2011, the manufacturer prices in the next fiscal year is estimated to have increased by 6.2% for UKA; 4.3-5.3% for artificial elbow joints; and 1.5-3.1% for artificial hip joints, TKA and artificial shoulder joints. This would have led to reimbursement prices in FY2014 being higher than the actual prices by 4.3% for UKA; 1.3-3.2% for artificial elbow joints; and 0.3-2.0% for artificial hip joints, TKA and artificial shoulder joints[8].

These results are consistent with the investigation results described in Section 5 above, and the JFTC took them into account in making its judgment[9].

7. Proposal of remedy by the Partires

The JFTC provided the Parties with explanations on the points of issues etc. regarding Sections 5.3.(6) and 5.5.(6) above. The Parties then submitted the proposal of Remedy on UKA and artificial elbow joints (hereinafter referred to as “the Remedy”) to the JFTC as follows:

(1) Tangible assets (e.g., inventory, design history, experimental and clinical data),

[8] The reason why there is a range in the estimated values is because artificial joints are divided into multiple reimbursement categories (categories specified by the Ministry of Health, Labour and Welfare, where medical equipment that are similar in terms of structure, intended use, medical efficacy, etc. are placed into one group) and the estimated values vary across reimbursement categories.

[9] When simulation analysis is applied to the review of a business combination as in the present case, it has to be recognized that the results by necessity rely on a set of assumptions. Therefore, the simulation results should be interpreted as supplementary information to the results of qualitative investigation, not as a definitive conclusion on the effects of this Consolidation.

intellectual property rights (patents, trademarks, know-how, etc. used in the subject goods), etc. pertaining to the Parties' leading brands corresponding to approximately 50% of the market share in the UKA market in FY2012 are to be divested;

(2) Tangible assets (same as above), intellectual property rights (same as above), etc. pertaining to the Parties' leading brands corresponding to approximately 20% of the market share in the artificial elbow joints market in FY2012 are to be divested;

(3) Buyers are to be enterprises which have adequate experience and capability in the orthopedics and artificial joints business and be independent of and financially unrelated to the Parties, that need to be selected in light of the criteria such as possessing the funds, specialty and insentive to maintain and develop the business subject to the dinestitures, The possible buyers are to be notified to and obtain an clearance from the JFTC after concluding contracts with the buyers;

(4) If the Parties don't reach to conclude contracts with buyers within a certain period of time, an independent third party (divestiture trustee) carries out disposal of the business listed in (1) and (2) above after obtaining an approval from the JFTC; and,

(5) The time limit to execute the divestitures is to be within 3 months from the day the clearance from the JFTC regarding possible buyers.

8. Assessment of the Remedy

On the premise that the Remedy would be taken, the Parties' combined market share and rank in the UKA market after the Transaction would be approximately 40% and the second place, respectively, and the Parties' combined market share and rank in the artificial elbow joints market after the Transaction would be approximately 40% and the first or second place, respectively. However, in both of the UKA market and artificial elbow joints market, the Parties' market share after the Transaction would be lower than the larger market share of the Parties before the Transaction.

Regarding buyers, it is considered that buyers who satisfy the requirements described in Section 7.(3) above would become independent competitors influential in the UKA and artificial knee joints markets. Whether the actual buyers satisfy the said requirements will be assessed by the JFTC after receiving reports from the Parties.

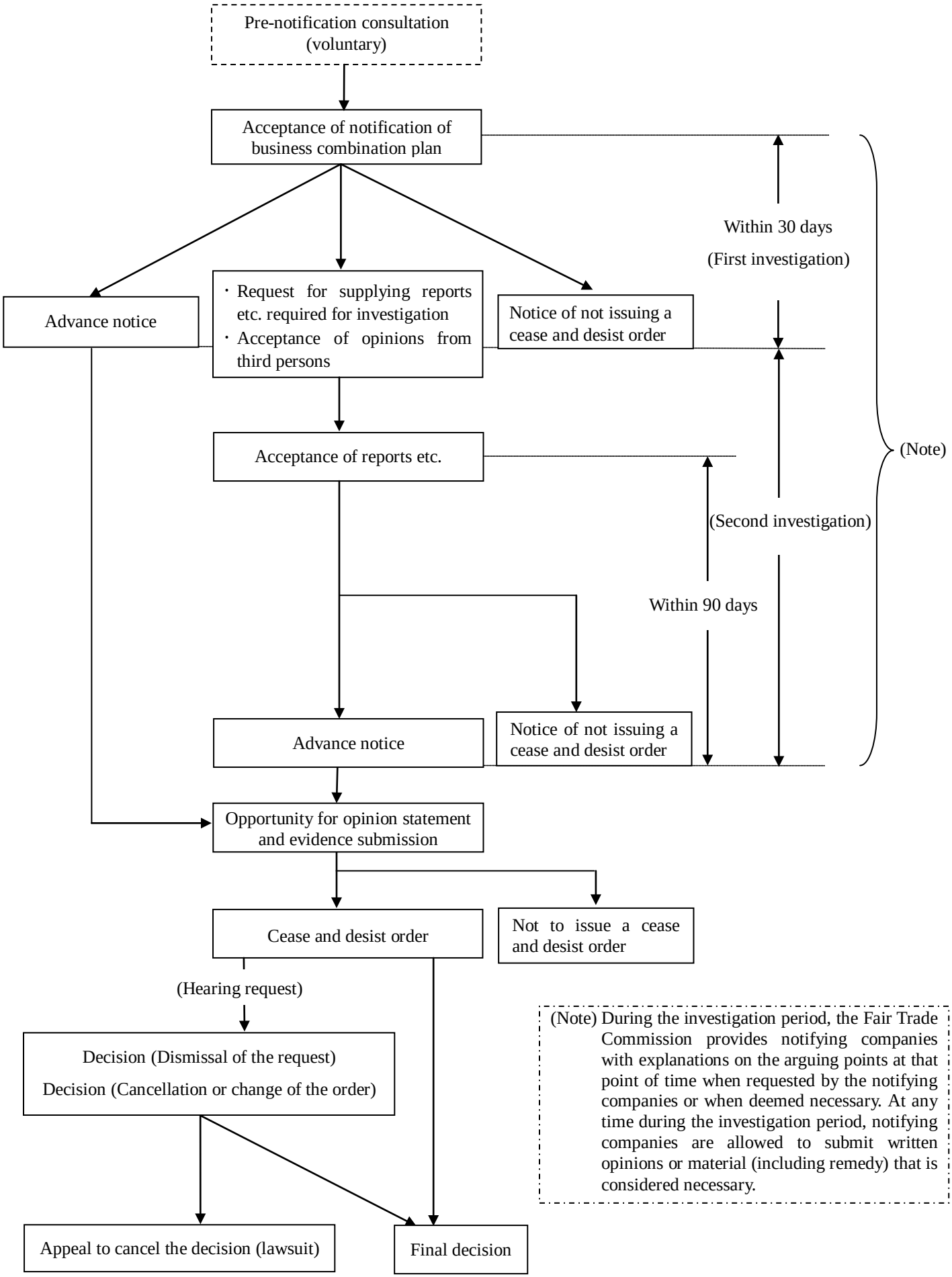
Additionally, even in the case where divestiture is carried out after acquiring the stocks in the Transaction, the time limit to take the Remedy is appropriately and clearly specified considering, for instance, the time limit to execute the divestiture is set to be within 3 months from the day the clearance from the JFTC regarding buyers.

Based on the abovementioned understanding, on the premise that the Remedy would be taken, the JFTC concluded that the Transaction would not substantially restrain competition in any particular fields of trades.

9. Conclusion

On the premise that the Remedy proposed to the JFTC by the Parties would be taken, the JFTC concluded that the Transaction would not substantially restrain competition in the UKA and artificial elbow joints markets.

(Reference) Flow chart of review of business combination



(Note) During the investigation period, the Fair Trade Commission provides notifying companies with explanations on the arguing points at that point of time when requested by the notifying companies or when deemed necessary. At any time during the investigation period, notifying companies are allowed to submit written opinions or material (including remedy) that is considered necessary.