



biopsy sampling devices to coordinates specific to regions within the breast. “Prone Stereotactic Breast Biopsy Systems” includes research and development, and clinical testing activities related to the incorporation of an ultrasound scanning mechanism on the Prone Stereotactic Breast Biopsy System and the use of the Prone Stereotactic Breast Biopsy System for purposes of patient positioning during brachytherapy procedures.

4. “Acquisition” means the acquisition of Fischer’s assets by Hologic, including Fischer’s intellectual property and other assets relating to its mammography and breast biopsy businesses, including the patents, trademarks, and other intellectual property relating to Fischer’s prone SBBS, MammoTest.

## **II. HOLOGIC**

5. Respondent Hologic is a for-profit corporation organized, existing and doing business under and by the virtue of the laws of the State of Delaware, with its principal place of business located at 35 Crosby Drive, Bedford, Massachusetts, 01730.
6. Hologic specializes in the development and marketing of diagnostic and imaging medical devices in the field of women’s health. Its products include mammography equipment, breast biopsy systems, and bone densitometry equipment.
7. Hologic is, and at all times relevant herein has been, engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

## **III. FISCHER**

8. At the time of the Acquisition, Fischer was a for-profit corporation organized, existing and doing business under and by the virtue of the laws of the State of Delaware, with its principal place of business located at 12300 North Grant Street, Denver, Colorado, 80241.
9. At the time of the Acquisition, Fischer was engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.
10. Prior to the acquisition, Fischer was actively developing, manufacturing, and marketing equipment used in the screening and diagnosis of breast cancer. The company’s chief products were its SenoScan digital mammography machine and its MammoTest prone SBBS. In 2004, the company employed approximately 263 individuals and reported revenues of approximately \$64 million.

#### **IV. HOLOGIC'S ACQUISITION OF FISCHER'S ASSETS**

11. On June 22, 2005, Fischer entered into an Asset Purchase Agreement with Hologic whereby Hologic acquired substantially all of Fischer's intellectual property and other assets relating to its mammography and breast biopsy businesses, including the patents, trademarks, and other intellectual property surrounding Fischer's prone SBBS, MammoTest ("Acquisition").
12. The Acquisition was valued at \$32 million, including \$27 million in cash and forgiveness of a \$5 million loan made to Fischer by Hologic upon entering the agreement. The parties consummated the transaction, which was not reportable under the Hart-Scott-Rodino Act, on September 29, 2005.
13. At the time of the Acquisition, Fischer was one of two significant suppliers of prone SBBSs in the United States. Hologic was the only other significant supplier of prone SBBSs in the United States. As a result of the acquisition, Fischer exited the mammography and breast biopsy businesses and is preparing to close down its remaining operations entirely within a few months.

#### **V. RELEVANT PRODUCT MARKET**

14. For the purposes of this Complaint, the relevant product market in which to analyze the effects of the Acquisition is the production and sale of prone SBBSs. Prone SBBSs are integrated systems that allow a physician to conduct a minimally-invasive biopsy using stereotactic guidance. SBBSs are the only minimally-invasive systems consistently capable of imaging a particular type of lesion called microcalcifications. For this type of lesion, a biopsy using a SBBS is the current standard of care, and the only method short of invasive surgery to determine whether a lesion is cancerous. Although SBBSs may also be "upright," there are significant drawbacks associated with the use of upright SBBSs, as compared to prone SBBSs. Upright SBBSs are less comfortable for patients, less precise, and carry with them a significant incidence of patient fainting. A small but significant and non-transitory price increase would not significantly reduce the demand for prone SBBSs.

#### **VI. RELEVANT GEOGRAPHIC MARKET**

15. For the purposes of this Complaint, the relevant geographic market in which to assess the effects of the Acquisition is the United States. To compete in the United States prone SBBS market, a firm must have FDA approval for its device, establish a local sales and service organization, and must not infringe any valid U.S. prone SBBS patents.

## **VII. MARKET STRUCTURE**

16. Pursuant to the Acquisition, the only two significant suppliers of prone SBBSs in the United States merged, leaving Hologic as a virtual monopolist in the \$40 million market. Prior to the Acquisition, Hologic and Fischer had substantially equivalent shares of the market and directly competed on price, service and product innovation. The only other firm that sells a prone SBBS is Giotto USA. Giotto has had minimal sales since its product's introduction to the U.S. market three years ago. Giotto's sales are unlikely to increase sufficiently to restore the lost competition, as Giotto lacks the infrastructure, track record, product acceptance, and resources to expand U.S. sales significantly. As a result, the transaction significantly increased concentration and resulted in a highly concentrated market.

## **VIII. EFFECTS OF THE ACQUISITION**

17. As the only significant suppliers of prone SBBSs in the United States, Hologic and Fischer competed head-to-head for over ten years before the Acquisition. Hologic's Acquisition has had or will have the effect of substantially lessening competition and tending to create a monopoly in the relevant market by, among other things:
  - a. eliminating Fischer as the only other significant competitor in the market for prone SBBSs;
  - b. eliminating actual, direct, and substantial competition between Hologic and Fischer, which before the Acquisition, directly competed on price, service and product innovation as next-best substitutes;
  - c. increasing the ability of Hologic to unilaterally raise prices of prone SBBSs in the United States; and
  - d. reducing Hologic's incentive to invest in prone SBBS innovations and service improvements, thereby adversely affecting product innovation and service.

## **IX. ENTRY CONDITIONS**

18. Entry into the market for the production and sale of prone SBBSs is unlikely and, in any event, cannot occur in a timely and sufficient manner so as to deter or counteract the anticompetitive effects likely to result from the Acquisition.
19. Potential entrants must overcome significant intellectual property barriers to develop a prone SBBS product. The strength and scope of Hologic's patent portfolio, including the patents that Hologic acquired from Fischer as a result of the Acquisition, pose a significant barrier to entry into this market. Hologic, for example, was only able to enter

the prone SBBS market by acquiring a license from Fischer in settlement of patent litigation.

20. In addition to the intellectual property barriers to entry, potential entrants must contend with the research, development, and regulatory hurdles that companies seeking to market medical devices typically face. After developing and obtaining FDA approval for a prone SBBS product, a new entrant would face the difficult task of gaining market approval without a proven product or track record, developing manufacturing capability, recruiting and training a sales force, and establishing the infrastructure necessary to provide service for the life of the product.

#### **X. VIOLATIONS CHARGED**

21. The allegations contained in paragraphs 1 through 20 are repeated and realleged as though fully set forth here.
22. The effect of the Acquisition may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C. this ninth day of August, 2006.

By the Commission.

Donald S. Clark  
Secretary

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