UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **Certain Mammography Systems with Focal Spot Compensation Technology and Components Thereof, Including X-Ray Tubes**	Investigation No. 337-TA-_____

COMPLAINANT'S PUBLIC INTEREST STATEMENT

Pursuant to 19 C.F.R. § 210.8(b), Complainant Hologic, Inc. ("Complainant" or "Hologic"), respectfully submits this Public Interest Statement concurrently with the above captioned Complaint. As set forth in the Complaint, Hologic contends that Siemens Healthineers AG, Siemens Healthcare GmbH, and Siemens Medical Solutions USA, Inc. (collectively, "Siemens" or "Proposed Respondents") violate Hologic's U.S. patent rights through the import and sale of mammography systems with focal spot compensation technology, including the MAMMOMAT B.brilliant system, and components thereof. At least one court has already held in Hologic's favor: on June 10, 2026, the Düsseldorf Local Division of the Unified Patent Court agreed that the MAMMOMAT B.brilliant system infringes a European counterpart to one of the U.S. patents being asserted by Hologic in the Complaint.

The issuance of a limited exclusion order and cease-and-desist orders covering the Accused Products will not adversely affect the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Thus, and for the reasons discussed below, this Investigation does not warrant delegating the development of a factual record on the statutory public interest factors to the ALJ.

I. HOW THE ARTICLES SUBJECT TO EXCLUSION ARE USED IN THE UNITED STATES

The Accused Products are mammography systems with focal spot compensation technology and components thereof, including X-ray tubes and X-ray tube assemblies. They are used in U.S. clinical settings for screening and diagnostic mammography, image-guided biopsy, and contrast-enhanced mammography. For example, the MAMMOMAT B.brilliant system is used to image the breast to detect and evaluate breast cancer and other breast abnormalities. X-ray tubes and X-ray tube assemblies are components used to generate the X-rays that are used to form the image. In addition to the X-ray tube itself, X-ray tube assemblies include adjacent mechanical and electrical subsystems.

II. THE REQUESTED EXCLUSION ORDER IS IN THE PUBLIC INTEREST

A. There are No Public Health, Safety, or Welfare Concerns Relating to the Requested Limited Exclusion Order

The issuance of the requested remedial order would not adversely affect the public health, safety, or welfare in the United States. While the Proposed Respondents' products are used in a medical setting, their products represent a small portion of the market for mammography systems. Hologic is more than capable of supplying substitutes for the Proposed Respondents' excluded products, obviating any concerns that the remedial orders would have adverse effects.

For example, Hologic has been recognized as the leader in the U.S. market for mammography equipment, while the Proposed Respondents have a relatively small U.S. market share that can be supplied by Hologic and other market participants. In 2023, GlobalData reported that Hologic held greater than half of the mammography equipment market in the United States, followed by GE Healthcare Technologies.[1] Similarly, according to IMV Medical Information

[1] https://www.medicaldevice-network.com/data-insights/market-share-analysis-mammography-equipment-the-us

Division's *2022 Mammography and Breast Imaging Market Outlook Report*, Hologic had the largest U.S. mammography installed base share with 69%, followed by GE HealthCare with 20% and Siemens Healthineers with 8%.[2] In 2025, Hologic's estimated share of the North American market for breast imaging equipment was approximately 65%, with Hologic and GE Healthcare together making up approximately 87% of the market. Siemens, on the other hand, had a corresponding estimated market share of less than 5%.

The ITC previously found that the public health, safety, and welfare would not be adversely affected when it analyzed the effect of the exclusion order in *Certain X-Ray Breast Imaging Devices and Components Thereof*, Inv. No. 337-TA-1063. In that investigation, Hologic sought an exclusion order against Fujifilm mammography devices and components that infringed Hologic's patents. Although then-ALJ Cheney recognized the importance of breast cancer screening, he found that "the public health and welfare [would] not be harmed in the event a limited exclusion order and cease and desist order are issued." *See Certain X-Ray Breast Imaging Devices and Components Thereof*, Inv. No. 337-TA-1063, Initial Determination at 284 (Sept. 13, 2018). The ALJ noted that Fujifilm "occupies a relatively small portion of the U.S. market and that other manufacturers can readily fill any void due to Fujifilm's absence." *Id*. The Staff in that case also recognized that "Hologic has the ability to increase its manufacturing capacity to meet market demand in the event the requested remedial orders are issued." *Id*. at 283.

Accordingly, given Hologic's relative market share and ability to increase manufacturing capacity, there are no public health, safety, or welfare considerations that caution against excluding the Proposed Respondents' infringing products.

[2] https://imvinfo.com/mammography-departments-expect-budgets-to-grow-by-nearly-10.

B. Like or Directly Competitive Articles Could Replace the Subject Articles if they were to be Excluded

The requested exclusion order will not harm the production of like or directly competitive articles in the United States. Hologic has the capacity to replace any articles subject to requested limited exclusion order in a commercially reasonable amount of time. Hologic is headquartered in Marlborough, Massachusetts and maintains the manufacturing facility for its patented Envision™ platform in Newark, Delaware. Hologic acquired its Newark manufacturing facility in 1999 and has expanded its operations to increase manufacturing capabilities. For instance, Hologic added a $14.8 million, 9,500 square-foot addition in 2012.[3] In 2021, Hologic announced a plan to invest more than $20 million to expand its operations in Delaware, including adding over 225 jobs.[4] Hologic has since completed that large-scale manufacturing expansion, including a 15,000 square-foot warehouse addition and 100,000 square-foot interior renovation, and is scaling production of its patented Envision™ platform. As a result, Hologic can meet the additional demand resulting from the Proposed Respondents' absence in the U.S. market.

C. The Requested Remedial Orders Would Not Adversely Impact Consumers

A limited exclusion order directed to the Accused Products would not adversely impact consumers because other manufacturers can supply mammography systems to the U.S. market, including to the more price-sensitive portions of that market. Hologic has sufficient production capacity in the United States to supply increased market demands resulting from the Proposed Respondents' absence, and "Hologic sells systems at a range of price points including lower cost systems." *See Certain X-Ray Breast Imaging Devices and Components Thereof*, Initial Determination at 291. The Proposed Respondents would also be free to revert back to their prior

[3] https://delawarebusinesstimes.com/news/hologic-expansion/
[4] https://www.choosedelaware.com/archives/global-womens-health-company-hologic-expands-in-delaware/

generation mammography devices, such as the MAMMOMAT Revelation, which did not include the infringing focal spot compensation technology.

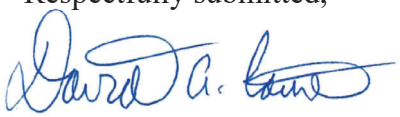
Moreover, the requested remedial orders would promote the public interest by enforcing U.S. patent rights. The Commission has made clear that the protection of intellectual property rights is strongly in the public interest. *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (III),* Inv. No. 337-TA-1076, Comm'n Op. at 64 (June 20, 2019); *see also Certain Digital Television Prods.*, Inv. No. 337-TA-617, Comm'n Op. at 9 (Aug. 2, 2009); *Certain Baseband Processor Chips*, Inv. No. 337-TA-543, Comm'n Op. at 136-37 (June 19, 2007) ("We must take into account the strong public interest in enforcing intellectual property rights"). By contrast, no plausible public interest would be served by continuing to allow the importation of infringing mammography systems and components. *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. (Pub. Version) at 68-69 (Apr. 9, 2019) (noting that the exclusion of infringing goods "is not a public interest concern."). Any public interest concerns implicated by this investigation, to the extent any exist, are outweighed by the countervailing interest in protecting Hologic's intellectual property rights.

III. CONCLUSION

Protecting Hologic's intellectual property rights and the associated domestic industry in the United States through the requested exclusion and cease and desist orders will serve the public interest without raising any concerns regarding public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. For these reasons, the Commission need not delegate fact finding on the statutory public interest factors to the ALJ.

Dated: November 16, 2026

Respectfully submitted,



Matthew M. Wolf
Brian D. Hill
David McMullen, Ph.D.
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave. NW
Washington, DC 20001
Tel: (202) 942-6745

David A. Caine
Arnold & Porter Kaye Scholer LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306-3807
Tel: (650) 319-4700

Ryan J. Casamiquela
Arnold & Porter Kaye Scholer LLP
Four Embarcadero Center, 14th Floor
San Francisco, CA 94111-4164
Tel: (415) 471-3100

Michelle Ban
Arnold & Porter Kaye Scholer LLP
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Tel: (213) 243-4000

Olivia Matthews
Arnold & Porter Kaye Scholer LLP
300 North LaSalle Drive, Suite 3500
Chicago, IL 60654
Tel: (312) 583-2300

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **Certain Mammography Systems with Focal Spot Compensation Technology and Components Thereof, Including X-Ray Tubes**	Investigation No. 337-TA-_____

COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

Complainant

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
USA
Phone: (508) 263-2900

Counsel for Complainant:

Matthew M. Wolf
Brian D. Hill
David McMullen, Ph.D.
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave. NW
Washington, DC 20001
Tel: (202) 942-6745

David A. Caine
Arnold & Porter Kaye Scholer LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306-3807
Tel: (650) 319-4700

Ryan J. Casamiquela
Arnold & Porter Kaye Scholer LLP
Four Embarcadero Center, 14th Floor
San Francisco, CA 94111-4164

Proposed Respondents

Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim
Germany
Phone: +49 69 797 6602

Siemens Healthcare GmbH
Henkestraße 127
91052 Erlangen
Germany
Phone: +49 62 243 3492

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
USA
Phone: (610) 448-4500

Tel: (415) 471-3100

Michelle Ban
Arnold & Porter Kaye Scholer LLP
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Tel: (213) 243-4000

Olivia Matthews
Arnold & Porter Kaye Scholer LLP
300 North LaSalle Drive, Suite 3500
Chicago, IL 60654
Tel: (312) 583-2300

TABLE OF CONTENTS

I. Introduction **1**
II. The Parties **3**
A. Complainant Hologic, Inc. 3
B. Proposed Respondents 6
1. Siemens Healthineers AG 6
2. Siemens Healthcare GmbH 6
3. Siemens Medical Solutions USA, Inc. 7
III. The Technology and Products at Issue **7**
A. The Technology at Issue 7
B. The Products at Issue 8
IV. The Asserted Patents 13
A. Ownership of the Asserted Patents 13
B. U.S. Patent No. 8,457,282 13
1. Identification of the Patent and Ownership 13
2. Non-Technical Description of the Patented Invention 14
3. Foreign Counterparts 15
C. U.S. Patent No. 8,515,005 15
1. Identification of the Patent and Ownership 15
2. Non-Technical Description of the Patented Invention 16
3. Foreign Counterparts 17
D. U.S. Patent No. 8,767,911 17
1. Identification of the Patent and Ownership 17
2. Non-Technical Description of the Patented Invention 18
3. Foreign Counterparts 19
E. U.S. Patent No. 9,502,148 19
1. Identification of the Patent and Ownership 19
2. Non-Technical Description of the Patented Invention 20
3. Foreign Counterparts 20
F. U.S. Patent No. 9,895,115 21
1. Identification of the Patent and Ownership 21
2. Non-Technical Description of the Patented Invention 22
3. Foreign Counterparts 22
G. Licensees Under the Asserted Patents 23
V. The Proposed Respondents' Unlawful and Unfair Acts 23
VI. Specific Instances of Unfair Importation and Sale 26
VII. Harmonized Tariff Schedule Numbers 29
VIII. Related Litigation 30
IX. Domestic Industry 31
A. Products that Practice the Asserted Patents 31
B. Domestic Investments in the United States Relating to the Products that Practice the Asserted Patents 32
1. Significant Investments in Plant and Equipment 32
2. Significant Employment of Labor or Capital 33

3. Substantial Investment in Engineering, Research and Development 33
4. Significance and Substantiality of Hologic's Domestic Investments 33
X. Relief Requested 34

LIST OF EXHIBITS

Exhibit Number	Description
1	Certified Copy of U.S. Patent No. 8,457,282
2	Certified Copy of U.S. Patent No. 8,515,005
3	Certified Copy of U.S. Patent No. 8,767,911
4	Certified Copy of U.S. Patent No. 9,502,148
5	Certified Copy of U.S. Patent No. 9,895,115
6	Certified Copy of Assignment for U.S. Patent No. 8,457,282
7	Certified Copy of Assignment for U.S. Patent No. 8,515,005
8	Certified Copy of Assignment for U.S. Patent No. 8,767,911
9	Certified Copy of Assignment for U.S. Patent No. 9,502,148
10	Certified Copy of Assignment for U.S. Patent No. 9,895,115
11	*3Dimensions Mammography System Named the Coolest Thing Made in Delaware*, Hologic Newsroom, https://www.hologic.com/about/newsroom/3dimensions-mammography-system-named-coolest-thing-made-delaware (last visited Sept. 21, 2026)
12	*FDA Approves New Innovations on Hologic's 3Dimensions™ Mammography System, the Fastest, Highest Resolution Breast Tomosynthesis System Ever*, Radiology Business (Mar. 27, 2018), https://radiologybusiness.com/topics/medical-imaging/diagnostic-imaging/fda-approves-new-innovations-hologics-3dimensionstm-mammography-system-fastest-highest-resolution (last visited Sept. 21, 2026)
13	*From 3D to AI and Beyond: How Hologic Continues to Shape the Future of Mammography*, Hologic Newsroom, https://www.hologic.com/about/newsroom/3d-ai-and-beyond-how-hologic-continues-shape-future-mammography (last visited Sept. 21, 2026)
14	*Hologic 3Dimensions Mammography System*, ICE Community (Oct. 1, 2024), https://theicecommunity.com/hologic-3dimensions-mammography-system-3/ (last visited Sept. 21, 2026)
15	*Hologic Ranked #1 for Mammography System Performance and Customer Satisfaction for 10th Consecutive Year*, Bus. Wire (Dec. 1, 2022), https://www.businesswire.com/news/home/20221201005352/en (last visited Sept. 21, 2026)
16	*Hologic Receives FDA Clearance for Genius AI Detection*, Imaging Tech. News (Dec. 2, 2020), https://www.itnonline.com/content/hologic-receives-fda-clearance-genius-ai-detection (last visited Sept. 21, 2026)
17	*Hologic Recognized as a Top Workplace by Forbes and Fortune*, Hologic Press Release (Sept. 23, 2025), https://www.hologic.com/about/press-release/hologic-recognized-top-workplace-forbes-and-fortune (last visited Sept. 21, 2026)

18	*Hologic's 3Dimensions System for 3D Mammography Receives EUREF Type Test Certification*, Imaging Tech. News (Nov. 3, 2022), https://www.itnonline.com/content/hologic%E2%80%99s-3dimensions-system-3d-mammography-receives-euref-type-test-certification (last visited Sept. 21, 2026)
19	*Hologic to Showcase AI-Powered Breast Imaging at RSNA*, 24x7 Mag. (Nov. 27, 2024), https://24x7mag.com/medical-equipment/imaging-equipment/mammography/hologic-to-showcase-ai-powered-breast-imaging-at-rsna/ (last visited Sept. 21, 2026)
20	*It's Genius: Hologic, Inc. Launches New Consumer Awareness Campaign for Its Breakthrough 3D Mammography Technology*, BioSpace (Oct. 1, 2014), https://www.biospace.com/it-s-genius-hologic-inc-launches-new-consumer-awareness-campaign-for-its-breakthrough-3d-mammography-technology (last visited Sept. 21, 2026)
21	*Why Every Patient's Breast Screening Experience Matters*, Imaging Tech. News (sponsored content) (Dec. 3, 2024), https://www.itnonline.com/article/why-every-patient%E2%80%99s-breast-screening-experience-matters (last visited Sept. 21, 2026)
22	Infringement Claim Chart of U.S. Patent No. 8,457,282 by the MAMMOMAT B.brilliant
23	Infringement Claim Chart of U.S. Patent No. 8,515,005 by the MAMMOMAT B.brilliant
24	Infringement Claim Chart of U.S. Patent No. 8,767,911 by the MAMMOMAT B.brilliant
25	Infringement Claim Chart of U.S. Patent No. 9,502,148 by the MAMMOMAT B.brilliant
26	Infringement Claim Chart of U.S. Patent No. 9,895,115 by the MAMMOMAT B.brilliant
27	Siemens Whitepaper, *Fast, high-resolution wide-angle digital breast tomosynthesis with MAMMOMAT B.brilliant*
28	*Hologic, Inc. v. Siemens Healthineers AG et al*., UPC_CFI_758/2024 & UPC_CFI_259/2025, Decision (LD Düsseldorf June 10, 2026)
29	*Siemens Healthcare GmbH v. Hologic, Inc.*, T 1762/21-3.2.02, Decision of the Technical Board of Appeal 3.2.02 (EPO Feb. 14, 2024)
30	510(k) Summary - K233539
31	Establishment Registration & Device Listing - 3004977335
32	510(k) Summary - K253678
33	Siemens Healthineers First U.S. Installation
34	Grace Imaging Spa - B.Brilliant Installation
35	Mountainside Medical Center - New Jersey's First MAMMOMAT B.brilliant Mammography System

36	[CONF] Claim Chart Showing Domestic Industry of U.S. Patent No. 8,457,282
37	[CONF] Claim Chart Showing Domestic Industry of U.S. Patent No. 8,515,005
38	[CONF] Claim Chart Showing Domestic Industry of U.S. Patent No. 8,767,911
39	[CONF] Claim Chart Showing Domestic Industry of U.S. Patent No. 9,502,148
40	[CONF] Claim Chart Showing Domestic Industry of U.S. Patent No. 9,895,115
41	MAMMOMAT B.brilliant 2D & 3D Turnover Workbook
42	MAMMOMAT B.brilliant Operator Manual QC VA10
43	MAMMOMAT B.brilliant Operator Manual Restrictions VA10
44	MAMMOMAT B.brilliant Operator Manual TSQC VA10
45	MAMMOMAT B.brilliant Operator Manual VA10
46	MAMMOMAT B.brilliant Quick Guide – Startup Guide
47	MAMMOMAT B.brilliant Customer Brochure
48	Press Release, Siemens Healthineers Presents Mammography System (2023)
49	[CONF] Envision User Guide
50	[CONF] Hologic PMA Supplement - Envision System
51	[CONF] Declaration of Jason Robards
52	[CONF] Hologic Lease Agreement - 250 Campus Drive
53	[CONF] Hologic Lease Agreement - Simarano Drive
54	[CONF] Hologic Lease Agreement – Newark
55	[CONF] Envision Resources - Program Life
56	[CONF] Envision Hours Reporting
57	[CONF] Envision PO Data Worksheet

APPENDICES

Appendix	Description
A1	Certified Prosecution History of U.S. Patent No. 8,457,282
A2	Certified Prosecution History of U.S. Patent No. 8,515,005
A3	Certified Prosecution History of U.S. Patent No. 8,767,911
A4	Certified Prosecution History of U.S. Patent No. 9,502,148
A5	Certified Prosecution History of U.S. Patent No. 9,895,115
B1	Prosecution History for Claimed Priority Provisional Application 61/117,453
B2	Prosecution History for Claimed Priority Application 14/319,170 (issued as U.S. Patent No. 9,226,721)

I. INTRODUCTION

1. Complainant Hologic, Inc. ("Hologic" or "Complainant"), files this Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"), based on the unlawful importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of certain mammography systems with focal spot compensation technology and components thereof, including X-ray tubes, that infringe Hologic's valid and enforceable U.S. patents.

2. Headquartered in Marlborough, Massachusetts, Hologic is an innovative medical technology company dedicated to improving women's health. Through operations across the United States, Hologic develops industry leading technologies relating to breast & skeletal health solutions, diagnostic solutions, and GYN surgical solutions. Hologic is known worldwide for pioneering commercial digital breast tomosynthesis (3D mammography), including transforming breast cancer screening through the introduction of the first FDA-approved 3D mammography system.

3. Hologic accuses Siemens Healthineers AG, Siemens Healthcare GmbH, and Siemens Medical Solutions USA, Inc. (collectively, "Siemens" or "Proposed Respondents") of infringing one or more claims of U.S. Patent No. 8,457,282 ("'282 Patent"), U.S. Patent No. 8,515,005 ("'005 Patent"), U.S. Patent No. 8,767,911 ("'911 Patent"), U.S. Patent No. 9,502,148 ("'148 Patent"), and U.S. Patent No. 9,895,115 ("'115 Patent") (together, the "Asserted Patents") based on the importation, sale for importation, or sale after importation of certain mammography systems with focal spot compensation technology, including the Siemens MAMMOMAT B.brilliant system and related configurations, and components thereof, including X-ray tubes and X-ray tube assemblies, whether imported within a system or separately ("Accused Products").

4. Hologic alleges that the Proposed Respondents infringe at least one or more of the following claims of the Asserted Patents in violation of Section 337(a)(1)(B)(i) and 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents:[5]

U.S. Patent No.	Asserted Claims[6]
8,457,282	**1**, **2**, 4, 5, 7 and **8**
8,515,005	**1**-4, 6-9, and **10**-18
8,767,911	**1**-8, and 10-19
9,502,148	**1**, 3-13, and **14**-18
9,895,115	**1**, 3-14, and **15**-20

Further investigation and discovery may reveal infringement of additional claims and/or additional accused models or configurations.

5. As required by 19 U.S.C. §§ 1337(a)(2) and (3), an industry exists in the United States relating to articles protected by the Asserted Patents. Hologic has its corporate headquarters in Marlborough, Massachusetts, alongside major operational, manufacturing, and R&D facilities across the United States and employs more than 4,000 employees in the United States across its operations, manufacturing, and research and development facilities. Hundreds of those United States employees play a critical role in the research, development, manufacture, and sale of its breakthrough Envision™ platform, a next-generation mammography system redesigned from the ground up to be the most advanced, patient-centric breast imaging platform on the market.

6. Hologic seeks a permanent limited exclusion order prohibiting entry into the United States of the Proposed Respondents' infringing Accused Products.

[5] All five Asserted Patents are related. The '005 Patent is a continuation-in-part of the '282 Patent and the '911, '148, and '115 Patents are related to the '005 Patent through a series of continuation applications.

[6] Independent claims are separately identified in bold and underlined.

7. Hologic also seeks permanent cease and desist orders prohibiting the Proposed Respondents from importing, admitting or withdrawing from a foreign trade zone, marketing, advertising, demonstrating, warehousing inventory of, distributing, offering for sale, selling, licensing, repairing, transferring (except for exportation), soliciting U.S. agents or distributors for, or aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of their Accused Products.

8. Hologic also requests that the Commission require an appropriate bond to protect it from injury from importations of Accused Products during the 60-day Presidential Review period.

II. THE PARTIES

A. Complainant Hologic, Inc.

9. Complainant Hologic, Inc. is a Delaware corporation with its headquarters at 250 Campus Drive, Marlborough, Massachusetts 01752.

10. Hologic is a global leader in women's health, dedicated to developing innovative medical technologies that detect, diagnose, and treat health conditions and raise the standard of care around the world. **Exhibit 17**. Hologic's core business units are focused on diagnostics, breast health, GYN surgical, and skeletal health, and Hologic describes its research and development program as being dedicated to "The Science of Sure." **Exhibit 20**.

11. Hologic has long been at the forefront of breast cancer detection technology. In the early 2000s, a small team within Hologic — including company co-founder Jay Stein — set out to build the first three-dimensional ("3D") mammography system. **Exhibit 13**. That effort led to the Selenia® Dimensions® system, which received the CE mark in Europe in 2008 and, in February 2011, became the first 3D mammography (digital breast tomosynthesis) system ever approved by the FDA. *Id*.; **Exhibit 20**. In 2013, Hologic earned FDA approval for its C-View® two-dimensional

image-reconstruction software, which allows radiologists to view a conventional 2D image reconstructed directly from the 3D scan itself — eliminating the need for a separate 2D exposure and thereby lowering the patient's radiation dose and shortening the overall scan time. **Exhibit 13**. Hologic is the pioneer behind the resulting Genius3D® exam —the only mammogram at the time it was introduced approved by the FDA as clinically superior to conventional 2D mammography for all women, including those with dense breasts. **Exhibit 12**; **Exhibit 15.**

12. Hologic has continued to build on this foundational technology. In 2018, the company earned FDA approval for its Hologic Clarity HD® high-resolution 3D imaging technology, together with Intelligent 2D™ imaging and the SmartCurve® breast stabilization system, further accelerating screening and analysis while improving patient comfort. **Exhibit 12**. The following year, in 2019, the FDA approved Hologic's 3DQuorum® imaging technology, powered by Genius AI® technology, which reduces the number of tomosynthesis images a radiologist must review without compromising image quality, sensitivity, or accuracy— the first of what would become a full suite of Hologic products built on the Company's Genius AI platform. **Exhibit 13.** Hologic's 3Dimensions™ system remains an industry leader, delivering the fastest and highest-resolution 3D images available at the same 70-micron pixel size as full-field digital mammography, and incorporating Hologic's Genius AI Detection solution, which achieves a 94% sensitivity rate in flagging lesions likely to represent breast cancer. **Exhibit 14**. In 2020, Hologic received FDA clearance for that Genius AI Detection software, a deep-learning technology designed to help radiologists identify subtle, early-stage cancers with fewer false positives. **Exhibit 16**.

13. More recently, Hologic introduced its Envision™ platform — the first FDA-approved mammography focusing technology of its kind — which acquires a high-speed 3D

mammogram in 2.5 seconds while enhancing detection of subtle findings and improving image sharpness. **Exhibit 19**; **Exhibit 21**. Consistent with Hologic's patient-first mission, the Envision platform's tilt positioning and SmartCurve system are designed to improve comfort and expand access to high-quality screening for historically underserved patients, including patients with limited mobility. **Exhibit 21**.

14. Hologic's commitment to women's health, and the quality of its technology, has been widely recognized. Hologic routinely ranks number one in the mammography industry for system performance and customer satisfaction, including sweeping the 2022 IMV ServiceTrak™ Awards for Mammography — including Best Service, Best Customer Satisfaction, and Best System Performance. **Exhibit 15**. Hologic also champions women's health more broadly through its Global Women's Health Index, which the company describes as a science-backed data roadmap for improving women's well-being worldwide. *Id*.

15. Hologic has received numerous additional accolades and industry recognitions, including the following:

- **EUREF Type Test Certification (2022).** Hologic's 3Dimensions™ system became the first digital breast tomosynthesis (DBT) system — and one of only nine mammography systems worldwide — to receive EUREF Type Test certification from the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services, reflecting compliance with rigorous European image-quality, dose, and stability standards. **Exhibit 18**.
- **Excellence in Imaging Informatics Award (2024).** Hologic became the first organization ever selected to receive the Excellence in Imaging Informatics Award from the American Board of Imaging Informatics, recognizing Hologic's commitment to imaging workflow and informatics integration. **Exhibit 19**.
- **"Coolest Thing Made in Delaware" (2024).** Hologic's 3Dimensions™ mammography system was voted the "Coolest Thing Made in Delaware" by the Delaware State Chamber of Commerce, beating out more than fifty products from forty companies manufactured in the state. **Exhibit 11**.

- **America's Best Employers for Company Culture (2025).** Forbes and Statista named Hologic to their "America's Best Employers for Company Culture 2025" list, based on survey responses from more than 218,000 workers nationwide. **Exhibit 17**.
- **America's Best Workplaces in Health Care (2025).** Fortune and Great Place to Work® named Hologic one of "America's Best Workplaces in Health Care in 2025," based on employee feedback regarding trust in management, connection with colleagues, and loyalty to the Company. *Id*.

16. As these and other recognitions reflect, Hologic has established itself as an innovative leader in medical technology generally, and in breast health and women's health specifically, with a decades-long record of pioneering technologies that have improved patient outcomes throughout the United States and around the world.

B. Proposed Respondents

17. As discussed in greater detail below, on information and belief, each of the Proposed Respondents sells the Accused Products for importation into the United States, imports the Accused Products into the United States, and/or sells the Accused Products within the United States after importation.

1. Siemens Healthineers AG

18. Siemens Healthineers AG is organized under the laws of Germany and has a principal place of business at Siemensstrasse 3, 91301 Forchheim, Germany. On information and belief, Siemens Healthineers AG is a parent company to Siemens Healthcare GmbH.

19. On information and belief, Siemens Healthineers AG manufactures and/or has manufactured on its behalf and sells the Accused Products for importation into the United States.

2. Siemens Healthcare GmbH

20. Siemens Healthcare GmbH is organized under the laws of Germany and has a principal place of business at Henkestraße 127, 91052 Erlangen, Germany.

21. On information and belief, Siemens Healthcare GmbH manufactures and/or has manufactured and sells the Accused Products for importation into the United States.

3. Siemens Medical Solutions USA, Inc.

22. Siemens Medical Solutions USA, Inc. is organized under the laws of Delaware and has a principal place of business at 40 Liberty Boulevard, Malvern, Pennsylvania 19355.

23. On information and belief, Siemens Medical Solutions USA, Inc. imports the Accused Products into the United States and then sells the Accused Products in the United States after importation.

III. THE TECHNOLOGY AND PRODUCTS AT ISSUE

A. The Technology at Issue

24. Breast tomosynthesis acquires multiple X-ray projection images of a compressed breast over a range of angles and reconstructs those projections into a three-dimensional image set. During a continuous scan, movement of the X-ray source during an exposure can enlarge the effective focal spot and introduce blur.

25. Hologic's patented technology addresses this problem by controlling focal-spot characteristics during image acquisition. In representative embodiments of the Asserted Patents, the focal spot is moved in a direction opposite to the movement of the X-ray source during an exposure, so that the effective focal spot remains substantially fixed relative to the breast and/or detector, thereby reducing blur and improving image clarity.

26. The Asserted Patents include two related groups of claims. Group I, which consists of the '282 Patent and '911 Patent, generally includes claims directed to opposite/synchronous focal-spot movement and, in certain claims, multiple imaging modes. Group II, which consists of the '148, '115, and '005 Patents, generally includes additional claim features concerning control of the focal spot and collimation during imaging.

27. The Proposed Respondents twice challenged the validity of Hologic's EP 2 352 431 ("EP '431")—the European counterpart to Hologic's '282 Patent. First, Proposed Respondent Siemens Healthcare GmbH challenged the patent before the European Patent Office (EPO); the Opposition Division rejected Proposed Respondent Siemens Healthcare GmbH's opposition, and the EPO Technical Board of Appeal rejected Proposed Respondent's appeal in February 2024. Subsequently, after Hologic sued Proposed Respondents Siemens Healthineers AG and Siemens Healthcare GmbH, as well as two other Siemens entities, Siemens Healthineers Nederland B.V. and Siemens Healthcare SAS, in the Unified Patent Court (UPC) alleging that MAMMOMAT B.brilliant infringed EP '431, Proposed Respondents Siemens Healthcare GmbH and Siemens Healthineers AG challenged EP '431's validity through a counterclaim for revocation. In June 2026, the UPC rejected that validity challenge and separately found that MAMMOMAT B.brilliant infringed EP '431.

B. The Products at Issue

28. Pursuant to 19 C.F.R. §§ 210.10(b)(1) and 210.12(a)(12), the Accused Products are mammography systems with focal spot compensation technology and components thereof, and specifically Siemens MAMMOMAT B.brilliant mammography systems, X-ray tubes, and X-ray tube assemblies that are imported, sold for importation, or sold after importation in the United States, whether imported within a MAMMOMAT B.brilliant system or separately.

29. The Proposed Respondents introduced MAMMOMAT B.brilliant to the market in September 2023 as their next-generation mammography platform. The system performs both conventional two-dimensional mammography and three-dimensional digital breast tomosynthesis and incorporates what Proposed Respondents call "PlatinumTomo," which combines 50° wide-angle tomosynthesis, a new detector, PREMIA image reconstruction, and a newly developed X-ray tube using flying-focal-spot technology. The MAMMOMAT B.brilliant is shown below.



Exhibit 47.

30. A central feature of MAMMOMAT B.brilliant is its flying-focal-spot technology. During tomosynthesis, the X-ray tube moves continuously through a 50° angular range while the system acquires 25 projection images. Proposed Respondents explain that, during each X-ray pulse, an electron beam is deflected by an electromagnetic field so that the focal spot on the anode moves linearly in the direction opposite the movement of the X-ray tube. According to Proposed Respondents, this counter-movement causes the focal spot to appear stationary when observed from outside the tube during the X-ray pulse, after which the focal spot is returned to its starting position for the next projection. Proposed Respondents state that this technology compensates for tube motion, reduces image blur, and permits B.brilliant to obtain high-resolution, wide-angle tomosynthesis images at increased scanning speeds. *See* **Exhibit 27** at 8–9. Proposed Respondents' own whitepaper describes the focal spot as moving opposite the tube during each pulse and returning after the pulse.

31. Proposed Respondents sought authorization to market the MAMMOMAT B.brilliant in the United States through FDA Premarket Notification K233539. FDA cleared that

submission on March 27, 2024. The cleared device was identified as the MAMMOMAT B.brilliant with VA10, and Proposed Respondents represented that the system uses the same intended use and fundamental scientific technology as its predicate mammography system. *See* **Exhibit 30**. Proposed Respondents thereafter commercially introduced B.brilliant in the United States, including installation of the first reported commercial U.S. system at Grace Breast Imaging & Medical Spa in Iowa in or around January 2025, as discussed below.

32. Proposed Respondents subsequently submitted a second 510(k), K253678, for MAMMOMAT B.brilliant, corresponding to the later VA11 configuration, which FDA cleared on June 18, 2026. That submission continues to identify the regulated device as "MAMMOMAT B.brilliant" and covers the same digital mammography platform, while adding or modifying functionality associated with the later product configuration, including additional biopsy and dual-energy capabilities. The indications for use continue to identify MAMMOMAT B.brilliant as a digital mammography system for mammography examinations, screening, diagnosis, biopsies, and dual-energy procedures. *See* **Exhibit 32.**

33. The later VA11 configuration does not constitute a materially different accused product with respect to the focal-spot-compensation technology at issue here. Rather, VA10 and VA11 are versions or configurations of the same MAMMOMAT B.brilliant platform. Proposed Respondents themselves market the platform as modular and "future-ready," including through software updates and upgrades over the product's lifecycle. *See* **Exhibit 47**. Both FDA clearances identify the device by the same MAMMOMAT B.brilliant product name, and the later clearance does not identify a replacement mammography platform. On information and belief, the VA11 configuration retains the B.brilliant hardware and flying-focal-spot functionality relevant to infringement of the Asserted Patents. Accordingly, unless otherwise indicated, references in this

Complaint to "MAMMOMAT B.brilliant" or the "Accused Products" encompass both the VA10 and VA11 versions and other B.brilliant configurations incorporating the accused technology.

34. The dispute between Hologic and Proposed Respondents concerning this technology predates this Investigation. Hologic owns EP '431, the European counterpart to Hologic's asserted '282 Patent. EP '431, like the '282 Patent, concerns controlling X-ray focal-spot characteristics during mammography and tomosynthesis. Proposed Respondent Siemens Healthcare GmbH challenged the validity of EP '431 in an EPO opposition filed in 2019. The EPO Opposition Division rejected Proposed Respondent's opposition in June 2021, and its written decision was posted on August 5, 2021, and the EPO Technical Board of Appeal rejected Proposed Respondent's subsequent appeal in February 2024, leaving the patent in force.

35. After Proposed Respondents introduced MAMMOMAT B.brilliant, Hologic brought an infringement action against Proposed Respondents Siemens Healthineers AG and Siemens Healthcare GmbH, as well as two other Siemens entities, Siemens Healthineers Nederland B.V. and Siemens Healthcare SAS, in the Düsseldorf Local Division of the Unified Patent Court asserting that the B.brilliant system infringed EP '431. Proposed Respondents Siemens Healthcare GmbH and Siemens Healthineers AG, and two other Siemens affiliates, denied infringement and again challenged the validity of Hologic's patent, this time through a counterclaim seeking revocation of EP '431. The UPC therefore considered both whether Hologic's patent remained valid and whether Proposed Respondents' MAMMOMAT B.brilliant practiced the patented focal-spot technology. *See* **Exhibit 28**. The UPC decision identifies the accused embodiment specifically as the MAMMOMAT B.brilliant, which Proposed Respondents introduced to the market in September 2023.

36. On June 10, 2026, the UPC ruled in Hologic's favor. The UPC rejected Proposed Respondents' validity challenge and found that MAMMOMAT B.brilliant infringes Hologic's EP '431 patent. Among other things, the court considered the B.brilliant X-ray tube and focal-spot-compensation functionality and found that the accused system satisfied the patent's requirements concerning movement of the focal spot during X-ray-tube movement. The European claims require, among other things, movement of the static focal spot within the X-ray tube in a direction opposite to and generally synchronized with tube movement so that the resulting effective focal spot appears fixed in space during the exposure. The court also rejected Proposed Respondents' position concerning the claimed "focusing cup" and found that the B.brilliant contains the required focusing-cup structure.

37. The UPC accordingly determined that Proposed Respondents' MAMMOMAT B.brilliant uses technology protected by Hologic's European patent and entered relief against Proposed Respondents based on that infringement. Although the claims asserted in this Investigation are U.S. patent claims and infringement must be determined independently under U.S. law, the UPC proceeding is significant to the history of the parties and the accused technology: a court has already considered Proposed Respondents' MAMMOMAT B.brilliant, evaluated its focal-spot-compensation implementation, rejected Siemens's validity challenge to Hologic's related European patent, and found B.brilliant to infringe that patent. The Asserted U.S. Patents protect Hologic innovations relating to the same general field of focal-spot control and related tomosynthesis technology.

38. Notwithstanding the UPC's infringement determination, Proposed Respondents continue to market and sell MAMMOMAT B.brilliant, including in the United States. As discussed below, Siemens manufactures the accused systems in Germany; Siemens Medical Solutions USA,

Inc. is identified in Siemens's FDA submissions as the U.S. importer and distributor; and B.brilliant systems have been imported, sold, installed, and used at healthcare facilities in the United States. Hologic brings this Investigation to prevent the continued importation and sale after importation of MAMMOMAT B.brilliant systems that infringe Hologic's U.S. patent rights.

IV. THE ASSERTED PATENTS

A. Ownership of the Asserted Patents

39. Hologic owns the entire right, title, and interest in and to each of the Asserted Patents. Certified copies of the assignments for each of the Asserted Patents are attached as **Exhibits 6-10**.

B. U.S. Patent No. 8,457,282

1. Identification of the Patent and Ownership

40. The '282 Patent, entitled "Method and System for Controlling X-Ray Focal Spot Characteristics for Tomosynthesis and Mammography Imaging," issued on June 4, 2013 and names Baorui Ren, Jay Stein, Zhenxue Jing, and Andrew Smith as inventors. The '282 Patent issued from U.S. Patent Application No. 12/623,472 ("'472 application"), which was filed November 23, 2009, and expires July 10, 2030.[7]

41. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '282 Patent is attached as **Exhibit 1**.

42. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each assignment for the '282 Patent is attached as **Exhibit 6**.

43. Pursuant to Commission Rule 210.12(c)(1), a certified copy of the prosecution history of the '282 Patent is attached as Appendix A1.

[7] Hologic has filed an application for patent term extension under 35 U.S.C. § 156 to extend the expiration date of the '282 Patent from July 10, 2030 to October 20, 2033.

44. The ’472 application claims priority to U.S. Provisional Patent Application No. 61/117,453 (“’453 provisional application”), which was filed November 24, 2008. Pursuant to Commission Rule 210.12(c)(2), a copy of the prosecution history of each priority application is attached as follows:

Priority Application	Attached As
61/117,453	Appendix B1

45. The ’282 Patent has 13 claims, of which 3 are independent. Hologic is asserting claims 1, 2, 4, 5, 7 and 8.

2. Non-Technical Description of the Patented Invention

46. Pursuant to Commission Rule 210.12(a)(9)(vi), the ’282 Patent generally concerns improved digital X-ray scanning systems and methods for imaging a patient’s breast using mammography and tomosynthesis. Breast tomosynthesis is a three-dimensional imaging technology that involves acquiring images of a stationary compressed breast at multiple angles during a short scan. The individual two-dimensional images are then reconstructed into a three-dimensional image. Reconstructed tomosynthesis slices reduce or eliminate the problems caused by tissue overlap and structure noise in single slice two-dimensional mammography imaging. Digital breast tomosynthesis also offers the possibility of increased scanning speed, reduced breast compression and compression time, improved diagnostic and screening accuracy, fewer recalls, and 3D lesion localization.

47. The system can include an X-ray tube, compression paddles, an anti-scatter grid and a detector, coupled to a gantry. The X-ray tube may include a cathode, an anode that is mounted on a shaft and rotated by a motor, and a tube port. More specifically, an X-ray tube is described that includes components for increasing X-ray image clarity in the presence of a moving X-ray source by modifying focal spot characteristics, including focal spot size and focal spot position. In

one embodiment, a static focal spot is moved in a direction opposite to the movement of the X-ray source so that an effective focal spot position is essentially fixed in space relative to one of the imaged object and/or detector during a tomosynthesis exposure.

3. Foreign Counterparts

48. Pursuant to Commission Rule 210.12(a)(9)(v), a list of each foreign patent, each foreign or domestic patent application (not already issued as a patent), and each foreign or domestic patent application that has been denied, abandoned or withdrawn, corresponding to the '282 Patent, with an indication of the prosecution status of each such patent application, is as follows:

Jurisdiction	Patent / Application Number	Status
US	14/521,790	Abandoned
EP	2352431	Granted
CN	102176866	Granted
CA	2736592	Granted
CN	103417236	Granted
KR	101639374	Granted
AU	2009316352	Abandoned
ES	2692344	Granted
WO	2010/060007	Expired
JP	2012509714	Granted

C. U.S. Patent No. 8,515,005

1. Identification of the Patent and Ownership

49. The '005 Patent, entitled "Tomosynthesis With Shifting Focal Spot and Oscillating Collimator Blades," issued on August 20, 2013 and names Baorui Ren, Andrew Smith, Thomas Farbizio, Zhenxue Jing, and Jay Stein as inventors. The '005 Patent issued from U.S. Patent Application No. 12/849,294 ("'294 application"), which was filed August 3, 2010, and expires March 27, 2031.

50. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the ’005 Patent is attached as **Exhibit 2**.

51. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each assignment for the ’005 Patent is attached as **Exhibit 7**.

52. Pursuant to Commission Rule 210.12(c)(1), a certified copy of the prosecution history of the ’005 Patent is attached as Appendix A2.

53. The ’294 application is a continuation-in-part of the ’472 application (issued as the ’282 Patent), which claims priority to the ’453 provisional application. Pursuant to Commission Rule 210.12(c)(2), a copy of the prosecution history of each priority application is attached as follows:

Priority Application	Attached As
61/117,453	Appendix B1
12/623,472 (8,457,282)	Appendix A1

54. The ’005 Patent has 18 claims, of which 2 are independent. Hologic is asserting claims 1-4, 6-9, and 10-18.

2. Non-Technical Description of the Patented Invention

55. Pursuant to Commission Rule 210.12(a)(9)(vi), the ’005 Patent generally concerns improving tomosynthesis image quality by coordinating movement of the X-ray source, focal spot, and collimator during image acquisition. The patent addresses the blurring that can result from continuous movement of the X-ray source during an exposure and describes moving the focal spot and collimator in a direction opposite to, and generally synchronized with, the X-ray source. The synchronized movement is intended to keep the effective focal spot fixed in space relative to the breast and maintain the X-ray field on the detector and breast, with the focal spot and collimator repositioned between successive exposures as the tomosynthesis scan progresses. The ’005 Patent

further describes using a motion controller and processor to coordinate these movements, including embodiments in which electron trajectory is controlled within the X-ray tube to shift the focal spot and the coordinated movements continue throughout an exposure.

3. Foreign Counterparts

56. Pursuant to Commission Rule 210.12(a)(9)(v), there are no known foreign patents, foreign or domestic patent applications (not already issued as a patent), or foreign or domestic patent applications that have been denied, abandoned or withdrawn, corresponding to the '005 Patent.

D. U.S. Patent No. 8,767,911

1. Identification of the Patent and Ownership

57. The '911 Patent, entitled "Tomosynthesis With Shifting Focal Spot and Oscillating Collimator Blades," issued July 1, 2014 and names Baorui Ren, Andrew Smith, Thomas Farbizio, Zhenxue Jing, and Jay Stein as inventors. The '911 Patent issued from U.S. Patent Application No. 13/966,606 ("'606 application"), which was filed August 14, 2013, and expires November 23, 2029.[8]

58. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '911 Patent is attached as **Exhibit 3**.

59. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each assignment for the '911 Patent is attached as **Exhibit 8**.

60. Pursuant to Commission Rule 210.12(c)(1), a certified copy of the prosecution history of the '911 Patent is attached as Appendix A3.

[8] Hologic has filed an application for patent term extension under 35 U.S.C. § 156 to extend the expiration date of the '911 Patent from November 23, 2029 to March 5, 2033.

61. The ’606 application is a continuation of the ’294 application (issued as the ’005 Patent), which is a continuation-in-part of the ’472 application (issued as the ’282 Patent), which claims priority to the ’453 provisional application. Pursuant to Commission Rule 210.12(c)(2), a copy of the prosecution history of each priority application is attached as follows:

Priority Document	Attached As
61/117,453	Appendix B1
12/623,472 (8,457,282)	Appendix A1
12/849,294 (8,515,005)	Appendix A2

62. The ’911 Patent has 19 claims, of which 1 is independent. Hologic is asserting claims 1-8, and 10-19.

2. Non-Technical Description of the Patented Invention

63. Pursuant to Commission Rule 210.12(a)(9)(vi), the ’911 Patent generally concerns reducing image blur in tomosynthesis systems caused by movement of the X-ray source during image acquisition. The patent describes coordinating movement of the X-ray source, focal spot, and collimator during an exposure so that the focal spot and collimator move opposite the direction of the X-ray source. This synchronized movement is intended to keep the effective focal spot fixed in space relative to the breast and maintain a static X-ray field on the breast and detector during the exposure. Between exposures, the focal spot and collimator return to their starting positions and repeat the process as the X-ray source continues through the tomosynthesis scan; the system can then return them to a center position for conventional 2D mammography. The ’911 Patent also describes controlling focal-spot position by deflecting the electron trajectory within the X-ray tube and coordinating the movements through system controllers.

3. Foreign Counterparts

64. Pursuant to Commission Rule 210.12(a)(9)(v), there are no known foreign patents, foreign or domestic patent applications (not already issued as a patent), or foreign or domestic patent applications that have been denied, abandoned or withdrawn, corresponding to the '911 Patent.

E. U.S. Patent No. 9,502,148

1. Identification of the Patent and Ownership

65. The '148 Patent, entitled "Tomosynthesis With Shifting Focal Spot and Oscillating Collimator Blades," issued November 22, 2016 and names Baorui Ren, Andrew Smith, Thomas Farbizio, Zhenxue Jing, and Jay Stein, as inventors. The '148 Patent issued from U.S. Patent Application No. 14/966,011 ("'011 application"), which was filed December 11, 2015, and expires November 23, 2029.

66. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '148 Patent is attached as **Exhibit 4**.

67. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each assignment for the '148 Patent is attached as **Exhibit 9**.

68. Pursuant to Commission Rule 210.12(c)(1), a certified copy of the prosecution history of the '148 Patent is attached as Appendix A4.

69. The '011 application is a continuation of U.S. Patent Application 14/319,170 ("'170 application"), filed June 30, 2014 (issued as U.S. Patent No. 9,226,721, the "'721 patent"), which is a continuation of the '606 application (issued as the '911 Patent), which is a continuation of the '294 application (issued as the '005 Patent), which is a continuation-in-part of the '472 application (issued as the '282 Patent), which claims priority to the '453 provisional application. Pursuant to

Commission Rule 210.12(c)(2), a copy of the prosecution history of each priority application is attached as follows:

Priority Document	Attached As
61/117,453	Appendix B1
12/623,472	Appendix A1
12/849,294	Appendix A2
13/966,606	Appendix A3
14/319,170	Appendix B2

70. The ’148 Patent has 18 claims, of which 2 are independent. Hologic is asserting claims 1, and 3-18.

2. Non-Technical Description of the Patented Invention

71. Pursuant to Commission Rule 210.12(a)(9)(vi), the ’148 Patent generally concerns improving tomosynthesis imaging by coordinating movement of components of the X-ray system during image acquisition. The patent addresses the image-blurring problem created when the X-ray source moves continuously during an exposure and describes synchronized movement of the X-ray source, collimator blades, and, in certain embodiments, the focal spot. In particular, the patent describes moving the collimator blades in coordination with the focal spot and X-ray tube to help maintain the effective focal spot and X-ray field in a stable position during an exposure, with the components repositioned as the system proceeds through the tomosynthesis scan. The ’148 Patent also describes use of a motion controller to synchronize these movements and embodiments in which the detector itself moves in coordination with the X-ray source.

3. Foreign Counterparts

72. Pursuant to Commission Rule 210.12(a)(9)(v), there are no known foreign patents, foreign or domestic patent applications (not already issued as a patent), or foreign or domestic

patent applications that have been denied, abandoned or withdrawn, corresponding to the '148 Patent.

F. U.S. Patent No. 9,895,115

1. Identification of the Patent and Ownership

73. The '115 Patent, entitled "Tomosynthesis With Shifting Focal Spot and Oscillating Collimator Blades," issued on February 20, 2018 and names Baorui Ren, Andrew Smith, Thomas Farbizio, Zhenxue Jing, and Jay Stein, as inventors. The '115 Patent issued from U.S. Patent Application No. 15/357,857 ("'857 application"), which was filed November 21, 2016, and expires November 23, 2029.[9]

74. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '115 Patent is attached as **Exhibit 5**.

75. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each assignment for the '115 Patent is attached as **Exhibit 10**.

76. Pursuant to Commission Rule 210.12(c)(1), a certified copy of the prosecution history of the '115 Patent is attached as Appendix A5.

77. The '857 application is a continuation of the '011 application (issued as the '148 Patent), which is a continuation of the '170 application (issued as the '721 patent), which is a continuation of the '606 application (issued as the '911 Patent), which is a continuation of the '294 application (issued as the '005 Patent), which is a continuation-in-part of the '472 application (issued as the '282 Patent), which claims priority to the '453 provisional application. Pursuant to Commission Rule 210.12(c)(2), a copy of the prosecution history of each priority application is attached as follows:

[9] Hologic has filed an application for patent term extension under 35 U.S.C. § 156 to extend the expiration date of the '002 patent from November 23, 2029 to January 29, 2033.

Priority Document	Attached As
61/117,453	Appendix B1
12/623,472	Appendix A1
12/849,294	Appendix A2
13/966,606	Appendix A3
14/966,011	Appendix A4
14/319,170	Appendix B2

78. The ’115 Patent has 20 claims, of which 2 are independent. Hologic is asserting claims 1, and 3-20.

2. Non-Technical Description of the Patented Invention

79. Pursuant to Commission Rule 210.12(a)(9)(vi), the ’115 Patent generally concerns improving tomosynthesis imaging by coordinating movement of the X-ray source, collimator, and focal spot during image acquisition. The patent addresses image blurring associated with movement of the X-ray source and describes moving the focal spot and collimator in coordination with, and generally opposite to, the X-ray source during an exposure. The synchronized movement is intended to control the size and/or position of the focal spot, including maintaining the effective focal spot fixed in space relative to the breast while maintaining the X-ray field on the detector and breast. The ’115 Patent also describes coordinated movement of the detector, positioning and repositioning of the collimator during the scan, and use of a motion controller to synchronize the system components.

3. Foreign Counterparts

80. Pursuant to Commission Rule 210.12(a)(9)(v), there are no known foreign patents, foreign or domestic patent applications (not already issued as a patent), or foreign or domestic patent applications that have been denied, abandoned or withdrawn, corresponding to the ’115 Patent.

G. Licensees Under the Asserted Patents

81. There have been no exclusive or non-exclusive licenses granted under any of the Asserted Patents.

V. THE PROPOSED RESPONDENTS' UNLAWFUL AND UNFAIR ACTS

82. The Proposed Respondents have engaged in unfair trade practices, including the sale for importation, importation, and/or sale after importation of the Accused Products that infringe the Asserted Patents. These activities by the Proposed Respondents constitute a violation of Section 337.

83. As discussed below, the Proposed Respondents directly infringe, literally or under the doctrine of equivalents, actively induce the infringement of, and/or contributorily infringe one or more asserted claims of the Asserted Patents in violation of Section 337(a)(1)(B)(i) and 35 U.S.C. §§ 271(a), (b), and/or (c). The infringement allegations contained in this Complaint include the Proposed Respondents' (i) direct infringement of the asserted claims (literally and/or under the doctrine of equivalents); (ii) infringement by inducement by exhibiting an affirmative intent to cause direct infringement of the asserted claims, and/or (iii) contributory infringement by knowingly selling products or components thereof without substantial non-infringing uses that are the same or especially made or especially adapted for use in an infringement of the asserted claims.

84. The Proposed Respondents have directly infringed, either literally or through the doctrine of equivalents, at least claims 1, 2, 4, 5, 7 and 8 of the '282 Patent, claims 1-4 and 6-18 of the '005 Patent, claims 1-8 and 10-19 of the '911 Patent, claims 1 and 3-18 of the '148 Patent, and claims 1 and 3-20 of the '115 Patent through the manufacture, importation, distribution, and sale of the Accused Products.

85. The Proposed Respondents have also induced, and continue to induce, others to infringe the asserted claims. The Proposed Respondents have taken active steps to encourage and

facilitate direct infringement by others, such as sellers, distributors, and users of the Accused Products, with knowledge of infringement. For example, the Proposed Respondents have encouraged customers and end users to use the Accused Products in an infringing manner, provided operating manuals instructing customers and end-users to use the Accused Products in an infringing manner, provided training and/or technical support to customers and end users instructing how to use the Accused Products in an infringing manner, and advertised, marketed, and promoted the use of the Accused Products in an infringing manner. *See* **Exhibits 42-46**. The use of the Accused Products in their ordinary and customary fashion results in infringement of the asserted claims.

86. The Proposed Respondents have also contributorily infringed, and continue to contributorily infringe, the asserted claims. The Proposed Respondents have sold for importation into the United States, offered for sale within the United States, and/or imported into the United States the Accused Products or components thereof that embody a material part of the claimed inventions, that are known by Proposed Respondents to be specially made or specially adapted for use in an infringing manner and that are not staple articles or commodities suitable for substantial non-infringing use. *See* **Exhibits 42-46**.

87. Upon information and belief, the direct infringers for Proposed Respondents' indirect infringement include, without limitation, the customers and end-users who use the Accused Products, to whom Proposed Respondents sell and offer to sell the Accused Products. *See, e.g.*, **Exhibit 33**; **Exhibit 35**. The Proposed Respondents have contributed to these customers' and end-users' infringement by selling and offering to sell the Accused Products to them, by advertising and promoting the Accused Products as embodying a material component of the patented invention, and by encouraging and providing instructions to their customers and end-

users for using the Accused Products as embodying a material component of the patented inventions.

88. Upon information and belief, the Proposed Respondents have had specific intent to infringe the Asserted Patents and/or were willfully blind to such infringement. The Proposed Respondents have knowledge of the Asserted Patents by, among other things, the filing of the European proceeding discussed in Section VIII where Hologic asserted related European Patent EP 2 352 431 against Siemens Healthineers AG and its subsidiaries.

89. The Accused Products directly and/or indirectly infringe claims 1, 2, 4, 5, 7, and 8 of the ’282 Patent. Pursuant to §210.12(a)(9)(viii), an exemplary claim chart that applies the independent asserted claims of the ’282 Patent to the accused Siemens MAMMOMAT B.brilliant product is attached hereto as **Exhibit 22**.

90. The Accused Products directly and/or indirectly infringe claims 1-4, 6-9, and 10-18 of the ’005 Patent. Pursuant to §210.12(a)(9)(viii), an exemplary chart that applies the independent asserted claims of the ’005 Patent to the accused Siemens MAMMOMAT B.brilliant product is attached hereto as **Exhibit 23**.

91. The Accused Products directly and/or indirectly infringe claims 1-8, and 10-19 of the ’911 Patent. Pursuant to §210.12(a)(9)(viii), an exemplary claim chart that applies the independent asserted claims of the ’911 Patent to the accused Siemens MAMMOMAT B.brilliant product is attached hereto as **Exhibit 24**.

92. The Accused Products directly and/or indirectly infringe claims 1 and 3-18 of the ’148 Patent. Pursuant to §210.12(a)(9)(viii), an exemplary claim chart that applies the independent asserted claims of the ’148 Patent to the accused Siemens MAMMOMAT B.brilliant product is attached hereto as **Exhibit 25**.

93. The Accused Products directly and/or indirectly infringe claims 1 and 3-20 of the '115 Patent. Pursuant to §210.12(a)(9)(viii), an exemplary claim chart that applies the independent asserted claims of the '115 Patent to the accused Siemens MAMMOMAT B.brilliant product is attached hereto as **Exhibit 26**.

VI. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

94. As stated above, on information and belief, the Proposed Respondents manufacture the Accused Products or have the Accused Products manufactured outside of the United States on their behalf, sell the Accused Products for importation into the United States, import the Accused Products into the United States, and/or sell the Accused Products within the United States after importation.

95. Specifically, on information and belief, Siemens Healthineers AG and Siemens Healthcare GmbH manufacture or have manufactured on their behalf the Accused Products in Germany and sell them to Siemens Medical Solutions USA, Inc. for importation into the United States. In addition, on information and belief, Siemens Medical Solutions USA, Inc. imports the Accused Products into the United States and then sells them after importation.

96. FDA reporting confirms that Siemens Healthcare GmbH and its parent company, Siemens Healthineers AG, manufacture the Accused Products in Germany. In the 510(k) submission for the MAMMOMAT B.brilliant cleared on March 27, 2024, Siemens Medical Solutions USA, Inc. identifies Siemens Healthcare GmbH as the manufacturer and Forchheim, Germany as the place of manufacture.

Location of Manufacturing Site
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number: 3004977335

See **Exhibit 30** at 4. The FDA Establishment Registration Number for the Forchheim, Germany manufacturing site identifies Siemens Healthineers AG as the owner and operator.

Establishment:
Siemens Healthineers AG
SIEMENSSTRASSE 1 -OR-
Rittigfeld 1
FORCHHEIM Bavaria 91301 DE
Registration Number: 3004977335
FEI Number*: 3004977335
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
Siemens Healthineers AG
Karlheinz-Kaske-Str. 5
Erlangen 91052 DE
Owner/Operator Number: 8010024

Exhibit 31.

97. The FDA reporting further confirms that Siemens Medical Solutions USA, Inc. imports the Accused Products into the United States and sells them after importation. In the 510(k) submission for the MAMMOMAT B.brilliant approved on March 27, 2024, Siemens Medical Solutions USA, Inc. identifies itself as the importer and distributor.

General Information:
Importer / Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number: 2240869

See **Exhibit 30** at 4.

98. A subsequent 510(k) submission for the MAMMOMAT B.brilliant approved on June 18, 2026, confirms that Siemens Healthineers AG and Siemens Healthcare GmbH continue to manufacture the Accused Products in Germany and sell them to Siemens Medical Solutions USA, Inc. for importation into the United States, and that Siemens Medical Solutions USA, Inc. continues to import the Accused Products into the United States and then sell them after

importation. **Exhibit 32** at 5 (identifying Siemens Medical Solutions USA, Inc. as the importer and distributor and Siemens Healthcare GmbH as the manufacturer with Establishment Registration Number 3004977335); **Exhibit 31** (identifying Siemens Healthineers AG as the owner and operator associated with Establishment Registration Number 3004977335).

99. In one instance, in or around January 2025, Siemens Medical Solutions USA, Inc. imported a MAMMOMAT B.brilliant system into the United States for sale to Grace Breast Imaging & Medical Spa in Clive, Iowa. *See* **Exhibit 33** ("Siemens Healthineers announced that an Iowa healthcare facility became the first in the U.S. to install its new Mammomat B.brilliant."); *see also* **Exhibit 34 at 2** ("GRACE is proud to have been the first clinic in the nation to commercially install the Siemens Mammomat B.Brillant [sic] wide angle tomosynthesis mammography system"). On information and belief, Siemens Healthineers AG and Siemens Healthcare GmbH manufactured the MAMMOMAT B.brilliant system in Germany and sold it to Siemens Medical Solutions USA, Inc. for importation into the United States.

100. In a second instance, in or around April 2026, Siemens Medical Solutions USA, Inc. imported a MAMMOMAT B.brilliant system into the United States for sale to Hackensack Meridian Mountainside Medical Center in Montclair, New Jersey. *See* **Exhibit 35**. For example, the image below shows an accused MAMMOMAT B.brilliant system imported from Germany located at Hackensack Meridian Health Mountainside Medical Center at 1 Bay Ave, Montclair, NJ 07042:



See **Exhibit 35**. On information and belief, Siemens Healthineers AG and Siemens Healthcare GmbH manufactured the MAMMOMAT B.brilliant system shown above in Germany and sold it to Siemens Medical Solutions USA, Inc. for importation into the United States.

VII. HARMONIZED TARIFF SCHEDULE NUMBERS

101. On information and belief, the Accused Products of which Hologic is currently aware may be classified and imported under at least the following headings under the Harmonized Tariff Schedule ("HTS") of the United States: 9022.12.00, 9022.14.00, 9022.30.00, 9022.90.40, 9022.90.60.

102. These HTS numbers are illustrative only and may not exhaustively reflect the HTS classification of all Accused Products. These HTS numbers are not intended to restrict the scope of this investigation or the scope of relief to which Hologic is entitled.

VIII. RELATED LITIGATION

103. In December 2024, Hologic filed an infringement action before the UPC Düsseldorf Local Division asserting EP ’431 against Siemens Healthineers AG and its subsidiaries Siemens Healthcare GmbH, Siemens Healthineers Nederland B.V., and Siemens Healthcare SAS. On June 10, 2026, the UPC determined that Siemens’ MAMMOMAT B.brilliant system infringed EP ’431. The court imposed an injunction barring Siemens Healthineers AG and the aforementioned subsidiaries from making, marketing, using, or importing the MAMMOMAT B.brilliant system in Germany, France, and the Netherlands, ordered a recall and destruction of unsold units, and awarded damages/penalties for non-compliance.

104. In May 2019, Proposed Respondent Siemens Healthcare GmbH filed an opposition before the European Patent Office (“EPO”) challenging the validity of Hologic’s EP ’431 patent. Siemens sought revocation on multiple grounds, including added subject matter, insufficiency of disclosure, lack of novelty, and lack of inventive step. On June 24, 2021, the EPO Opposition Division rejected Siemens Healthcare GmbH’s opposition, and its written decision was posted on August 5, 2021 maintaining EP ’431 as granted. Siemens Healthcare GmbH appealed that decision to the EPO Technical Board of Appeal. *See* **Exhibit 29**. On February 14, 2024, the Technical Board of Appeal rejected Siemens’s challenges, dismissed the appeal, and left EP ’431 in force as granted.

105. Concurrent with the instant Complaint, Hologic filed a complaint in the U.S. District Court for the District of Delaware alleging infringement of the Asserted Patents against Siemens Healthineers AG, Siemens Healthcare GmbH, and Siemens Medical Solutions USA, Inc.

106. To Hologic’s knowledge, the unfair acts described herein, or the subject matter thereof, have not been the subject of any court or agency litigation or arbitration other than that described above.

IX. DOMESTIC INDUSTRY

107. An industry as required by Section 337(a)(2) and as defined by Section 337(a)(3) exists in the United States. Hologic has made significant investments in plants and equipment, employed significant labor and capital, and made substantial investments in engineering, research, and development related to products and services that embody the Asserted Patents.

A. Products that Practice the Asserted Patents

108. The claims of the Asserted Patents are practiced by Hologic's Envision™ platform ("Domestic Industry Product"). The Domestic Industry Product practices at least one valid claim of each of the Asserted Patents. Hologic's Envision™ platform is described in more detail in **Exhibits 49 – 50**. For example, **Exhibit 49** shows a user guide for the Domestic Industry Product, including a detailed description of the Domestic Industry Product's functionality and technical information related to specific components.

109. A claim chart showing that the Domestic Industry Product practices at least exemplary claim 8 of the '282 Patent is attached as **Exhibit 36**.

110. A claim chart showing that the Domestic Industry Product practices at least exemplary claim 1 of the '005 Patent is attached as **Exhibit 37**.

111. A claim chart showing that the Domestic Industry Product practices at least exemplary claim 1 of the '911 Patent is attached as **Exhibit 38**.

112. A claim chart showing that the Domestic Industry Product practices at least exemplary claim 1 of the '148 Patent is attached as **Exhibit 39**.

113. A claim chart showing that the Domestic Industry Product practices at least exemplary claim 15 of the '115 Patent is attached as **Exhibit 40**.

114. The charted claims are only representative of the claims practiced by the Domestic Industry Product, and Hologic may demonstrate the technical prong through other claims.

B. Domestic Investments in the United States Relating to the Products that Practice the Asserted Patents

115. A non-confidential summary of some of Hologic's significant and substantial domestic investments is provided below. A confidential narrative providing further detail is submitted herewith and is incorporated by reference. *See* **Exhibit 51**.

1. Significant Investments in Plant and Equipment

116. Hologic has made and continues to make significant investments in plant and equipment in the United States related to the engineering, research, development, and manufacture of the Domestic Industry Product. *See* **Exhibit 51** at ¶¶ 8-21.

117. For instance, Hologic maintains numerous physical locations in the United States that perform a variety of functions directly related to the Domestic Industry Product. This includes Hologic's global headquarters in Marlborough, Massachusetts, where employees perform corporate management and executive leadership, oversee research and development efforts, and direct worldwide sales, marketing, and regulatory compliance efforts. *See* **Exhibit 51** at ¶ 9. Hologic maintains a second facility in Marlborough, Massachusetts that supports the Domestic Industry Product through training labs and clinical imaging evaluations. *See* **Exhibit 51** at ¶ 12.

118. The Domestic Industry Product is manufactured in the United States at Hologic's facility in Newark, Delaware. *See* **Exhibit 51** at ¶ 15. This facility includes a main building where the Domestic Industry Product is manufactured, as well as a warehousing facility. *Id*. Since 2021, Hologic has spent millions of dollars updating and expanding this facility to add approximately 100,000 square feet of facility space. *See* **Exhibit 51** at ¶ 17.

119. Between these three facilities alone, Hologic maintains more than 650,000 square feet of facility space in the United States that directly supports the Domestic Industry Product.

Hologic's investments in plant and equipment related to the Domestic Industry Product from 2023-2026 are shown in **Exhibit 51** at ¶¶ 8-21.

2. Significant Employment of Labor or Capital

120. Hologic has made and continues to make significant investments in labor and capital in the United States related to the engineering, research, development, and manufacture of the Domestic Industry Product. *See* **Exhibit 51** at ¶¶ 22-26.

121. For example, Hologic has more than 4,000 employees in the United States, making up more than 60% of Hologic's global workforce. Hundreds of Hologic's domestic employees have been involved and are still involved in the engineering, research, development, and manufacture of the Domestic Industry Product. *See* **Exhibit 51** at ¶¶ 22-24. Hologic's investments in labor from 2023-2026 are shown in **Exhibit 51** at ¶ 24.

122. Hologic has also employed a significant amount of capital in the United States relating to the engineering, research, development, and manufacture of the Domestic Industry Product. *See* **Exhibit 51** at ¶¶ 25-26. Hologic's investments in capital from 2023-2026 are shown in **Exhibit 51** at ¶ 26.

3. Substantial Investment in Engineering, Research and Development

123. Hologic has also made substantial investments in engineering, research and development in the United States of the Domestic Industry Product, including the investments identified above. *See* **Exhibit 51** at ¶ 27. A significant portion of Hologic's domestic investments in exploitation of the Asserted Patents through engineering, research and development can be attributed to the Domestic Industry Product. *See* **Exhibit 51** at ¶¶ 27-28.

4. Significance and Substantiality of Hologic's Domestic Investments

124. Hologic's domestic investments in plant and equipment, labor and capital, and engineering, research and development are significant and substantial at least because they are

directed to resources that are critical to the Domestic Industry Product, including Hologic's global headquarters in Marlborough, Massachusetts and its manufacturing facility in Newark, Delaware. See **Exhibit 51** at ¶¶ 27-28. Because the Domestic Industry Product is and will continue to be manufactured in the United States, the investments incurred in manufacturing the product are necessarily significant. *See Certain Apparatus & Methods of Opening Containers*, Inv. No. 337-TA-1255, ID at 34-35 (Dec. 20, 2021). Manufacturing in the United States is one of the activities that Congress intended to form the basis for a domestic industry. *Certain Bone Cements, Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-1153, Comm'n Op. at 24 (Jan. 25, 2021). The Envision™ platform is also a significant product for Hologic as it represents Hologic's flagship, next-generation mammography system.

X. RELIEF REQUESTED

125. In view of the Proposed Respondents' continued unfair import activities, Complainant requests that the U.S. International Trade Commission:

A. Institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to violations of Section 337 based upon the sale for importation into the United States, the importation into the United States, and/or the sale within the United States after importation of Accused Products that infringe one or more claims of the Asserted Patents;

B. Schedule and conduct a hearing pursuant to Section 337(c) for the purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and, following the hearing, determine that there have been violations of Section 337 by each Proposed Respondent;

C. Issue a permanent limited exclusion order pursuant to 19 U.S.C. § 1337(d), prohibiting entry into the United States of the Proposed Respondents' Accused Products that infringe one or more claims of the Asserted Patents;

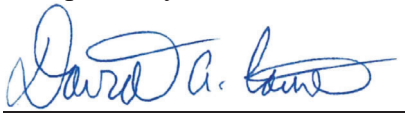
D. Issue permanent cease and desist orders, pursuant to 19 U.S.C. § 1337(f), prohibiting the Proposed Respondents, or their parents, subsidiaries, related companies, other affiliates, or agents, from importing, admitting or withdrawing from a foreign trade zone, marketing, advertising, demonstrating, warehousing inventory of, distributing, offering for sale, selling, transferring (except for exportation), licensing, repairing, soliciting U.S. agents or distributors for, or aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of the Proposed Respondents' Accused Products that infringe one or more claims of the Asserted Patents;

E. Require appropriate bond be posted, pursuant to 19 U.S.C. § 1337(j), with U.S. Customs and Border Protection for entry of any Accused Product or component thereof, and for each proscribed activity pursuant to the cease and desist order, during the Presidential Review period; and

F. Grant such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Dated: November 16, 2026

Respectfully submitted,



Matthew M. Wolf
Brian D. Hill

David McMullen, Ph.D.
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave. NW
Washington, DC 20001
Tel: (202) 942-6745

David A. Caine
Arnold & Porter Kaye Scholer LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306-3807
Tel: (650) 319-4700

Ryan J. Casamiquela
Arnold & Porter Kaye Scholer LLP
Four Embarcadero Center, 14th Floor
San Francisco, CA 94111-4164
Tel: (415) 471-3100

Michelle Ban
Arnold & Porter Kaye Scholer LLP
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Tel: (213) 243-4000

Olivia Matthews
Arnold & Porter Kaye Scholer LLP
300 North LaSalle Drive, Suite 3500
Chicago, IL 60654
Tel: (312) 583-2300

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **Certain Mammography Systems with Focal Spot Compensation Technology and Components Thereof, Including X-Ray Tubes**	Investigation No. 337-TA-_____

VERIFICATION OF COMPLAINT

I, Julia Mathis, do hereby declare and state:

1. I am a Senior IP Counsel at Hologic, Inc. and I am duly authorized to verify this Complaint;

2. I submit this verification in accordance with 19 C.F.R. §§ 210.4 and 210.12(a);

3. I have read the Complaint and am aware of its contents;

4. The Complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding;

5. To the best of my knowledge, information, and belief founded upon reasonable inquiry, the claims and legal contentions of this Complaint are warranted by existing law or a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and

6. To the best of my knowledge, information, and belief founded upon reasonable inquiry, the allegations and other factual contentions in the Complaint have evidentiary support or,

if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

Dated: November 16, 2026

Julia Mathis

Julia Mathis
Senior IP Counsel
Breast and Skeletal Health
Hologic, Inc.