

The proposed acquisition of the stock of Guidant Corporation by Johnson & Johnson

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Japan Fair Trade Commission

The Japan Fair Trade Commission (hereinafter "JFTC") had been reviewing the competitive impact of the proposed acquisition of the stock of Guidant Corporation (based in the United States; hereinafter "Guidant") by Johnson & Johnson (based in the United States; hereinafter "J&J") on Japanese medical devices market, and recognized that some possible substantial restraint of competition on the market for a certain product might exist. However, if the remedies planned by the parties are certainly fulfilled, such possibility to substantially restrain competition on the market for the product above would be solved. Accordingly, the JFTC decided that there would be no violation of the Antimonopoly Act..

In addition to the JFTC, this case has also been examined by the U.S. Federal Trade Commission (hereinafter "US-FTC") and the European Commission (hereinafter "EC"), and the JFTC has been conducting the examination exchanging information with these foreign competition authorities.

The EC and the US-FTC announced (on August 25 and on November 2, respectively) their examination results to the effect that the proposed acquisition would not violate competition laws, on condition that the remedies be fulfilled by the parties.

I. Outline of the stock acquisition

Subject to Guidant shareholder approval and other customary closing conditions, in 2006, J&J, which manufactures and distributes medical devices, plans to acquire all of the stock of Guidant, which also manufactures and distributes medical devices.

The parties distribute medical devices all over the world, and they also distribute their products in Japan through their Japanese affiliates or importers of medical devices.

Medical devices which both J&J and Guidant manufacture and distribute are those that are used for treatments of coronary artery diseases and those used for treatments of other vessels diseases.

II. Views under the Antimonopoly Act

1. Relevant markets

There exist following treatments for coronary artery diseases, which cause myocardial infarction and angina pectoris: percutaneous transluminal coronary angioplasty

(hereinafter "PTCA") which is the procedure to deliver a catheter to narrow or blocked coronary arteries to dilate them, and coronary artery bypass grafting (hereinafter "CABG") which is the procedure to bypass the narrow coronary arteries by grafting another blood vessel to the site of lesion.

As for treatments for diseases of the vessels other than coronary arteries (such as carotid, renal, iliac or femoral arteries), percutaneous transluminal angioplasty (hereinafter "PTA") is adopted, which is the procedure to deliver a catheter to narrow peripheral vasculars to dilate them.

The JFTC, examining whether or not the devices used for these procedures have similar functions and efficacy to the physicians (who are users), found that relevant markets in Japan are constituted by the following 12 medical devices, respectively.

- 1) PTCA Guiding Catheters
- 2) PTCA Guidewires
- 3) PTCA Balloon Catheters
- 4) PTCA Drug Eluting Stents (hereinafter "DES")
- 5) PTCA Bare Metal Stents (hereinafter "BMS")
- 6) CABG Endoscopic Vessel Harvesting Systems (hereinafter "EVH devices")
- 7) CABG Stabilizers
- 8) PTA Guiding Catheters
- 9) PTA Guidewires
- 10) PTA Balloon Catheters
- 11) PTA Stents
- 12) Inferior Vena Cava Filters

2. Market Scale

The market scale of entire medical devices in Japan was about 2.06 trillion yen in 2004. Market scales for the 12 medical devices listed above are as follows and they account for about 6% of the entire medical devices.

- a. Medical devices for PTCA (Guiding Catheters, Guidewires, Balloon Catheters, DES and BMS): about 100 billion yen
- b. Medical devices for CABG (EVH devices and Stabilizers): about 0.5 billion yen
- c. Medical devices for PTA (Guiding Catheters, Guidewires, Balloon Catheters, Stents and Inferior Vena Cava Filters): about 18.5 billion yen

3. Competition Status in the Market

(1) Markets in which the acquisition would not result in substantially restraining

competition immediately

It is considered that, of the 12 markets listed above, with regard to the 10 markets excluding the DES and EVH devices, the implementation of the acquisition would not result in substantially restraining competition in the relevant market immediately, as explained below.

(a) PTCA Guiding Catheters, PTCA Guidewires, PTCA Balloon Catheters, BMS

The parties are competing with each other in these 4 markets, but the proposed stock acquisition may not substantially restrain competition in these markets immediately, considering that the increment of the parties' combined share is small, that there exist strong competitors with 10% and more market share, and that there are many competitors.

(b) CABG Stabilizers

The parties are competing with each other in this market, but considering that the increment of the parties' combined share is small and that there exists a strong competitor which has almost the same share as the parties, the proposed stock acquisition may not substantially restrain competition in this market immediately.

(c) PTA Guiding Catheters, PTA Guidewires, PTA Balloon Catheters, PTA Stents, Inferior Vena Cava Filter

Several companies including J&J have entered these markets in Japan. However, Guidant products are not distributed in Japan, although they are now distributed in the United States and Europe. Thus the parties' combined share will not be increased and therefore the proposed stock acquisition may not substantially restrain competition in these markets at present.

Further, while the proposed acquisition would eliminate a potential competitor, Guidant, considering that there exist one or more strong competitors with 10% and more market share and that Guidant is unlikely to immediately acquire comparable share with these strong competitors even if its products enter the Japanese market, the proposed acquisition may not substantially restrain competition in these markets.

(2) Markets which require detailed examination

Of the 12 markets listed above, with regard to the 2 markets including the DES and EVH devices, we conducted a concentrated examination since the Japanese markets would

be monopolized by the parties following the proposed stock acquisition.

4. Assessments under the Antimonopoly Act for the 2 Markets Examined in Detail

The assessments under the Antimonopoly Act for the DES and EVH devices were as follows:

(a) DES

- i) In Japan, since only J&J's DES is distributed with the approval of the Ministry of Health, Labor and Welfare, J&J is currently the only supplier of DES in Japan.
- ii) However, there are several companies including Guidant which are planning to enter the Japanese DES market, and the market is expected to become competitive after several years.
- iii) Guidant is a potential competitor of J&J, although it is still at the stage of preparing trials in Japan and the specific timing of entry is unknown. On the other hand, there exists a medical device manufacturer which is J&J's rival and which now distributes its DES in foreign markets and has larger market shares than J&J's. That competitor is now conducting trials for approval of distribution of DES in Japan and it is expected that it will enter the Japanese DES market before Guidant and become an extremely strong competitor which is stronger than Guidant.
Moreover, several other medical device manufacturers are developing DES and are expected to enter the Japanese DES market, although the timing of entry might be somewhat later. Their products may have the same or superior performance compared to the products that Guidant is developing.
- iv) In view of the several possible entrants mentioned above, the proposed stock acquisition may not substantially restrain competition in the Japanese DES market after the entries of the above companies.

(b) EVH devices

- i) As for EVH devices, only J&J's and Guidant's products were distributed in Japan. In October this year, a medical device manufacturer has launched its EVH devices in Japan, but currently its share is negligibly small.
- ii) Therefore, the proposed stock acquisition would virtually constitute a monopoly in the Japanese EVH devices market. As a consequence, the acquisition is considered to substantially restrain competition in the relevant market.
- iii) However, since the US-FTC and the EC pointed out the same problem as ii) in their reviews, the parties proposed to sell to a third party the worldwide EVH devices business owned by J&J's subsidiary (both the manufacture and distribution

divisions). J&J has already reached an agreement to sell these assets to a third party medical device manufacturer in the United States.

Since the divestiture includes the business of distribution to the Japanese market, the implementation of such divestiture will solve the problems arising under the Antimonopoly Act in respect of the acquisition.

- iv) Therefore, the proposed stock acquisition may not substantially restrain competition in the EVH devices market, on condition that the aforementioned divestiture of the EVH business be completed.

III. Conclusion

In view of the above circumstances, the JFTC has considered that the proposed stock acquisition may not substantially restrain competition in any relevant market of medical devices, on condition that the above measure concerning EVH devices be implemented by the parties.

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