ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of Hologic, Inc., File No. 0510263

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Hologic, Inc. ("Hologic"). The purpose of the proposed Consent Agreement is to remedy the competitive harm resulting from Hologic's consummated acquisition of certain assets of Fischer Imaging Corporation ("Fischer"). Under the terms of the proposed Consent Agreement, Hologic is required to divest to Siemens AG ("Siemens") all assets it acquired from Fischer relating to Fischer's prone stereotactic breast biopsy system ("prone SBBS") business.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw the proposed Consent Agreement or make it final.

On September 29, 2005, Hologic paid $32 million to acquire substantially all of Fischer's intellectual property and certain other assets relating to its mammography and breast biopsy businesses, including the patents, trademarks, customer lists, and vendor lists relating to Fischer's prone SBBS product, MammoTest ("Acquisition"). As a result of the Acquisition, Fischer -- the only significant competitor to Hologic in the U.S. market for prone SBBSs -- relinquished all rights to develop, manufacture, market, and sell prone SBBSs in the United States. The Commission's complaint alleges that the Acquisition violated Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by eliminating Hologic's only significant competitor in the U.S. market for prone SBBSs. The proposed Consent Agreement would restore the competition eliminated by the Acquisition by ensuring the prompt competitive viability of Siemens as an additional supplier of prone SBBSs in the United States.

II. The Parties

Hologic is a developer, manufacturer, and marketer of diagnostic and imaging medical devices. Its chief product areas are mammography equipment, breast biopsy systems (including the MultiCare Platinum prone SBBS), and bone densitometry equipment. In 2005, Hologic reported worldwide revenues of approximately $288 million.

Prior to the Acquisition, Fischer was actively involved in developing, manufacturing, and marketing equipment used in the screening and diagnosis of breast cancer. The company's chief products were its SenoScan digital mammography system and its MammoTest prone SBBS. In

2004, Fischer reported revenues of approximately $64 million. For the first nine months of 2005, prior to the Acquisition, Fischer reported revenues of $39 million.

III. Prone SBBSs

A prone SBBS is an integrated system that allows a physician to conduct a highly precise, minimally-invasive breast biopsy using x-ray guidance. During the procedure, the patient lies prone on a table with her breast suspended through an aperture in the table. With the patient's breast compressed, the physician utilizes the system's x-ray imaging to guide a needle to the precise location of the suspected lesion and extracts small tissue samples for diagnosis. The entire procedure is conducted beneath the table and is obscured from the patient's view.

There are several other methods of performing breast biopsies, including open surgical biopsies and other types of minimally-invasive systems. None of these other methods, however, are viable economic substitutes for prone SBBSs. Indeed, most hospitals have the capability to perform breast biopsies using multiple methods to ensure that the most appropriate system is used for each procedure.

Surgical biopsies were once the only method of biopsying breast tissue, but these procedures have declined significantly in popularity in response to the availability of newer, minimally-invasive, biopsy systems. Minimally-invasive biopsies provide accurate diagnosis while avoiding the economic costs and patient hardship associated with surgical breast biopsies. Surgical breast biopsies are performed under general anesthesia, require a longer hospital stay, and result in noticeable scarring. For these reasons, surgical procedures are typically performed only in circumstances in which none of the minimally-invasive alternatives is appropriate or available. An ability to perform surgical breast biopsies does not provide a meaningful competitive restraint on the exercise of market power by a prone SBBS monopolist.

There are two other types of minimally-invasive breast biopsy systems: ultrasound and magnetic resonance ("MR") systems. These systems are complementary treatment modalities, however, and are not competitive substitutes for a prone SBBS. Ultrasound-guided breast biopsies are the most prevalent type of minimally-invasive breast biopsy performed in the United States, and are typically used to biopsy suspicious masses. Ultrasound systems are not well suited for visualizing lesions called microcalcifications, however, and patients with this type of lesion are typically sent for biopsy using a prone SBBS. MR breast biopsy systems are currently considered a niche technology, and are significantly more expensive than prone SBBSs. Further, MR biopsies are cumbersome and time consuming compared to biopsies performed with a prone SBBS. Thus, MR-guided systems are used infrequently, and only in cases for which ultrasound or stereotactic systems would not be appropriate.

Stereotactic breast biopsies may also be performed using an "upright" system, which consists of a biopsy unit that attaches to an existing mammography system. There are significant disadvantages associated with using upright systems as compared to prone SBBS procedures,

including reduced comfort and a risk of vasovagal reactions (fainting). These problems result from the fact that an upright system performs the biopsy in plain view of the patient. Also, upright systems occupy a mammography machine that could otherwise be used to conduct mammograms, thereby reducing the number of screening mammographies that can be performed in a given day. This makes upright systems a particularly unattractive option for a breast care center that has a significant patient volume. For these reasons, even though upright systems are much less expensive, they are not used commonly in the United States, and do not provide meaningful competition to prone SBBS suppliers.

The relevant geographic market in which to analyze the effects of the Acquisition is the United States. Prone SBBSs are medical devices, and thus cannot be marketed or sold in the United States without prior approval by the United States Food and Drug Administration ("FDA"). Further, a firm wishing to sell prone SBBSs in the United States must establish a local sales and service organization and must not infringe any U.S. patents.

IV. Competitive Effects and Entry Conditions

Fischer pioneered the prone SBBS market when it introduced its MammoTest product in the late 1980s. In 1992, Lorad, a company subsequently acquired by Hologic, introduced the MultiCare prone SBBS to the U.S. market as the first competitor to MammoTest. Over the next fourteen years, Hologic's MultiCare and Fischer's MammoTest competed head-to-head in the U.S. market, with each firm supplying approximately fifty percent of the U.S. market for prone SBBSs. This competition directly benefitted U.S. consumers in the form of lower prices, better service, and product innovations. Evidence gathered in the Commission's investigation demonstrates that, prior to the acquisition, customers received lower prices and other economic benefits such as extended warranties and favorable service or payment terms as a result of the competition between Hologic and Fischer. The evidence also shows that the competition between the two companies has resulted in product improvements, including higher resolution detectors and improved software for image manipulation and storage. Since the Acquisition in September 2005, Hologic has enjoyed a virtual monopoly in the U.S. prone SBBS market.

The only other firm that sells a prone SBBS in the United States is Giotto USA. Giotto currently is not a significant competitor, however, having achieved minimal sales in the three years during which its product has been available in the United States. It is unlikely that Giotto could significantly expand its U.S. sales because it does not have access to critical prone SBBS patents, and in any event lacks the necessary infrastructure, track record, product acceptance, and resources to do so.

There is little prospect for new entry into the U.S. prone SBBS market. The strength and breadth of Hologic's patent portfolio, including the patents it acquired from Fischer, insulate the U.S. prone SBBS market from entry. In fact, no company has ever had a meaningful impact on the U.S. prone SBBS market without access to these critical patents. Hologic's MultiCare product, the only prone SBBS ever to compete effectively with Fischer's MammoTest, was able

to compete in the U.S. market only by virtue of a license to the Fischer patents that Hologic acquired as part of the settlement of patent infringement litigation. 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. Finally, a new entrant would also need to develop manufacturing capability and potentially recruit and train a local sales force in order to gain market acceptance and have an impact on price in the U.S. prone SBBS market.

V. The Proposed Consent Agreement

The proposed Consent Agreement effectively remedies the competitive harm that resulted from the Acquisition. Pursuant to the proposed Consent Agreement, Hologic is required to divest to Siemens all of the prone SBBS-related assets it acquired from Fischer no later than five (5) days after the Consent Agreement is accepted for public comment. Hologic will retain a license to Fischer's prone SBBS patents to ensure that Hologic can continue to compete in the U.S. prone SBBS market after the divestiture.

Siemens is particularly well-positioned to manufacture and sell prone SBBSs in the United States. Siemens is one of the world's largest public corporations, with 461,000 employees and over 600 manufacturing plants, research facilities and sales offices worldwide. Siemens Medical Solutions Group is a worldwide leader in medical imaging, with product offerings including angiography, fluoroscopy, magnetic resonance imaging, ultrasound, and mammography. As an established supplier of breast cancer related imaging products, Siemens has earned a strong reputation in the field of breast cancer screening and detection, and already has a domestic sales and service network in place to make it a vigorous prone SBBS competitor. Further, although it already has a mammography business, Siemens does not currently compete in the prone SBBS market, and thus does not present any competitive problems as an acquirer of the divested assets.

If the Commission determines that Siemens is not an acceptable purchaser, or that the manner of the divestiture is not acceptable, Hologic must unwind the sale and divest the prone SBBS assets within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If Hologic fails to divest within that time frame, the Commission may appoint a trustee to divest the prone SBBS assets.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the Consent Agreement or to modify its terms in any way.