

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,)
600 Pennsylvania Avenue, N.W.)
Washington, D.C. 20580)

Plaintiff,)

v.)

No. 09 -cv- 1000

CSL LIMITED)
45 Poplar Road, Parkville)
Victoria 3052 Australia)

and)

CERBERUS-PLASMA HOLDINGS, LLC)
299 Park Avenue, 22nd Floor)
New York, New York 10171)

Defendants.)

**COMPLAINT FOR TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION PURSUANT TO
SECTION 13(b) OF THE FEDERAL TRADE COMMISSION ACT**

Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), by its designated attorneys, petitions the Court, pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), and Section 16 of the Clayton Act, 15 U.S.C. § 26, for a temporary restraining order and preliminary injunction enjoining defendants CSL Limited (“CSL”) and Cerberus-Plasma Holdings, LLC (“Cerberus”), including their domestic and foreign agents, divisions, parents, subsidiaries, affiliates, partnerships, or joint ventures, from taking any steps toward combining or acquiring any stock, assets, or other interest of one another, either directly or indirectly; thereby maintaining the *status quo* during the pendency of an administrative proceeding that has been initiated by the Commission pursuant to Section 5 of the FTC Act, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. § 18.

I.

NATURE OF THE CASE

1. This is an action to stop defendants from consummating or otherwise taking any steps toward an anticompetitive merger or acquisition until the completion of an administrative proceeding that has been initiated by the Commission. The Commission has deemed that a plenary administrative trial will begin on October 27, 2009. Absent injunctive relief granted by this Court, however, defendants may merge on or after May 29, 2009.

2. 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.

3. 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.

4. 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

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

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.

5. 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 “stability,” 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 “rational” and “disciplined” behavior. CSL and Baxter even have explored means of punishing firms that dare to “break ranks’ and chase market share.”

6. By acquiring Talecris, CSL would eliminate the only significant threat to this durable and highly profitable oligopoly. Talecris “has significantly and consistently increased production and U.S. supply year after year – more than any other manufacturer,” and it plans to significantly expand manufacturing capacity and output in the coming years. 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.

7. Not surprisingly, according to Cerberus (Talecris’ majority shareholder), CSL was “truly scared that Talecris might actually succeed with its planned center expansion” and the resulting increase in output. This fear provided motivation for the Merger and the significant premium that CSL agreed to pay.

8. 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. As CSL's Chief Economist professes, an "[i]ncrease in industry concentration should make price stability and/or price increases easier to sustain" because "competition erodes rents." Baxter has publicly expressed its concurring view that CSL's proposed acquisition of Talecris would be "a positive stabilizing move within the industry."

9. Other firms would be unable to replace the competition eliminated by the Merger. Barriers to entry are – by CSL's own admission – "immense." Efficiencies likewise are insufficient to offset the Merger's anticompetitive effects.

10. Temporary and preliminary injunctive relief therefore is imperative to preserve the *status quo* and allow the Commission to examine the Merger on the merits. Permitting CSL and Talecris to combine during the pending administrative proceeding would harm consumers and undermine the Commission's ability to remedy the anticompetitive effects of the transaction, if it determines after a plenary trial that the Merger is unlawful.

II.

BACKGROUND

A.

Jurisdiction and Venue

11. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and Section 16 of the Clayton Act, 15 U.S.C. § 26, and upon 28 U.S.C. §§ 1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action. CSL, Cerberus, and their relevant operating subsidiaries 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.

12. Both CSL and Cerberus transact business in the District of Columbia and are subject to personal jurisdiction therein. Venue therefore is proper in this district under 28 U.S.C. § 1391 (b) and (c).

13. Section 13(b) of the FTC Act, 15 U.S.C. 53(b), provides in pertinent part:

(b) Whenever the Commission has reason to believe –

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public – the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission’s likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond . . .

B.

The Parties

14. Plaintiff, the Commission, is an administrative agency of the United States Government established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The Commission is vested with authority and responsibility for enforcing, *inter alia*, Section 7 of the

Clayton Act.

15. Defendant 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. 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.

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

17. Defendant 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.

18. 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.

C.

The Merger and the Commission's Response

19. 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. This is the culmination of a two-year effort by CSL to acquire Talecris. During final negotiations in 2008, CSL agreed to pay approximately \$800 million more for Talecris than it was willing to pay in 2007. The 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.

20. Pursuant to the Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. § 18a, and a timing agreement between defendants and the FTC staff, unless restrained or enjoined by this Court, defendants may consummate the Merger on or after May 29, 2009.

21. On May 27, 2009, the Commission authorized the commencement of this action under Section 13(b) of the FTC Act to seek a temporary restraining order and preliminary injunction barring the Merger until resolution of the pending administrative proceeding. The Commission has deemed that a plenary trial on the merits of the Merger will begin on October 27, 2009. Following issuance of an initial decision by an FTC Administrative Law Judge, the Commission will determine the legality of the Merger under Section 7 of the Clayton Act, along with an appropriate remedy in the event liability is found. Pursuant to Section 5(c) of the FTC Act, 15 U.S.C. § 45(c), respondent may appeal an adverse Commission decision directly to any U.S. Court of Appeals within whose jurisdiction the respondent resides or carries on business.

22. In authorizing the commencement of this action, the Commission determined that (1) it has reason to believe that the Merger would violate Section 7 of the Clayton Act and the

FTC Act by substantially reducing competition in one or more lines of commerce, and (2) it will promote the public interest for this Court to enjoin the Merger pending resolution of the Commission's administrative proceedings, and any appeals, so as to minimize the potential harm to competition and preserve the Commission's ability to grant an adequate remedy if it concludes, after plenary administrative proceedings, that the Merger is unlawful.

III.

THE PLASMA-DERIVATIVE PROTEIN PRODUCTS INDUSTRY

A.

General Market Characteristics

23. 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.

24. 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.

25. 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.

26. 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.

27. 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

28. 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.

29. 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.

30. 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.

31. In 2004, after acquiring one of its competitors, Aventis-Behring, CSL predicted the effects of “[o]ne further round of consolidation,” such as this Merger, stating:

If the number of significant market participants were reduced from 5 to 4, and the new entity were to reduce capacity by 25% (*not atypical*), then

1. The new entity would be more profitable than would be the aggregate of the separated firms (depending on the merger combinations). That is, the merged entity could appropriate some of the gains.
2. Market prices would rise soon after the capacity rationalisation.

3. The market would become less risky because the number of firms that profit by raising output would be reduced from 3 to 1 (or from 3 to two).
4. [CSL] would benefit as a participant in the merger, or as a bystander.

CSL further concluded that it is “less likely that a further [CSL] or Baxter acquisition (affecting the US market) would get FTC approval.”

32. 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.

33. 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.

34. 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.”

35. In 2008, Talecris conducted an industry analysis, concluding that the “current drivers” of the plasma-derivative protein products industry include a “positive pricing environment” and an “oligopoly/disciplined approach” to supply.

36. 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.

37. 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.

38. 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.

39. 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. For its part, Talecris acknowledges that industry consolidation has led to “reduction in plasma collection and fractionation capacity.”

40. CSL and Baxter, in particular, have focused on preventing oversupply of IVIG and plasma. CSL lists as a “critical success factor” maintaining the supply/demand equilibrium and driving price increases.

41. The firms are keenly aware that restrained output is profitable only if all firms cooperate. CSL refers to this as the “OPEC problem”: “Whenever capacity is greater than profit maximizing output levels, there is a danger that a firm will ‘break ranks’ and chase market share,

with the result that prices will fall.” 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.

42. 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.

43. Baxter and CSL have developed sophisticated oligopoly models to estimate and predict changes in supply and demand. As CSL’s Chief Economist has explained, “economics can help is [sic] understand how to loosen the shackles of competition.”

44. 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.)

45. Talecris is the one firm in the industry that can thwart the prevailing restrained, oligopolistic approach. In past years, Talecris has increased its capacity and output more than any other firm, subjecting it to punishment by CSL and Baxter. Moreover, before agreeing to the Merger, Talecris planned to be responsible for 45% of the industry’s future output expansion over the next two years – a business strategy labeled “irrational” by CSL.

46. In contrast, the remaining competitors in the industry, Grifols and Octapharma, are too small to have a significant market impact. In high-level, internal communications,

Talecris executives discuss this very issue: “[S]o really the question is whether grf [Grifols] and octa[pharma] would trash the market. And they’re not big enough to strongly shock supply. . . .”

47. Cerberus executives concluded during merger negotiations that CSL was “truly **scared that Talecris might actually succeed** with its planned center expansion,” and CSL executives were, “worried . . . that [Talecris]’ expansion will have a negative effect on the market as a whole.” (Emphasis in original.)

48. Consistent with CSL’s own predictions about the likely effects of further consolidation, 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.

IV.

THE RELEVANT PRODUCT MARKETS

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

A.

Ig

50. 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”).

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

52. There are no good substitutes for Ig.

B.

Albumin

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

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

55. 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

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

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

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

D.

Rho-D

59. 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.

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

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

V.

THE RELEVANT GEOGRAPHIC MARKET

62. The relevant geographic market in which to analyze the effects of the Merger is the United States.

63. 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.

64. 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.

VI.

MARKET STRUCTURE AND THE MERGER GUIDELINES PRESUMPTION

65. 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.

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

VII.

ANTICOMPETITIVE EFFECTS

A.

Ig and Albumin

67. As described *supra* in Part III, these markets are not competitive today.

68. CSL feared the destabilizing effect that Talecris’ expansion would have on industry profitability, and this served as motivation for the Merger.

69. 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.

70. The Merger would decrease the number of firms with control over supply of the relevant products, while significantly increasing industry concentration. As the number of firms decreases and concentration increases, it becomes easier to reach and enforce an understanding with respect to the control of supply – 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.

71. The elimination of Talecris – itself a unique competitive constraint in the relevant markets – would be particularly detrimental to competition. Talecris “has significantly and consistently increased production and U.S. supply year after year – more than any other manufacturer[.]” And, absent the Merger, Talecris planned to undertake significant output expansion going forward.

B.

Alpha-1

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

73. CSL’s acquisition of Talecris would eliminate the vigorous competition that has existed in the alpha-1 market for the last five years as CSL attacked Talecris’ “predominant position,” and Talecris responded to protect its market share. 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.

74. Prior to the Merger, both CSL and Talecris anticipated that, without proactive measures by Talecris, CSL’s share of the alpha-1 market would continue to grow substantially at Talecris’ expense. Post-merger, the combined company would control over 80% of alpha-1 sales, and the existing vigorous competition for patients would end.

75. 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

76. 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.

77. 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. Talecris has responded to competition from CSL by further lowering its price and increasing its marketing and promotional activities in an effort to defend market share. Patients and doctors have benefitted significantly from this head-to-head competition.

78. 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.

VIII.

ENTRY BARRIERS

79. In CSL’s own words, there are “immense barriers to entering the market” for plasma-derivative protein products. CSL identifies “significant barriers to entry” as one of the

six “key characteristics of the Ig market,” and notes that there is “[n]o realistic prospect for an increase in the number of firms.” Talecris shares this view, noting that “significant regulatory, IP, and capital barriers to entry mitigate the threat of new competitors as well as capacity increases for several years.”

80. 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.

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

82. 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.

83. 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.

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

85. Outside of the Big Three (Baxter, CSL, and 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.

IX.

EFFICIENCIES

86. 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.

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

88. 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.

X.

LIKELIHOOD OF SUCCESS ON THE MERITS AND NEED FOR RELIEF

89. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the *public* equities, using a sliding scale. Equities affecting only the defendants cannot tip the scale.

90. The Commission's complaint raises questions about the lawfulness of defendants' Merger under the Clayton Act and the FTC Act that are serious, substantial, difficult, and doubtful enough to make them fair ground for thorough investigation, study, deliberation, and determination by the Commission during the administrative proceeding in the first instance, and ultimately, by a federal Court of Appeals.

91. The Commission has reason to believe that the Merger would violate Section 7 of the Clayton Act and that the Merger agreement violates Section 5 of the FTC Act. In particular, Complaint Counsel for the Commission is likely ultimately to succeed in demonstrating, among other things, that:

- a. The Merger would have anticompetitive effects in the Ig, albumin, alpha-1, and Rho-D markets;

- b. Substantial and effective entry into these markets is difficult, and would not be likely, timely, or sufficient to offset the anticompetitive effects of the Merger; and
- c. Any efficiencies that defendants may assert will result from the Merger are speculative, not merger-specific, and are, in any event, insufficient as a matter of law to justify the Merger.

92. Should the Commission rule, after the full administrative trial, that the Merger is unlawful, completely reestablishing the *status quo ante* of competition would be difficult, if not impossible, if the Merger already has occurred. Moreover, substantial harm to competition would likely occur in the interim, even if suitable divestiture remedies could be devised.

93. Accordingly, the equitable relief requested here is in the public interest.

WHEREFORE, the Commission respectfully requests that the Court:

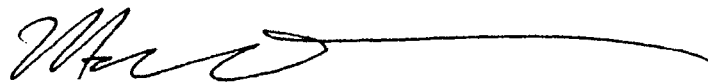
- a. Temporarily restrain and preliminarily enjoin CSL and Cerberus from taking any further steps to consummate the Merger, or any other acquisition of stock, assets, or other interests, either directly or indirectly;
- b. Retain jurisdiction and maintain the *status quo* until resolution of the administrative proceeding that the Commission has initiated; and
- c. Award such other and further relief as the Court may determine is appropriate, just, and proper.

Respectfully submitted,

May 28, 2009

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Appendix A - Market Concentration by 2008 U.S. IVIG Sales Volumes

Plasma Fractionator	Pre-Acquisition		Post-Acquisition	
	Sales (kilograms)	Share	Sales (kilograms)	Share
CSL	10,123	27.5%	17,827	48.5%
Talecris	7,704	20.9%	---	---
Baxter	13,010	35.4%	13,010	35.4%
Grifols	3,312	9.0%	3,312	9.0%
Octapharma	2,639	7.2%	2,639	7.2%
TOTAL:	36,788	100%	36,788	100%
Pre-Merger HHI	2,579			
Post-Merger HHI	3,731			
Increase in HHI	1,153			

Appendix B - Market Concentration by 2008 U.S. 5% and 25% Albumin Sales Volumes

Plasma Fractionator	Pre-Acquisition		Post-Acquisition	
	Sales (kilograms)	Share	Sales (kilograms)	Share
CSL	43,311	36.61%	53,757	45.44%
Talecris	10,446	8.83%	---	---
Baxter	43,117	36.44%	43,117	36.44%
Grifols	15,449	13.06%	15,449	13.06%
Octapharma	5,993	5.07%	5,993	5.07%
TOTAL:	118,316	100%	118,316	100%
Pre-Merger HHI	2,942			
Post-Merger HHI	3,589			
Increase in HHI	646			

Appendix C - Market Concentration by 2007 U.S. Rho-D Sales by Revenue

Plasma Fractionator	Pre-Acquisition		Post-Acquisition	
	Revenue (US\$ Millions)	Share	Revenue (US\$ Millions)	Share
CSL	24.49	29.0%	35.41	42.0%
Talecris	10.92	13.0%	---	---
Ortho Clinical Diagnostics (Johnson and Johnson)	48.8	58.0%	48.8	58.0%
TOTAL:	84.21	100%	84.21	100%
Pre-Merger HHI	4372			
Post-Merger HHI	5126			
Increase in HHI	754			

Appendix D - Market Concentration by 2007 U.S. Alpha-1 Sales by Revenue

Plasma Fractionator	Pre-Acquisition		Post-Acquisition	
	Revenue (US\$ Millions)	Share	Revenue (US\$ Millions)	Share
CSL	32.62	12.6%	214.11	82.7%
Talecris	181.49	70.1%	---	---
Baxter	45.05	17.4%	45.05	17.4%
TOTAL:	258.90	100%	258.90	100%
Pre-Merger HHI	5,376			
Post-Merger HHI	7142			
Increase in HHI	1767			