The JFTC Issued a Cease and Desist Order
against ASP Japan G.K.

July 26, 2024
Japan Fair Trade Commission

The Japan Fair Trade Commission (hereinafter referred to as the "JFTC") today issued a cease and desist order against ASP Japan G.K. (hereinafter referred to as the "ASP Japan") pursuant to the provision of the Antimonopoly Act (hereinafter referred to as the "Act").

In this case, ASP Japan has been committing an act that violates the provisions of Article 19 of the Act (the Paragraph 10 (Tie-in Sales, etc.), Unfair Trade Practices).

1. Violated Company

Enterprise identification number	3010403019385
Corporate Name	ASP Japan G.K.
Address	2-15-2 Konan, Minato-ku, Tokyo
Representative	Advanced Product Sterilization Holding GmbH
Executive Officer	Akira Yuzawa
Outline of business	Sale of medical devices and medicines, etc.

(Note 1) On April 1, 2019, ASP Japan succeeded to the business related to the manufacture and sale of phtharal (Note 2) and succeeded to the sale of automated endoscope reprocessor using phtharal (Note 3) from Johnson & Johnson K.K. (hereinafter referred to as the "Johnson & Johnson") through an absorption-type company split.

Johnson & Johnson has not been engaged in the business related to the manufacture and sale of phtharal and the sale of automated endoscope reprocessor that use phtharal since April 1, 2019.

(Note 2) "Phtharal" is a disinfectant used for chemical sterilization and disinfection of medical instruments, including gastrointestinal endoscopes, for example, by feeding it into automated endoscope reprocessor, and is a medical product with a 0.55 w/v% concentration level.

(Note 3) In this case, "automated endoscope reprocessors" mean medical devices that clean and disinfect gastrointestinal endoscopes.

2. Summary of automated endoscope reprocessor sold by ASP Japan and phtharal

(1) Johnson & Johnson and Amano Co., Ltd. (hereinafter referred to as the "Amano")

entered into an agreement on the manufacture of automated endoscope reprocessors, etc., in August 2003. The agreement stipulated that Amano manufactures automated endoscope reprocessors, etc., as Johnson & Johnson's OEM products, while Johnson & Johnson had exclusive right to receive and sell such products. Due to the absorption-type company split on April 1, 2019, the contractual status was transferred from Johnson & Johnson to ASP Japan. As a result, since April 1, 2019, Amano has manufactured automated endoscope reprocessors that use phtharal as the OEM products of ASP Japan, and ASP Japan has exclusively received supply of such products and sold them.

Automated endoscope reprocessors manufactured by Amano are the only automated endoscope reprocessors that can use phtharal as a disinfectant, and phthral is the only disinfectant that can be used in the New Type Endoclens (Note 4).

(Note 4) "the New Type Endoclens" mean model name "Endoclens Neo", "Endoclens Neo-D Advanced" or "Endoclens Neo-S Advanced". The "Endoclens Neo" has already been discontinued.

(2) Until April 2013, a business entity belonging to a corporate group to which Johnson & Johnson belonged held patent right related to phtharal, and the only phtharal on market in Japan was "Disopa Solution 0.55%" (hereinafter referred to as the "DISOPA") manufactured and sold by Johnson & Johnson.

With an expiration of the patent right, the manufacture and sale of generics of phthalal began since around October 2014, and as of July 2024, there are five companies manufacturing and selling of phtharal in total, including ASP Japan and four generic companies. Generics of phtharal are generally less expensive than the DISOPA.

3. Summary of the Violation

(1) Johnson & Johnson had long been concerned that, with the expiration of the patent right regarding phtharal, sales of the DISOPA would decrease due to the use of lower-priced generics of phtharal by medical institutions. Since around October 2014, the manufacture and sale of generics of phtharal began and some medical institutions that had purchased the Legacy Endoclens (Note 5) from Johnson & Johnson began to use generics of phtharal as the disinfectant used for the Legacy Endoclens.

(Note 5) "the Legacy Endoclens" mean model name "Endoclens-S" or "Endoclens-D", all of which have already been discontinued.

(2) Since around September 2015, Johnson & Johnson, in developing a successor model to the Legacy Endoclens, for the purpose of preventing the use of generics of phtharal on the devices, decided to install the bar code reader to the successor model and to make cleaning and disinfecting

function of the successor model inoperable unless the 2D Code (Note 6) affixed to the bottle of the DISOPA was read by the bar code reader.

The New Type Endoclens manufactured based on this decision cannot activate the cleaning and disinfecting function unless the bar code reader reads the 2D Code affixed to the bottle of the DISOPA.

Therefore, it is not possible to clean and disinfect with the New Type Endoclens using generics of phtharal.

(Note 6) "the 2D Code" means a two-dimensional code (a bar code that has information in two directions, horizontally and vertically) containing the information necessary to activate the cleaning and disinfecting function of the New Type Endoclens.

(3) In order to secure sales of the DISOPA, Johnson & Johnson established a policy of actively promoting the replacement of the Legacy Endoclens with the New Type Endoclens, thereby compelling the medical institutions to switch the disinfectants from generics to the DISOPA, as well as to prevent the use of generics in advance for the future.

Then, based on this policy, Johnson & Johnson sold the DISOPA to the medical institutions by affixing the 2D Code to the bottles of the DISOPA from around October 2016 and sold the New Type Endoclens to the medical institutions from around March 2017.

(4) After ASP Japan succeeded to the business from Johnson & Johnson through the absorption-type company split, ASP Japan took over that policy mentioned in (3) above. And, based on that policy, ASP Japan has sold the New Type Endoclens and DISOPA to the medical institutions.

(5) In January 2020, one of the generic manufacturers of phtharal requested Amano to disclose information regarding the 2D Code in order to affix a 2D code with the same specifications as the 2D Code to the manufacturer's own bottle, so that it could be used as a disinfectant for the New Type Endoclens. In May 2020, ASP Japan instructed Amano not to disclose the information regarding the 2D Code, and in accordance with the said instruction, Amano refused the aforementioned request.

4. Summary of the Cease and Desist Order

(1) ASP Japan shall cease the act of forcing medical institutions using the New Type Endoclens to purchase the DISOPA in conjunction with the supply of the New Type Endoclens by way of attaching the bar code reader to the New Type Endoclens and affixing the 2D Code to the bottle of the DISOPA so that the cleaning and disinfecting function of the New Type Endoclens will not activate without reading the 2D code with the bar code reader.

(2) ASP Japan shall confirm the following matters at its business execution organization.

(a) The act described in (1) above is to be ceased.

(b) It will not, from now on, compel medical institutions to purchase phtharal in conjunction with the supply of automated endoscope reprocessors that use phtharal.

(3) ASP Japan shall notify Amano, the generic manufacturers of phtharal and its own sales distributors the measures taken in accordance with (1) and (2) above, and shall inform medical institutions that have purchased the New Type Endoclens, and shall have such measures thoroughly disseminated to its own employees.

(4) ASP Japan shall not, from now on, compel medical institutions to purchase the phtharal in conjunction with the supply of automated endoscope reprocessors that use phtharal.

(5) ASP Japan shall take the necessary measures to implement the followings:

(a) A preparation of guidelines for compliance with the Act in connection with the business of selling automated endoscope reprocessors that use phtharal, and an dissemination of them to all of its employees.

(b) Regular training for members who execute the business of the company who is a member of ASP Japan (Note 7) and its employees, as well as regular audits by third parties, regarding compliance with the Act in connection with the business of selling automated endoscope reprocessors that use phtharal.

(Note 7) If members of the company are natural persons, ASP Japan shall take the necessary measures to do regular training for such natural persons.

(6) ASP Japan shall promptly report the measures taken in accordance with (1), (2), (3) and (5) above to the JFTC.

* This announcement is a tentative translation. Please refer to the original text written in Japanese.