UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. BAXTER TRAVENOL LABORATORIES, INC. and AMERICAN HOSPITAL SUPPLY CORPORATION, Defendants.	CIVIL ACTION NO. 85C09856 FILED: November 22, 1985 Judge Moran

COMPLAINT

The United States of America, by its attorneys, acting under the direction of the Attorney General of the United States, brings this civil action to obtain equitable and other relief against the defendants named herein and complains and alleges as follows:

I

JURISDICTION AND VENUE

1. This complaint is filed and this action is instituted under Section 15 of the Clayton Act, as amended (15 U.S.C. § 25), to prevent the violation by the defendants, as hereinafter alleged, of Section 7 of the Clayton Act, as amended (15 U.S.C. § 18).

2. Baxter Travenol Laboratories, Inc. transacts business, maintains offices, and is found within the Northern District of Illinois.

3. American Hospital Supply Corporation transacts business, maintains offices, and is found within the Northern District of Illinois.

II

DEFINITIONS

4. "Parenteral solutions" means various sterile fluids which are administered to patients intravenously ("IV") to replace depleted fluids and electrolytes (such as sodium and potassium); to provide nutrition for patients suffering from a metabolic disturbance; as a medium for administering drugs; as a sterile fluid for cleansing, washing, or irrigation; and in the treatment of kidney failure.

5. "Fluid administration sets" means various disposable devices and related add-on components which are attached to a parenteral solutions container and/or blood container to carry the solutions and/or blood from the container(s) to an IV catheter placed in the patient's vein.

6. "Electronic flow control devices" means electro-mechanical fluid infusion control devices used to pump, infuse or meter fluids, including parenteral solutions and drugs, at pre-determined rates into a patient during intravenous therapy.

7. "Therapeutic hemapheresis equipment" means electronic machines and related disposable systems used to separate whole blood into components for therapeutic purposes.

8. "Surgeons gloves" means anatomically correct (right and left handed with an offset thumb), long cuffed, talc-free, sterile, thin latex hand coverings that are sized according to palm circumference and are used in gowned surgical procedures performed inside the operating room and non-gowned surgical procedures performed outside of the operating room.

9. "Procedure gloves" means either surgeons gloves with cosmetic defects (such as a misaligned date, brand or size stamping), or anatomically correct, talc-free, sterile, thin latex gloves with slightly shorter cuffs than surgeons gloves that are used in ungowned surgical procedures performed outside the operating room.

10. "HHI" means the Herfindahl-Hirschman Index, a measure of market concentration calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 ($30^2+30^2+20^2+20^2=2,600$). The HHI takes into account the relative size and distribution of the firms in a market. It approaches zero when a market is occupied by a large number of firms of relatively equal size and reaches its maximum of 10,000 when a market is controlled by a single firm. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.

III

THE DEFENDANTS

11. Baxter Travenol Laboratories, Inc. ("Baxter") is made a defendant herein. Baxter is a corporation organized and existing under the laws of the State of Delaware, with its principal offices located at One Baxter Parkway, Deerfield, Illinois. Baxter is engaged generally in the worldwide development, manufacture and sale of a diversified line of medical care products and services that are used principally by hospitals, blood centers, clinical laboratories, dialysis centers, and patients at home under physician supervision. Baxter manufactures and sells, among other things, parenteral solutions, fluid administration sets, electronic flow control devices, therapeutic hemapheresis equipment, and surgeons and procedure gloves. Baxter's net sales of all products were about $1.8 billion in 1984.

12. American Hospital Supply Corporation ("AHS") is made a defendant herein. AHS is a corporation organized and existing under the laws of the State of Illinois, with its principal offices located at One American Plaza, Evanston, Illinois. It is engaged generally in the worldwide development, manufacture, sale and distribution of a wide range of products and services used primarily by healthcare institutions, including hospitals, clinical and medical research labs, rehabilitation centers, nursing homes, doctors' offices and related institutions and facilities. AHS also sells, rents and services a broad line of

durable medical equipment, accessories, and supplies to the home healthcare market. AHS manufactures and sells, among other things, parenteral solutions, fluid administration sets, electronic flow control devices, therapeutic hemapheresis equipment, and surgeons and procedure gloves. AHS' net sales of all products in 1984 were about $3.4 billion, 46 percent of which represented the sale of products manufactured by AHS and the remainder consisting of products made by other companies but distributed by AHS.

13. Baxter and AHS currently purchase supplies from out-of-state sources and sell healthcare products to out-of-state purchasers. Such transactions regularly result in interstate transfer of products and funds. Baxter and AHS have offices and personnel throughout the United States. Each company is engaged in interstate commerce, and its activities are in the flow of, and substantially affect, interstate commerce.

IV

TRADE AND COMMERCE

Parenteral Solutions

14. There are different types of parenteral solutions, including: general IV solutions such as sterile water and dextrose, sodium chloride or electrolytes; premix specialty IV solutions, such as dopamine in dextrose and sterile water; nutritional fluids, such as amino acids, lipids (fats), and carbohydrates; irrigation and urological solutions, such as

saline, distilled water, glycine, and sorbitol irrigation solutions; and peritoneal dialysis solutions.

15. Parenteral solutions are manufactured by mixing dry ingredients with sterile water in large mixing tanks and filling containers in a bottling-type operation. The production process and equipment used to manufacture any one of the types of parenterals can easily be converted to manufacture each of the other types. Parenteral solutions are packaged in glass, flexible plastic bags, or semi-rigid plastic containers in sizes ranging from 2 ml to 1000 ml or more. The containers are then capped under vacuum, in the case of glass containers, or sealed, in the case of plastic containers, and sterilized.

16. Customers consider particular solutions packaged in any of the three types of containers--glass, flexible plastic bags, or semi-rigid plastic--to be substitutes for each other. Baxter manufactures parenteral solutions packaged in glass containers and flexible plastic bags. AHS manufactures parenteral solutions packaged in glass and semi-rigid plastic containers.

17. Other products are not competitive substitutes for parenteral solutions. The manufacture and sale of parenteral solutions comprises a relevant product market for antitrust purposes.

18. Baxter and AHS are direct competitors in the manufacture and sale of parenteral solutions in the United States. There are only three companies in the United States

that manufacture and sell a full line of parenteral solutions: Baxter, AHS, and Abbott Laboratories ("Abbott"). These three companies sell their parenteral solutions throughout the United States, and together in 1984 accounted for about 95% of the approximately $1 billion sales of parenteral solutions in the United States.

19. Baxter is the largest manufacturer of parenteral solutions in the United States. In 1984, Baxter's sales of parenteral solutions in the United States were approximately $505.6 million.

20. AHS, through its American McGaw division, is the third largest manufacturer of parenteral solutions in the United States. In 1984, AHS' sales of parenteral solutions in the United States were approximately $166.4 million.

21. Based upon 1984 sales in the United States, Baxter had a 50.5% share of the parenteral solutions market; AHS had a 16.6% share. The parenteral solutions market in the United States is highly concentrated. The HHI calculated on the basis of 1984 sales in the United States is about 3648. Baxter's proposed acquisition of AHS would increase this HHI by about 1682 to about 5330.

22. There are substantial barriers to entry into the manufacture and sale of parenteral solutions. Parenteral solutions are regulated by the United States Food and Drug Administration ("FDA") as "drugs." Before a new manufacturer of parenteral solutions can sell its products, it must obtain

FDA approval, a process that typically takes from two to five years. The cost of constructing a parenteral solutions manufacturing facility ranges from $100-200 million. In addition, because hospitals generally contract with only one manufacturer for the purchase of all their parenteral solutions, a new entrant would have to produce a full product line of solutions to be an effective competitor.

23. Baxter and AHS regularly sell substantial quantities of parenteral solutions in interstate commerce. Both companies operate manufacturing facilities whose parenteral solutions are regularly shipped across state lines. Baxter and AHS are each engaged in interstate commerce and their activities with respect to parenteral solutions are in the flow of, and substantially affect, interstate commerce.

Fluid Administration Sets

24. A basic fluid administration set consists of several parts: a spike, an injection molded plastic part used to pierce the parenteral solution or blood container and through which the fluid flows into the set; a drip chamber, a clear plastic chamber into which the solution or blood drips, allowing the medical personnel to measure the fluid flow rate; a long extruded plastic tube through which the solution or blood flows to the patient; Y-sites, short pieces of plastic tubing connected to the long tube so that drugs or additional fluids can be infused through the set to the patient; a roller clamp, which can squeeze the tube partially (or totally) closed,

thereby regulating the rate at which the parenteral solution or blood flows into the patient; a filter, which removes any particulate matter or bacteria that might have entered the fluid delivery system; and an adapter, which connects the fluid administration set to the IV catheter inserted into the patient's vein.

25. Additional add-on components, such as extension sets, secondary sets, filters, and other accessories are sometimes used as part of fluid administration sets.

26. All fluid administration sets are manufactured in a similar manner. Some plastic parts of the sets are injection molded; others, such as tubing, are made through an extrusion process. The individual parts are assembled manually and by machine into sub-assemblies. Various sub-assemblies are then manually attached, using a solvent or heat seal process, to tubing cut to specific lengths to form the fluid administration set. The sets are placed in individual boxes, wrapped, and sterilized. The production process used to manufacture one type of fluid administration set can be easily converted to produce other types of fluid administration sets.

27. Other products are not competitive substitutes for fluid administration sets. The manufacture and sale of fluid administration sets comprises a relevant product market for antitrust purposes.

28. Baxter and AHS are direct competitors in the manufacture and sale of fluid administration sets. There are

only three companies that manufacture and sell a complete line of fluid administration sets in the United States: Baxter, AHS, and Abbott. In 1984, these companies accounted for about 90 percent of the $438.4 million total sales of fluid administration sets in the United States.

29. Baxter is the second largest manufacturer of fluid administration sets in the United States. In 1984, Baxter's sales of fluid administration sets in the United States were approximately $172.2 million.

30. AHS, through its American McGaw division, is the third largest manufacturer of fluid administration sets in the United States. AHS' sales of fluid administration sets in the United States in 1984 were approximately $61 million.

31. Based upon 1984 sales in the United States, Baxter had a 39.3% share of the fluid administration sets market; AHS had a 13.9% share. The fluid administration sets market in the United States is highly concentrated. The HHI calculated on the basis of 1984 sales in the United States is approximately 3307. Baxter's proposed acquisition of AHS would increase this HHI by about 1098 to about 4405.

32. There are substantial barriers to entry into the manufacture and sale of fluid administration sets. For successful entry, a manufacturer of fluid administration sets must, among other things, establish a reputation for the quality and reliability of its fluid administration sets.

33. Baxter and AHS regularly sell substantial quantities of fluid administration sets in interstate commerce. Both companies operate manufacturing facilities whose fluid administration sets are regularly shipped across state lines. Baxter and AHS are each engaged in interstate commerce and their activities with respect to fluid administration sets are in the flow of, and substantially affect, interstate commerce.

Electronic Flow Control Devices

34. Electronic flow control devices are used to monitor electronically the flow of parenteral solutions to the patient to insure that the fluid is infused into the patient at the desired rate. These devices allow parenteral solutions to be administered far more accurately (± 2-15 percent of the desired infusion rate) than is possible through the use of fluid administration sets alone (± 40 percent of the desired infusion rate). For patients where such accuracy is needed, such as certain patients in critical or intensive care units, other products such as fluid administration sets are not competitive substitutes for electronic flow control devices.

35. There are two basic types of electronic flow control devices: IV pumps, which control the rate of fluid infusion by pumping the fluid into the patient under positive pressure; and IV controllers, which control the rate of fluid infusion by electronically monitoring the flow rate of the fluid, but do so only under the force of gravity.

36. IV pumps and IV controllers perform the same general function and are substantially interchangeable in use. Although there are certain limited circumstances when an IV pump must be used to infuse fluids into a patient, in the majority of cases the use of either type of electronic flow control device is satisfactory.

37. Most electronic flow control devices require the use of a disposable dedicated fluid administration set (that plugs directly into the device) through which the fluid flows. A particular manufacturer's dedicated administration set will only work in conjunction with its own electronic flow control device, and the two products are marketed together.

38. The manufacture and sale of electronic flow control devices comprises a relevant product market for antitrust purposes.

39. Baxter and AHS are direct competitors in the manufacture and sale of electronic flow control devices in the United States. In 1984, there were about 94,000 electronic flow control devices, with a total value of about $102 million, sold in the United States. Approximately 91 percent of the 1984 sales in the United States were made by five companies; the remaining nine percent were made by several smaller companies.

40. Baxter is the fifth largest seller of electronic flow control devices in the United States. In 1984, Baxter sold

approximately 8,900 electronic flow control devices in the United States.

41. AHS is the second largest seller of electronic flow control devices in the United States. American Edwards, a subsidiary of AHS, manufactures IV pumps sold exclusively by AHS' McGaw division, which also distributes, under its own name, IV controllers manufactured for it by IVENT. American McGaw also sells products manufactured by other companies. In 1984, AHS sold approximately 20,000 devices in the United States.

42. Based upon 1984 sales in the United States, Baxter had a 9.5% share of the electronic flow control devices market; AHS had a 21.3% share. The electronic flow control devices market in the United States is highly concentrated. The HHI calculated on the basis of 1984 unit sales in the United States is about 1917. Baxter's proposed acquisition of AHS would increase the HHI by about 402 to about 2319.

43. There are substantial barriers to entry into the manufacture and sale of electronic flow control devices. The devices are technologically complex, and it would take a company a minimum of two years or more to design, develop and begin commercial production of a new competitive product. Virtually all existing manufacturers of electronic flow control devices have patents protecting the critical components of their devices and dedicated administration sets. A new entrant

must also establish a specialized sales force to compete effectively.

44. Baxter and AHS regularly sell substantial quantities of electronic flow control devices in interstate commerce. Both companies operate manufacturing facilities whose electronic flow control devices are regularly shipped across state lines. Baxter and AHS are engaged in interstate commerce and their activities with respect to electronic flow control devices are within the flow of, and substantially affect, interstate commerce.

Therapeutic Hemapheresis Equipment

45. Therapeutic hemapheresis equipment is used to break down blood into components for two primary therapeutic purposes: collection of individual components for future patient treatment and removal of a particular blood component.

46. There are two basic types of therapeutic hemapheresis equipment: centrifugal blood cell separators and plasma-specific membrane cell separators. Both types of equipment have two components: a hardware portion that electro-mechanically pumps the blood from the patient and controls the component separation; and a dedicated, disposable, single-use item in which the actual separation of the components takes place.

47. Centrifugal blood cell separators and plasma-specific membrane cell separators are both capable of therapeutic plasma extraction and can be used interchangeably for that purpose.

Centrifugal blood cell separators also have the capability of separately removing red cells, white cells, and platelets. Sellers of centrifugal blood cell separators cannot price discriminate between customers who buy their product for plasma extraction and customers who buy their product for the other uses and so must market their products in direct competition with plasma-specific membrane separators. Baxter manufactures and sells both centrifugal blood cell separators and plasma-specific membrane separators. AHS manufactures and sells centrifugal blood cell separators through its American Haemonetics subsidiary.

48. Other products are not competitive substitutes for therapeutic hemapheresis equipment. The manufacture and sale of hemapheresis equipment constitutes a relevant product market for antitrust purposes.

49. Baxter and AHS are direct competitors in the manufacture and sale of therapeutic hemapheresis equipment. There are three major companies in the United States that manufacture and sell therapeutic hemapheresis equipment: Baxter, AHS, and Cobe Laboratories. These three companies sell their therapeutic hemapheresis equipment throughout the United States, and together in 1984 accounted for almost all sales of centrifugal blood cell separators and plasma-specific membrane cell separators in the United States.

50. Baxter is the second largest manufacturer and seller of therapeutic hemapheresis equipment in the United States. In

1984, it sold 91 machines and 75,665 disposable procedure units in the United States, with a combined total value of about $6.7 million.

51. AHS is the third largest manufacturer and seller of therapeutic hemapheresis equipment in the United States. In 1984, it sold 74 machines and 75,500 disposable procedure units in the United States, with a combined value of about $5.6 million.

52. Based upon 1984 unit sales in the United States, Baxter had a 28% share of the therapeutic hemapheresis equipment market; AHS had a 23% share. The therapeutic hemapheresis market is highly concentrated. The HHI calculated on the basis of 1984 sales of therapeutic hemapheresis equipment in the United States is about 2700. Baxter's proposed acquisition of AHS would increase this HHI by about 1300 to about 4000.

53. There are substantial barriers to entry into the manufacture and sale of therapeutic hemapheresis equipment. Existing technology is protected by patents and FDA approval is required before the equipment can be sold. A new entrant would also have to develop brand name recognition to successfully compete in the market.

54. Baxter and AHS regularly sell substantial quantities of therapeutic hemapheresis equipment in interstate commerce. Both companies operate manufacturing facilities whose therapeutic hemapheresis equipment is regularly shipped across

state lines. Baxter and AHS are each engaged in interstate commerce and their activities with respect to therapeutic hemapheresis equipment are in the flow of, and substantially affect, interstate commerce.

Surgeons and Procedure Gloves

55. Surgeons and procedure gloves, because of their design, sizing, and thinness, closely resemble the shape of a surgeon's hand and fit the hands more exactly than other types of medical gloves such as examination gloves, thereby allowing the surgeon dexterity and tactile sensitivity while decreasing the possibility of hand fatigue. Although procedure gloves are not used in the performance of gowned surgical procedures in the operating room, surgeons gloves and procedure gloves are substitutable in use for non-gowned surgical procedures performed outside the operating room. Sellers of surgeons gloves cannot price discriminate between customers who buy their gloves for use inside and outside the operating room and so must market their products in direct competition with procedure gloves.

56. Surgeons and procedure gloves are manufactured similarly through a multi-step production process. Anatomically correct porcelain molds, which are attached to racks on an overhead conveyor line, are dipped into a coagulant compound and then into a latex compound. Upon removal from the latex compound, the rack of molds is dipped into a leaching tank to remove impurities from the latex. The rack of molds is

put into a low-temperature pre-curing oven, after which the outer edge of the top of the glove is rolled to reinforce the cuff. The molds are then run through a high-temperature curing oven to complete the drying phase of the process, and the gloves are lubricated so they do not stick to themselves when they are removed from the molds. Once removed from the molds, the gloves are tested for defects, and reversed if they were turned inside out during a stripping process. Finally, the gloves are washed and dried, packaged in pairs, and sterilized.

57. AHS is the only company that markets "true" procedure gloves, as opposed to the cosmetically defective surgeons gloves sold by other competitors. AHS procedure gloves are made with specially-designed porcelain molds that are shorter than surgeons gloves molds.

58. Other products are not competitive substitutes for surgeons and procedure gloves. Examination gloves are used to perform routine medical examinations and diagnostic and therapeutic procedures, but they cannot be used to perform surgical procedures either inside or outside the operating room. Exam gloves are ambidextrous, shorter than either surgeons or procedure gloves, and sized only generally as small, medium or large. These gloves, which are usually worn to protect the user rather than the patient, do not offer surgeons the glove strength and quality of fit or feel that they require to perform surgical procedures.

59. The manufacture and sale of surgeons and procedure gloves comprises a relevant product market for antitrust purposes.

60. Baxter and AHS are direct competitors in the manufacture and sale of surgeons and procedure gloves in the United States. There are presently eight companies that manufacture and sell surgeons and procedure gloves in the United States, and one company that imports surgeons and procedure gloves into the United States. In 1984, six of these companies accounted for about 90 percent of all sales of surgeons and procedure gloves in the United States, which totalled about 269 million pairs valued at about $112.2 million.

61. Baxter is the largest manufacturer of surgeons and procedure gloves in the United States. In 1984, Baxter sold about 71 million pairs of surgeons and procedure gloves in the United States, valued at about $27.5 million.

62. AHS is the second largest manufacturer and seller of surgeons and procedure gloves in the United States. AHS' Pharmaseal division is responsible for manufacturing and marketing surgeons gloves made in Tucson, Arizona and procedure gloves made in Johnson City, Tennessee. Another AHS subsidiary, American Hospital Supply Company, is responsible for the distribution of AHS' surgeons and procedure gloves. In 1984, AHS sold about 36.5 million pair of surgeons and

procedure gloves in the United States, valued at about $15.5 million.

63. Based upon 1984 unit sales in the United States, Baxter had a 26.2% share of the surgeons and procedure gloves market; AHS had a 13.5% share. The surgeons and procedure gloves market in the United States is highly concentrated. The HHI calculated on the basis of 1984 sales in the United States is about 1667. Baxter's proposed acquisition of AHS would increase this HHI by about 708 to about 2375.

64. There are substantial barriers to entry into the manufacture and sale of surgeons and procedure gloves. An entrant must establish a reputation for quality and reliability to induce surgeons, who have strong preferences for brand name products, to try a new glove. An entrant must also develop a latex compound and an acceptable technique to lubricate the gloves, obtain custom designed dipping and drying equipment, and order molds from one of the two companies that make them.

65. Baxter and AHS regularly sell substantial quantities of surgeons and procedure gloves in interstate commerce. Both companies operate manufacturing facilities whose surgeons and procedure gloves are regularly shipped across state lines. Baxter and AHS are each engaged in interstate commerce and their activities with respect to surgeons and procedure gloves are in the flow of, and substantially affect, interstate commerce.

V

VIOLATION ALLEGED

66. On July 15, 1985, Baxter and AHS entered into an agreement and plan of acquisition pursuant to which Baxter will acquire all of the outstanding stock of AHS at a price of $51 per share in cash or in combination with Baxter securities. Both companies' shareholders are scheduled to meet on November 22 to vote on the proposed acquisition. The sale would, in effect, merge all of AHS' business, including its parenteral solutions, fluid administration sets, electronic flow control devices, therapeutic hemapheresis equipment, and surgeons and procedure gloves business, into Baxter, and give Baxter complete control of AHS' operation. The parties have agreed not to consummate the acquisition prior to 12:01 a.m., November 25, 1985.

67. The effect of Baxter's proposed acquisition and merger with AHS may be substantially to lessen competition in the United States markets for the manufacture and sale of parenteral solutions, fluid administration sets, electronic flow control devices, therapeutic hemapheresis equipment, and surgeons and procedure gloves, in violation of Section 7 of the Clayton Act, in the following ways, among others:

(a) Actual and potential competition between Baxter and AHS in the parenteral solutions, fluid administration sets, electronic flow control devices, therapeutic

hemapheresis equipment, and surgeons and procedure gloves markets in the United States will be eliminated; and

(b) Competition generally in the parenteral solutions, fluid administration sets, electronic flow control devices, therapeutic hemapheresis equipment, and surgeons and procedure gloves markets in the United States may be substantially lessened.

VI

PRAYER

WHEREFORE, plaintiff prays:

1. That a temporary restraining order and preliminary and permanent injunctions be issued against the defendants Baxter and AHS preventing each of them; any subsidiary, direct or indirect, of Baxter or AHS; and any and all other persons acting on their behalf, from taking any action, directly or indirectly, in furtherance of Baxter's proposed acquisition of AHS' common stock and merger of AHS into Baxter or a subsidiary thereof;

2. That the proposed acquisition by Baxter of all AHS' common stock and merger of AHS into Baxter be adjudged to be in violation of Section 7 of the Clayton Act;

3. That the plaintiff have such other and further relief as the nature of this case may require and as this Court may deem just and proper; and

4. That the plaintiff recover the costs of this action.

Dated: November ____, 1985

Respectfully submitted,

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