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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

In the Matter of	)	
Grifols, S.A.,	)	**Docket No. C-4322**
a corporation	)	
and	)	
Talecris Biotherapeutics Holdings Corp.,	)	
a corporation	)	

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by said Act, 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 agreed to acquire Respondent Talecris Biotherapeutics Holdings Corp. ("Talecris"), a corporation subject to the jurisdiction of the Commission, 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, 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 public company, headquartered in Barcelona, Spain. With its primary production facilities in Barcelona and Los Angeles, California, Grifols develops, manufacturers, and sells human blood plasma-derived products. Grifols also owns a network of U.S. plasma collection centers to supply its production facilities. Grifols employs approximately 6,000 people worldwide and had global 2009 revenues of $1.3 billion, roughly one-third of which came from sales in the United States.

2. Respondent Talecris is a public company – owned in part by the private investment firm Cerberus Capital Management, L.P. – that specializes in the development, manufacture, and sale of human blood plasma-derived products. Talecris is headquartered in Research Triangle Park, North Carolina, with additional regional headquarters in Canada and Germany. Talecris has production facilities in Clayton, North Carolina, and Melville, New York, and like Grifols, Talecris owns a network of U.S. plasma collection centers to supply those facilities. Talecris employs approximately 5,000 people worldwide and had global 2009 revenues of approximately $1.5 billion, roughly two-thirds of which came from sales in the United States.

3. The plasma-derived products manufactured and sold by Respondents are life-sustaining and life-enhancing biologics indicated for, among other things, the treatment of primary immune deficiency diseases, neurological conditions, severe burns, liver failure, and blood coagulation disorders.

II. THE ACQUISITION

4. Pursuant to an Agreement and Plan of Merger dated June 6, 2010, Grifols agreed to acquire Talecris for $3.4 billion in cash and stock (the "Acquisition"). The Acquisition would combine two of the largest manufacturers of life-sustaining plasma-derived products.

III. JURISDICTION

5. Respondents, and each of their relevant operating subsidiaries and parent entities are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. The Acquisition constitutes an acquisition under Section 7 of the Clayton Act.

IV. THE RELEVANT PRODUCTS

6. The relevant product markets in which to analyze the Acquisition are: (i) Ig, (ii) albumin, and (iii) plasma-derived Factor VIII ("pdFVIII").

A. Ig

7. Ig is a widely used drug that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the more predominant form, has numerous indications approved by the U.S. Food and Drug Administration ("FDA"), and as many as 150 off-label uses. The most common uses involve the treatment of Primary Immunodeficiency Diseases and neurological conditions – *e.g.*, Guillain-Barré Syndrome and Chronic Inflammatory Demyelinating Polyneuropathy.

8. There are no substitutes for Ig for certain indications. For other indications, physicians and hospitals regard Ig as far superior to all potential substitutes.

9. Ig constitutes a relevant product market in which to analyze the Acquisition's effects.

B. Albumin

10. Albumin is used as a blood volume expander and to prime heart valves during surgery, treat burn victims, and replace proteins in treating liver failure.

11. There are no good substitutes for albumin. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

12. Albumin constitutes a relevant product market in which to analyze the Acquisition's effects.

C. Plasma-Derived Factor VIII

13. pdFVIII is an essential protein responsible for blood coagulation (*i.e.*, clotting), and products containing pdFVIII are FDA-approved to treat individuals with either Hemophilia A or von Willebrand Disease, or in some instances, both.

14. Recombinant Factor VIII ("rFVIII") is made from non-human sources and can also be used to treat Hemophilia A. Due to perceived differences in safety, rFVIII is the standard of care for previously untreated Hemophilia A patients.

15. For certain treatments, neither rFVIII nor any other product is a clinical substitute for pdFVIII. For example, rFVIII products do not contain von Willebrand Factor and therefore cannot be used to treat von Willebrand disease. Purchasers and patients would not switch from pdFVIII to rFVIII in response to a small but significant and non-transitory increase in price of pdFVIII.

16. pdFVIII constitutes a relevant product market in which to analyze the Acquisition's effects.

V. THE RELEVANT GEOGRAPHIC MARKET

17. The United States is the relevant geographic market in which to analyze the Acquisition's effects. To compete in the relevant product markets in the United States, a firm must establish a local sales force, service infrastructure, and reputation among purchasers.

18. Like pharmaceutical products, Ig, albumin, and pdFVIII must be FDA-approved for sale in the United States. To obtain approval, the products must be made from plasma collected in the United States at FDA-approved collection centers. These products must also be manufactured at FDA-approved facilities.

19. Performing the necessary clinical trials and navigating the FDA approval process for plasma and plasma-derived products takes well in excess of two years. Thus, Ig, albumin, and pdFVIII currently sold outside of the United States are not viable competitive alternatives for U.S. customers, who cannot and do not turn to these products even in the event of a price increase for products currently available in the United States.

VI. MARKET STRUCTURE

20. Under the 2010 Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines") and relevant case law, the Acquisition is presumptively unlawful in the Ig and albumin markets. Under the Herfindahl-Hirschman Index ("HHI"), which is the standard measure of market concentration under the Merger Guidelines, an acquisition is presumed to enhance market power if it increases the HHI by more than 200 points and results in a post-acquisition HHI that exceeds 2,500 points. The Acquisition creates market concentration levels well in excess of these thresholds for Ig and albumin.

    a. Based on 2009 sales volume, the combined firm would have approximately 31.2% of the Ig market and face meaningful competition from only two firms: Baxter International, Inc. ("Baxter") and CSL Limited ("CSL"). As of 2009, Baxter and CSL commanded approximately 35% and 25% of the Ig market, respectively, meaning the three largest suppliers would control more than 91% of the market after the Acquisition. According to 2009 sales volume, the Acquisition would increase the HHI in the Ig market by 383 points, from 2,518 to 2,901.

    b. In September 2010, another Ig supplier, Octapharma AG ("Octapharma"), withdrew its Ig product from the U.S. market because of concerns about serious adverse events. Before the withdrawal, Octapharma accounted for approximately 8.8% of the Ig market. Now, Octapharma is not selling any Ig in the United States, and its future competitive significance is uncertain.

c. In addition, the Acquisition would also increase concentration in the albumin market by 333 points, from 2,743 to 3,076, leaving only four meaningful competitors.

21. Under the Merger Guidelines, acquisitions that increase the HHI by between 100 and 200 points and result in a post-acquisition HHI that exceeds 2,500 points raise potentially significant competitive concerns and often warrant scrutiny. Here, the Acquisition would increase the HHI in the pdFVIII market by 166 points, from 3,491 to 3,657, leaving only three meaningful competitors controlling nearly 100% of the market.

VII. ENTRY CONDITIONS

22. Entry into the relevant markets would not be timely, likely, or sufficient to prevent or defeat the Acquisition's likely anticompetitive effects.

23. The manufacturing process for plasma-derived products is complex and highly regulated and involves technical know-how and proprietary processes involving (i) plasma collection, (ii) plasma testing, (iii) fractionation (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.), (iv) finishing or purification, (v) quality control, and (vi) lot release.

24. Currently, the U.S. markets for Ig, albumin, and pdFVIII are controlled by a handful of vertically integrated manufacturers, each of which has its own plasma collection, fractionation, and purification facilities. To be successful, a new entrant must develop and produce a product that is at least on par with the incumbent products in terms of safety, efficacy, and reliability. A new entrant – including existing manufacturers outside the United States – also must establish a U.S. sales force, plasma supply, support, manufacturing capability, and a reputation for safety, efficacy, and reliability.

25. Building the necessary facilities and infrastructure to manufacture Ig, albumin, and pdFVIII takes years and costs tens of millions of dollars. In particular, entry into the relevant product markets *de novo* requires a massive commitment of time and resources.

VIII. INDUSTRY BACKGROUND AND THE ACQUISITION'S EFFECTS

26. Historically, the plasma-derived products industry has operated as a tight oligopoly, characterized by a high level of transparency and coordination. Absent relief, Grifols' acquisition of Talecris would eliminate a significant threat to that dynamic.

a. A decade ago, there was robust competition in the plasma-derived products industry. After supply increases in the early 2000s led to lower prices, producers "rationalized" production and plasma collection capacity and began to vertically integrate, placing plasma collection almost entirely in the control of the few remaining firms in the market. Manufacturers also underwent horizontal

consolidation, leading to an industry dominated by three large firms – Baxter, CSL, and Talecris – and two smaller ones – Grifols and Octapharma. In the years that followed, the market saw supply shortages and dramatic year-over-year price increases.

b. Signaling among suppliers – *i.e.*, intentional sharing of competitive information for purposes of securing accommodating reactions from other firms – allows them to gain real time insight into each other's strategies and plans. Sensitive competitive information is widely available from a vast array of reports, market analyses, discussions with downstream purchasers, and the suppliers themselves, as firms collect and catalog an extraordinary wealth of timely "competitive intelligence."

c. The industry's primary trade group, the Plasma Protein Therapeutics Association ("PPTA"), facilitates this free exchange of competitive intelligence. The PPTA regularly publicizes aggregated plasma collection, inventory, and throughput data for IVIG, albumin, and pdFVIII, among other products.

d. Manufacturers routinely use PPTA data and other competitive intelligence to calibrate their own collections, output, and pricing decisions and avoid "irrational" behavior, such as oversupplying the market or starting a price war. When this information is combined with the long production cycle for plasma-derived products, suppliers have little opportunity to "cheat" by increasing output, without being detected and potentially punished by other suppliers well in advance of realizing any benefits from such cheating.

27. The Acquisition would substantially lessen competition in the relevant markets 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. eliminating actual, direct, and substantial competition between Respondents for the sale of Ig, albumin, and pdFVIII in the United States;

b. enabling the combined firm and other firms selling Ig, albumin, and pdFVIII to engage more successfully and completely in coordinated interaction that harms consumers;

c. increasing the likelihood that U.S. consumers would be forced to pay higher prices for Ig, albumin, and pdFVIII; and

d. increasing the likelihood that consumers would experience lower levels of innovation and service in the U.S. markets for Ig, albumin, and pdFVIII.

IX. VIOLATIONS CHARGED

28. The allegations of Paragraphs 1 through 27 above are incorporated by reference as though fully set forth here.

29. The Acquisition constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

30. The Acquisition, 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.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this Complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this thirty-first day of May, 2011.

By the Commission, Commissioner Kovacic recused.

Donald S. Clark
Secretary

SEAL: