**UNITED STATES INTERNATIONAL TRADE COMMISSION**
**Washington, D.C.**

| **In the Matter of**<br><br>**CERTAIN X-RAY BREAST IMAGING DEVICES AND COMPONENTS THEREOF** | **Inv. No. 337-TA-1063** |
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# NOTICE OF A COMMISSION DETERMINATION TO REVIEW THE FINAL INITIAL DETERMINATION IN-PART; EXTENSION OF THE TARGET DATE

**AGENCY**: U.S. International Trade Commission.

**ACTION**: Notice.

**SUMMARY**: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination ("ID") in-part and extend the target date for completion of the investigation until January 25, 2019.

**FOR FURTHER INFORMATION CONTACT**: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, D.C. 20436, telephone (202) 205-2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION**: The Commission instituted this investigation on August 1, 2017, based on a complaint and supplement, filed on behalf of Hologic, Inc. of Marlborough, Massachusetts ("Hologic"). 82 FR 35829-24 (Aug. 1, 2017). The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain x-ray breast imaging and components thereof by reason of infringement of certain claims of U.S. Patent No. 7,831,296 ("the '296 patent"); U.S. Patent No. 8,452,379 ("the '379 patent"); U.S. Patent No. 7,688,940 ("the '940 patent"); U.S. Patent No. 7,986,765 ("the '765 patent"); and U.S. Patent No. 7,123,684 ("the '684 patent"). The complaint further alleges that an industry in the United States exists as required by section 337. The Notice of Investigation named FUJIFILM Corporation of Tokyo, Japan; FUJIFILM Medical Systems USA, Inc. of Stamford, Connecticut; and FUJIFILM Techno Products Co., Ltd. of Hanamaki-Shi Iwate, Japan

(collectively, "Fujifilm") as respondents. The Office of Unfair Import Investigations ("OUII") was named as a party. On January 18, 2018, the '765 patent was terminated in its entirety from the investigation. *See* Order No. 18 (Jan. 18, 2018) (unreviewed).

On July 26, 2018, the ALJ issued the final ID and found a violation of section 337 has occurred. On August 8, 2018, Fujifilm and OUII each filed petitions for review of the final ID. On August 16, 2018, OUII and Hologic filed responses to the petitions for review.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, the Commission has determined to review the ID's findings on (1) *in rem* jurisdiction and importation; (2) all findings concerning infringement; (3) claim construction of the "dose" limitations of the '379 and '296 patents; (3) claim construction of the limitations including terms of degree (*i.e.*, similar, substantially less, much less, and substantially higher) in the '379 and '296 patents; (4) the "control"/"motion control" and "processor" limitations of the '379 and '296 patents; (5) the technical prong of domestic industry for the '379 and '296 patents; (6) claim construction of the "control" limitations of the '940 patent; (7) anticipation by the Kopans 2000 Army Report for the '379 and '296 patents; (8) anticipation by MGH/GE Prototype #2 for the '379 and '296 patents; (9) obviousness based on the publicly available MGH/GE References related to the MGH/GE Prototypes for the '379 and '296 patents; (10) anticipation by GE Senographe 2000D System and/or Manual for the '940 patent; (11) obviousness based on GE Senographe 2000D System and/or Manual with Dornheim for the '940 patent; (12) obviousness based on Niklason article, the GE Senographe DMR System and Dornheim for the '940 patent; and (13) indefiniteness under 35 U.S.C. § 112 for the '940 patent.

In connection with its review, the Commission is interested in responses to the following questions:

1. Was the argument that "conventional mammogram," as used in the '379 and '296 patents, should be construed to include diagnostic images waived? *See, e.g.,* OUII Petition for Review at 9-12; Complainant's Resp. to OUII Petition at 2-3.

2. Does the claimed "dose" for a "conventional mammogram," as used in the '379 and '296 patents, meet the indefiniteness standard set forth in *Nautilus, Inc.* v. *Biosig Instruments, Inc.,* 134 S. Ct. 2120 (2014). The Commission is most interested in a discussion of the relevant Federal Circuit precedent.

3. To what extent are the ID's findings on whether the "dose" for a conventional mammogram has changed over time necessary in establishing whether the "dose" for conventional mammogram is definite/indefinite? *See* ID at 60-61.

4. Please discuss whether the terms of degree, as used in the asserted claims of '379 and '296 patents, are indefinite. The Commission is interested in evidence that would provide an understanding of the terms to a person of ordinary skill in the art and the relevant case law.

5. The asserted claims of the '379 and '296 patents require a comparison of different x-ray doses and in particular, to a dose used for a conventional mammogram. Does the specification, claims, prosecution history, or extrinsic record shed light on whether the

comparison is made to a conventional two-dimensional system or whether the comparison is made to the two-dimensional mode on a device that performs both two-dimensional and three-dimensional imaging? *See, e.g.,* Fujifilm Petition for Review at 17.

6. Would claims 1, 2, and 22 of the '940 patent be anticipated by the GE Senographe 2000D System and/or Manual if the Commission were to find that the claims allow for the anti-scatter grid to be completely removed? *See, e.g.,* Fujifilm Petition for Review at 55-59.

The parties are requested to brief only the discrete issues above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

The Commission has also determined to extend the target date for completion of this investigation until January 25, 2019.

**WRITTEN SUBMISSIONS:** The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on public interest, remedy, and bonding. Complainant and the OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the subject patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the Respondents' products at issue in this investigation. Also specifically, with respect to the public interest, the Commission requests briefing on the following issue:

> Please discuss whether the accused Fujifilm products have been proven to be more effective in screening for breast cancer than comparable systems available in the United States (*e.g.,* systems from Hologic, Siemens, or GE). Please include evidence to support your position.

The written submissions and proposed remedial orders must be filed no later than close of business on November 5, 2018. Reply submissions must be filed no later than the close of business on November 13, 2018. Opening submissions are limited to 75 pages. Reply submissions are limited to 50 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) Of the Commission's Rules of Practice and Procedure (19 C.F.R. 2.10.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1063") in a prominent place on the cover page and/or the first page. *(See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/ handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[1] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

[1] All contract personnel will sign appropriate nondisclosure agreements.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 24, 2018