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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
CSL Limited, **a corporation**	)	**Docket No. 9337**
and	)	
Cerberus-Plasma Holdings, LLC, **a limited liability company.**	)	**REDACTED PUBLIC VERSION**

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Respondents CSL Limited ("CSL") and Cerberus-Plasma Holdings, LLC ("Cerberus") have entered into a merger agreement in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and which merger, if consummated, would violate Section 5 of the FTC Act, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I.

NATURE OF THE CASE

1. CSL's proposed $3.1 billion acquisition of Talecris Biotherapeutics Holdings Corporation ("Talecris") from Cerberus (the "Merger") threatens to substantially lessen competition in the markets for several life-sustaining plasma-derivative protein therapies. The effect will be further tightening of supply relative to demand and steeper price increases – potentially leaving critically ill patients without the treatments they need most.

2. The Merger would reduce the number of competitors for certain plasma products from three to two and, for other plasma products, from five to four. Following the Merger, CSL would have just one significant competitor – Baxter International ("Baxter"). The other two industry firms, Grifols, S.A. ("Grifols") and Octapharma AG ("Octapharma"), are much smaller, with market shares in the single digits, and limited ability to expand their presence in the United States.

3. Combined, CSL/Talecris would command nearly one-half of the U.S. sales of immune globulin ("Ig"[1]), albumin, and Rho-D (each), and over 80% of alpha-1 antitrypsin ("alpha-1") sales. Concentration levels in each of these relevant markets far exceed the thresholds provided in the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines"), giving rise to a strong presumption that the transaction will harm competition.

4. The industry already operates as a tight oligopoly, with a high level of information sharing and interdependence among firms. Suppliers have learned they can maximize profits if each firm does its part to maintain overall industry [redacted] holding back on expanding output to avoid driving prices lower. Firms closely monitor each other, collecting and cataloging an extraordinary wealth of timely competitive information, to ensure that all are engaging in desired [redacted] and [redacted] behavior. [redacted]

5. By acquiring Talecris, CSL would eliminate the only significant threat to this durable and highly profitable oligopoly. [redacted] The resulting increase in availability of plasma-derivative therapies would have real benefits for patients, but would negatively impact industry profit margins as increased supply would result in lower prices.

6. [redacted] provided motivation for the Merger and the significant premium that CSL agreed to pay.

7. Without the aggressively expanding Talecris, CSL and Baxter, the only two remaining significant firms in the plasma industry, could more successfully and completely suppress industry output relative to demand. [redacted] Baxter has publicly expressed its

[1] Immune globulin for intravenous administration commonly is referred to as "IVIG" or "IGIV."

concurring view that CSL's proposed acquisition of Talecris would be "a positive stabilizing move within the industry."

8. Other firms would be unable to replace the competition eliminated by the Merger. Barriers to entry are [redacted] Efficiencies likewise are insufficient to offset the Merger's anticompetitive effects.

II.

RESPONDENTS

A.

CSL Limited

9. Respondent CSL is a company incorporated and domiciled in Australia, with its office and principal place of business located at 45 Poplar Road, Parkville, Victoria, 3052, Australia.

10. The second-largest supplier of plasma-derivative protein therapies in the world, CSL produces and sells biotherapies indicated for the treatment of several rare primary immune deficiency diseases, coagulation disorders, and inherited respiratory disease. CSL is a vertically integrated company, owning and operating more than 70 plasma collection facilities in the United States and Germany and three manufacturing centers in Switzerland, Germany, and Illinois. CSL's worldwide sales for its 2008 fiscal year were approximately $2.5 billion.

11. CSL's wholly-owned U.S. subsidiary, CSL Behring, is headquartered at 1020 First Avenue, King of Prussia, Pennsylvania 19406-0901.

12. CSL is, and at all relevant times has been, engaged in "commerce" as defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is an entity whose business is in or affects "commerce" as defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

B.

Cerberus-Plasma Holdings, LLC

13. Respondent Cerberus is a limited liability company existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 299 Park Avenue, 22nd Floor, New York, New York 10171. Cerberus is the majority owner and ultimate parent entity of Talecris.

14. Talecris, a wholly-owned subsidiary of Cerberus, is headquartered at 4101 Research Commons, 79 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709. Talecris is the third-largest producer of plasma-derivative protein therapies in the world. Talecris began operations in the United States in 2005, when it acquired Bayer's worldwide plasma business. Like CSL, Talecris is a vertically integrated company, owning a number of plasma collection centers in the United States, as well as manufacturing facilities in Clayton, North Carolina, and Melville, New York. Talecris' worldwide revenues were $1.2 billion in 2007.

15. Cerberus is, and at all relevant times has been, engaged in "commerce" as defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is an entity whose business is in or affects "commerce" as defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III.

THE MERGER

16. Pursuant to an Agreement and Plan of Merger dated August 12, 2008, CSL proposes to acquire all of the outstanding voting securities of Talecris in a transaction valued at approximately $3.1 billion.

17. [redacted] he agreement reached between the parties includes a $75 million breakup fee and a deal under which CSL will supply Talecris with plasma for a period of five years even if the transaction is not consummated.

IV.

THE PLASMA-DERIVATIVE PROTEIN PRODUCTS INDUSTRY

A.

General Market Characteristics

18. The manufacturing process for plasma-derivative protein products involves (1) plasma collection, (2) plasma testing, (3) fractionation (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.), (4) finishing or purification, (5) quality control, and (6) lot release. The time required to complete the full manufacturing process ranges from seven months to one year.

19. The manufacturing process is highly regulated because plasma products run the risk of containing and transmitting infections. Regulators include the U.S. Food and Drug

Administration ("FDA"), state regulatory agencies, and the Plasma Protein Therapeutics Association ("PPTA"), an industry self-regulatory body.

20. Plasma-derivative protein therapies are essential for treating a number of serious illnesses. The annual cost for these treatments can exceed $90,000 per patient in some cases.

21. Purchasers (usually hospitals through contracts negotiated by Group Purchasing Organizations ("GPOs")) of plasma-derivative protein products will pay very high prices if necessary to make treatment available to critically ill patients. As a result, small changes in production levels cause dramatic swings in prices for products, and producers stand to increase profits greatly by controlling output relative to demand.

22. Within each relevant market, the product offerings of the competing plasma firms are largely homogenous. Pricing and other product variables on which firms compete are standardized, enhancing the high degree of transparency in the industry.

B.

Fewer Competitors, Tightening Supply, and Higher Prices

23. Aggressive competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation.

24. In 1990, there were 13 producers of plasma-derivative products; in 2003, there were nine. Today there are only five: CSL, Talecris, Baxter, Grifols, and Octapharma.

25. Several firms recently merged or were acquired, and a major non-profit entity, the American Red Cross, exited the industry. Independent plasma collectors also have been acquired by the large fractionators.

26. [redacted]

[redacted]

27. Indeed, over time, as consolidation has occurred in the plasma industry, prices have increased. GPOs, hospitals, physicians – and ultimately patients – have experienced tightening supplies and rising prices in recent years.

28. These price increases have been caused by the consolidation of competitors and the resulting increases in concentration. The remaining participants have recognized that they are operating in an oligopoly in which they are better off avoiding competition, restricting supply, and raising prices.

29. In a recent investor call, Baxter explained how competitors have "lived through the events of the early 2000s," referring to a period of ample supply and lower prices, and have now returned to a time of "very good stock prices and very good returns for shareholders."

30. [redacted]

31. GPOs, hospitals, and physicians are concerned about tight supplies and rising prices, and the effect that the Merger will have on an already strained marketplace.

32. Others also have recognized the movement towards an oligopoly and higher prices. In 2006, the Department of Health and Human Services ("HHS") investigated reports that patients were having problems obtaining Ig. HHS concluded in its key findings that Ig "manufacturing is a tight oligopoly in which the leading three manufacturers . . . have a combined market share of around 85%." HHS went on to find:

> Manufacturers are currently allocating IGIV to their customers. Under this allocation system, most customers are expected to justify their current IGIV use to the manufacturer to maintain and/or increase their allocations. In economic terms, current IGIV supplies are being rationed.

. . . .

> The existence of a secondary market with high IGIV prices combined with a manufacturer instituted allocation system for IGIV are symptomatic of a market in which demand exceeds supply.

33. In particular, the industry recognizes that controlling capacity is critical to preventing price competition and that consolidation has been an effective way to eliminate or control capacity.

34. In fact, firms in the plasma industry have used consolidation as a tool to eliminate excess capacity and reduce supply, rather than to produce benefits for consumers. CSL and Baxter each have reduced capacity following past acquisitions. [redacted]

35. CSL and Baxter, in particular, have focused on preventing oversupply of IVIG and plasma. [redacted]

36. The firms are keenly aware that restrained output is profitable only if all firms cooperate. [redacted] Similarly, Baxter recognizes that as long as competitors are not "irrational" and do not "trash price and take share," Baxter can increase supply steadily in line with market demand to keep prices high.

37. Competitive information is widely available from industry sources and the competitors themselves, and firms closely monitor each others' activities with respect to plasma collection, manufacturing, and output.

38. Baxter and CSL have developed sophisticated oligopoly models to estimate and predict changes in supply and demand. [redacted]

39. Firms also engage in signaling – *i.e.*, intentional sharing of competitive information for purposes of securing accommodating reactions from other firms. Baxter's CFO acknowledged this in a recent investor call, stating: "Why any of us would, for a very short-term gain, do anything to change [the current marketplace dynamics], I just don't see why we would. It wouldn't make sense and ***from everything we read and all the signals we get, there is nothing that says anyone would do that. I think people are very consistent in the messages they deliver***, which are pretty consistent with what we have told you today." (Emphasis added.)

40. Talecris is the one firm in the industry that can thwart the prevailing restrained, oligopolistic approach. [redacted]

41. In contrast, the remaining competitors in the industry, Grifols and Octapharma, are too small to have a significant market impact. [redacted]

42. [redacted]

43. [redacted] this Merger will substantially lessen competition in an already oligopolistic industry. The remaining sellers – CSL and Baxter chief among them – will continue to tighten supply relative to demand, forcing critically ill patients to struggle to obtain, and pay even more for, life-saving and life-sustaining therapies.

V.

THE RELEVANT PRODUCT MARKETS

44. The relevant product markets in which to analyze the Merger are (1) Ig, (2) albumin, (3) alpha-1, and (4) Rho-D.

A.

Ig

45. Ig is a widely used drug that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the more predominant form, has over 20 FDA-approved indications, and as many as 150 off-label uses. The most common uses involve the treatment of Primary Immunodeficiency Diseases ("PID") and neurological conditions – *e.g.*, Guillain-Barré Syndrome ("GBS") and chronic inflammatory demyelinating polyneuropathy ("CIDP").

46. Ig constitutes a relevant product market in which to analyze the effects of CSL's proposed acquisition of Talecris.

47. There are no good substitutes for Ig.

B.

Albumin

48. Albumin is used as a blood volume expander and to prime heart valves during surgery.

49. Albumin constitutes a relevant product market in which to analyze the effects of CSL's proposed acquisition of Talecris.

50. 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.

C.

Alpha-1

51. Alpha-1 is FDA-indicated to treat individuals with alpha-1 antitrypsin deficiency-related lung disease.

52. Alpha-1 constitutes a relevant product market in which to analyze the effects of CSL's proposed acquisition of Talecris.

53. There are no good substitutes for alpha-1.

D.

Rho-D

54. Rho-D is the preparation of Rho-D/Anti-Rh IgG antibodies used to prevent hemolytic disease of the newborn ("HDN"). HDN develops when a mother who is Rh-negative conceives a fetus that is Rh-positive, which without treatment results in serious health consequences for the fetus. When administered to Rh-negative mothers, Rho-D can bind to and destroy the fetal Rh-positive red blood cells.

55. Rho-D constitutes a relevant product market in which to analyze the effects of CSL's proposed acquisition of Talecris.

56. There are no good substitutes for Rho-D.

VI.

THE RELEVANT GEOGRAPHIC MARKET

57. The relevant geographic market in which to analyze the effects of the proposed transaction is the United States.

58. Like pharmaceutical products, each of the relevant plasma-derivative protein products must be approved for sale in the United States by the FDA. To obtain approval, the products must be made from plasma collected in the United States at collection centers approved by the FDA. Plasma-derivative protein products must also be manufactured at plants approved by the FDA.

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

VII.

MARKET STRUCTURE AND THE MERGER GUIDELINES PRESUMPTION

60. Under both case law and the government's Merger Guidelines, the Merger is presumptively unlawful in each of the relevant markets. The post-merger market share of the merged firm would range from 42% to 82%, depending on the market. The Merger Guidelines measure concentration using the Herfindahl-Hirschman Index ("HHI"). Under that test, a merger is presumed likely to create or enhance market power (and presumed illegal) when the post-merger HHI exceeds 1,800 and the merger increases the HHI by more than 100. Here, the post-merger HHIs range from 3,557 to 7,152, and the HHI increase is between 646 and 1,787, depending on the market.

61. Appendices A, B, C, and D set forth product-specific market concentration calculations for Ig, albumin, Rho-D, and alpha-1, respectively.

VIII.

ANTICOMPETITIVE EFFECTS

A.

Ig and Albumin

62. As described *supra* in Part IV, these markets are not competitive today.

63. [redacted]

64. CSL's proposed acquisition of Talecris would substantially lessen competition by enabling CSL, Baxter, and the other firms selling Ig and albumin to engage more successfully and more completely in coordinated interaction that harms consumers.

65. The Merger would decrease the number of firms with control over supply of the relevant products, and it would significantly increase industry concentration. As the number of firms decreases and concentration increases, the difficulties and costs of reaching and enforcing an understanding with respect to the control of supply are reduced – as demonstrated by prior consolidations in the industry. Factors such as market transparency, firm and product homogeneity, and available means for punishing deviations from agreed terms will facilitate coordination going forward.

66. The elimination of Talecris – itself a unique competitive constraint in the relevant markets – would be particularly detrimental to competition. [redacted]

B.

Alpha-1

67. The Merger would reduce the number of alpha-1 suppliers from three to two and substantially increase market concentration.

68. CSL's acquisition of Talecris would eliminate the vigorous competition that has existed in the alpha-1 market for the last five years as [redacted] Alpha-1 patients and doctors benefitted significantly from this non-price and price competition through better education and diagnosis programs, new product introductions and improvements, and lower prices.

69. [redacted] Post-merger, the combined company would control over 80% of alpha-1 sales, and the existing vigorous competition for patients would end.

70. The two remaining competitors in this market post-merger – CSL and Baxter – would be able to coordinate more successfully and completely on price. With very timely, accurate pricing information as exists in this industry, this Merger to duopoly would make price coordination easier and facilitate prompt detection of deviations from the terms of coordination.

C.

Rho-D

71. Like the alpha-1 market, the market for Rho-D drugs is highly concentrated today with only three competitors. The market will be significantly more concentrated, and less competitive, with the elimination of Talecris as an independent competitor.

72. Since their entry into this market in 2004, CSL and Talecris have competed aggressively against one another, as the only two (relatively) low-price suppliers of Rho-D. The only other Rho-D supplier, Ortho-Clinical Diagnostics ("Ortho"), has stayed out of the fray, maintaining its position as a premium, higher-priced supplier. [redacted] atients and doctors have benefitted significantly from this head-to-head competition.

73. Following the Merger, the combined company would control over 40% of the Rho-D sales. With this significantly higher share of the market, and no remaining low-priced alternatives, CSL/Talecris would be less likely to engage in competitive pricing, thereby risking more aggressive competition from the sole remaining supplier, Ortho. In addition, this Merger to duopoly would make price coordination easier and facilitate prompt detection of deviations from the terms of coordination.

IX.

ENTRY BARRIERS

74. [redacted]

75. No firm has entered *de novo* in recent history. Current prospective entrants have scant chances of making a significant market impact in a timely manner.

76. Each step of the manufacturing process involves significant up-front, sunk costs, onerous and lengthy regulatory approvals, and specialized technical expertise.

77. Entry into the plasma-derivative protein product markets also requires a significant amount of intellectual property, including trade secrets relating to purification and safety, and substantial product research and development.

78. In addition, regulatory hurdles impose significant costs to new entry and extend the time it would take to enter the U.S. market with a plasma-derivative protein product, let alone to achieve a significant market impact.

79. Thus, new entry will not be timely, likely, or sufficient to defeat the anticompetitive effects stemming from the Merger.

80. Outside of the Big Three (Baxter, CSL, Talecris), only Grifols and Octapharma have an existing presence in the U.S. Ig or albumin markets. Similar barriers preclude these firms from significantly expanding production in a timely manner to counteract anticompetitive quantity restrictions and price increases.

X.

EFFICIENCIES

81. Extraordinarily great merger-specific efficiencies would be necessary to justify the Merger in light of its vast potential to harm competition. Such efficiencies are lacking here.

82. The Merger is not necessary to permit the parties to achieve substantial efficiencies from manufacturing complementarities and supply cost reductions.

83. Similarly, CSL and Talecris need not merge in order for Talecris to reduce its plasma collection costs, which currently are higher than the industry norm. As Talecris continues to build up its collection platform, and its centers mature, it likely will become more efficient on its own.

XI.

VIOLATIONS

COUNT I - ILLEGAL MERGER

84. The allegations of Paragraphs 1 through 83 above are incorporated by reference as though fully set forth.

85. The Merger, if consummated, 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 Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

COUNT II - ILLEGAL MERGER AGREEMENT

86. The allegations of Paragraphs 1 through 83 above are incorporated by reference as though fully set forth.

87. Respondents CSL and Cerberus, through the merger agreement described in paragraphs 16-17 above, have engaged in unfair methods of competition in or affecting commerce in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the twenty-seventh day of October, 2009, at 10:00 a.m. is hereby fixed as the time, and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission and Clayton Acts to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14^{th}) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

In such answer, you may, however, reserve the right to submit proposed findings and conclusions under § 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge will schedule an initial pre-hearing scheduling conference to be held not later than ten (10) days after the answer is filed by the last answering respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (and in any event no later than five (5) days after the answer is filed by the last answering respondent). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving a respondent's answer, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Merger challenged in this proceeding violates Section 7 of the Clayton Act, as amended, or Section 5 of the Federal Trade Commission Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Merger is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as CSL and Cerberus were offering and planning to offer prior to the Merger.

2. A prohibition against any transaction between CSL and Cerberus that combines their businesses in the relevant markets, except as may be approved by the Commission.

3. A requirement that, for a period of time, CSL and Cerberus provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets.

4. A requirement to file periodic compliance reports with the Commission.

5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to ensure the creation of one or more viable, competitive independent entities to compete against CSL/Cerberus in the relevant markets.

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 twenty-seventh day of May, 2009.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

Donald S. Clark
Secretary

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