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2. Respondent Takeda is a public company – owned in part by the private investment firm Cerberus Capital Management, LP. – that specializes in the development, manufacture, and sale of human blood plasma derived products. Takeda is headquartered in Research Triangle Park, North Carolina, with additional regional headqua

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, rFVII 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.

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

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: