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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Maureen K. Ohlhausen
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter

IN THE MATTER OF	)	
GRIFOLS, S.A., **a corporation;**	)	
	)	**Docket No. C-4654**
and	)	
GRIFOLS SHARED SERVICES NORTH AMERICA, INC., **a corporation.**	)	

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Grifols, S.A. ("Grifols"), a corporation subject to the jurisdiction of the Commission, has entered into an acquisition with Biotest US Corporation ("Biotest US"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Grifols, is a corporation organized, existing, and doing business under and by virtue of the laws of the Kingdom of Spain with its executive offices and principal place of business located at Avinguda de la Generalitat, 152-158, Parc de Negocis Can Sant Joan, Barcelona, Spain 08174. Its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: General Counsel, c/o Grifols Shared Services North America, Inc., 2410 Lillyvale

Avenue, Los Angeles, California 90032. In 2016, Grifols had net revenues of approximately $4.3 billion, of which 66 percent was generated from its North American operations.

2. Respondent Grifols Shared Services North America, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Virginia with its executive offices and principal place of business located at 2410 Lillyvale Avenue, Los Angeles, California 90032.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. PARTIES

4. Biotest US, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 901 Yamato Road, Suite 101, Boca Raton, Florida 33431. Through its subsidiary, Biotest Pharmaceutical Corporation, Biotest US owns a network of 22 U.S. plasma collection centers. Prior to July 20, 2018 it also owned 41 percent of the stock of ADMA Biologics, Inc. ("ADMA"). ADMA develops, manufactures and sells human blood plasma-derived products in the United States. In 2017, Biotest US generated approximately $187 million in revenues.

5. The Biotest Divestiture Trust, is a statutory trust organized under the laws of the State of Maryland and pursuant to the terms of a declaration of trust, dated January 17, 2018, and an Amended and Restated Declaration of Trust, dated July 8, 2018, by and among Biotest AG (an Aktiengesellschaft organized under the laws of the Federal Republic of Germany), as grantor, and Eric Rosenbach, a U.S. citizen. The mailing address of The Biotest Divestiture Trust is c/o Eric Rosenbach, Trustee, 402 Norfolk Street, Cambridge, Massachusetts 02139.

III. THE PROPOSED ACQUISITION

6. Pursuant to agreements dated December 22, 2017, Grifols agreed to acquire all of the outstanding voting securities of Biotest US from The Biotest Divestiture Trust, which included the outstanding securities of ADMA owned by Biotest US ("acquisition agreement"). Grifols and Biotest US subsequently modified the acquisition agreement ("modified acquisition") to exclude the outstanding securities of ADMA and revalued the

acquisition. The acquisition agreement and the modified acquisition (collectively, "the Acquisition") are subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

IV. THE RELEVANT MARKETS

7. The relevant lines of commerce in which to analyze the effects of the Acquisition are:

   a. the development, license, manufacture, marketing, distribution, and sale of hepatitis B immune globulin; and

   b. the collection of human source plasma.

8. Hepatitis B immune globulin is a plasma-derived injectable medicine used to provide patients with hepatitis B antibodies to prevent hepatitis B infections.

9. Human source plasma is a critical input for a variety of medical products that are used to treat diseases and conditions in a variety of therapeutic areas, including pulmonology, hematology, immunology, infectious disease and trauma. Human source plasma is collected from donors at plasma collection centers.

10. The relevant geographic area in which to assess the competitive effects of the Acquisition on the hepatitis B immune globulin market is the United States.

11. The relevant geographic areas in which to assess the competitive effects of the Acquisition on the collection of human plasma market are Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio.

V. THE STRUCTURE OF THE MARKETS

12. Only three companies—Grifols, ADMA and Saol—sell hepatitis B immune globulin in the United States. ADMA has the largest share, followed by Saol and then Grifols. Biotest US owned 41 percent of the outstanding shares of ADMA. Without the modification of the acquisition agreement, the Acquisition would have resulted in Respondent Grifols owning 41 percent of the stock of its most significant competitor.

13. Respondent Grifols and Biotest US are the only two participants in the human source plasma collection market in the three geographic areas identified in Paragraph 11. The Acquisition would give Respondent Grifols a monopoly in each of the relevant markets.

VI. ENTRY CONDITIONS

14. Entry into the hepatitis B immune globulin relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to have deterred or counteracted the anticompetitive effects of the acquisition agreement. Entry would not be timely because of lengthy drug development and FDA approval timelines. In addition, entry sufficient to deter or counteract the likely competitive harm of the acquisition agreement was unlikely to occur.

15. Entry into the collection of human source plasma markets is unlikely to be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition. Entry is impeded by the scarcity of qualified donors in the geographic areas identified in Paragraph 11, such that these areas are unlikely to support a new human source plasma collection center.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

    a. by increasing the likelihood that Respondent Grifols would unilaterally exercise market power in the market for hepatitis B immune globulin;

    b. by eliminating actual, direct, and substantial competition between Grifols and Biotest US in the market for the collection human source plasma;

    c. by increasing the ability of the merged entity unilaterally to decrease donation fees in the market for the collection of human source plasma; and

    d. by reducing incentives to improve service or quality in the market for the collection of human source plasma.

VIII. VIOLATIONS CHARGED

17. The Acquisition described in Paragraph 6 constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 6, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirty-first day of July, 2018 issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: