UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: PLASMA-DERIVATIVE PROTEIN THERAPIES ANTITRUST LITIGATION This Document Relates To All Actions	Case No. 09 C 7666 MDL No. 2109 Judge Joan B. Gottschall

CONSOLIDATED AMENDED COMPLAINT

The University of Utah, Hospital Damas Inc., Mak Medical LLC, and Ravi Patel, M.D., Inc. d/b/a Comprehensive Blood and Cancer Center ("Plaintiffs"), individually and on behalf of a class of all others similarly situated, bring this action for treble damages under the antitrust laws of the United States against Defendants, and demand a jury trial.

NATURE OF THE CASE

1. Plaintiffs allege that Defendants, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, conspired, combined, or contracted to restrict output and to fix, raise, maintain, or stabilize the prices of Plasma-Derivative Protein Therapies that they sold to Plaintiffs and the other members of the Class from at least as early as July 1, 2003 through the present. As a result of Defendants' unlawful conduct, Plaintiffs and other members of the Class paid supra-competitive prices for Plasma-Derivative Protein Therapies, and thus suffered injury of the type the federal antitrust laws are designed to prevent.

2. Defendants CSL Limited, CSL Behring LLC, CSL Plasma (collectively "CSL"), and Baxter International Inc. ("Baxter") develop, manufacture, and sell Plasma-Derivative Protein Therapies, which are used primarily by hospitals and other healthcare

providers to treat critically ill patients suffering from, among other diseases, various immune disorders. Defendant Plasma Protein Therapeutics Association ("PPTA") is the trade association for plasma-protein therapy manufacturers. CSL Behring LLC and Baxter are important members of, and occupy significant leadership positions within, the PPTA.

3. Although the conspiracy began no later than mid-2003, Defendants laid the groundwork for the conspiracy in the late 1990s, when safety-related plant closures led to supply shortages in the industry, triggering government intervention. In June 1999, the vice-president of the plasma manufacturing industry's trade association (a precursor to the PPTA), several consulting firms, and government representatives met to explore ways to increase industry inventory and supply transparency so that future shortages could be averted. Defendants also used this meeting as an opportunity to begin exploring ways to increase the level of transparency among themselves, in order to facilitate effective communication of price and supply information. Over the next few years, Defendants developed a data monitoring system that would enable them to track each supplier's current distribution and inventory levels. Defendants used the pretext of avoiding future supply shortages to justify the information exchange, when in fact they had every intention of working together to drive down supply in order to artificially inflate prices.

4. Indeed, CSL's Chief Economist presciently noted that "economics can help [us] understand how to loosen the shackles of competition." *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 43 (D.D.C. Nov. 11, 2009).

5. He proved to be right, as the information exchange system Defendants developed would serve as an excellent mechanism to effectuate and monitor Defendants' anticompetitive conspiracy.

6. Meanwhile, the government intervention served its purpose. Plasma manufacturers implemented stricter safety guidelines and, once the temporarily closed plants came back on line, increased production of Plasma-Derivative Protein Therapies. The early 2000s witnessed a period of abundant supply of Plasma-Derivative Protein Therapies, and manufacturers, including Baxter and CSL, suffered severe drops in profitability.

7. As a result of the supply contraction and rising prices of the late 1990s, followed by a period of increased supply and declining prices, the industry learned that suppliers could maximize profits if each firm did its part to limit overall industry supply by holding back on expanding output.

8. The sinking profits of the early 2000s spurred Baxter and CSL to unlawfully agree to reduce supply and fix prices of Plasma-Derivative Protein Therapies, and to unlawfully agree to exchange information regarding supply and production capacity, that had the effect of reducing supply and fixing prices. As more fully described below, Baxter and CSL took various actions forming the crux of the conspiracy by reducing supply and raising prices, thereby increasing profitability. *First,* Baxter and CSL gained significant market share by acquiring competitors and soon thereafter closing many of these newly acquired plants, thereby reducing industry supply. *Second*, Baxter and CSL worked with the PPTA to refine the data monitoring system, initiated in 1999, so that they could determine their fellow suppliers' current inventory and supply levels,

in order to permit effective policing of the conspiracy. *Third*, Defendants signaled to each other and to other suppliers the desirability of restricting supply to the marketplace. *Fourth*, Defendants engaged in anticompetitive discussions involving supply and pricing issues at PPTA meetings, and continued those discussions privately at bars and restaurants after trade association meetings and at business meetings. *Fifth*, in an effort to ward off government intervention once the conspiracy began to produce results, Baxter and CSL, in coordination with the PPTA, publicly and falsely denied supply shortages, significantly over-reported industry supply figures, and misleadingly blamed Medicare reimbursement rates for patients' difficulties in obtaining crucial plasma therapies.

9. Beginning in the early 2000s, and particularly between 2003 and 2005, Baxter and CSL made key competitor acquisitions so that they would be in a better position to control the supply of Plasma-Derivative Protein Therapies. Shortly after several of these acquisitions, Baxter and CSL curbed output at many of the newly acquired facilities.

10. Each defendant curbed output at these newly acquired facilities in such a way as to signal to other defendants that it was reducing output.

11. By the latter part of this period, only five suppliers of these therapies remained, and Baxter and CSL each had substantial shares of the market for each therapy. The result was an oligopoly in which the ability to reach an agreement on output and price became easier, as there were fewer firms to coordinate output and prices.

12. In late 2002, the PPTA, with the extensive involvement of Baxter and CSL, launched a new data monitoring system. The system, developed in close collaboration with economists and data collection experts, identified benchmark ratios for

inventory versus distribution levels of Plasma-Derivative Protein Therapies. As the industry consolidated, fewer and fewer members reported data, until there were only five suppliers left, and Baxter and CSL each represented more than 25% of the industry supply. Given that there were only five suppliers, that two of them each possessed over 25% of the market for each therapy, and that the inventory and distribution information being shared was current in nature, Defendants were able to determine each supplier's present inventory and supply levels, and thus use the exchange of such information to effectively monitor and police the conspiracy, as well as to reduce supply and increase prices.

13. The PPTA asserted that its data-gathering effort promoted the public good by helping to alert both manufacturers and the government to potential impending supply shortages, but this was mere pretext. Instead, the PPTA's efforts to gather and monitor supply data actually facilitated anticompetitive information exchange among manufacturers and further assisted Defendants in concealing their conspiracy by providing a ready mechanism with which to report falsely inflated supply numbers.

14. No later than late 2003, anticompetitive communications among Defendants began in earnest. The PPTA, as well as Baxter and CSL, signaled the industry to restrict the supply of Plasma-Derivative Protein Therapies. Jan Bult, President of the PPTA, publicly stated that "we will see—and this is my prediction—that individual companies, in response to their economic challenges, will tighten supply." CSL and Baxter similarly signaled each other and the industry, through analysts, investor calls, and the press, to restrict the supply of Plasma-Derivative Protein Therapies.

15. A reduction in supply by either Baxter or CSL only made economic sense if other suppliers also reduced supply; otherwise, it would have been in the manufacturer Defendants' interest to increase output and seek additional market share.

16. Executives from Baxter and CSL met privately in bars or restaurants in the United States after trade association and other industry meetings. Baxter and CSL discussed supply and pricing of Plasma-Derivative Protein Therapies during these private meetings. Additionally, Executives of Baxter and CSL met on several occasions, including at PPTA meetings, to exchange information relating to supply and pricing.

17. Nor were the anticompetitive discussions restricted to the private confines of bars or restaurants. For example, the minutes from ostensibly legitimate meetings involving Baxter and CSL were regularly "scrubbed" of anticompetitive discussions relating to pricing and supply.

18. Executives from smaller suppliers of Plasma-Derivative Protein Therapies voiced concerns that CSL and Baxter improperly exchanged anticompetitive information relating to the supply and pricing of Plasma-Derivative Protein Therapies, but were ignored by Defendants.

19. Once the conspiracy was underway, Defendants took active steps to conceal their illicit activities. In 2006, patients and doctors jointly asked the government to declare the shortage of Plasma-Derivative Protein Therapies to be a public health emergency. Defendants employed two primary strategies to avoid increased government involvement similar to that which occurred in the late 1990s. Through the PPTA, Defendants falsely denied supply shortages and significantly over-reported the supply of plasma therapies in the marketplace. Defendants, again through the PPTA, also sought to

shift the government and the public away from reports of a supply shortage by pointing to Medicare reimbursement rates as the purported sole cause for patients' access problems. By falsely denying shortages and manipulating the debate, Defendants managed to avoid a government declaration of a public health emergency and maintained and concealed their conspiracy.

20. The emergence of another plasma manufacturer with the capacity to significantly increase industry output could potentially have threatened the efficacy of Defendants' conspiracy. By 2006, Talecris Biotherapeutics Holdings Corporation ("Talecris") was the only other company with the manufacturing capacity even potentially capable of undermining Defendants' conspiracy. Recognizing the potential threat posed by Talecris, and with the public support of ostensible competitor Baxter, CSL Limited attempted to acquire Talecris in 2009 and thereby neutralize a potential threat to Defendants' ongoing conspiracy.

21. Soon thereafter, the Federal Trade Commission ("FTC") filed an administrative complaint seeking to block CSL Limited's attempted acquisition of Talecris, on the basis that the deal would substantially reduce competition in the United States for Plasma-Derivative Protein Therapies. *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 41 (D.D.C. Nov. 11, 2009). Soon after the FTC filed its complaint, CSL Limited abandoned the proposed acquisition.

22. In an FTC press release accompanying the filing of its lawsuit, the Director of the FTC's Bureau of Competition stated that "[s]ubstantial consolidation has already occurred in the plasma protein industry, and these highly concentrated markets are already exhibiting troubling signs of coordinated behavior." Moreover, the FTC

alleged that if the proposed acquisition were approved, Defendants "would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products."

23. In evaluating the anticompetitive effects the proposed deal would produce, the FTC discovered evidence from Defendants' own files that "suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry." The FTC has remarked that some of the language discovered in Defendants' documents "is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy," and thus could expose Defendants to "possible treble damages actions."

24. The FTC's complaint describes, among other things, "troubling signs of coordinated behavior" by Defendants including signaling—*i.e.*, the intentional sharing of competitive information to ensure that manufacturers all restrain output and curb growth, resulting in higher prices.

25. The FTC also noted that Defendants used specific key words to: (1) suggest to each other that increasing production of Plasma-Derivative Protein Therapies could hurt Defendants' collective ability to reap the significant profits that they had all gained during an extended period where demand exceeded supply for these products; (2) remind each other that, during a period when supply increased, prices and profitability for producers of Plasma-Derivative Protein Therapies had dropped substantially; and (3) encourage one another to increase supply only incrementally to keep pace with increases in demand, while discouraging one another from increasing

supply to the extent that the firms actually would have to compete with one another for market share.

26. As a result of Defendants' conspiracy, many patients were forced to go without critical Plasma-Derivative Protein Therapies. According to a survey by the Immune Deficiency Foundation ("IDF") of physicians conducted in 2005, 33% of responding doctors had significant difficulty obtaining Ig, one of the therapies at issue. These doctors also reported that 40% of those patients denied access to Ig therapy had suffered adverse health effects.

27. Defendants' coordinated efforts to restrict supply have produced favorable financial results for Defendants, however, as the prices of Plasma-Derivative Protein Therapies have risen dramatically since 2003, and Defendants have enjoyed large profit margins on these therapies ever since.

28. As a result of Defendants' conspiracy, prices for Plasma-Derivative Protein Therapies were higher than they otherwise would have been. Beginning on or about July 1, 2003, and continuing through the present, prices for Plasma-Derivative Protein Therapies have increased substantially.

29. Plaintiffs and all others similarly situated paid supra-competitive prices for these products, and have suffered injury to their business and property. Plaintiffs bring this action, on behalf of themselves and all those similarly situated that purchased Plasma-Derivative Protein Therapies in the United States directly from Defendants from July 1, 2003 through the present, seeking recovery from the Defendants for the financial harm that the conspiracy has inflicted on Plaintiffs and the Class.

JURISDICTION AND VENUE

30. Plaintiffs bring this action under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries that Plaintiffs and the other Class members have suffered from Defendants' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

31. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337 and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26.

32. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a) and 22 and 28 U.S.C § 1391(b), (c) and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District.

33. This Court has personal jurisdiction over each Defendant, because each Defendant: transacted business throughout the United States, including in this District; sold Plasma-Derivative Protein Therapies throughout the United States, including in this District; had substantial contacts with the United States, including in this District; or committed overt acts in furtherance of their illegal scheme and price-fixing conspiracy in the United States. In addition, the conspiracy was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

PARTIES

PLAINTIFFS

34. Plaintiff University of Utah, a body politic and corporate of the State of Utah, is acting on behalf of its University of Utah Hospitals & Clinics ("UUHC"). The University of Utah and UUHC have their principal place of business in Salt Lake City, Salt Lake County, Utah. Plaintiff, through its UUHC, operates approximately 469 beds. During the Class Period, Plaintiff purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conspiracy alleged, Plaintiff was injured in its business or property.

35. Plaintiff Hospital Damas, Inc. is a non-profit organization with its principal place of business in Ponce, Puerto Rico. Plaintiff, through its hospital, operates approximately 356 beds. During the Class Period, Plaintiff purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conspiracy alleged, Plaintiff was injured in its business or property.

36. Plaintiff MAK Medical is a limited liability company organized under the laws of the state of Georgia with its principal place of business in Camilla, Georgia. Plaintiff operates a specialty pharmacy and home infusion company. During the Class Period, Plaintiff purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conspiracy alleged, Plaintiff was injured in its business or property.

37. Plaintiff Ravi Patel, M.D., Inc. doing business as Comprehensive Blood & Cancer Center, is a California corporation with its principal place of business located in Bakersfield, California. Plaintiff is the largest free-standing cancer center on the West

Coast and provides a wide range of services for cancer patients including chemotherapy and infusion services, radiation treatments, patient and community education, genetic and nutritional counseling, occupational therapy, and social services. During the Class Period, Plaintiff purchased Plasma-Derivative Protein Therapies directly from one or more Defendants. As a result of the conspiracy alleged, Plaintiff was injured in its business or property.

DEFENDANTS

38. Defendant CSL Limited is a company incorporated and domiciled in Australia, with its principal place of business located at 45 Poplar Road, Parkville, Victoria, 3052, Australia. CSL Limited is the second-largest supplier of Plasma-Derivative Protein Therapies in the world. It produces and sells biotherapies indicated for the treatment of several rare primary immune deficiency diseases, coagulation disorders, and inherited respiratory disease. CSL Limited is a vertically integrated company. It owns and operates one of the world's largest plasma collection networks, CSL Plasma, with collection facilities and laboratories in Boca Raton, Florida and Marburg, Germany. It also owns and operates manufacturing sites through its wholly owned subsidiaries in Marburg, Germany and Bern, Switzerland. CSL Limited's worldwide sales for its 2008 fiscal year were about $2.5 billion. Ig sales accounted for approximately 34% of CSL Limited's total sales and albumin accounted for approximately 10% of total sales.

39. Defendant CSL Behring LLC ("CSL Behring") is a wholly owned U.S. subsidiary of CSL Limited and is headquartered at 1020 First Avenue, King of Prussia, Pennsylvania 19406-0901. CSL Behring is the second largest producer of plasma

products in the United States. CSL Behring's products are indicated for the treatment of coagulation disorders including hemophilia and von Willebrand disease, primary immune deficiencies, and inherited respiratory diseases. Its products also are used in cardiac surgery, organ transplantation, and burn treatment, and for the prevention of hemolytic diseases in newborns. CSL Behring has a manufacturing site in Kankakee, Illinois. CSL Behring's sales revenue was approximately $1.8 billion for its 2008 fiscal year.

40. Defendant CSL Plasma is a wholly owned U.S. subsidiary of CSL Behring and has its principle place of business at 5201 Congress Avenue, Suite C220, Boca Raton, FL 33487. CSL Plasma, previously known as ZLB Plasma, is one of the world's largest collectors of human plasma for the manufacture of Plasma-Derivative Protein Therapies.

41. Defendant Baxter International Inc. ("Baxter") is a global, diversified healthcare company incorporated in Delaware and has its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Baxter is the largest producer of Plasma-Derivative Protein Therapies in the world, and is the largest producer of plasma products in the United States. Baxter is divided into three business segments: BioScience; Medication Delivery; and Renal. The BioScience business manufactures and sells, among other products, recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders, and plasma-based therapies to treat immune deficiencies, alpha 1-antritrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions. Baxter maintains 15 manufacturing facilities in the United States and its territories, as well as facilities in 23 other countries. Its BioScience segment has 11 manufacturing sites domestically and abroad, including sites in Hayward, Thousand

Oaks, and Los Angeles, California and in Beltsville, Maryland. In 2008, Baxter's revenues exceeded $12.3 billion, and it derives about 20% of its sales from plasma products.

42. Defendant Plasma Protein Therapeutics Association ("PPTA") is a trade association comprised of the collectors of source plasma and manufacturers of Plasma-Derivative Protein Therapies. The PPTA is headquartered at 147 Old Solomons Island Road, Suite 100, Annapolis, Maryland 21401. The PPTA consists of global and regional boards of directors which represent the geographic interests of its members. It does not include purchasers or patients of Plasma-Derivative Protein Therapies or any entities or groups that advocate for those groups' interests. The PPTA participated in and facilitated the conspiracy during the Class Period.

CO-CONSPIRATORS

43. Various other individuals, firms and corporations, not named as Defendants herein, may have participated as co-conspirators with Defendants and performed acts and made statements in furtherance of the conspiracy. Plaintiffs reserve the right to name subsequently some or all of these persons as defendants.

44. Whenever in this Complaint reference is made to any act, deed or transaction of any corporation, the allegation means that the corporation engaged in the act, deed or transaction by or through its officers, directors, agents, employees or representatives while they were actively engaged in the management, direction, control or transaction of the corporation's business or affairs.

INTERSTATE TRADE AND COMMERCE

45. The activities of Defendants and their co-conspirators, as described in this Complaint, were within the flow of and substantially affected interstate commerce.

46. During the Class Period, Defendants and their co-conspirators sold substantial quantities of Plasma-Derivative Protein Therapies in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

47. The conspiracy in which the Defendants and their co-conspirators participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

FACTUAL ALLEGATIONS

THE PLASMA-DERIVATIVE PROTEIN THERAPIES INDUSTRY

Background

48. The manufacturing process for Plasma-Derivative Protein Therapies 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 approximately seven months to one year.

49. The manufacturing process is highly regulated because plasma products run the risk of containing and transmitting infections. Relevant regulatory bodies include the United States Food and Drug Administration ("FDA"), and state regulatory agencies. The PPTA purports to operate as an industry self-regulatory body.

50. Plasma-Derivative Protein Therapies are essential for treating a number of serious illnesses, including immune deficiency diseases, coagulation disorders, and

respiratory diseases. The annual cost for such treatments, at current prices, can exceed $90,000 per patient in some cases.

51. For certain illnesses, Plasma-Derivative Protein Therapies are absolutely necessary. There is no practical substitute. Purchasers of Plasma-Derivative Protein Therapies—especially hospitals and other health care facilities—will pay very high prices if necessary to make treatment available to critically ill patients. Because demand for these therapies is relatively inelastic to price, Defendants were able to drastically increase their prices and profits by controlling output.

52. The most prominent plasma-derivative protein therapies are: (1) Ig; (2) albumin; (3) alpha-1; and (4) Rho-D. The relevant plasma-derivative protein therapy products for purposes of this Complaint are Ig and albumin ("Plasma-Derivative Protein Therapies").

Relevant Products

Ig

53. Ig—short for immune globulin—is a widely used plasma-derived biologic that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the predominant form, has over 20 FDA-approved indications, and as many as 150 off-label uses. Ig products are antibody-rich plasma therapies that have long been used in the treatment of primary immune deficiencies (to provide antibodies a patient is unable to make) and certain autoimmune disorders where it is believed to act as an immune modulator. In addition, physicians frequently prescribe Ig for a wide variety of diseases, although some of these uses are not described in the product's labeling and differ from those tested in clinical studies and approved by the FDA or other regulatory agencies in

other countries. These unapproved, or "off-label," uses constitute the preferred standard of care or treatment of last resort for many patients in varied circumstances.

54. Ig represents the largest Plasma-Derivative Protein Therapy by value. It is estimated that 70% of IVIG sold in the United States in 2007 was purchased by hospitals. Physician offices represented about 13% of IGIV volume, and homecare companies and specialty pharmacies represented about 17% of IGIV volume.

55. Ig is a commodity-like product essential for the treatment of certain conditions for which there are no good or reasonably interchangeable substitutes.

Albumin

56. Albumin is the most abundant protein in human plasma. It is synthesized by the liver and performs multiple functions, including the transport of many small molecules in the blood and the binding of toxins and heavy metals, which prevents damage that such toxins and heavy metals otherwise might cause. Albumin is used to expand blood volume and to prime heart valves during surgery.

57. Albumin generally is used in surgical and trauma settings and typically is sold to hospital groups.

58. Albumin is a commodity-like product essential for the treatment of certain conditions for which there are no good or reasonably interchangeable substitutes. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

Relevant Geography

59. Like pharmaceutical products, each Plasma-Derivative Protein Therapy must be approved for sale in the United States by the FDA. To obtain approval, the

products must be produced from plasma collected in the United States at collection centers approved by the FDA. The products also must be manufactured at plants approved by the FDA.

60. Performing the requisite clinical trials and undergoing the FDA approval process for plasma and Plasma-Derivative Protein Therapies takes well over two years. Accordingly, Plasma-Derivative Protein Therapies sold outside of the United States are not viable competitive alternatives for United States customers, who cannot buy products produced abroad even in the event of a price increase for products produced in the United States.

PRE-CLASS PERIOD INDUSTRY DYNAMICS AND CONDUCT

Late 1990s: Decreased Supply, Growing Demand, And Government Intervention

61. In the late 1990s, a series of events brought about by temporary plant closures resulted in extensive changes in supply for both the domestic and global plasma-derivative protein therapy industries.

62. In 1997, in the wake of a recall of albumin produced by a company called Centeon, the FDA mandated the temporary closure of the plant then owned by Centeon at Kankakee, Illinois (now owned by CSL Behring). In 1999, the Alpha Therapeutic Corporation plant in Los Angeles, California (which Baxter now owns) temporarily closed. The shortages that resulted from these disruptions caused higher prices in the United States, spurring producers to increase plasma collections as well as output of Plasma-Derivative Protein Therapies.

63. These plant closures and supply shortages attracted the national spotlight in 1997 and 1998. Congress held hearings on the safety of plasma-derivative protein

therapy products, and the television program "60 Minutes" produced a segment addressing Ig supply shortages.

64. This attention led directly to increased regulation of Plasma-Derivative Protein Therapy manufacturers. The FDA mandated that the industry implement various "good manufacturing procedures."

65. Additionally, the FDA required the industry to monitor the distribution levels of Plasma-Derivative Protein Therapies. Pursuant to its regulatory authority, the FDA required suppliers to provide the Center for Biologics Evaluation and Research (CBER), a division of the FDA, with twice-yearly data regarding the distribution levels for all Plasma-Derivative Protein Therapies.

66. The International Plasma Products Industry Association (IPPIA), a trade association that represented industry manufacturers, voluntarily promised to submit *monthly* data to the FDA/CBER regarding distribution *and* inventory of Plasma-Derivative Protein Therapies for each of its members. The IPPIA promised to make aggregated data available to the public at large; competitor-specific data would be made available to the Center for Biologics Evaluation and Research. The data volunteered by the IPPIA went beyond that required by the FDA, and assisted Defendants in implementing and monitoring their conspiracy.

June 1999 Meeting Regarding Industry Supply Monitoring

67. On June 17, 1999, the Blood Products Advisory Committee, an FDA/CBER committee, held a meeting in Rockville, Maryland to address supply of and demand for plasma derivatives. FDA employees, industry representatives, and patient representatives attended.

68. Plasma manufacturers were represented at this meeting by Dennis Jackman. At the time, Mr. Jackman was the Vice-President of the IPPIA. Mr. Jackman currently serves as a Senior Vice-President at CSL Behring. As the Vice-President of the IPPIA, Mr. Jackman had access to distribution and inventory data for the entire industry, some of which he presented at the meeting.

69. Mr. Jackman was present when the FDA presented company-by-company, month-by-month distribution data for 1998. The actual distribution figures for individual companies were modified to preserve confidentiality, but someone with knowledge of each company's market share easily could determine each competitor's distribution totals.

70. Mr. Jackman emphasized the industry's desire to meet demand, stating: "Individual companies and members of our association . . . are going to seek to meet demand." Blood Products Advisory Comm. Mtg., Tr. 217:21-22 (Jun. 16, 1999). According to Mr. Jackman, however, the industry had to be very careful in how it went about meeting demand because of antitrust laws. Despite these hurdles, he stressed, "we are trying to collaborate in any way we can and cooperate by providing our monthly data." *Id.* at 215:5-6. He further predicted that future supply would be "heavily impacted" by the industry's "investment in plant capacity and new processes." *Id.* 215:8-10.

71. Mr. Jackman thus verbalized what would become a key component of Defendants' eventual strategy for restricting supply and increasing price in the marketplace: "collaborating" and sharing sensitive data regarding output and inventories.

72. This meeting also involved several detailed discussions regarding future demand for Plasma-Derivative Protein Therapies. From this meeting it became clear that the demand for Plasma-Derivative Protein Therapies—particularly Ig—had grown and would continue to grow.

73. Representatives from the Marketing Research Bureau, Inc. attended the meeting to discuss demand trends. The Marketing Research Bureau is an organization that monitors the plasma-derivatives market and provides Defendants and other manufacturers with regular reports related to distribution, price, and demand for plasma derivative products. The Market Research Bureau continues to provide the industry—including Defendants—with annual reports detailing the demand for plasma-derivative products and pricing information across the industry.

74. At this meeting, the Marketing Research Bureau reported that the market for IVIG had seen "fairly steady growth" in the last 17 years. The market for IVIG in 1998 was 15.5 million grams, and the Marketing Research Bureau estimated that the market in 2000 would be 18 million grams—a 16 percent increase. The Bureau emphasized that "demand is still growing."

75. Manufacturers, including CSL and Baxter, were well aware of the growing demand for Plasma-Derivative Protein Therapies. According to remarks from a distributor at the meeting, executives from the plasma fractionation market estimated annual demand at 21 to 25 million grams for 1998, estimates well above those of other attendees.

76. Georgetown Economic Services also made a presentation at the meeting. The IPPIA contracted with Georgetown Economic Services to aggregate and average

distribution and inventory data provided by the plasma manufacturers. Georgetown Economic Services continues to provide this service for the PPTA. (The PPTA is the current iteration of the trade organization representing industry participants that previously was known as the IPPIA).

77. Georgetown Economic Services reported its plan to assemble information to predict demand for plasma-derivative products over the next year, three years, and five years. To paint a picture of future demand, Georgetown Economic Services intended to gather distribution data from manufacturers, wholesalers, group purchasing organizations, and home health care providers. Next, they planned to interview private and government scientists to assess future demand related to scientific breakthroughs and potential off-label uses.

78. This meeting laid the groundwork for several key components of Defendants' conspiracy: Defendants' trade association began its inventory and supply data monitoring effort; the Marketing Research Bureau and Georgetown Economic Services announced plans to monitor future demand for the industry collectively; and Dennis Jackman was made privy to inventory and supply data for the major plasma derivative manufacturers.

Early 2000s: Increased Supply and Decreased Profits

79. Between 2000 and 2003, once CSL Behring's Kankakee facility and Baxter's Los Angeles facility had resumed production, there was an abundant supply of Plasma-Derivative Protein Therapies. This led to dramatic price declines and, in turn, to a 30% reduction in gross operating margins among producers, including Baxter and CSL.

Because fixed costs represent a high proportion of the total costs of plasma protein production, this translated into a significant downturn in profits for the industry.

80. This period of abundant supply, in turn, resulted in another significant change in the industry. The producers reduced production and plasma collection capacity and began in earnest to vertically integrate.

81. Notably, during this period of excess supply Defendants' trade association, the PPTA, refined its data monitoring system and began exploring the parameters of the antitrust laws. (In 2000, the IPPIA had merged with a similar trade association in Europe to become the PPTA.)

82. On April 20, 2001, the PPTA's President, Jan Bult, noted that because the plasma derivative manufacturing industry was concentrated, it had to be especially careful of running afoul of the antitrust laws. He explained that the association had to walk a fine line to avoid antitrust liability and that the industry was "not allowed to facilitate information exchange among members which are focusing on the future situation. Of course, we are free to talk about what has happened and what is the retrospective data, but about future issues it's very difficult." *See* Advisory Comm. on Blood Safety and Availability, (Apr. 20, 2001) available at http://www.hhs.gov/ophs/bloodsafety/advisorycommittee/pastmeetings/transcripts/20010420.html (last accessed May 28, 2010).

83. Mr. Bult reiterated how careful the PPTA and industry participants had to be when discussing supply data: "You can think you can be very creative and find ways to have public announcements and organize meetings and do it that way. It doesn't work. It doesn't work because there are statements that say these disclosures could be viewed as

a means of signaling competitors so they can make plans based upon the activities of the other manufacturers. And we cannot do that." *Id.*

84. Mr. Bult acknowledged that the PPTA's effort to gather current supply information from industry participants was of questionable legality. He admitted that *"Well, we had a discussion today about inventories. I just want to make you aware that we are at the edge [of] what we can do from a legal point of view." Id*. (emphasis added).

September 2002: Launch Of "Light System"

85. In September 2002, the PPTA launched a new data monitoring system that would allow manufacturers to monitor total industry output—and would become a key method for monitoring and policing the conspiracy. The PPTA presented its "light system," which sought to warn industry participants when inventory levels of Plasma-Derivative Protein Therapies reached certain levels. Working closely with economists, the PPTA identified ideal inventory-to-distribution "ratios" for the industry. Inventories were labeled "red" when approximately two weeks or less of inventory was available; "yellow" when two to five weeks of inventory was available; and "green" when greater than five weeks of inventory was available. Desired inventory levels were based on the ratio of the existing inventory on the first day of the month to the average distribution of a particular protein therapy over the previous 12 months.

86. Julie Birkofer, the Vice President of the PPTA, admitted that "these ratios were developed in very close consultation with economists and experts in the field of data collection and analyses."

87. In a highly concentrated industry such as the Plasma-Derivative Protein Therapies industry, a monthly warning system that reports current inventory levels is a potentially very effective mechanism to monitor competitor compliance with supply restrictions. However, when the system was first implemented, the PPTA did not represent all Plasma-Derivative Protein Therapies manufacturers; two manufacturers were not members, which limited somewhat the potential effectiveness of the "light system" as a mechanism for facilitating a conspiracy to limit supply and increase prices. But this would change shortly.

Industry Consolidation

88. In 1990, there were 13 domestic producers of plasma-derivative protein therapy products. In 2003, that number dropped to nine. Since 2005, there have been only five: CSL Behring, Baxter, Talecris, Grifols, and Octapharma. According to a study by the Department of Health and Human Services (HHS) in 2006, the three leading manufacturers of Ig (CSL Behring, Baxter, and Talecris) had a combined market share of 85%.

89. Effectively, the U.S. market consists of three large producers: CSL Behring, Baxter and Talecris. Grifols and Octapharma are much smaller, with market shares in the single digits, and a limited ability to expand their presence in the United States.

90. The result of this highly concentrated industry structure is that the contract, combination and conspiracy alleged herein need not include the smaller firms to be effective. In particular, the two smallest firms, Grifols and Octapharma, are not in a position to effectively compete or to blunt any price increase by the larger firms, because

the smaller firms have limited production capacity. They could lower prices, but could not capture enough volume to make the cartel price unprofitable. As Talecris grew it presented somewhat more of a potential threat to Defendants' conspiracy, which is why CSL Limited, with support from Baxter, attempted to acquire it.

91. Several firms merged or were acquired. The large, integrated suppliers, most notably Defendants Baxter and CSL, have acquired numerous independent plasma collectors and facilities, and continue to do so. Soon after acquiring these facilities, Defendants shut down many of them in order to reduce supply.

92. CSL acquired the Swiss Red Cross fractionator, ZLB, in July 2000, and acquired 47 plasma collection centers and laboratory facilities operated by Nabi in 2001. It acquired Aventis Behring's plasma products business in 2004, combining it with ZLB Bioplasma to create ZLB Behring, today known as CSL Behring. CSL subsequently closed 35 plasma collection centers in the United States, reduced plasma collections by 1 million liters, and reduced plant output by 1.1 million liters.

93. Baxter acquired Sera-Tec Biologicals LP in 2001 for the stated purpose of ensuring "[l]ong-term access to a consistent, stable supply of source plasma." In late 2002, Baxter acquired 42 plasma collection centers and a laboratory from Alpha Therapeutic Corporation (Mitsubishi Pharma). Baxter subsequently closed 26 of its own plasma collection centers and 38 collection centers that it acquired from Alpha Therapeutic, as well as a plasma manufacturing plant in Rochester, Michigan.

94. As one investment firm with knowledge of the industry has noted, "[a]bout 80% of the [plasma collection] centers are now owned by plasma-products companies such as Baxter International, CSL Limited, Grifols, and Talecris

Biotherapeutics. This represents a complete reversal in ownership since 2000, when 80% of the centers were independent enterprises." *See* Turner Investment Partners, "Will plasma products' prospects remain sunny?" (Feb. 6 2008) *available at http://www.turnerinvestments.com/index.cfm/fuseaction/commentary.detail/ID/2500/CSID/387/* (last accessed May 28, 2010).

95. In 2005, a major non-profit entity, the American Red Cross, exited the plasma products industry. Baxter purchased the Red Cross's existing supply of plasma.

96. The plasma products industry as it now exists has significantly fewer suppliers than it did even six years ago. The remaining suppliers, most notably among them Defendants Baxter and CSL, are larger and more vertically integrated than ever before.

97. All five of the remaining plasma manufacturers are members of the PPTA. As members, they submit monthly distribution and inventory data to the PPTA, as well as attend regular meetings.

THE CONSPIRACY

98. As consolidation has occurred in the Plasma-Derivative Protein Therapies industry, supply has been limited in the face of increasing demand, and prices consequently have increased in recent years. GPOs, distributors, hospitals, physicians—and ultimately patients—have experienced tightening supplies and rising prices. Defendants' conspiracy to restrict supply and increase prices for Plasma-Derivative Protein Therapies began at least as early as July 1, 2003 and has continued through the present.

99. The PPTA has played an integral role in facilitating information exchanges between CSL and Baxter, explaining the economics of the industry, and gathering data to monitor Defendants' compliance with agreements to restrict supply. Once Defendants agreed to restrict the supply of Plasma-Derivative Protein Therapies, the PPTA helped maintain the efficacy of the conspiracy by coordinating an effort to prevent a government declaration of a public health emergency due to supply shortages.

100. Defendants implemented their illegal agreement by coordinating and restricting output and by signaling to one another to do the same. Indeed, during and after the period of abundant supply in the early 2000s, Defendants recognized that controlling capacity was critical to reducing price competition and increasing profits.

101. A key component of the conspiracy was Defendants' focus on coordinating the limitation of supply of Plasma-Derivative Protein Therapies in the marketplace, as the firms were acutely aware that restrained output was profitable only if they cooperated. CSL referred to this as the *"OPEC problem,"* explaining that "[w]henever 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." See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 41 (D.D.C. Nov. 11, 2009) (emphasis added). Baxter similarly has recognized that as long as competitors are not "*irrational*" and do not "*trash price and take share*," they can increase supply steadily in line with market demand to keep prices high. *Id.* (emphasis added).

Defendants Acquired Competitors To Reduce Output

102. At least as early as 2003, CSL and Baxter began taking steps to control the supply of plasma products. CSL recognized the importance of doing so, listing as a "critical success factor" maintaining the supply/demand equilibrium and driving prices.

103. In particular, CSL and Baxter focused on limiting the supply of IVIG and plasma. As a key part of this strategy, CSL and Baxter initiated the purchase of plasma donation and manufacturing facilities and promptly closed those facilities to limit supply.

104. Importantly, by 2003, Dennis Jackman had left his position at the PPTA to become a Senior Vice-President at CSL Behring. In this position at CSL Behring, Mr. Jackman was in a position to fully implement the strategy, first laid out in 1999, of restricting supply and increasing prices by acquiring and closing collection and fractionation facilities.

105. In July 2003, Baxter announced plans to improve its plasma economics by reducing the amount of plasma collected and fractionated. Baxter reported that it planned to reduce its total annual plasma production from 4.6 million liters to 4.0 million liters, a total reduction of about 13%. At that same time, Baxter also announced that it planned to close 26 plasma collection centers as well as its Rochester, Michigan fractionation facility. This appears to have marked the beginning of Defendants' coordinated reduction of supply.

106. Just a few months later, in December 2003, CSL Limited announced that it had agreed to acquire rival Aventis Behring. Initially, CSL described the acquisition as an opportunity for CSL to acquire synergies of operation. In February 2004, after the deal cleared key regulatory hurdles, CSL's managing director, Dr. Brian McNamee,

stated that he believed full integration of the two companies could take 18 months, but predicted that benefits of the merger would be seen within a year.

107. CSL's acquisition of Aventis Behring became final on April 1, 2004. Immediately afterwards, CSL publicly announced that it would reduce plasma input at its Kankakee facility (acquired in the deal) by 50% and that the Kankakee facility would cease production of three plasma products. CSL thus signaled to Baxter that it would join Baxter's efforts to reduce supply.

108. CSL admitted in federal court that the worldwide oversupply of Plasma-Derivative Protein Therapies prompted CSL to acquire Aventis Behring and reduce production at the Kankakee facility, contrary to CSL's statements before the deal closed. These admissions occurred in a suit unrelated to this action. *Gloria Fletcher, et al. v. ZLB Behring*, No. 05-cv-2695 (N.D. Ill. Jul. 12, 2007).

109. In 2004, soon after its acquisition of Aventis Behring, CSL set its sights on yet more consolidation in the industry and the effects that it believed "[o]ne further round of consolidation" would produce:

> 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 was "less likely that a further [CSL] or Baxter acquisition (affecting the US market) would get FTC approval." *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 11 (D.D.C. Nov. 11, 2009).

110. Also, CSL destroyed plasma paste on at least one occasion at its Kankakee manufacturing facility. Plasma paste is derived from plasma during manufacturing; it is an intermediate product before plasma can be manufactured into Ig or albumin. By destroying plasma paste, CSL further limited the supply of Plasma-Derivative Protein Therapies.

111. That same year, on April 22, 2004, Baxter publicly announced that it intended to further reduce plasma production by another 13% (or 400,000 liters). And in 2005, Baxter closed some of the collection facilities it had acquired when it purchased the American Red Cross's plasma supply.

112. Defendants initially tried to downplay shortages resulting from their coordinated supply restrictions. In the summer of 2004, CSL Behring informed one of its salespeople that it did not foresee a shortage of IVIG or albumin. But less than two months later, and shortly after a similar announcement from Baxter, CSL Behring announced a shortage of IVIG and albumin. CSL Behring gave its employees no advance warning of the shortage.

113. CSL and Baxter collusively and intentionally precipitated these shortages, and provided pretextual explanations for the shortages they had worked to create.

The PPTA Helped CSL And Baxter Implement The Conspiracy

114. As previously noted, CSL Behring and Baxter are members of the PPTA. The PPTA is "the primary advocate for the world's leading source plasma collectors and producers of plasma-based and recombinant biological therapeutics." *See* PPTA Home Page, www.pptaglobal.org (last accessed May 28, 2010).

115. High-level executives from CSL and Baxter dominate the PPTA Board of Directors so that they effectively control the PPTA. Current examples include:

- Paul Perreault, Executive Vice President, Worldwide Commercial Operations and Business Development of CSL Behring, and Larry Guiheen, President of Baxter BioScience, serve on the PPTA's Global Board of Directors. Mr. Guiheen currently serves as the Board's Chairman.

- Dennis Jackman, Senior Vice President of Public Affairs of CSL Behring, and Jean Marie Vlassembrouck, Vice President of Industry Affairs at Baxter, serve on the PPTA's Global Management Committee. Mr. Jackman chairs that committee.

- Lynn Powell, Senior Vice President, North America Commercial Operations**,** and Peter O'Malley, Vice President of Business Alliances at Baxter, serve on the PPTA's North American Board of Directors.

- Randy Furby, Senior Vice President of CSL Behring and General Manager of CSL Plasma, serves on the association's Source Board of Directors.

- Roland Martin, Senior Vice President and General Manager of CSL Behring, and Daniel Kenny, Vice President of Baxter BioScience Europe, serve on the association's European Board of Directors.

Additionally, Peter Turner, the current President of CSL Behring and recently appointed Chief Operating Officer of CSL Limited, previously served as the Chairman of the PPTA's Global Board of Directors from 2003 to 2007. Robert Lefebvre, Vice President and General Manager of U.S. Operations at CSL Behring previously served on the

PPTA's North American Board of Directors. Until the filing of this lawsuit, Gordon Naylor, Executive Vice President of Plasma, Supply Chain, and Information Systems at CSL Behring, and Joe Rosen, Director of Business Development and Planning at Baxter BioLife, served on the PPTA's Source Board of Directors and Mr. Naylor served as the Board's Chairman. Mr. Naylor was recently tapped to serve as the Finance Director at CSL Limited.

116. The purpose and effect of this PPTA participation was to facilitate Defendants' repeated opportunities to use PPTA meetings and resources in furtherance of the conspiracy. The participation of the manufacturer Defendants' high-level executives on PPTA's Board of Directors provided the manufacturer Defendants with ample opportunity to conspire directly as well as to direct the actions of the PPTA to facilitate the antitrust violations alleged herein.

117. The PPTA publicly laid out the economic rationale for Defendants' conspiracy and signaled to the industry's suppliers to continue to restrict output. On August 26, 2004, the President of the PPTA, Jan Bult, gave a presentation to the Health and Human Services Advisory Committee on Blood Safety and Availability. At this presentation, Mr. Bult explained the economics of the plasma-protein business: if supply continued to increase, Defendants would not realize any profit, but if Defendants continued to control supply, prices (and profits) would rise.

118. CSL and Baxter had ready access to Mr. Bult's presentation because senior executives from both companies serve as board members for the PPTA. Additionally, transcripts of the presentation, a slide presentation, and minutes from the meeting are available on the Health and Human Services website.

119. Mr. Bult opened his presentation by recognizing the economic perils the industry had faced and noting the need for change: "if we talk about long-term viability of this industry, we need to make economic adjustments. There is no other way around it." Advisory Comm. on Blood Safety and Availability Mtg., Tr. 287 (Aug. 26, 2004) *available at http://www.hhs.gov/bloodsafety/transcripts/ACBSA08262004.pdf* (last accessed May 28, 2010).

120. The plasma-protein industry is, however, "highly concentrated" and therefore Mr. Bult warned that manufacturers must be "extremely sensitive to Anti-trust laws." He explained that exchanging certain types of information was illegal and that *"even when we would like to do it, we can't." Id.* at 288-89 (emphasis added).

121. With that warning in place, Mr. Bult nonetheless proceeded to inform participants that a system was in place to give Defendants ready access to inventory levels. The system gathered data monthly and posted the results to a public website. Although the system had been created in response to supply shortages in the late 1990s, Mr. Bult believed the monitoring system continued to serve an important purpose.

122. Following plasma-protein shortages in the late 1990s, Mr. Bult explained, the industry responded to consumer demand by increasing production. But in 2004 the industry faced a new dilemma. He noted that: "*The question now is do we have the right balance? In '98 we had the situation where demand exceeded supply. Is that still the case? If we have increases in supply, is this balanced with demand or are we building and filling inventories?*" *Id.* at 291 (emphasis added).

123. To answer this question, Mr. Bult explained, one must understand the economics behind plasma manufacturing. According to Mr. Bult, manufacturing plasma

into just one protein, like Ig or albumin, is not profitable—for revenue to exceed cost, a company must manufacture multiple proteins. Mr. Bult went on to explain that "the best revenue comes from the first liter of plasma that is manufactured and the further you get into the system the more problematic it becomes." *Id.* at 292. Thus, the more plasma protein manufactured, the less profit Defendants would realize.

124. Mr. Bult signaled to the plasma industry that the only way to maintain and increase profits was to limit supply: "[I]f there is any concern about immune globulins and, as I told you before, we don't see a near-term threat for immune globulins, but you can ask the question why don't you make more? Just make more so you can avoid all the problems. Well, if that is the case this is going to happen. You can make more but you can't sell it. So you put it in inventory and also you get more albumin and it is still below your cost of manufacture. *That leads to a situation where this industry is going to lose a significant amount of money and, as we have seen with the changes in the marketplace, we are not in a position to do that. So, this will not happen, especially not if you look at the revenue that we have seen over the last years that has come down significantly.* All the changes that you see in the marketplace right now are a clear response to the economic pressures." *Id.* at 294 (emphasis added).

125. He reiterated that "based on what we know today we do not see a near-term short supply." Nevertheless, Bult continued by signaling to suppliers what they should do going forward: "we will see—and that is my prediction—that individual companies, in response to their economic challenges, will tighten supply." *Id*. at 289.

126. After signaling that supply should and would be controlled, Mr. Bult ended his presentation with an ominous warning clearly intended for industry

participants: "*We will continue to make the point that economic adjustments are needed* because look around and look at the companies that were in place in 1998—let me just give you a couple of examples, Alpha Therapeutics Corporation no longer exists. Biopharma has decided to divest and Baxter has significantly reduced its activities. Aventis Behring or Cention is now part of CSL. So, that is the reality. . . . [J]ust look around you and you will see what has happened as a result of the economic challenges." *Id.* at 298 (emphasis added).

127. With this presentation, the PPTA President succinctly explained that the only way for Defendants to achieve acceptable profit margins was to restrict supply.

Defendants Met Privately And Concealed Topics of Industry Meetings

128. As a key part of the conspiracy, Defendants regularly met privately. Executives of CSL and Baxter exchanged information related to the supply and price of Plasma-Derivative Protein Therapies in the course of these private meetings. While Defendants regularly met at PPTA meetings, their contacts with each other did not stop at the conclusion of those meetings. *After some of these meetings, Defendants gathered at bars for drinks or at restaurants for dinner away from the watchful eyes of association attorneys and other outsiders, and continued to discuss supply levels and pricing in furtherance of the conspiracy*.

129. At one recent meeting in Boston involving Defendants, Dennis Jackman expressed a desire for a better sense of the global supply of plasma-protein derivative products, in order to be more accurate about the optimal production levels needed to maximize profits. *Mr. Jackman went so far as to suggest that the PPTA hire an economist to evaluate global demand for Plasma-Derivative Protein Therapies and*

determine the exact amount of supply each manufacturer should produce to achieve the greatest profit overall.

130. Defendants, however, have taken active steps to conceal the anticompetitive elements of their conversations and meetings. Minutes from PPTA meetings, including the foregoing meeting in Boston, are routinely "scrubbed" to remove references to any topic of conversation that potentially violated antitrust laws.

131. Defendants also gathered regularly for the stated purpose of discussing proposed industry regulations, but used these discussions to discuss pricing and supply of plasma products. Throughout 2008, executives from CSL and Baxter, as well as other suppliers, gathered monthly with the IDF. These meetings took place at either the IDF headquarters or the offices of the manufacturers' lobbyist firms.

132. The purported purpose of these meetings was to develop legislation to restore access to IVIG supply to hospitals, homecare, and other sites that used the product. But conversation routinely shifted to discussions of pricing and supply.

133. Top executives from the industry attended the IDF meetings, including, but not limited to: Dennis Jackman, Senior Vice President of Public Affairs for CSL; Deb Williams, a lobbyist for Baxter; and Peter O'Malley, President of Baxter's Bioscience division. As previously noted, both Mr. Jackman and Mr. O'Malley also serve on PPTA boards.

134. Defendants used the meetings, both formal and informal, described in the preceding paragraphs to conspire and reach agreement between themselves regarding supply and pricing of plasma.

135. Executives from smaller manufacturers of Plasma-Derivative Protein Therapies have voiced concerns that they believe CSL and Baxter overstepped the bounds of antitrust laws by discussing the supply and pricing of Plasma-Derivative Protein Therapies at PPTA and other industry meetings.

Baxter And CSL Signaled Each Other To Reduce Supply

136. In addition to the direct conspiratorial communications described in the preceding paragraphs, Defendants also signaled each other using public statements to keep supply under control. These "signals" served several purposes, including providing a pretext for the implementation of the agreements reached during private conspiratorial meetings.

137. Some competitive information is widely available from industry sources and the competitors themselves. Firms closely monitor each other's activities with respect to plasma collection, manufacturing, and output, and firms collect and catalogue an extraordinary wealth of timely competitive information.

138. For example, CSL executives told employees at town-hall meetings that they kept track of their competitors' information, in part by monitoring 10-K filings.

139. This wealth of publicly available data allowed Defendants to police the conspiracy and ensure agreements reached were actually implemented.

140. Defendants took advantage of this timely competitive information by engaging in signaling—*i.e.*, the intentional sharing of competitive information for purposes of seeking to ensure that manufacturers all were restraining output, curbing growth, and maintaining high prices as agreed upon.

141. In particular, Defendants used specific key words to: (1) suggest to each other that increasing the production of Plasma-Derivative Protein Therapies could hurt the firms' ability to reap significant profits that they had all gained during an extended period where, as a result of the conspiracy, demand exceeded supply for these products; (2) remind each other of how, during an earlier period when supply was not artificially suppressed, prices and profitability for firms dropped substantially; and (3) encourage one another to increase supply only incrementally to keep pace with increases in demand, and not to increase supply to the extent that the firms would actually compete with one another for market share.

142. Baxter and CSL signaled each other to reduce plasma fractionization capacity and *actually reduced capacity by the same amount*. During an investor call on November 18, 2004, Baxter's CFO at the time, John Greisch, stated:

> We've reduced our throughput capacity by about 30 percent. We have shut the number of plasma collection centers and significantly reduced the cost in this business.
>
> In addition, there's quite a bit of industry consolidation going on in the plasma business. Many of you are aware CSL has acquired the Aventis plasma business, *and has similarly reduced their capacity by a similar amount, approximately 1 million liters*. And Bayer, which is the third major player in this business, has its business up for sale. So the economics in this business which deteriorated significantly in approximately 2002 and early '03 as a result of significant excess supply, which drove reduced pricing, has begun to improve. We are seeing improved pricing, particularly in the U.S. IGIV of the [sic] market, which is our largest single market and our largest single product line. And as the industry consolidation continues, we're confident the economics of this business will improve. (emphasis added.)

143. Although Baxter had the capability to increase its output of Plasma-Derivative Protein Therapies, along with its sales volume and market share, it signaled its

competitors that it had no plans to take advantage of those capabilities. During an investor call on April 21, 2005, Mr. Greisch admitted that Baxter had the capacity to increase fractionization, stating: "To your question about whether we have capacity for more volume, the answer is yes." But then he signaled the industry that Baxter did not intend to take advantage of that capacity, stating, "we brought our production levels down to a specific level to optimize the profitability of this business; and we have no intention, right now, of bringing that production capacity up."

144. Baxter's new strategy shifted the company's focus from market-share growth to an emphasis on profitability. On the November 18, 2004 call, Mr. Greisch explained that the company's strategy "*has changed fundamentally to more of a straight focus on improving profitability, maximizing the cash flow out of this business and not chase growth going forward*." (emphasis added.) Additionally, he explained, that "*this is not going to be a high-growth business for the Company over the next several years, but it should be the source of improved profitability and cash flow*." (emphasis added.) Similarly, during an investor call on June 21, 2006, Mr. Greisch noted that Baxter, as well as CSL, had reduced production in an attempt to increase profitability:

> The Plasma business, as I mentioned, this really was a business that took some significant profit hits in '01 and '02. It was an industry that ended up with some significant excess supply dynamics in that period. In the middle of '03 we bit the bullet and significantly restructured our business. We took about a third of our production capacity and at the same time the industry was going through some pretty significant consolidation with CSL, which is a large Australian competitor in the business. . . . from a micro-perspective, *Baxter reduced our commitment to this business by taking out about a third of our production capacity, and industry wide, about 20% of the industry capacity came out on the back of our actions and CSLs* [sic]. (emphasis added.)

145. CSL publicly admitted to a similar strategy that de-emphasized growth in favor of increased profitability. During an investor call on August 21, 2007, the CEO of CSL Ltd., Brian McNamee, explained:

> If I just want to step back and say, "What drives our Plasma business?" I think it's important that -- we get a lot of questioning about volume. *And certainly volume growth is a factor but it's actually a relatively small factor in our thinking. I just wanted to highlight that.* I think that maintaining the quality of our business, having efficient cost base is fundamental. So having a really -- an outstanding plasma collection capability, having efficient high quality manufacturing units is really first and foremost. (emphasis added.)

146. Defendants understood that the industry consolidation described in the preceding paragraphs was integral to the success of their cartel. In a September 11, 2006 industry conference hosted by Bear Stearns, Rob Davis, the current CFO of Baxter, laid out the case for capacity reductions in order to improve prices, emphasizing that this strategy was only possible due to the consolidation that had occurred:

> The market has . . . consolidated going from approximately 12 players down to really three major players, and five players of significance overall. As well as both within the industry and within Baxter, you've seen a significant reduction in the amounts of plasma collections. *For instance within Baxter we actually took out half of our plasma collection capacity through a restructuring we had in both 2003 and 2004* as well as in the overall level of fractionation that is in the market. Given this reduction in supply we now have seen the market come back into equilibrium between supply and demand which has allowed the pricing to stabilize and given the long leadtimes it takes to bring new fractionization capacity on line which is roughly three to five years puts us in a very good position to see stable growth in this business going forward over the next three to five years. (emphasis added.)

147. CSL responded in kind, echoing Mr. Davis's sentiment regarding the opportunities presented by a more consolidated industry and committing to limit CSL's

supply increases to the single digits. During an investor call on August 22, 2006, Mr. McNamee publicly signaled:

> *What we see now is, I think, the industry now heading to a much more predictable phase of stability because we have a much more consolidated industry*, and it's truly global. Particularly Baxter and ourselves, we're truly global as the major players. Talecris is a very significant U.S.-centric player, and we have the two niche players of Grifols and Octopharma [sic] also fundamentally attempting to be global as niche players. And we think that the combination of consolidation, global players, with vertical integration of the supply chain, particularly three majors of Baxter, ourselves, and Grifols have significant supply chain issues. We think that that vertical integration gives a degree of – high degree of planning in the supply chain that the sector previously didn't have. So we are certainly forecasting a continued steady growth in IVIG usage across the globe. We think, as we've always said, around the 6 to 7% is a reasonable underlying growth pattern for the tradable market in immunoglobulin. The U.S. might be a little higher sometimes, Europe might be a little low, but we think the blended long term sectors is an approximately that, and assuming there are no significant surprises we think that we're entering a period of stable growth.

148. Just a month later, on October 19, 2006, Baxter responded by signaling its commitment to refrain from significantly increasing supply. Baxter CEO Bob Parkinson stated that, "[w]e continue to see anywhere between what I could characterize as price stability to pricing buoyancy. . . . We don't really see anything in what I will call the supply demand equilibrium in the marketplace that has changed or in our view is likely to change going forward. . . . the stability continues to be very good and so there will be some pricing latitude there going forward." Later on, he succinctly stated, "[t]here certainly aren't any major initiatives to dramatically expand plasma collection." In fact, on September 10, 2007, Mr. Davis admitted that Baxter's minimal volume growth had been limited to "the mid to high-single digits" just like CSL's.

149. Mr. Parkinson has repeatedly reiterated Baxter's commitment not to significantly increase its market share. During an investor call on January 28, 2008 he stated that, "it would seem that people [competitors] are doing what they need to do to ensure that the global demand can be met collectively by the industry." During another investor call on May 1, 2008, Mr. Davis expounded on this thought and signaled Baxter's competitors that it did not make sense for any competitor to lower price and to try to gain market share. He made it clear that, if everyone kept prices up collectively, they could all expect continued high profits. Indeed, Mr. Davis essentially acknowledged that the Baxter and its competitors were signaling one another not to chase "short-term gain" at the expense of collective profitability:

> No, no one has really [been] signaling a dramatically different view on demand from one another. We might be all off a percent or two from each other, but no one is saying a significantly different signal. . . . Why any of us would, for a very short-term gain, do anything to change that, 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.)

Similarly, during an investor call on January 22, 2009, Mr. Davis indicated that despite increasing demand for Plasma-Derivative Protein Therapies, *"we're going to see or promote total market perspective, growth, and volume of the highest single digits and growth in price of low to mid-single digits longer term."*

150. CSL Behring's President, Peter Turner, has publicly signaled that CSL Behring would not dramatically increase its production of Plasma-Derivative Protein Therapies, despite the existence of supply shortages. Mr. Turner stated: "In terms of

2005-2006, we will have a similar supply to the last 12 months plus we hope to have a new product, which is a subcutaneous immune globulin infusion." Although Mr. Turner acknowledged some supply shortages, stating, "I accept that supply may be tight, certainly tighter than it's been in recent years," he confirmed that CSL Behring's manufacturing levels would remain relatively stable, stating that "if you look at the status quo, *we will continue to supply the equivalent volume that we've been supplying to the U.S. market*." *See Key Issues Dialogue: The Partnership Between the Modell Foundation and ZLB Behring*, available at http://www.cslbehring.com/s1/cs/enco/1154398192290/content/1154398189443/content.htm (last accessed June 3, 2010).

151. Defendants' signaling included statements made in public forums that the industry should avoid "cheating" on the cartel by adding capacity, and that by disciplining their manufacturing, producers could avoid increases in capacity that would lead to pricing declines. For example, at a May 3, 2006 conference hosted by Morgan Stanley, John Greisch, Baxter's CFO, stated, in response to questions by Glenn Reicin of Morgan Stanley, that the decline in the number of competitors would help the competitors monitor each other to rationalize production and avoid doing "silly" things that, in the past, had led to increases supply and lower prices:

> Glenn Reicin [Morgan Stanley analyst]: Now the BioScience division in the past has always been sort of linked to the behavior of others, right? So the better pricing hits, the more tempted manufacturers are to sort of cheat and add capacity. The difference now is you have three public companies … they are all in the same situation enjoying better pricing with disciplined manufacturing ….
>
> John Greisch [Baxter CFO]: Sure. More predictable industry dynamics I think are definitely there today. Not only have the number of – has the number of competitors declined but as you

> said, Glenn, at least the two big ones, us and CSL, obviously are more visible to the investment community in terms of how the business is managed. And if Telecris [sic] ends up going publicly and even if they don't, I think the financial discipline that they've got under [Cerberus]' ownership brings a much stronger stability and I think rationalization to the industry leaders in terms of avoiding doing some of the silly things that have happened in the past.

152. Defendants have acknowledged the importance and utility of signaling. During an investor call at Credit Suisse Group on November 18, 2008, Mr. Davis acknowledged that "more visibility and transparency among the players" facilitated the "very stable situation in the plasma business" that Baxter did not foresee changing. Likewise, in May of that year, Mr. Davis acknowledged that, "based on anything we look at, whether you look at PPTA data, . . . or looking at months on hand in the chain, if we look at our data, all of the competitive intelligence we can draw, *tracking at what our competitors are signaling,* nothing tells us that this is going to get out of whack over the near term." (emphasis added.)

Supply Restrictions Did Not Result From Natural Market Forces

153. The restriction of supply and corresponding increase in prices did not result from natural market forces. Rather, supply restrictions and price increases were caused by Defendants' conspiracy, which Defendants formed in response to the abundant supply and resulting decreased prices that occurred as a result of natural market forces earlier in the decade.

154. Defendants' coordinated acquisition and closure of collection and fractionation plants were not consistent with free and open competition, and thus are themselves evidence of coordinated activity. Because demand for Plasma-Derivative Protein Therapies grew throughout the Class Period, Defendants would have been

irrational to restrict supply absent an illicit agreement that included assurances that other leading manufacturers would do likewise. Otherwise, one manufacturer Defendant's supply restrictions merely would have provided an opportunity for the other to increase production and expand its market share, thereby increasing sales volume and revenue.

155. In moments of candor, Defendants admitted that supply shortages did not result from insufficient plasma donations. Although Defendants falsely told patient advocates that any shortages were caused by a lack of volunteer donors, they told their investors otherwise. During one investor call, Baxter CEO Bob Parkinson responded to a question about the cause of reduced plasma supplies by stating that he did not "believe that the number of people coming forward willing to donate plasma necessarily ha[d] any impact relative to overall supply." Furthermore, Rob Davis, VP and CFO of Baxter explained that the "bottleneck" existed not at the collection end, but rather at the manufacturing centers.

156. According to a major distributor of Plasma-Derivative Protein Therapies, distributors began to see "a tightened supply trend" around October of 2003 and throughout that year, "[s]upply was gradually, almost imperceptibly starting to tighten." This same distributor attributed difficulties in obtaining IVIG to the "new market reality—fewer suppliers and rising prices."

Defendants' Conspiracy Caused A Public Health Crisis

157. The aim of Defendants' conspiracy was to maintain the supply of Plasma-Derivative Protein Therapies at low enough levels to keep prices high. Defendants' coordinated supply restrictions were implemented, however, during a period of growing demand for these therapies, and as a result, there was insufficient supply to meet patients'

needs. Insufficient supply, in turn, caused patients, doctors, and patient advocates to urge the government to declare a public health emergency.

158. Patients, physicians, and insurance companies first began reporting supply shortages of Plasma-Derivative Protein Therapies in 2005—approximately one year after Defendants completed their coordinated efforts to close plasma collection and manufacturing facilities. As previously explained, it typically takes between seven months to one year to manufacture plasma into Plasma-Derivative Protein Therapies. Thus, one would expect to see the full effects of Defendants' efforts to control supply in 2005 and 2006.

159. In 2005, the IDF conducted a survey of physicians to assess the scope of Ig shortages that patients and physicians had been reporting. According to that survey, 33% of responding physicians reported significant difficulty obtaining IVIG products for their patients. Physicians also reported that 40% of their patients had suffered adverse health effects due to problems accessing sufficient Ig supply.

160. Insurance companies began noticing supply shortages (and increased prices) in 2005 as well. That year Kaiser Permanente informed patients that because of "an acute nationwide shortage of IVIG due to pharmaceutical manufacturing shortages" it could not cover patients' IVIG treatment.

161. By 2006, supply shortages of Plasma-Derivative Protein Therapies, particularly IVIG, had caused a crisis in the patient community. The CBER Product Shortages e-mail address received dozens of emails that year from patients, doctors, and pharmacists unable to obtain sufficient supply. According to one such patient with Common Variable Immune Deficiency, "I just received a phone call from my pharmacy

telling me they do not have the product and am not sure when they will receive any. IVIG keeps me alive. Once my levels get too low, I will get very sick with pneumonia and be put in the hospital. Please restore access to IVIG so I can be healthy and not be sick in the hospital!" Similarly, a mother of three children receiving IVIG for Common Variable Immune Deficiency wrote "to confirm the fact that there is indeed a shortage of IVIG" that threatened to put her children's lives in danger, "It is difficult enough to keep my kids out of the hospital with bacterial infections—let alone think what will happen if they miss their infusions due to a lack of IVIG." These two emails reflect the worries felt by many other patients who communicated their concerns regarding the supply shortage to the CBER.

162. That year, patients and doctors, along with a bipartisan coalition of 55 members of Congress, asked the Secretary of Health and Human Services (HHS) to declare IVIG shortages a public health emergency. The HHS Committee on Blood Safety and Availability joined this coalition in urging the Secretary to declare a public health emergency, stating "there is a worsening crisis in the availability of and access to IGIV products that is affecting and placing patients' lives at risk."

163. Defendants' agreed-upon supply restrictions led directly to rationing of Plasma-Derivative Protein Therapies to purchasers. In 2006, HHS investigated reports that patients were experiencing problems purchasing IGIV. HHS stated that *"[m]anufacturers 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."* HHS also noted that "[t]he 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." (emphasis added.) HHS concluded that a majority of hospitals surveyed could not purchase enough IGIV to meet all of their patient needs, and calculated that the shortfall of supply relative to demand was approximately 14%.

164. Indeed, participants across the industry reported supply shortages of Plasma-Derivative Protein Therapies. According to one GPO, the industry would collect 3 million fewer units of plasma in 2006 for the purpose of making plasma-derivative products such as IVIG. A representative from another GPO noted that "the market is certainly tight" and explained that distributors were forced "to manage inventories to the gram level."

165. The effects of these supply shortages were not limited to one geographic area. According to the IDF, patients and doctors in almost every state had reported inadequate IGIV access.

166. Additionally, evidence suggests that hospitals and pharmacies experienced trouble obtaining sufficient supplies of albumin. According to an email from the American Society of Health Pharmacies to CBER Product Shortages, pharmacies in Virginia experienced an albumin shortage in 2006. An email from the University of Michigan Blood Bank and Transfusion Center to CBER Product Shortages expresses the frustration and confusion felt throughout the industry in the face of these shortages: "[w]e have a market shortage of human albumin . . . I am told this is a national problem, but I do not see anything on the CBER shortage web page. What is going on?" Hospitals in

Arizona, Illinois, Indiana, North Carolina, and Tennessee similarly reported trouble obtaining sufficient amounts of albumin due to a supply shortage.

167. Defendants' conspiracy resulted in critically low supplies of Plasma-Derivative Protein Therapies that caused many patients to go without crucial treatments. According to a survey of hospital pharmacies administered by the IDF in 2006, 32% of hospitals had turned away patients seeking Ig. Similarly, 57% of physicians surveyed reported that they had been unable to provide patients with adequate amounts of Ig during the first quarter of 2006. According to the same survey, 100% of the distributors asked responded that they had been unable to obtain extra Ig from manufacturers.

168. As a result of Defendants' supply restrictions, patients were forced to go without Plasma-Derivative Protein Therapies, endangering their health. Some patients reportedly suffered side-effects from alternative treatments and infections caused by delayed treatment. In some instances, patients reportedly died when they had to wait too long to receive treatment. The difficulties faced by patients experiencing Ig access problems is perhaps best summarized by one patient from Florida who said, in a statement to the IDF, "It's disgusting. What do they expect us to do? Are we supposed to just get sicker and sicker until we pass away?" Another patient from Missouri called the IDF, stating "I am an 81 year old Medicare PID [primary immunodeficiency disorder] patient . . . I am sick all the time, and am not sure if I will be able to live long enough to get my next infusion. I had an infusion scheduled at the hospital. As I was leaving for the hospital, they called to cancel my appointment. They told me that they will not be able to infuse me." These are but two representative statements out of hundreds from

patients who contacted IDF to report problems obtaining Plasma-Derivative Protein Therapies.

169. Another element of Defendants' conspiracy involved the systematic and concerted refusal to sell Plasma-Derivative Protein Therapies at federally mandated discounted prices. Hospitals serving disproportionate numbers of Medicaid patients are entitled to front-end discounts on drugs under Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992).

170. Hospitals eligible for 340B discounts were routinely informed that there was insufficient supply of Ig to fill orders. According to a survey of eligible hospitals conducted by the Public Hospital Pharmacy Coalition, nearly 80% of eligible hospitals were denied access to IGIV at the discounted 340B price. However, 68.22% of eligible hospitals were able to fill orders at prices higher than the discounted rate.

171. The foregoing evidence of a supply shortage makes it irrational for the manufacturer Defendants individually, absent an agreement, to have reduced or simply maintained their supply levels during the relevant time period. Rather, the rational reaction to this shortage by CSL Behring or Baxter, individually, would have been to increase supply. Their mutual failure to do so only makes economic sense in light of Defendants' agreement to limit supply in order to increase prices.

Defendants Falsely Deny Supply Shortages, Over-Report Industry Supply, And Blame Medicare

172. A key aspect of Defendants' fraudulent concealment of their conspiracy involved their concerted attempts to dissuade HHS from declaring a public health emergency. Defendants' executives, particularly Dennis Jackman, had learned from the events of the late 1990s that declaration of a public health emergency would likely lead to

an invasive government investigation into the industry, and to efforts to increase supply. Such government intrusion could have rendered the conspiracy ineffective and/or subjected the participants to civil or criminal liability.

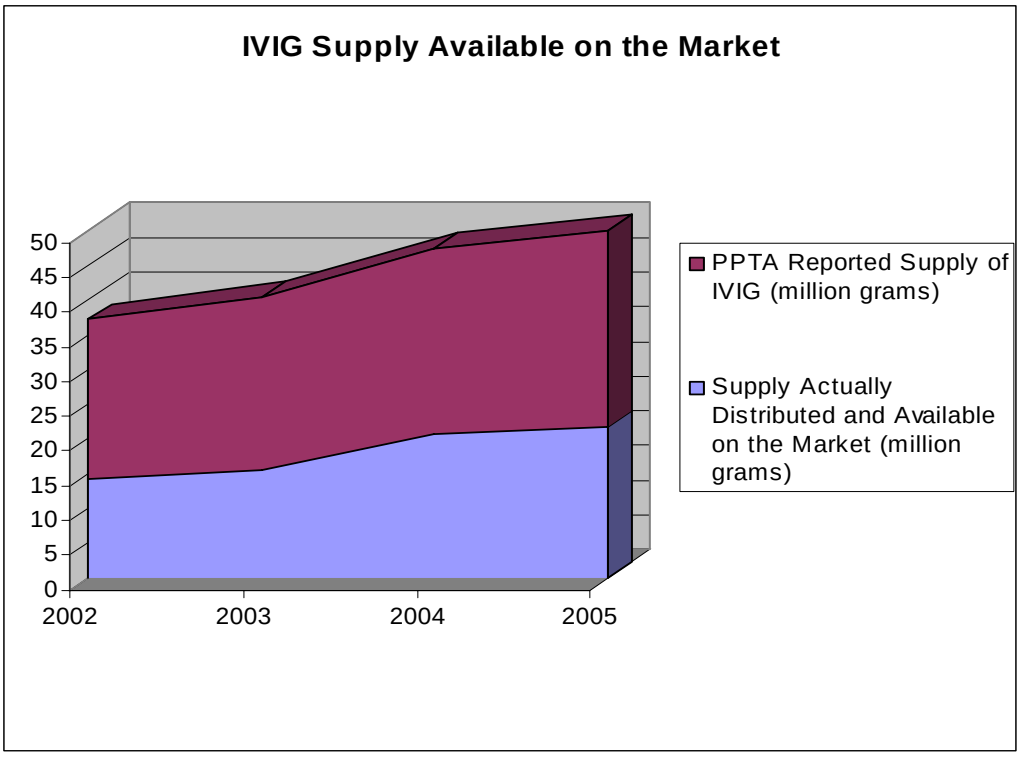
173. Defendants employed two primary strategies to dissuade HHS from declaring a public health emergency (and thus prevent an industry investigation): (1) Defendants, via the PPTA, falsely denied and concealed supply shortages and significantly over-reported the actual supply of Plasma-Derivative Protein Therapies in the industry, and (2) Defendants, again via the PPTA, sought to shift the focus away from reports of a supply shortage by focusing on Medicare reimbursement rates as the purported sole cause of patients' access problems.

174. Despite the inability of purchasers to obtain sufficient supply, Defendants steadfastly and falsely denied the existence of a supply shortage. The most striking example of Defendants' cover-up involves the supply of IVIG. Throughout 2006 and 2007, HHS investigated claims of an IVIG shortage. In response to this investigation, the PPTA provided HHS with incorrect data regarding the supply of IVIG available for distribution. As part of this same investigation, an independent company often relied upon by participants in health care industries, IMS Health, also evaluated the amount of IVIG available for distribution. *According to the 2007 HHS report, the PPTA reported nearly twice as much IVIG available for distribution as did the independent company*.

175. Three explanations were proffered for this discrepancy: rounding error; exports; and manufacturer and distributor inventories. The unlikelihood of a rounding error accounting for a 30 million gram difference in reported data is self-evident. And the PPTA verified that the submitted data did not include exported IVIG. A much more

plausible explanation is that Defendants restricted supply to manipulate prices, and then misreported this supply to HHS to avoid a public health emergency declaration that would lead to government intervention, increased supply, and lower prices.

176. The following graph illustrates the difference in the amount of supply PPTA reported compared with what was actually available on the market:



177. In this instance, the PPTA's data monitoring system served as an effective means of concealing Baxter and CSL's supply restrictions. By establishing a regular supply monitoring system, the PPTA was perfectly poised to help conceal supply limitations and shortages.

178. Defendants also took steps to conceal their conspiracy by shifting government and patient attention away from reported supply shortages. Defendants did this mostly by focusing the debate on a convenient common enemy: Medicare reimbursement rates. Defendants misleadingly blamed patients' inability to obtain

sufficient amounts of Plasma-Derivative Protein Therapies entirely on the failure of Medicare reimbursement rates to keep up with the price for these therapies.

179. Julie Birkofer, Vice President of the PPTA, made numerous presentations to HHS advocating for new Medicare reimbursement formulas to compute plasma protein reimbursement rates.

180. Defendants told the IDF and other patient-advocacy groups not to discuss allegations from physicians and patients that a supply shortage existed and instead to focus only on problems related to Medicare reimbursements. This included efforts on the part of Defendants to encourage the IDF not to report physician survey data verifying their allegations of a supply shortage. Similarly, on at least one occasion, Defendants actually censored a patient advocate's presentation in an effort to keep advocates on-message and off the topic of supply shortages. Defendants edited advocate messages to eliminate any implications that the industry was acting collectively regarding IVIG supply or that patients or GPO's were unable to obtain sufficient supply.

181. By falsely denying supply shortages and shifting attention away from supply and to Medicare reimbursement rates, Defendants were able to conceal their conspiracy and avoid the declaration of a public health emergency, which likely would have lead to an intrusive government investigation into the industry that could well have uncovered and thwarted Defendants' conspiracy.

Defendants Monitored Their Conspiracy Using PPTA Data

182. The PPTA's data gathering effort allowed the manufacturer Defendants to monitor each other's compliance with agreed-upon supply restrictions, and thus allowed Defendants to police their conspiracy. Indeed, as CSL's Chief Economist has remarked

in the context of Defendant's efforts at monitoring supply and demand, *"economics can help [us] understand how to loosen the shackles of competition."*

183. When the industry first implemented its data monitoring system in the late 1990s, the industry consisted of 13 different companies, two of which were not members of the trade association. Because there were more participants submitting data, and some who were not submitting data, the aggregated data could not easily be used as a tool to monitor individual competitors' production.

184. But as the industry consolidated, the aggregated data collected by the PPTA represented fewer companies, making it far easier for any individual company to assess what proportion of the data came from which company. Indeed, since Baxter and CSL each possessed more than 25% of the market shares of both Ig and albumin (Baxter has approximately 35.4% of the Ig market and 36.44% of the albumin market; CSL possesses approximately 27.5% of the Ig market and 36.61% of the albumin market), the data reported by the PPTA could be easily attributed to specific suppliers. The data therefore provides an effective means for Defendants to monitor compliance with agreed-upon supply restrictions.

Defendants Pressured Smaller Competitors Not To Appreciably Increase Capacity

185. Defendants have explored means of punishing firms, most notably Talecris, that have attempted to undermine Defendants' conspiracy to artificially limit output.

186. Baxter and CSL closely monitor each other and other suppliers, collecting and cataloguing an extraordinary wealth of timely competitive information, to ensure that all suppliers are engaging in desired "rational" and "disciplined" behavior. According to

the FTC, *CSL and Baxter even have explored means of punishing firms that dare to "'break ranks' and chase market share." See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 5 (D.D.C. Nov. 11, 2009).

187. According to the FTC, Talecris is "the one firm that has consistently and significantly expanded output in the United States." Statements from Defendants' files corroborate this, noting that Talecris "has significantly and consistently increased production and U.S. supply year after year—more than any other manufacturer," and that it planned to continue to do so in the coming years. *Id*.

188. Talecris stated in a 2008 SEC filing that it "intend[ed] to serve the overall market growth with incremental increases in production capacity" in 2008 and 2009. And before agreeing to CSL's planned acquisition, Talecris planned to account for 45% of the industry's future output expansion over the next two years—a business strategy that made perfect sense absent a conspiracy to limit supply but which CSL labeled *"irrational."*

189. Talecris's announced business strategy thus was at odds with Defendants' conspiracy to restrict supply, subjecting it to punishment by CSL and Baxter.

190. Not surprisingly, in the words of Cerberus-Plasma Holdings LLC (Talecris' majority shareholder) executives, CSL was "truly scared that Talecris might actually succeed with its planned center expansion" and the consequent increase in output. Cerberus executives further remarked that CSL executives were "worried . . . that [Talecris'] expansion will have a negative effect on the market as a whole."

191. Indeed, absent an aggressively expanding Talecris, Baxter and CSL Behring, the two largest producers of Protein-Derivative Plasma Therapies (and the only

two producers other than Talecris with double-digit market shares), more successfully and completely could control industry output and increase prices. As CSL's Chief Economist remarked, an "[i]ncrease in industry concentration should make price stability and/or price increases easier to sustain" because "competition erodes rents."

192. CSL's fear of the price-reducing effect that Talecris' planned expansion could have in the market provided motivation both for CSL Limited's attempted acquisition of Talecris and for the significant premium that CSL Limited agreed to pay in 2008—about $800 million more than it was willing to pay in 2007. Consequently, in a further attempt to limit industry production and maintain high prices and margins, CSL Limited attempted to acquire Talecris.

193. In an unusual move for a company whose largest competitor was contemplating a key acquisition, Baxter publicly expressed its view that CSL Limited's attempted acquisition of Talecris would be "*a positive stabilizing move within the industry*." The FTC subsequently filed suit to block the attempted acquisition. (The FTC action is further discussed below.)

194. In contrast to Talecris, the remaining competitors in the industry, Grifols and Octopharma, are too small to have a significant market impact. In high-level, internal communications, Talecris executives discussed this 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. . . ."

195. Defendants' agreement to restrict supply and raise prices has been assisted by increased industry consolidation and the resulting oligopolistic market structure. The potentially non-conspiring participants in the industry have recognized that they are

operating in an oligopoly where they are better off avoiding competition, restricting supply, and raising prices. Defendants' unlawful signaling has aided and reinforced this recognition on behalf of all industry participants.

Defendants' Conspiracy Has Worked

196. Defendants' conspiracy has worked, causing Plaintiffs and other Class members to purchase Plasma-Derivative Protein Therapies at supra-competitive prices. Beginning at least as early as July 1, 2003 and continuing through the present, prices for Plasma-Derivative Protein Therapies stabilized and then consistently increased.

197. The average sales price for a gram of IVIG has increased from about $47.60 in 2005 to about $57 in 2009, according to an analyst presentation that Grifols gave on March 5, 2008. The same presentation stated that "IVIG, which remains the driver of the plasma derivatives market, has witnessed price increases since 2005, coinciding with increased demand related to product availability."

198. The average sales price for a gram of albumin has also increased from about $1.25 in 2005 to about $2.20, according to the same Grifols presentation. The presentation also reports that "average albumin prices have steadily increased since 2005 from U.S. $14 to around U.S. $35 per 12.5 g. vial at present." A Talecris 2008 SEC filing similarly notes that "[p]rices for albumin have increased significantly since 2005 . . . . The average selling price in 2007 was $28.55, having grown at a CAGR of 35% since 2005, when the U.S. average selling price (ASP) was $15.58."

199. CSL's and Baxter's contemporaneous business reports have borne out these facts. For example, CSL Limited reported in its October 2004 Annual General Meeting presentation: "IVIG—prices have been stable with upward pressure going

forward; currently experiencing solid demand;" and "Albumin—prices stable after period of weakness; inventory oversupply reducing." In its October 2005 Annual General Meeting presentation, CSL Limited remarked "US IVIG pricing environment improving," and that with respect to CSL Behring, it is "managing plasma throughput to match: run down in inventory benefit; reduction of inventory levels; [and] demand." The Chairman's Address from the same 2005 meeting stated that CSL "Behring is well positioned to develop its global business through," among other things, "an effective balance between supply and demand." And in its October 2006 Annual General Meeting presentation, CSL Limited noted both that the "strong global demand for plasma therapies continues," and "plasma sector stability."

200. Defendants' conspiracy has resulted not only in supra-competitive pricing, but also extraordinary profits for CSL and Baxter, even as most other industries have experienced drastically lower earnings in the face of the global economic crisis.

201. According to a March 2009 report issued by CSL's chairman, CSL experienced a post-tax net profit of $502 million for the half-year ended December 31, 2008, an increase of 44% from the same period the previous year. The report also notes that "[t]he global financial crisis has had little to no impact so far on sales of CSL's portfolio of life-saving therapies and essential vaccines . . . . [a]nd we anticipate broadly stable market conditions to continue."

202. CSL Behring's sales revenue increased 33% to $1.8 billion compared with the same period during the previous year, "with strong contributions from both core and specialty plasma products," according to the same March 2009 CSL report.

203. Revenues from Baxter's BioScience unit climbed 12% to $1.36 billion in 2008, largely due to sales of plasma-based hemophilia and immune disorder treatments, vaccines and biosurgery products. Due to the profit its BioScience unit has generated, one news article noted that "Baxter is one of a handful of stocks that have proven somewhat resistant to the global recession."

FTC INVESTIGATION

204. On March 27, 2009, the FTC authorized a lawsuit to block CSL Limited's proposed $3.1 billion acquisition of Talecris, charging that the deal would be illegal and would substantially reduce competition in the United States markets for Ig, albumin, Rho-D, and Alpha-1. On the same day, the FTC also sought a preliminary injunction in federal district court in the District of Columbia to stop the transaction pending completion of an administrative trial.

205. In an FTC press release accompanying the filing of the lawsuit, Richard Feinstein, Director of the FTC's Bureau of Competition, stated that "[s]ubstantial consolidation has already occurred in the plasma protein industry, and *these highly concentrated markets are already exhibiting troubling signs of coordinated behavior*."

206. The FTC described in its complaint, among other "troubling signs of coordinated behavior," Defendants' signaling, product rationing, and other statements and actions by Defendants indicative of anticompetitive conduct.

207. The FTC alleged that, "with the elimination of Talecris— the one firm that has consistently and significantly expanded output in the United States—*CSL and Baxter International, Inc. ("Baxter") would face no remaining significant obstacle in their*

efforts to coordinate and tighten supply conditions for the relevant products, to the great detriment of consumers."

208. The FTC has stated that language contained in documents of CSL and Baxter suggests *a strong possibility of ongoing coordinated interaction between firms in the plasma industry*. Evidence of transparency, interdependence, and signaling among firms is particularly relevant to the allegations in this matter. The language at issue bears on these very important points, and demonstrates how firms used specific key words to:

- suggest to each other that increasing the production of lifesaving drugs could hurt the firms' ability to reap the significant profits they all achieved during an extended period where demand exceeded supply for the key products;
- remind each other of how, during a period when supply increased, prices and profitability for the firms in the market dropped significantly; and
- encourage each other to only increase supply incrementally to keep pace with increases in demand, and not to the extent the firms would actually compete with each other for market share.

209. The FTC also has noted that the "quoted language" in its complaint taken from the files of Baxter and CSL "is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy. *See, e.g., In re High Fructose Corn Syrup Antitrust Litigation*, 295 F.3d 651, 662 (7th Cir. 2002) (Posner, J.) (referring to competitor as a 'friendly competitor,' mentioning an 'understanding between the companies that . . . causes [them] not to . . . make irrational decisions,' and querying whether competitors 'will play by the rules (discipline)' can all be evidence of an explicit agreement to fix prices)."

210. The FTC has recognized that some of the language from the files of CSL and Baxter would cause them "*embarrassment*" and "*could 'expose [CSL] to possible treble damages actions.*'"

211. Shortly after the filing of the FTC complaint, on June 8, 2009, CSL Limited and Talecris publicly announced that they would abandon their proposed merger. On June 15, 2009, the FTC and the two firms jointly filed a motion to dismiss the FTC's complaint on that basis, and on June 22, 2009, the Court dismissed the complaint.

MARKET CHARACTERISTICS

212. The structure and characteristics of the Plasma-Derivative Protein Therapies markets in the United States are particularly conducive to a price-fixing agreement, and make allegations of collusion particularly plausible in this market. These factors are discussed below.

Commodity Products

213. A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers both to agree on prices for the product and to monitor these prices.

214. Plasma-Derivative Protein Therapies are homogeneous, commodity products within a given product category (*e.g.*, Albumin or Ig), and one Defendant's Plasma-Derivative Protein Therapies easily can be substituted for corresponding products made by the other Defendant. Indeed, Talecris noted in a 2008 SEC filing that "[a]mong

albumin products, competition is generally based on price, given that the products tend to be homogeneous."

215. Because Plasma-Derivative Protein Therapies are commodity products, purchasers make purchase decisions based predominantly, if not entirely, on price.

Lack of Substitutes

216. The lack of available substitutes for a product also helps facilitate an effective price-fixing conspiracy. Without substitutes, producers of the product can raise prices without losing significant sales to closely competing products.

217. For hospitals, physicians, patients, and others that use Plasma-Derivative Protein Therapies, there simply are no suitable substitutes for these products, at any price. They must purchase Plasma-Derivative Protein Therapies regardless of the price; nothing else will do. Indeed, as Patrick Robert of the Marketing Research Bureau Inc. has noted, "therapeutic plasma proteins [including Plasma-Derivative Protein Therapies] remain essential life-saving drugs for which there is still no competitive drug."

Industry Concentration

218. A high degree of concentration facilitates coordination among co-conspirators. The fewer competitors in a market, the easier it is for those competitors to collude.

219. The manufacturer Defendants control a high percentage of the United States plasma-derivative protein industry, collectively possessing about a 60% market share. In particular, Baxter controls about 36% of the market, and CSL Behring controls about 24% of the market. The remaining manufacturers, Talecris, Grifols USA ("Grifols"), and Octapharma USA, Inc. ("Octapharma"), possess shares of approximately

23%, 7% and 5%, respectively. Defendants' collective shares of the Ig and Albumin markets are even higher than their shares of the overall Plasma-Derivative Protein Industry.

220. With respect to the domestic Ig market, according to 2008 sales volumes, Defendants collectively possess approximately a 62.9% market share. CSL Behring has about a 27.5% market share, and Baxter has about a 35.4% market share. The remaining manufacturers, Talecris, Grifols, and Octapharma, possess shares of approximately 20%, 9% and 7.2%, respectively. The market is highly concentrated, with a Herfindahl-Hirschman Index ("HHI") of 2,579. (The HHI test is used by the FTC and DOJ to gauge market concentration. An industry with an HHI exceeding 1,800 is deemed "highly concentrated.")

221. With respect to the domestic albumin market, according to 2008 sales volumes, Defendants collectively possess approximately a 73.05% market share. CSL possesses about a 36.61% market share, and Baxter maintains about a 36.44% share. The remaining competitors, Talecris, Grifols, and Octapharma, possess shares of 8.83%, 13.06%, and 5.07%, respectively. The market is highly concentrated, with an HHI of 2,942.

222. The foregoing indicates that there are effectively two large competitors (Baxter and CSL Limited), one medium-sized competitor (Talecris) and two very small competitors (Grifols and Octapharma). Such a market structure makes collusion more plausible because it is easier for the major competitors to reach a consensus and monitor each other. The major competitors do not have to worry about the small competitors because, even if the small competitors are not part of the agreement to restrict output,

they do not have enough capacity to significantly blunt price increases caused by the large competitors' conspiracy to limit supply. The result is that the smaller competitors simply follow the lead of the large competitors.

223. Throughout the Class Period, Defendants collectively possessed market power to raise prices above competitive levels in the Plasma-Derivative Protein Therapies markets in the United States without losing appreciable market share to non-conspirators.

Barriers to Entry

224. The presence of significant entry barriers to potential competitors that could otherwise cause the incumbents to reduce their prices helps facilitate coordination among co-conspirators.

225. The market for Plasma-Derivative Protein Therapies is characterized by very high entry barriers. No firm has entered the market in recent history, and prospective entrants have little chance of making a meaningful market impact in a timely fashion.

226. By CSL's own admission, there are "immense barriers to entering the market" for Plasma-Derivative Protein Therapies. Furthermore, 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 agrees, noting that "significant regulatory, IP, and capital barriers to entry mitigate the threat of new competitors as well as capacity increases for several years."

227. Each step of the manufacturing process for Plasma-Derivative Protein Therapies involves substantial up-front costs, onerous and lengthy regulatory approvals by federal and state agencies, and specialized technical expertise.

228. Entry into the Plasma-Derivative Protein Therapies markets also requires a significant amount of intellectual property, including trade secrets relating to purification of products and pathogen safety, and substantial product research and development.

229. Regulatory hurdles impose significant barriers to entry and extend the time it would take to enter the United States market, let alone make a significant impact in the market.

230. In addition, the construction and maintenance of production facilities, including regular improvements necessitated by evolving standards of manufacturing practices, require extensive capital expenditures and may involve long lead times to obtain the necessary governmental approval.

231. Any new competitors in the United States also would need to secure an adequate supply of domestic plasma, because only plasma collected in the United States is certified for use in products sold domestically. Because there currently are only a very limited number of independent plasma suppliers, most of whose plasma collection and center development capacity is already contracted to existing manufacturers, any new competitor likely would have to develop its own domestic-based plasma collection centers and related infrastructure.

Demand Inelasticity

232. Price elasticity of demand is the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. Inelastic

demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue. Inelastic demand is another indicator that a price-fixing conspiracy would be successful.

233. The demand for Plasma-Derivative Protein Therapies is highly inelastic. Plasma-Derivative Protein Therapies are considered medical necessities that must be purchased by hospitals, physicians, and others at whatever the cost. Moreover, there are no close substitutes for these products.

Opportunity for Conspiratorial Communications

234. Defendants CSL and Baxter are members of trade associations, such as Defendant PPTA and the IDF, and regularly attend association meetings together and meet privately before or after these association meetings.

235. As previously noted, the PPTA is "the primary advocate for the world's leading source plasma collectors and producers of plasma-based and recombinant biological therapeutics;" Baxter and CSL Behring are members of the PPTA; and no purchasers or patient advocacy groups count themselves as members of the PPTA.

236. The PPTA convenes its annual meeting, known as the Plasma Protein Forum, in June in the Washington, D.C. metropolitan area, and high-level executives from Defendants, such as Mr. Turner and Mr. Guiheen, routinely attend. The PPTA also holds regular conferences such as the PPTA Business Forum, which took place in New Orleans, Louisiana on October 25, 2009.

237. Defendants also gather regularly for the stated purpose of discussing relevant regulation, providing Defendants with an opportunity to share information.

238. As previously discussed, in 2008 executives from CSL and Baxter gathered monthly with the IDF for the stated purpose of developing legislation to restore access to IVIG supply to hospitals, homecare, and other sites.

239. Such meetings provide the opportunity for participants in anticompetitive conspiracies such as this one to meet, have improper discussions under the guise of legitimate business contacts, and perform acts necessary for the operation and furtherance of the conspiracy.

240. Defendants also used private analysts as go-betweens to swap competitive information about their stock of plasma-protein supplies. Analysts regularly called Defendants to ascertain supply levels because supply is closely correlated to price in the plasma-protein derivative market. After having spoken with one manufacturer Defendant, analysts would call the other manufacturer Defendant and relay supply information.

241. Moreover, Defendants use the same market research firm, the Marketing Research Bureau, to estimate future demand for Plasma-Derivative Protein Therapies and to monitor pricing trends.

ANTITRUST VIOLATIONS

242. Beginning at least as early as July 1, 2003, and continuing through the present, Defendants and their co-conspirators engaged in a continuing agreement, understanding, and conspiracy in restraint of trade to restrict output and to artificially raise, fix, maintain, or stabilize the prices of Plasma-Derivative Protein Therapies in the United States.

243. Based on the foregoing, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to restrict output and to artificially raise, fix, maintain, or stabilize the price of Plasma-Derivative Protein Therapies sold in the U.S. These activities included:

(a) Defendants participated in meetings, conversations, and communications to discuss the supply and price of Plasma-Derivative Protein Therapies in the United States; and

(b) Defendants agreed during those meetings, conversations, and communications to restrict output and to charge prices at specified levels and otherwise to fix, raise, maintain, or stabilize prices of Plasma-Derivative Protein Therapies sold in the United States.

244. Defendants and their co-conspirators engaged in the activities described above for the purpose of effectuating the unlawful agreements described in this Complaint.

245. Throughout the Class Period, Plaintiffs and the other Class members purchased Plasma-Derivative Protein Therapies from Defendants (or their subsidiaries or controlled affiliates) or their co-conspirators at supra-competitive prices.

246. Defendants also agreed to exchange information regarding output and production capacity that had the effect of restricting output and of fixing, raising, maintaining, or stabilizing the prices of Plasma-Derivative Protein Therapies.

247. Defendants' contract, combination or conspiracy constitutes an unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

EFFECTS OF THE CONSPIRACY

248. As a result of Defendants' unlawful conduct, Plaintiffs and the other Class members have been injured in their business and property because they have paid more for Plasma-Derivative Protein Therapies than they would have paid in a competitive market.

249. Defendants' unlawful contract, combination, or conspiracy has had at least the following effects:

(a) price competition in the markets for Plasma-Derivative Protein Therapies has been artificially restrained;

(b) prices for Plasma-Derivative Protein Therapies sold by Defendants have been raised, fixed, maintained, or stabilized at supra-competitive levels; and

(c) purchasers of Plasma-Derivative Protein Therapies from Defendants have been deprived of the benefit of free and open competition in the Plasma-Derivative Protein Therapies markets.

FRAUDULENT CONCEALMENT

250. Plaintiffs and members of the Class did not discover, and could not have discovered through the exercise of reasonable diligence, the existence of the conspiracy alleged herein until May 27, 2009, when the FTC's redacted complaint was filed.

251. Because Defendants' alleged conspiracy was kept secret until May 27, 2009, Plaintiffs and members of the Class before that time were unaware of Defendants' unlawful conduct alleged herein, and they did not know before that time that they were paying supra-competitive prices for Plasma-Derivative Protein Therapies throughout the United States during the Class Period.

252. The affirmative acts of Defendants alleged herein, including acts in furtherance of the conspiracy, were wrongfully concealed and carried out in a manner that precluded detection.

253. By its very nature, Defendants' conspiracy was inherently self-concealing. Plasma-Derivative Protein Therapies are not exempt from antitrust regulation, and thus, before May 27, 2009, Plaintiffs reasonably considered the plasma-derivative protein therapy industry to be a well-regulated, competitive industry.

254. In addition, as detailed previously, Defendants, through their trade association, the PPTA, intentionally misrepresented the supply of Plasma-Derivative Protein Therapies to the marketplace during the Class Period in order to avoid governmental and public scrutiny of their sales and marketing practices, and to conceal the existence of the shortages created by their conspiracy.

255. Under the circumstances surrounding Defendants' pricing practices, Defendants' acts of concealment were more than sufficient to preclude suspicion by a reasonable person that Defendants' pricing was conspiratorial. Accordingly, a reasonable person under the circumstances would not have been alerted to investigate the legitimacy of Defendants' Plasma-Derivative Protein Therapies prices before May 27, 2009.

256. Plaintiffs and members of the Class could not have discovered the alleged conspiracy at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by Defendants and their co-conspirators to avoid detection of and fraudulently conceal their conspiracy.

257. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiffs and members of the Class

had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, until May 27, 2009, when the redacted FTC complaint, and its corresponding factual allegations of anti-competitive conduct concerning Plasma-Derivative Protein Therapies, was first publicly disseminated.

258. None of the facts or information available to Plaintiffs and members of the Class prior to May 27, 2009, if investigated with reasonable diligence, could or would have led to the discovery of the conspiracy alleged herein prior to that date.

259. As a result of Defendants' fraudulent concealment of their conspiracy, any statute of limitations has been tolled with respect to any claims that Plaintiffs and members of the Class have alleged in this Complaint.

260. Defendants and their co-conspirators engaged in a successful anti-competitive conspiracy concerning Plasma-Derivative Protein Therapies, which they affirmatively concealed, at least in the following respects:

(a) By communicating secretly to discuss output and prices of Plasma-Derivative Protein Therapies in the United States;

(b) By agreeing among themselves not to discuss publicly, or otherwise reveal, the nature and substance of the acts and communications in furtherance of their illegal scheme;

(c) By mis-reporting supply to HHS in order to conceal the dangerous shortages caused by their conspiracy;

(d) By falsely denying the existences of supply shortages for Plasma-Derivative Protein Therapies; and

(e) By "scrubbing" the minutes of trade association meetings to remove references to anti-competitive discussions.

261. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiffs' and the Class's claims have been tolled.

CLASS ACTION ALLEGATIONS

262. Plaintiffs bring this action on behalf of themselves and as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the following class (the "Class"):

> All persons and entities in the United States who purchased Plasma-Derivative Protein Therapies directly from any Defendant at any time from July 1, 2003 through the present ("the Class Period"). Excluded from the Class are Defendants, their parent companies, subsidiaries and affiliates, any co-conspirators, federal governmental entities and instrumentalities of the federal government.

263. Plaintiffs believe that there are hundreds of Class members located throughout the United States, the exact number and their identities being known by Defendants, making the Class so numerous and geographically dispersed that joinder of all members is impracticable.

264. There are questions of law and fact common to the Class, including:

(a) Whether Defendants and their co-conspirators engaged in a combination and conspiracy among themselves to restrict output and to fix, raise, maintain, or stabilize the prices of Plasma-Derivative Protein Therapies sold in the United States;

(b) The identity of the conspiracy's participants;

(c) The duration of the conspiracy alleged in this Complaint and the acts carried out by Defendants and their co-conspirators in furtherance of the conspiracy;

(d) Whether the alleged conspiracy violated Section 1 of the Sherman Act;

(e) Whether the conduct of Defendants and their co-conspirators, as alleged in this Complaint, caused injury to the business and property of Plaintiffs and the other Class members;

(f) The effect of the conspiracy on the prices of Plasma-Derivative Protein Therapies sold in the United States during the Class Period; and

(g) The appropriate Class-wide measure of damages.

265. Plaintiffs' claims are typical of the claims of Class members, and Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs and all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the antitrust laws, in that they paid artificially inflated prices for products purchased directly from Defendants or their co-conspirators. Plaintiffs' claims arise out of the same common course of conduct giving rise to the claims of the other Class members. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other Class members.

266. Plaintiffs are represented by counsel who are competent and experienced in the prosecution of antitrust and class action litigation.

267. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

268. The questions of law and fact common to the members of the Class predominate over any questions affecting only individual members.

269. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The Class is readily definable. Prosecution as a class action will eliminate the possibility of repetitious litigation. Treatment as a class action will permit a large number of similarly situated persons to adjudicate their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would engender. This action presents no difficulties in management that would preclude maintenance as a class action.

CAUSE OF ACTION

VIOLATION OF SECTION 1 OF THE SHERMAN ACT -15 U.S.C. § 1

270. Plaintiffs incorporate and re-allege each allegation set forth in the preceding paragraphs of this Complaint.

271. Beginning at least as early as July 1, 2003, and continuing thereafter, Defendants and their co-conspirators, by and through their officers, directors, employees, agents, or other representatives, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, entered into a continuing agreement, understanding, and conspiracy in restraint of trade to restrict output and to artificially raise, fix, maintain, or stabilize prices for Plasma-Derivative Protein Therapies in the United States, and entered into a continuing agreement, understanding and conspiracy in restraint of trade to exchange information regarding output and production capacity that had the effect of restricting output and of fixing, raising, maintaining, or stabilizing the prices of Plasma-Derivative Protein Therapies.

272. Plaintiffs and the other Class members have been injured in their business and property by reason of Defendants' unlawful combination, contract, conspiracy, and

agreement. Plaintiffs and Class members have paid more for Plasma-Derivative Protein Therapies than they otherwise would have paid in the absence of Defendants' conduct. This injury is of the type the federal antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

273. Accordingly, Plaintiffs and Class members seek damages, to be trebled pursuant to federal antitrust law, and costs of suit, including reasonable attorneys' fees.

DEMAND FOR JURY TRIAL

274. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a jury trial as to all issues triable by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray as follows:

A. That the Court determine that this action may be maintained as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure.

B. That the contract, combination, or conspiracy, and the acts done in furtherance thereof by Defendants and their co-conspirators be adjudged to have violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

C. That judgment be entered for Plaintiffs and Class members against Defendants for three times the amount of damages sustained by Plaintiffs and the Class as allowed by law.

D. That Plaintiffs and the Class recover pre-judgment and post-judgment interest as permitted by law.

E. That Plaintiffs and the Class recover their costs of the suit, including attorneys' fees, as provided by law.

F. That Defendants be enjoined from continuing their participation in the alleged conspiracy.

G. For such other and further relief as is just and proper under the circumstances.

Dated: June 4, 2010

Respectfully submitted,

/s/ Richard A. Koffman

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CERTIFICATE OF SERVICE BY ELECTRONIC MEANS

I, Richard A. Koffman, one of the attorneys for plaintiffs, hereby certify that on June 4, 2010, service of the Consolidated Amended Complaint was accomplished pursuant to ECF as to Filing Users and I shall comply with LR 5.5 as to any party who is not a Filing User or represented by a Filing User.

/s/ Richard A. Koffman
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