

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITED STATES OF AMERICA,
Department of Justice
Antitrust Division
325 Seventh Street, N.W., Suite 300
Washington, D.C. 20530,

Plaintiff,

v.

GENERAL ELECTRIC COMPANY,
3135 Easton Turnpike
Fairfield, Connecticut 06431,

and

INSTRUMENTARIUM OYJ,
Kuortaneenkatu 2
FIN-00510
Helsinki, Finland,

Defendants.

Civil Action No.: 1:03CV01923

Filed: September 16, 2003

COMPLAINT

The United States, acting under the direction of the Attorney General of the United States, brings this civil antitrust action to enjoin General Electric Company (“GE”) from acquiring Instrumentarium OYJ (“Instrumentarium”) and to obtain other relief as appropriate.

Plaintiff alleges as follows:

1. GE and Instrumentarium are two of the nation’s three leading suppliers of patient monitors used to take the vital physiologic measurements of patients requiring critical care (“critical care monitors”). They compete head to head in the development, manufacture, and sale of these important medical devices used by hospitals and other healthcare facilities.

2. GE dominates the sale of mobile, full-size C-arms used for surgical, orthopedic, pain management, and basic vascular procedures, with a market share of over 65 percent of all units sold. Instrumentarium is one of the few companies in the United States that provides competition to GE in the development, manufacture, and sale of these products. C-arms are fluoroscopic x-ray devices that offer real-time, continuous viewing during medical procedures.

3. The proposed acquisition, if consummated, would eliminate the head-to-head competition that currently exists between GE and Instrumentarium and would substantially increase the likelihood that GE will unilaterally increase the prices or reduce the product quality of critical care monitors and mobile, full-size C-arms used for surgical, orthopedic, pain management, and basic vascular procedures, to the detriment of consumers. Unless blocked, the proposed acquisition would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

I.

JURISDICTION AND VENUE

4. The United States brings this action under Section 15 of the Clayton Act, as amended, 15 U.S.C. § 25, to restrain defendants from violating Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

5. Defendants are engaged in interstate commerce and in activities that substantially affect interstate commerce. The Court has jurisdiction of this action and jurisdiction over the parties pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §§ 1331 and 1337.

6. Defendant GE transacts business in the District of Columbia. Venue is proper in this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(c).

7. Defendant Instrumentarium is a foreign corporation that transacts business in the District of Columbia. Venue is proper in this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(d).

II.

DEFENDANTS AND THE TRANSACTION

8. GE is a global technology and services company that has its principal offices in Fairfield, Connecticut. GE's subsidiary, GE Medical Systems, is a major worldwide provider of medical equipment products and services, including patient monitors and C-arms, and has its principal offices in Waukesha, Wisconsin. In 2002, GE had total revenues of approximately \$131.7 billion, and GE Medical Systems had revenues of approximately \$9 billion.

9. Instrumentarium is a major worldwide provider of medical equipment products and services, including patient monitors and C-arms, and has its principal offices in Helsinki, Finland. Instrumentarium manufactures and sells patient monitors through its Datex-Ohmeda and Spacelabs subsidiaries, and manufactures and sells C-arms through its Ziehm operations. Instrumentarium's revenues were approximately \$1 billion in 2002.

10. GE and Instrumentarium reached an agreement on December 18, 2002 that provides for GE to purchase Instrumentarium through a cash tender offer valued at approximately \$2 billion.

III.

REDUCED COMPETITION IN CRITICAL CARE MONITORS

A. The Relevant Product Market

11. Patient monitors are routinely used throughout hospitals and other healthcare facilities to measure and display information about various patient physiologic parameters. The parameters range from basic measurements, such as temperature, noninvasive blood pressure, and electrocardiography, to sophisticated invasive blood pressures (measurements of the blood pressure in various internal organs through the use of catheters). The information allows healthcare providers to monitor the health and stability of patients and is vital to the provision of healthcare.

12. The medical condition of patients varies throughout the hospital. Patients in higher-acuity areas—such as intensive care units, coronary care units, post-anesthesia care units, and emergency rooms—are generally in more serious condition than patients in lower-acuity areas, such as general ward floors. Many patients in these higher-acuity areas require critical care, and need more and different parameters monitored than do patients in lower-acuity areas. In order to treat the patients requiring critical care, these higher-acuity areas must have monitors with the functionality to measure and simultaneously display information about a large number of parameters.

13. Patient monitors vary significantly based on the number and type of parameters they measure and the amount of information that can be simultaneously displayed on the screen. Critical care monitors are sophisticated machines that can measure and display information regarding six or more patient parameters. In addition to basic parameters, critical care monitors typically measure cardiac output (the volume of blood pumped by the heart in a specific time

period) and multiple invasive blood pressures. Critical care monitors also require significant networking capabilities so that information can be sent to and displayed at a central station. Critical care monitors are distinct from low-acuity monitors, which are basic machines that measure fewer parameters and which cost significantly less.

14. Critical care monitors are also distinct from monitors that are used in the operating room (“OR”). Patient monitors in the OR are also sophisticated units, but they use specialized software and technologies not required elsewhere in the hospital. OR monitors must be configured for anesthesia machine compatibility, monitor different parameters, such as the level of anesthetic gas in a patient’s airway, and tend to be significantly more expensive. Different personnel in the hospital or other healthcare facility are involved in making the purchasing decisions for critical care and OR monitors.

15. Hospitals and other healthcare facilities individually negotiate the purchase of critical care monitors with one or more vendors. Hospitals and other healthcare facilities seeking to purchase a critical care monitor would not consider a low-acuity monitor, or an OR monitor, to be a realistic substitute. They also have no realistic substitutes for patient monitors, because no other equipment can monitor and display a patient’s vital physiologic parameters. Thus, a small but significant increase in the price of a critical care monitor would not cause a sufficient number of hospitals or other healthcare facilities seeking to purchase a critical care monitor to switch to an OR monitor, a low-acuity monitor, or any other type of medical device so as to make such a price increase unprofitable and unsustainable.

16. Critical care monitors are a separate and distinct relevant product market for purposes of analyzing this acquisition under Section 7 of the Clayton Act.

B. Relevant Geographic Market

17. Defendants sell critical care monitors throughout the United States to hospitals and other healthcare facilities. Any company seeking to sell critical care monitors in the United States must register with the Food and Drug Administration (“FDA”), which regulates patient monitors, and cannot begin domestic sales until receiving FDA approval for its products. Purchasers in the United States cannot turn to any provider of critical care monitors that has not obtained FDA approval for its products. Further, in order to be a competitive supplier within the United States, vendors need local distribution, service, and support. A small but significant increase in the price of a critical care monitor would not cause a sufficient number of purchasers in the United States to turn to providers of critical care monitors that have not established a sales and service presence in the United States so as to make such a price increase unprofitable and unsustainable. Therefore, the United States is a relevant geographic market within the meaning of Section 7 of the Clayton Act.

C. Concentration

18. The market for critical care monitors is highly concentrated. GE, Instrumentarium, and one other firm are the leading suppliers. Based on shares of unit sales, GE has a share of approximately 33 percent of the market, and Instrumentarium has a share of approximately 16 percent.

19. While there are other firms that manufacture critical care monitors, product limitations and other factors, such as their degree of customer acceptance, lessen the ability of these firms to compete for many customers. All but two of these firms also have only marginal sales of critical care monitors.

20. The market for critical care monitors would become substantially more concentrated if GE acquires Instrumentarium. Using a measure of market concentration called the Herfindahl-Hirschman Index (“HHI”) (defined and explained in Appendix A), the proposed transaction will increase the HHI in the market for critical care monitors by approximately 1,134 points to a postacquisition level of approximately 3,795, significantly increasing concentration in an already concentrated market.

D. Harm To Competition

21. Critical care monitors are highly differentiated products, which are distinguished from each other by price, product features, vendor reputation, and customer service. Customers for these products negotiate the transactions individually with one or more vendors and have distinct preferences for certain products and specific providers.

22. GE and Instrumentarium have competed vigorously in the development, manufacture, and sale of critical care monitors. A significant number of customers view GE’s and Instrumentarium’s monitors as particularly close substitutes and do not view the products of the other vendors as equally close. In individualized negotiations, these customers have benefitted from the rivalry between GE and Instrumentarium, and received lower prices, better quality, or improved service as a result. Hospitals and other healthcare facilities that purchase critical care monitors have also benefitted generally from competition between GE and Instrumentarium on price, innovation, product features, and service.

23. The proposed transaction would eliminate the competition between GE and Instrumentarium, reduce the number of significant suppliers of critical care monitors from three to two, and substantially increase the likelihood that GE will unilaterally increase the price of

critical care monitors to a significant number of customers.

E. Entry

24. Successful entry or expansion in the development, manufacture, and sale of critical care monitors is difficult, time-consuming, and costly. First, suppliers must receive FDA approval in order to begin marketing a critical care monitor, or to introduce a new model. The product development and approval process is costly and time-consuming.

25. Second, a vendor's reputation and name recognition are important factors in effectively selling critical care monitors. Hospitals and other healthcare facilities rely on critical care monitors when treating patients that are in critical condition; the consequences of a product failure under these circumstances are extremely serious and could be life-threatening. Thus, customers are reluctant to purchase from suppliers whose products are not well known, such as new entrants or fringe suppliers.

26. Third, it takes substantial time and resources to develop the expertise necessary to successfully produce and market critical care monitors. Vendors must also maintain significant ongoing research and development efforts to continue innovations that meet customer demand as well as stringent safety standards.

27. Finally, suppliers of critical care monitors must establish extensive sales and service networks. Customers rely on sales representatives to inform them about new products and technologies. Many hospitals and other healthcare facilities also rely on critical care monitor providers for service and are reluctant to purchase from vendors without an established presence and service network in their area.

28. Therefore, timely entry or expansion by any other firm is unlikely to be sufficient

to defeat an anticompetitive price increase or reduction in product quality in the event that GE acquires Instrumentarium.

IV.

REDUCED COMPETITION IN C-ARM MARKET

A. The Relevant Product Market

29. C-arms are fluoroscopic x-ray devices that offer real-time, continuous images during certain medical and surgical procedures. C-arms may be mobile (“mobile C-arms”), stationary (“fixed C-arms”), or small (“mini C-arms”). Mobile C-arms typically consist of two-wheeled units, one to support the C-arm unit and the other to support the display monitors and imaging processor. The C-arm unit consists of a curved arm with an x-ray tube mounted on one end and an image intensifier, which converts the x-rays into a viewable image, on the other end.

30. Mobile C-arms are used during general and orthopedic surgery, various pain management procedures, basic vascular procedures, and advanced vascular and cardiac procedures.

31. Some mobile C-arms are largely designed for general surgery, orthopedic, and pain management procedures. These procedures include, but are not limited to, placing splints, localized needle biopsy, endoscopy, and colonoscopy. Other mobile C-arms are designed for basic vascular procedures, such as balloon angiography and endovascular stent graphs, and contain special software for digital subtraction, which allows the surgeon or technician to view a patient’s veins and arteries.

32. Many hospitals and healthcare facilities use mobile C-arms designed for basic vascular procedures for general surgery, orthopedic, and pain management procedures. When

seeking to purchase a mobile C-arm for general surgery, orthopedic, and pain management procedures, these customers would consider a mobile C-arm that performs basic vascular procedures to be a realistic substitute. “Orthopedic-vascular C-arms” refers to mobile C-arms designed for general surgery, orthopedic, pain management, or basic vascular procedures.

33. Another type of mobile C-arm is designed for advanced vascular and cardiac procedures. These mobile C-arms are designed to image a moving heart or the brain. To produce a good image, these mobile C-arms are equipped with greater hardware and software functionality. They are priced at much higher levels than orthopedic-vascular C-arms.

34. Hospitals and other healthcare facilities individually negotiate the purchase of orthopedic-vascular C-arms with one or more vendors. A hospital or other healthcare facility seeking to purchase an orthopedic-vascular C-arm would not consider any other imaging equipment, such as a fixed C-arm, mini C-arm, CT scanner, or other X-ray equipment, to be a realistic substitute. CT scanners and other X-ray equipment do not have the functionality to provide real-time, continuous viewing during medical procedures. Fixed C-arms are dedicated to a specific room, are generally used for cardiac procedures, and cost significantly more than any mobile C-arm. Mini C-arms cannot image an entire torso and are limited in the medical procedures in which they can be used.

35. A hospital or other healthcare facility seeking to purchase an orthopedic-vascular C-arm also would not consider a mobile C-arm designed for advanced vascular and cardiac procedures to be a realistic substitute, because advanced vascular and cardiac C-arms are priced significantly higher and offer more and different functionality than would be needed for general orthopedic, surgical, and vascular procedures. Thus, a small but significant increase in the price

of an orthopedic-vascular C-arm would not cause a sufficient number of hospitals or other healthcare facilities seeking to purchase an orthopedic-vascular C-arm to switch to any alternative product so as to make such a price increase unprofitable and unsustainable.

36. Orthopedic-vascular C-arms constitute a separate and distinct market for purposes of analyzing this acquisition under Section 7 of the Clayton Act.

B. Relevant Geographic Market

37. Defendants sell orthopedic-vascular C-arms throughout the United States to hospitals and other healthcare facilities. Any company seeking to sell orthopedic-vascular C-arms in the United States must register with the FDA and receive FDA approval for its products. Purchasers in the United States cannot turn to any provider of orthopedic-vascular C-arms that has not obtained FDA approval for its products. Further, in order to be a competitive supplier within the United States, vendors need local distribution, service, and support. A small but significant increase in the price of an orthopedic-vascular C-arm would not cause a sufficient number of purchasers in the United States to turn to providers of orthopedic-vascular C-arms that have not established a sales and service presence in the United States so as to make such a price increase unprofitable and unsustainable. Therefore, the United States is a relevant geographic market within the meaning of Section 7 of the Clayton Act.

C. Concentration

38. The market for orthopedic-vascular C-arms is highly concentrated. GE dominates the sale of orthopedic-vascular C-arms, with approximately 68 percent of unit sales. Instrumentarium and two other firms have smaller market shares.

39. The market for orthopedic-vascular C-arms would become even more

concentrated if GE acquired Instrumentarium. Using the HHI measure of market concentration (discussed above and defined and explained in Appendix A), the proposed transaction will increase the HHI in the market for orthopedic-vascular C-arms by approximately 1,098 points to a postacquisition level of approximately 6,145. Accordingly, this acquisition would significantly increase concentration in an already highly concentrated market.

D. Harm to Competition

40. Orthopedic-vascular C-arms are differentiated on the basis of image quality, ease of use, weight and size, firm reputation, and customer service. Customers of these mobile C-arms negotiate transactions individually with one or more vendors and have distinct and varying preferences for certain products and specific mobile C-arm vendors.

41. Instrumentarium provides GE with significant competition in the development, manufacture, and sale of orthopedic-vascular C-arms. This has included competition on price, service, innovation, and product features, such as image quality.

42. A significant number of customers view the GE and Instrumentarium orthopedic-vascular C-arm products as close substitutes, and do not view the products of other vendors to be equally close. During individual negotiations, these customers have benefitted from the competition between GE and Instrumentarium to obtain lower prices, improved product quality and services, and better contract terms. Hospitals and other healthcare facilities that purchase orthopedic-vascular C-arms have also benefitted generally from the competition between GE and Instrumentarium on price, innovation, product features, and service.

43. The proposed transaction would eliminate the competition between GE and Instrumentarium, remove one of the few vendors providing competition to GE in orthopedic-

vascular C-arm sales, and substantially increase the likelihood that GE will unilaterally increase the price of orthopedic-vascular C-arms to a significant number of customers.

E. Entry

44. If GE acquires Instrumentarium, there is unlikely to be timely entry by any firm that would be sufficient to defeat an anticompetitive price increase or reduction in product quality.

45. Successful entry and expansion is difficult, time-consuming, and costly. First, in order to sell an orthopedic-vascular C-arm to a customer in the United States, a firm must gain FDA approval. The product development and approval process is costly and time-consuming.

46. Second, a vendor's reputation and name recognition are extremely important factors in effectively selling orthopedic-vascular C-arms. Hospitals and healthcare facilities seek to purchase products with proven records of reliability, and are unlikely to purchase from firms without an established presence or strong reputation in mobile C-arm sales. Mobile C-arms are used during important medical procedures, and a mobile C-arm's poor performance is costly and can endanger a patient's life or physical condition.

47. Suppliers of orthopedic-vascular C-arms must also establish sales, distribution, and service networks. Hospitals and other healthcare facilities rely on visits from sales representatives to learn about new products and technologies. They also often rely on vendors to perform their ongoing service needs. Hospitals and other healthcare facilities consider it critical to keep their orthopedic-vascular C-arms operational. They are thus unlikely to purchase from a vendor that does not have a sales, distribution, and service network in their area.

48. Finally, it takes substantial time and resources to develop the expertise necessary

to successfully produce and market orthopedic-vascular C-arms. Suppliers must also maintain significant ongoing research and development efforts to continue innovations that meet customer demand as well as stringent safety standards in order to ensure future sales.

V.

VIOLATIONS ALLEGED

49. The effect of GE's acquisition of Instrumentarium would likely be to lessen competition substantially in interstate trade and commerce in violation of Section 7 of the Clayton Act.

50. Unless restrained, the transaction will likely have the following effects, among others:

- a. Actual and future competition between GE and Instrumentarium will be eliminated in the markets for critical care monitors and orthopedic-vascular C-arms;
- b. Competition generally in the markets for critical care monitors and orthopedic-vascular C-arms will likely be substantially lessened; and
- c. Prices for critical care monitors and orthopedic-vascular C-arms will likely increase.

VI.

REQUEST FOR RELIEF

51. Plaintiff requests: (a) that GE's proposed acquisition of Instrumentarium be adjudged to violate Section 7 of the Clayton Act; (b) that defendants be permanently enjoined from consummating the proposed acquisition or from entering into or carrying out any agreement, understanding, or plan, the effect of which would be to exchange those assets between the defendants; (c) that plaintiff be awarded its costs for this action; and (d) that plaintiff

have such other relief as the Court may deem just and proper.

Dated: September 16, 2003.

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APPENDIX A

DEFINITION OF “HHI”

The term “HHI” means the Herfindahl-Hirschman Index, a commonly accepted measure of market concentration. The HHI is 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.

Markets in which the HHI is between 1000 and 1800 points are considered to be moderately concentrated, and markets in which the HHI is in excess of 1800 points are considered to be highly concentrated. Transactions that increase the HHI by more than 100 points in highly concentrated markets presumptively raise significant antitrust concerns under the Department of Justice and Federal Trade Commission 1992 Horizontal Merger Guidelines.