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UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **CERTAIN MAMMOGRAPHY SYSTEMS AND COMPONENTS THEREOF**	Investigation No. 337-TA- _____

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

Complainant

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3	Prosecution History for PCT Appl. No. PCT/IB2009/051257
4	Prosecution History for EP Priority No. 08103234
5	Certified Copy of Record Assignments for U.S. Patent No. 8,284,894
6	Infringement Claim Chart for U.S. Patent No. 8,284,894
7C	Domestic Industry Claim Chart for U.S. Patent No. 8,284,894 (Confidential)
7-1	Technical Data Sheet
7-2C	Technical Concept Book (Excerpts) (Confidential)
7-3	MAMMOMAT B.brilliant® - Mammography System, Siemens Healthineers AG (video), https://www.youtube.com/watch?v=Hqs-VHPaXgw
8	Siemens Healthineers, MedMuseum: 175 Years of Innovations, https://www.medmuseum.siemens-healthineers.com/en/innovations
9	Siemens Healthineers, 50 Years of Mammography, https://www.siemens-healthineers.com/en-us/mammography/50-years-of-mammo
10	Siemens Healthineers, Breast Cancer, https://www.siemens-healthineers.com/clinical-specialities/oncology/cancer-types/breast-cancer
11	Siemens Healthineers USA: About, https://www.siemens-healthineers.com/en-us/about
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14	Siemens Healthineers: MAMMOMAT Revelation® — U.S. Service and Applications Support, https://www.siemens-healthineers.com/en-us/mammography/digital-mammography/mammomat-revelation
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16	Siemens Healthineers Invests in New and Expanded U.S. Facilities, https://www.siemens-healthineers.com/en-us/press-room/press-releases/us-investments
17	Siemens Healthineers: Mobile Mammography, https://www.siemens-healthineers.com/en-us/mammography/mobile-mammo

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18	Siemens Healthineers: MAMMOMAT B.brilliant®, https://www.siemens-healthineers.com/en-us/mammography/digital-mammography/mammomat-bbrilliant
19	Hologic: About, https://www.hologic.com/about
20	Hologic Envision® Mammography Platform, https://www.hologic.com/hologic-products/breast-health-solutions/envision-mammography-platform
21	USPTO Letter to the FDA Regarding Hologic's Request for Patent-term Extension of U.S. Patent No. 8,457,282
22	Hologic, Hologic Invites Attendees to Step Into the Future of Breast Health and AI at RSNA 2024 (Nov. 25, 2024), https://www.businesswire.com/news/home/20241125586668/en/
23	Hologic, Inc., FY2025 Proxy Statement (Form DEF 14A), https://www.sec.gov/Archives/edgar/data/859737/000114036125001287/ny20038205x1_def14a.htm
24C	Siemens Healthineers Email to Hologic dated August 13, 2026 (Confidential)
25	Hologic, From 3D to AI and Beyond, https://www.hologic.com/about/newsroom/3d-ai-and-beyond-how-hologic-continues-shape-future-mammography
26	Hologic, Mammography, Reimagined — Hologic Envision® Mammography Platform (video), https://www.youtube.com/watch?v=rQvmxkNFvxA
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31	Hologic Transfers Breast Health Capital Equipment Manufacturing from Danbury, Connecticut to Newark, Delaware, https://www.medtechdive.com/news/hologic-lay-off-86-people-closure-connecticut-facility/730684/
32	Hologic, Inc., Annual Report on Form 10-K for Fiscal Year 2025
33	Hologic Comment to U.S. Department of Commerce, Section 232 Semiconductor Investigation (Apr. 25, 2025)

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34	Hologic Comment to U.S. Department of Commerce, Section 232 Investigation of Imports of Medical Equipment (Oct. 17, 2025)
35	Harmonized Tariff Schedule, Heading 9022, https://hts.usitc.gov/search?query=9022
36	LinkedIn Post by Anthony Collard (Campaign Strategy Lead, Digital Marketing, Siemens Healthineers) Regarding Siemens Healthineers' U.S. Manufacturing of the MAMMOMAT B.brilliant®, https://www.linkedin.com/posts/antho-brand_medtech-madeinusa-siemenshealthineers-share-7493296149047660545-39x8/
37	Faulhaber Group, Locations – Dr. Fritz Faulhaber GmbH & Co. KG, https://www.faulhaber.com/en/about-us/locations/dr-fritz-faulhaber-gmbh-co-kg-de/
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40	Hologic, Inc., Annual Report on Form 10-K for Fiscal Year 2007
41	Panjiva Import Records for Hologic
42	Prospective Multicenter Clinical Evaluation of the Envision® Platform
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45-2C	[redacted] (Confidential) (With Certified English Translation)
46C	Medical Valley 'Integrated Breast Care' (BD-04) Cluster Project Description (Vorhabensbeschreibung), March 2010 (Confidential) (With Certified English Translation)
47C	Siemens Technology Assessment of Multi-Focus X-Ray Tube Systems with Dispenser Cathodes (Technologiebewertung), September 2011 (Confidential) (With Certified English Translation)
48C	Siemens Status Report on [redacted] Mammography X-Ray Tube (P40), March 2012 (Confidential) (With Certified English Translation)
49C	Amendment Request for the 'Integrated Breast Care' (BD-04) Subproject A1 (Änderungsantrag), Dated March 12, 2012 (Confidential) (With Certified English Translation)
50C	Siemens [redacted] Project Presentation, April 2013 (Confidential) (With Certified English Translation)
51C	Siemens [redacted] Innovation Project Application and Approval, Dated August 15, 2013 (Confidential) (With Certified English Translation)
52	Hologic, Groundbreaking New Data on Hologic's AI-Powered Mammography Technology to Be Presented at SBI (Apr. 24, 2025), https://www.businesswire.com/news/home/20250424821675/en/
53	Hologic LinkedIn Post Regarding the Society of Breast Imaging (SBI) 2025 Annual Symposium, https://www.linkedin.com/posts/hologic_sbi2025-activity-7321556234803789825-ea_L/
54	Hologic Showcases Mammography, AI, Breast Biopsy, and Surgical Solutions at RSNA, Applied Radiology, https://appliedradiology.com/Articles/hologic-showcases-mammography-ai-breast-biopsy-and-surgical-solutions-at-rsna
55C	Photographs Regarding Confidential Importation Evidence (Confidential)
55-1C	Additional Photographs Regarding Confidential Importation Evidence (Confidential)
56	ClinicalTrials.gov, A Prospective Study of the Envision™ Mammography System (NCT05199701) (archived Nov. 21, 2025), https://web.archive.org/web/20251121070038/https://clinicaltrials.gov/study/NCT05199701

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57	U.S. Food & Drug Administration, Premarket Approval (PMA) Database — Envision® Mammography Platform, PMA No. P080003/S009 (approved July 5, 2024), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003S009
58	Brochure: MAMMOMAT B.brilliant® Exclude the maybes
59	Siemens Healthineers: 50° Wide-Angle Tomosynthesis, https://www.siemens-healthineers.com/en-us/mammography/tomosynthesis
59-1	Siemens Healthineers: 50° Wide-Angle Tomosynthesis (video)
60	Hologic's Breast Health Unit Stays In Focus in 2026: What Lies Ahead? (Jan. 6, 2026), https://finance.yahoo.com/news/hologics-breast-health-unit-stays-131700736.html
61	Audubon County Memorial Hospital & Clinics: Foundation, https://www.acmhhosp.org/foundation/
62C	Confidential Exhibit Regarding Licensing of U.S. Patent No. 8,284,894 (Confidential)
63C	Evidence of Hologic's Importation of Components Incorporated into the Envision® Mammography Platform (Confidential)
64C	Patent Assignment Agreement Dated May 29, 2026 Between Koninklijke Philips N.V. and Siemens Healthineers AG (Confidential)
65C	Patent Assignment Agreement Dated September 29, 2026 Between Siemens Healthineers AG and Siemens Medical Solutions USA, Inc. (Confidential)

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I. INTRODUCTION

1. Complainant Siemens Medical Solutions USA, Inc. ("Siemens Healthineers USA" or "Complainant") respectfully files this Complaint under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on proposed respondent Hologic, Inc.'s ("Hologic" or "Respondent") unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain accused Hologic mammography systems and components thereof that infringe one or more claims of U.S. Patent No. 8,284,894.

2. Siemens Healthineers USA asserts U.S. Patent No. 8,284,894 ("the '894 Patent") (Exhibit 1). Exhibit 1 contains a certified copy of the '894 Patent. A certified copy of the prosecution history for the '894 Patent is attached as Exhibit 2. Non-duplicative copies of the prosecution histories of priority applications associated with the '894 Patent are attached as Exhibits 3–4. A certified copy of the record assignments of the '894 Patent is attached as Exhibit 5.

3. This Complaint is directed to Hologic mammography systems, including the Envision® Mammography Platform, and components thereof, that directly or indirectly infringe one or more claims of the '894 Patent, either literally or under the doctrine of equivalents (collectively, the "Accused Products" or "Accused Hologic Products"). The Accused Hologic Products include components imported into the United States and incorporated into Hologic's mammography systems, as identified later in this Complaint. Exemplary models and components of the Accused Hologic Products are also identified later in this Complaint. Any identification of a specific model, configuration, component, or type of Accused Hologic Product

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in this Complaint is not intended to limit the scope of this Complaint or the Investigation to the specific models, configurations, components, or types identified.

4. The claims identified below are asserted against each of the Accused Products, with independent claims identified in bold:

Asserted Patent	Asserted Claims
'894 Patent	**1**, 2–9, **10**, 11–14

5. Discovery may reveal additional infringing products.

6. A chart demonstrating how the Accused Products infringe the '894 Patent is attached as Exhibit 6.

II. BACKGROUND

7. Siemens Healthineers USA, along with its corporate parent[1] Siemens Healthineers AG (collectively "Siemens Healthineers"), is a pioneer in medical imaging with a history of innovation spanning more than a century. Shortly after the discovery of X-rays in 1895, engineers at Siemens Healthineers' predecessor companies began developing X-ray equipment for medical applications. *See* Exhibit 8. By 1896, those predecessor companies were producing X-ray equipment, including an industrially manufactured X-ray tube for medical diagnostics. *Id.* Siemens Healthineers has continued to advance X-ray imaging technology since that early work. *Id.*

8. Building on its early work in medical X-ray technology, Siemens Healthineers has been developing mammography systems and related breast-imaging technologies for decades. Siemens Healthineers introduced its first dedicated mammography system in 1971, marking the beginning of the MAMMOMAT® product line, and has continued to develop new

[1] Siemens Medical Solutions USA, Inc. is a wholly owned subsidiary of Siemens Healthineers Beteiligungen GmbH & Co KG Germany, which is a wholly owned subsidiary of Siemens Healthineers AG.

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mammography systems and technologies for more than fifty years. *See* Exhibit 9. Today, Siemens Healthineers remains a leading developer and provider of mammography systems used for breast-cancer screening, diagnosis, and biopsy. *See* Exhibit 10.

9. Siemens Healthineers maintains a substantial and longstanding presence in the United States through Complainant Siemens Healthineers USA and other affiliated United States entities such as Siemens Healthcare Diagnostics Inc. and Varian Medical Systems, Inc. *See* Exhibit 11. Headquartered in Malvern, Pennsylvania, Siemens Healthineers USA conducts significant business operations relating to Siemens Healthineers' diagnostic imaging business such as magnetic resonance imaging, nuclear imaging, computed tomography imaging and X-ray imaging that includes mammography systems. By way of example, in the United States, Siemens Healthineers USA's operations include research and development, the manufacture, marketing, sales, warehousing, distribution, installation, and servicing with respect to its mammography systems as well as related system training, education, and customer support. *See* Exhibits 12–14; Conf. Exhibit 15C.

10. The United States is Siemens Healthineers' largest market and an integral part of its mammography business. *See* Exhibit 11. Siemens Healthineers employs approximately 17,000 people across 18 locations in the United States in the business fields of diagnostics, diagnostic imaging and precision therapy and maintains substantial domestic operations supporting its customers. *Id.* Siemens Healthineers has invested more than $1 billion in United States facilities, acquisitions, and strategic partnerships since 2019 and invests approximately $900 million annually in research and development in the United States. *Id.* With respect to mammography, Siemens Healthineers' United States activities include research and

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development, manufacturing, sales, marketing, warehousing, distribution, installation, training, education, servicing, and customer support. *See* Conf. Exhibit 15C; Exhibits 16–17.

11. Siemens Healthineers continues to expand its domestic mammography operations. Most recently, Siemens Healthineers transferred manufacturing activities relating to its mammography systems to the United States. Conf. Exhibit 15C, at ¶ 12; Exhibit 36. This expansion complements Siemens Healthineers' existing United States personnel, facilities, and operations supporting its mammography systems and customers. *See generally* Conf. Exhibit 15C.

12. Siemens Healthineers' mammography portfolio includes the MAMMOMAT B.brilliant® and MAMMOMAT Revelation® systems. *See* Exhibits 14, 18. The MAMMOMAT B.brilliant® is Siemens Healthineers' current-generation mammography system and provides digital mammography and wide-angle three-dimensional breast tomosynthesis. *See* Exhibits 18, 58–59. The MAMMOMAT Revelation® likewise provides digital mammography and wide-angle breast tomosynthesis and supports broader breast-cancer screening, diagnostic imaging, and biopsy procedures. Exhibit 14.

13. The MAMMOMAT B.brilliant® system reflects Siemens Healthineers' continued efforts to advance mammography and breast-tomosynthesis technology, improve diagnostic confidence, and support patient care. The MAMMOMAT B.brilliant® is referred to as the "Domestic Industry Product."

14. The Domestic Industry Product practices one or more claims of the '894 Patent, as demonstrated in the claim chart attached as Confidential Exhibit 7C. Siemens Healthineers has made and continues to make substantial investments in the United States relating to the Domestic Industry Product and related mammography business. Those investments and

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activities are described in greater detail below and in the accompanying Declaration of Philipp Schmidt. *See* Conf. Exhibit 15C.

15. By assignment, Siemens Healthineers USA owns all right, title, and interest in the '894 Patent, including the right to enforce the '894 Patent. *See* Exhibit 5. The '894 Patent reflects Siemens Healthineers' continuing commitment to developing, protecting, and commercializing innovations in mammography, breast tomosynthesis, and related medical-imaging technologies in the United States.

16. Siemens Healthineers' innovations in three-dimensional mammography reflect a decades-long history of research and cross-innovation in medical imaging, including with Koninklijke Philips N.V. ("Philips"). This relationship, including with respect to the '894 Patent, is described in detail in Confidential Exhibit 62C. Under that relationship, Siemens Healthineers held a license to practice the '894 Patent from the time the patent was filed—nearly two decades before Siemens Healthineers acquired the '894 Patent outright in 2026. *See* Exhibit 5; Conf. Exhibits 45C, 62C.

17. During that same period, Siemens Healthineers invested heavily in improving three-dimensional breast tomosynthesis. A central challenge in tomosynthesis is that movement of the X-ray tube during image acquisition blurs the focal spot and degrades image quality, and Siemens Healthineers pursued several approaches to address it, including stationary multi-focus X-ray tubes and magnetic deflection of the X-ray focal spot. *See* Conf. Exhibits 46C–48C. Siemens Healthineers ultimately concentrated its tomosynthesis development on flying-focus technology—deflecting the X-ray focal spot to compensate for the motion of the X-ray tube—redirecting its research toward that approach and, in 2013, launching a dedicated "Flying Focus for Tomosynthesis" development project. *See* Conf. Exhibits 49C–51C. The development of

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flying-focus technology was based on the experiences gained in Siemens Healthineers' computed tomography business in connection with the so-called spring focus. That sustained effort produced the flying-focus tomosynthesis capability embodied in Siemens Healthineers' current MAMMOMAT B.brilliant® Domestic Industry Product. *See* Exhibit 18. Siemens Healthineers' longstanding license to the '894 Patent, its sustained development and commercialization of a product practicing the '894 Patent, and its ultimate acquisition of the '894 Patent thus reflect a sustained, decades-long commitment to the technology at issue in this Investigation. *See* Conf. Exhibit 15C, at ¶¶ 5, 8, 11.

18. Further, and more specifically, at all times relevant to the domestic industry investments described in this Complaint, each of Siemens Healthineers USA and Siemens Healthineers AG has been either the owner of, or a non-exclusive licensee under, the '894 Patent, making both entities' domestic investments applicable to the domestic industry requirement. *See* Conf. Exhibit 15C, at ¶ 5; Conf. Exhibit 62C.

III. PARTIES

A. Siemens Healthineers USA

19. Complainant Siemens Medical Solutions USA, Inc. is a Delaware corporation with its principal place of business at 40 Liberty Boulevard, Malvern, Pennsylvania 19355. Siemens Healthineers USA is a subsidiary of Siemens Healthineers AG.[2]

20. By assignment, Siemens Healthineers USA owns all right, title, and interest in the '894 Patent, including the right to enforce the '894 Patent. *See* Exhibit 5.

21. Siemens Healthineers USA conducts substantial operations in the United States relating to Siemens Healthineers' mammography systems, including research and development,

[2] Siemens Healthineers AG is a stock corporation organized under the laws of Germany with its principal place of business at Siemensstrasse 3, 91301 Forchheim, Germany.

[redacted]

manufacturing, sales, marketing, warehousing, distribution, installation, servicing, training, education, and customer support. *See* Conf. Exhibit 15C. These operations are described in greater detail below.

B. Hologic

22. Proposed respondent Hologic, Inc. is a Delaware corporation with headquarters at 250 Campus Drive, Marlborough, Massachusetts 01752, as identified on Hologic's website: Hologic: About (Exhibit 19).

23. Hologic manufactures-in-part, markets, sells, and distributes the Accused Products in the United States. *See* Exhibits 21–23, 27–31, 42.

24. Hologic offers the Accused Products through its website, including the Envision® Mammography Platform. *See* Exhibit 20.

IV. THE TECHNOLOGIES AND PRODUCTS AT ISSUE

A. Products At Issue

25. Pursuant to Commission Rules 210.10(b)(1) and 210.12(a)(12), the categories of Accused Products are three-dimensional mammography systems and components thereof.

26. Hologic's three-dimensional mammography systems include the Envision® Mammography Platform.[3] Exhibit 20.

B. Background of the Technology

27. The technology at issue in this Investigation generally relates to three-dimensional mammography systems and, more particularly, to digital breast tomosynthesis systems that acquire two-dimensional projection images of breast tissue from multiple angles and reconstruct

[3] The inclusion of these products is not meant to be limiting.

[redacted]

those images to provide three-dimensional structural information concerning the breast. Exhibit 1, at 1:8–18, 1:50–64.

28. The ’894 Patent explains that conventional mammography generally relies on two-dimensional X-ray images taken of compressed breast tissue from different directions. *Id.* at 1:20–28. The patent identifies as a problem with conventional mammography that overlapping normal breast tissue may obscure small cancerous regions and other pathological tissue abnormalities, resulting in false-negative findings and reduced sensitivity. *Id.* at 1:33–44. Conversely, overlapping tissue may create the appearance of an abnormality, potentially producing false-positive findings and unnecessary patient callbacks. *Id.* at 1:44–49.

29. The ’894 Patent explains that digital breast tomosynthesis can reduce the problems caused by overlapping breast tissue by providing multiple high-resolution image slices located at different depths within the breast. *Id.* at 1:50–53. A digital breast-tomosynthesis system acquires a series of low-dose, two-dimensional projection images of compressed breast tissue from different angles as the X-ray tube moves along an arc. *Id.* at 1:54–64. Those projection images are then reconstructed into a stack of image slices corresponding to different depth layers within the breast. *Id.* at 1:54–2:2. This allows physicians to view the interior of the breast with less obstruction from surrounding superimposed tissue. *Id.* at 2:2–4.

30. The ’894 Patent identifies additional problems associated with image acquisition in conventional digital breast-tomosynthesis systems. *Id.* at 2:36–67. To obtain high-quality images, a conventional system may use a “stop-and-shoot” procedure in which the X-ray tube remains stationary during acquisition of each projection image. *Id.* at 2:36–51. But repeatedly stopping the X-ray tube, acquiring an image, and moving the tube to the next imaging position increases the total acquisition time. *Id.* at 2:51–56. Longer acquisition times are undesirable

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because the patient must remain still while the system acquires the complete series of projection images. *See id.* at 2:36–56, 6:66–7:2.

31. Alternatively, a system may move the X-ray tube continuously while acquiring the projection images. *See id.* at 2:56–67. The '894 Patent explains, however, that continuous movement of the X-ray tube during image acquisition may also move the focal spot from which the X-rays are emitted. *Id.* According to the patent, that focal-spot movement may produce "serious image blur" that significantly reduces the quality of the acquired images. *Id.* at 2:56–67. Conventional systems therefore presented a tradeoff between stopping the tube to reduce image blur and moving the tube continuously to reduce total acquisition time. *See id.* at 2:36–67.

32. To address these problems, the '894 Patent describes an improved three-dimensional tomosynthesis scanner that acquires a set of two-dimensional projection images during continuous rotational movement of an X-ray tube along an arc around the breast tissue being examined. *Id.* at 3:1–10; claim 1. During the acquisition of each projection image, the electron-beam focal spot on the X-ray tube's anode moves in the direction opposite the movement of the X-ray tube. *Id.* at 3:11–23; claim 1. The opposing focal-spot movement compensates for the distance traveled by the X-ray tube during the image-acquisition period. *Id.* at 3:11–23; claim 1.

33. More specifically, the '894 Patent describes superimposing the focal spot's compensation movement on the continuous rotational movement of the X-ray tube. *Id.* at 3:30–49. Because the focal spot moves within the tube housing in the direction opposite the tube's movement, the combined movements produce a stationary net focal-spot position relative to the breast tissue and the stationary X-ray detector during acquisition of each projection image. *Id.* at 3:49–55. The patent describes the focal spot's compensation movement using a discontinuous

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sawtooth function, with the focal spot repeatedly moving to compensate for the tube's movement and returning to its starting position before acquisition of the next projection image. *Id.* at 3:24–29; claims 2–4.

34. The '894 Patent further describes implementations that use position sensors, an actuator unit, and an actuator control unit to control the focal-spot compensation movement. *Id.* at 3:56–4:10; claims 6–8. A first position sensor may detect the focal spot's position relative to the X-ray tube housing, while a second position sensor may detect the X-ray tube's position along its rotational path. *Id.* at 3:56–4:10; 8:14–34; claims 6–7. An actuator unit moves the focal spot within the X-ray tube, and an actuator control unit controls that movement based on the detected positions of the focal spot and the rotating X-ray tube. *Id.* at 3:56–4:10; 8:18–35; claim 7. The actuator may use an electric or magnetic field to deflect the electron beam and thereby move the resulting focal spot along the X-ray tube's anode. *Id.* at 4:3–11; claim 8.

35. By permitting rotation of the X-ray tube and acquisition of the projection images to occur in parallel, the patented technology reduces the total time required to acquire the image sequence. *Id.* at 6:66–7:10. At the same time, maintaining a stationary net focal-spot position during acquisition reduces motion blur in the resulting projection images. *Id.* at 6:66–7:10. The patent explains that the disclosed system can therefore produce motion-blur-free images in a shorter total acquisition time and require less mechanical control than conventional stop-and-shoot systems. *Id.* at 6:66–7:10.

36. The technologies disclosed and claimed in the '894 Patent are central to Hologic's Accused Products. Hologic's Accused Products are three-dimensional mammography systems that acquire projection images as an X-ray tube moves around the breast and use those images to provide three-dimensional breast-imaging information. *See* Exhibits 20–21. In particular,

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Hologic promotes the Envision® Mammography Platform as providing high-speed, high-resolution three-dimensional imaging through its "Hologic Focusing Technology." *See* Exhibit 20. Hologic expressly advertises that its Focusing Technology "minimizes focal spot blur and improves 3D image sharpness." Exhibit 25. Hologic further advertises that the Envision® platform provides a 2.5-second three-dimensional scan time without sacrificing image resolution. *See* Exhibit 20. Those advertised benefits, which are central to the Accused Products—reducing focal-spot blur while acquiring three-dimensional breast images rapidly—directly concern the technological problems addressed by the '894 Patent. *See* Exhibit 1, at 2:36–67, 6:66–7:10.

37. As described in the Introduction and demonstrated in the infringement claim chart attached as Exhibit 6, the Accused Products employ the technologies disclosed and claimed in the '894 Patent and directly or indirectly infringe one or more claims of that patent.

V. THE '894 PATENT AND NON-TECHNICAL DESCRIPTION OF THE INVENTION[4]

A. U.S. Patent No. 8,284,894

1. Identification and Ownership of the '894 Patent

38. The '894 Patent was duly and lawfully issued by the United States Patent and Trademark Office on October 9, 2012. The '894 Patent is titled "Fast Tomosynthesis Scanner Apparatus And CT-Based Method Based On Rotational Step-And-Shoot Image Acquisition Without Focal Spot Motion During Continuous Tube Movement For Use In Cone-Beam Volume CT Mammography Imaging," names Tiemen Poorter as the inventor, and issued from U.S.

[4]All non-technical descriptions of the '894 Patent herein are presented to give a general background of the '894 Patent. These statements are not intended to be used nor should they be used for purposes of patent claim construction. Siemens Healthineers USA presents these statements subject to and without waiver of its right to argue that no claim construction is necessary, or that claim terms should be construed in a particular way under claim interpretation jurisprudence and the relevant evidence.

[redacted]

Patent Application No. 12/933,922, which is the national stage of PCT/IB2009/051257, filed March 26, 2009. The '894 Patent will expire on October 3, 2029.

39. Siemens Healthineers USA is the duly assigned owner of the '894 Patent and owns all right, title, and interest therein. *See* Exhibit 5.

40. Siemens Healthineers AG acquired all right, title, and interest in the '894 Patent by assignment from Koninklijke Philips N.V., recorded in July 2026. *See* Exhibit 5. Subsequently, Siemens Healthineers USA acquired all right, title, and interest in the '894 Patent by assignment from Siemens Healthineers AG, recorded in October 2026. *Id.* Siemens Healthineers' acquisition of the '894 Patent, however, followed nearly two decades during which Siemens Healthineers held a license to the '894 Patent and developed and commercialized products practicing it. *See* Conf. Exhibits 45C–51C.

2. Non-Technical Description of the '894 Patent

41. The '894 Patent generally relates to improved three-dimensional tomosynthesis scanner systems and methods for acquiring three-dimensional mammography images while reducing motion artifacts and blurring effects. Exhibit 1, at Abstract; 1:8–18.

42. The improved systems and methods of the '894 Patent acquire a series of two-dimensional projection images while an X-ray tube moves continuously along an arc around the breast tissue being examined. *Id.* at 3:1–10; claims 1, 10. During acquisition of each projection image, the electron-beam focal spot moves within the X-ray tube housing in the direction opposite the tube's movement, thereby compensating for the distance traveled by the X-ray tube during image acquisition. *Id.* at 3:11–23; claims 1, 10. The opposing movements maintain a stationary net focal-spot position relative to the breast tissue and the stationary X-ray detector,

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allowing the system to acquire motion-blur-free images in a shorter total acquisition time. *Id.* at 3:49–55, 6:66–7:10.

B. Corresponding Domestic and Foreign Patents

43. Other than U.S. Patent Appl. No. 12/933,922, which was ultimately granted as the ’894 Patent, there are no corresponding domestic patents or patent applications to the ’894 Patent.

44. The following foreign patent(s) and/or patent application(s) correspond to the ’894 Patent: EP2262428B1 (granted), CN101983034A (granted), JP5384612B2 (granted), IN6640CHENP2010A (abandoned), ATE542479T1 (abandoned), and PCT/IB2009/051257. Upon a reasonable investigation, Siemens Healthineers is aware of no other foreign counterparts or foreign counterpart applications corresponding to the ’894 Patent that have been issued, abandoned, denied, withdrawn, or which remain pending.

C. Licensees to the ’894 Patent

45. A discussion of the licensing of the ’894 Patent, including the identification of known licensees, is included in Confidential Exhibit 62C.

VI. HOLOGIC’S INFRINGEMENT OF THE ’894 PATENT

46. As detailed below, Hologic directly infringes the ’894 Patent, inter alia, by making, using, offering for sale, and/or selling within the United States after importation of components of the Accused Products, and it indirectly infringes the ’894 Patent by inducing its customers to infringe, and by contributing to its customers’ infringement.

47. Hologic imports components of the Accused Products into the United States, sells the Accused Products for importation of components thereof into the United States, and/or sells the Accused Products within the United States after importation of components thereof. *See*

[redacted]

infra Section VII; Exhibits 20, 22–23. Hologic offers and promotes the Accused Products throughout the United States, including through its website. *See* Exhibit 20.

48. Hologic has offered to sell the Accused Products, including the Envision® Mammography Platform, in the United States. *See* Exhibits 20, 22–23. The Envision® Mammography Platform is an FDA-approved mammography system (PMA No. P080003/S009, approved July 5, 2024). *See* Exhibit 21, at 6–7. Hologic unveiled the Envision® Mammography Platform in the United States at the annual meeting of the Radiological Society of North America in December 2024, and has continued to market and promote the system to hospitals and imaging centers in the United States since that time. *See* Exhibit 22; *see also* Exhibit 23, at 5 (stating that Hologic "unveiled our next generation Envision mammography platform" in December 2024). On information and belief, Hologic has sold, installed, and/or delivered Envision® Mammography Platform systems to customers in the United States.

49. Hologic has publicly and formally described the operation of the Accused Products, including in submissions to the United States Patent and Trademark Office. In a patent term extension application submitted to the USPTO, Hologic provided a detailed technical description of the Envision® Mammography Platform and its "moving focal spot" capability. *See* Exhibit 21. Hologic's own description of the Accused Products confirms that it practices the technology claimed in the '894 Patent, as set forth in the claim chart attached as Exhibit 6 and as described further below.

50. Prior to filing this Complaint, Siemens Healthineers sent an email to Hologic on August 13, 2026, identifying the '894 Patent and Hologic's infringement. *See* Conf. Exhibit 24C.

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51. The ’894 Patent family also played a significant role as prior art documents in a European Patent Office opposition proceeding initiated on May 14, 2019 (appeal T 1762/21), and in a Unified Patent Court (UPC) proceeding (UPC_CFI_758/2024), in which Siemens Healthineers AG and its European affiliates relied on the ’894 Patent family in their Statement of Defence and Counterclaim for Revocation filed on March 26, 2025. This further demonstrates that Hologic has had deep knowledge and understanding of the ’894 Patent since at least August 13, 2026. *See id.* Additionally, Hologic has, at a minimum, actual knowledge of the ’894 Patent as of the filing of Siemens Healthineers USA’s patent infringement complaint against Hologic in the United States District Court for the District of Delaware (No. 1:26-cv-01460) on November 13, 2026,[5] as well as of filing and service of this Complaint.

52. Hologic instructs and encourages others—including hospitals, imaging centers, radiologists, and technologists—to use the Accused Products in ways that directly infringe the ’894 Patent. *See* Exhibits 26–30.

53. Hologic actively promotes the Accused Products throughout the United States. *See* Exhibits 20, 22–23, 25–30.

54. Hologic markets the Accused Products by touting the very benefits that the patented technology provides. For example, Hologic promotes the Envision® Mammography Platform as incorporating a patented “Hologic Focusing Technology,” Exhibit 20, that, according to Hologic, “minimizes focal spot blur and improves 3D image sharpness,” Exhibit 25, while delivering a 2.5-second three-dimensional scan. Hologic advertises that, compared to its prior 3Dimensions® system, the Envision® platform’s Focusing Technology “improves image sharpness an average of 19% at 6 cm and an impressive 42% at 8 cm.” *See* Exhibit 20.

[5] Shortly after filing the complaint in Delaware, Siemens Healthineers sent a copy to Hologic on the same day.

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55. Hologic also teaches and instructs customers and end users how to use the Accused Products in the United States, including through videos, product literature, and training materials. *See* Exhibits 26–30.

56. For example, Hologic posted a video on its YouTube channel, "Mammography, Reimagined. Hologic Envision™ Mammography Platform," that promotes and describes the operation of the Accused Envision® Mammography Platform. *See* Exhibit 26 (https://www.youtube.com/watch?v=rQvmxkNFvxA). Hologic has not taken the video offline.

57. Similarly, Hologic posted a video on its YouTube channel, "Hologic Envision™ Mammography Platform," describing the next-generation three-dimensional mammography platform and its features. *See* Exhibit 27 (https://www.youtube.com/watch?v=d0n0tzP-Ubw). Hologic has not taken the video offline.

58. Hologic further offers training and medical-education resources to assist customers in operating the Accused Products, including through its Hologic Medical Education program. *See* Exhibits 28–29.

59. On information and belief, Hologic also provides operator manuals, user guides, installation and service documentation, and other written instructions with the Accused Products, including with each Envision® Mammography Platform, that direct and instruct customers and end users to operate the Accused Products in the tomosynthesis imaging mode that practices the '894 Patent. By supplying these manuals and instructions with the Accused Products, Hologic instructs, encourages, and facilitates the direct infringement of the '894 Patent by others.

60. Hologic also creates and distributes marketing, promotional, and educational product literature directed to the Accused Products. For example, Hologic publishes and distributes the *Envision® Mammography Platform Brochure*, which describes the platform's

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patented Focusing Technology, and its 70µm high-resolution three-dimensional imaging. *See* Exhibit 30, at 2–3 (Envision® Mammography Platform Brochure).

61. Through promoting the Accused Products and educating and training customers and end users on how to use the Accused Products in the United States, Hologic actuates direct infringement of the ’894 Patent by others.

A. Infringement of the ’894 Patent

62. Hologic infringes claims 1–14 of the ’894 Patent, directly and/or indirectly via induced infringement and/or contributory infringement. In particular, the Accused Products, including the Envision® Mammography Platform, infringe the ’894 Patent. Hologic infringes these claims by making, using, offering to sell, and/or selling within the United States, and by importing, selling for importation, and/or selling after importation into the United States, the Accused Products in violation of 35 U.S.C. §§ 271(a)–(c). The Accused Products satisfy all limitations of the asserted claims of the ’894 Patent after certain components thereof are imported into the United States and incorporated into the Accused Products. A claim chart applying the asserted independent claims of the ’894 Patent to a representative Accused Product is attached as Exhibit 6.

63. As shown in the claim chart attached as Exhibit 6, the Accused Products practice each limitation of the asserted claims of the ’894 Patent. Hologic’s own technical description of the Envision® Mammography Platform confirms as much. In its submission to the USPTO, Hologic describes the Envision® System as “a mammography device that provides digital 2D and tomosynthesis images for the screening and diagnosis of breast cancer,” having a tube arm that “houses an x-ray tube” and that “rotates independently relative to the compression arm for a

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tomosynthesis imaging mode acquiring a number of images across a 15° arc of rotation." *See* Exhibit 21, at 2; *see also* Exhibit 6 (claim chart).

64. Hologic's description further confirms that the Accused Products practice the focal-spot compensation limitations at the heart of the '894 Patent. Hologic states that the Envision® System "employs moving focal spot capability in order to support faster tomosynthesis imaging scans by reducing focal spot blur," and that, "[o]ver the course of an exposure period, the electrons are moved across the anode to keep the x-ray beam centered over the imaging area and so that the X-ray beam appears stationary relative to the detector." *See* Exhibit 21, at 5–6. Hologic further admits that "[t]his focal spot movement is in an opposite direction and synchronous speed to that of the tube arm position movement during the exposures of the tomosynthesis imaging scan." *Id.* at 6; *see also* Exhibit 6 (claim chart). That admitted operation—moving the focal spot along the anode in the direction opposite the continuous rotational movement of the X-ray tube so that the beam appears stationary relative to the detector during each exposure—corresponds directly to the claimed compensation movement recited in claim 1 of the '894 Patent.

65. Hologic's public marketing of the Accused Products reflects the same infringing functionality. Hologic promotes the Envision® platform's patented "Focusing Technology" as "minimiz[ing] focal spot blur" and improving three-dimensional image sharpness while enabling a high-speed 2.5-second scan—precisely the advantages the '894 Patent describes achieving through its focal-spot compensation movement during continuous tube rotation. *See* Exhibit 20; Exhibit 30, at 2; Exhibit 1, at 2:36–67, 6:66–7:10.

66. Hologic directly infringes the asserted claims of the '894 Patent by making, using, offering to sell, and/or selling the Accused Products in the United States and by importing the

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Accused Products into the United States in violation of 35 U.S.C. § 271(a). For example, Hologic makes and assembles the final Envision® machine in Newark, Delaware. *See* Exhibit 31. Additionally, Hologic has engaged in infringing use of the Envision® system during pre-sale demonstrations and product unveilings, including Hologic's December 2024 unveiling of the Envision® Mammography Platform at the annual meeting of the Radiological Society of North America.[6] *See* Exhibits 22–23.

67. Hologic's customers and end users—including hospitals, imaging centers, radiologists, and technologists—directly infringe one or more asserted claims of the '894 Patent under 35 U.S.C. § 271(a) by using the Accused Products for screening and diagnosis in the United States. *See, e.g.*, Exhibits 60–61; *infra* ¶¶ 68–69.

68. For example, hospitals, imaging centers, radiologists, and technologists directly infringed one or more asserted claims of the '894 Patent under 35 U.S.C. § 271(a) each time they used the Envision® Mammography Platform to perform tomosynthesis mammograms on patients in Hologic's prospective, multicenter clinical evaluation of the Envision® platform. *See* Exhibit 42. That evaluation was conducted across nine breast-imaging sites in the United States and enrolled 929 women who each received a standard four-view bilateral examination (RCC, RMLO, LCC, and LMLO) on the Envision® platform, including in the tomosynthesis imaging mode that practices the '894 Patent. *See id.* Each such examination was performed by, or under the direction of, a radiologist or technologist at the participating site using the Accused Product in the ordinary, intended manner—including its patented moving-focal-spot tomosynthesis functionality—and therefore constitutes a separate act of direct infringement.[7] *See id.*

[6] On information and belief, Hologic's infringing use further includes design-verification, validation, quality-control, and other internal and clinical testing of the Envision® system.

[7] The FDA approved the Envision® platform on July 5, 2024. *See* Exhibit 21, at 6–7. Hologic continued to enroll patients in the evaluation (NCT05199701) after that approval, with recruitment continuing into 2025, and the study

[redacted]

69. Additionally, on information and belief, radiologists, technologists, and other attendees directly infringed one or more asserted claims of the '894 Patent under 35 U.S.C. § 271(a) when they operated and tested the physical Envision® system that Hologic brought to, and displayed at, at least two industry trade shows. First, Hologic displayed a physical Envision® system at the 2024 annual meeting of the Radiological Society of North America (RSNA) in Chicago, Illinois, where Hologic stated that, "for the first time," attendees could "experience the cutting-edge Envision™ Mammography Platform" at Booth #1919, and independent event coverage stated that the system was physically on display and available for attendees to explore. *See* Exhibits 22, 54. Second, Hologic displayed a physical Envision® system at the 2025 Society of Breast Imaging (SBI) Annual Symposium in Colorado Springs, Colorado, where Hologic publicly stated that it would "highlight" and was "showcas[ing]" the Envision® platform at Booth #207. *See* Exhibits 52–53.

70. Hologic actively, knowingly, and intentionally induces infringement of the asserted claims of the '894 Patent by actively encouraging others—including hospitals, imaging centers, radiologists, and technologists—to make, use, offer to sell, and/or sell the Accused Products in the United States and/or import the Accused Products into the United States in violation of 35 U.S.C. § 271(b). Hologic does so with the specific intent to encourage such infringement, through activities such as designing, making, selling, offering to sell, importing, marketing, advertising, and promoting the Accused Products; creating and distributing marketing, promotional, educational, and other product literature for the Accused Products; publishing instructional and promotional videos describing operation of the Accused Products;

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protocol required each enrolled subject to undergo tomosynthesis mammography on the Envision® system. *See* Exhibit 56 (showing the trial as actively recruiting and with an estimated 7,500 enrollees, as updated on October 17, 2024). The FDA's premarket-approval order for the Envision® platform did not require Hologic to conduct or continue that evaluation, or to perform continued patient examinations, to obtain or maintain approval. *See* Exhibit 57 (PMA No. P080003/S009).

[redacted]

and providing training, medical education, and customer support directed to the Accused Products. *See supra*. These activities are designed to invite, instruct, encourage, enable, and facilitate the use of the Accused Products in a manner that infringes the '894 Patent.

71. Hologic also contributes to, and continues to contribute to, infringement of the '894 Patent by offering to sell or selling within the United States, or importing into the United States, the Accused Products (where each of the Accused Products is or contains a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention), knowing the same to be especially made or especially adapted for use in an infringement of the '894 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, in violation of 35 U.S.C. § 271(c). The moving-focal-spot acquisition functionality of the Accused Products has no substantial non-infringing use.

72. Hologic's inducement of, and contribution to, the direct infringement of the '894 Patent has been, and is, continuous and ongoing through the acts described above in connection with Hologic's provision of the Accused Products.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

73. Hologic imports components of the Accused Products into the United States, sells the Accused Products for importation of components thereof into the United States, and/or sells the Accused Products within the United States after importation of components thereof. *See* Exhibits 20–22, 32–35, 37–38, 40–41.

74. Specifically, on information and belief, Hologic directly or indirectly imports foreign-manufactured components of the Envision® Mammography Platform and incorporates those components into Envision® during final assembly in Newark, Delaware, which is where

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Hologic conducts its U.S. Breast Health capital equipment manufacturing operations, *see* Exhibit 31, and then sells, offers for sale, delivers, installs, services, and supports the completed systems in the United States.

75. Hologic has publicly acknowledged that it relies on foreign-sourced semiconductors and other components. *See* Exhibits 32–34. For example, Hologic stated in its Annual Report on Form 10-K for Fiscal Year 2025 that its ability to manufacture its Breast Health capital equipment products depends on the supply of raw materials and components "including semiconductor chips," and that certain components "are available only from one or a limited number of suppliers." *See* Exhibit 32, at 12, 28.

76. In an April 25, 2025 comment to the U.S. Department of Commerce in the Section 232 semiconductor investigation, Hologic represented that it "relies on advanced semiconductors and related components" for its medical devices and cautioned against additional tariffs on those components. *See* Exhibit 33, at 1.

77. In a further October 17, 2025 comment to the Department in its Section 232 investigation of imports of medical equipment, Hologic acknowledged that it relies on "highly specialized global supply chains" for "specialized components and technologies that are not always available domestically," including "precision optics, electronics, and high-grade polymers." Exhibit 34, at 3–5. Hologic also stated that its manufacturing model is intentionally designed to concentrate final assembly of its consoles in the United States while sourcing components and consumables from abroad. *See id.* at 3. Notably, Hologic cautioned the Department to "careful[ly] consider" any reciprocal tariffs on medical goods classified under the

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principal mammography-related Harmonized Tariff Schedule (HTS) heading—9022[8]—noting it "encompass[es] essential devices, components, and consumables." *See id.* at 4, 6.

78. On information and belief, the Envision® Mammography Platform relies on imported components, such as semiconductor-based electronics—including field-programmable gate arrays (FPGAs), thin-film-transistor (TFT) arrays, application-specific integrated circuits (ASICs), and other integrated circuits—to implement its imaging functionality, including the moving-focal-spot functionality that steers the electron-beam focal spot across the anode in the direction opposite to, and at synchronous speed with, the movement of the X-ray tube during each tomosynthesis scan. *See* Conf. Exhibit 55C, at Figs. 6–9; Conf. Exhibit 55-1C, at Figs. 5–8; *see also* Exhibit 21, at 5–6.

79. Further evidence of Hologic's importation of foreign-manufactured components that are incorporated into the Envision® Mammography Platform is set forth in Confidential Exhibit 63C.

80. The Panjiva trade platform also reflects that Hologic has recently imported X-ray-apparatus components, detector components, and image receptors—some of which classified under heading 9022 of the HTS—from foreign suppliers, as reflected in the following representative shipment records:

Date	**Shipper → Consignee**	**Goods Shipped (as described in record)**	**HTS / HS**	**Panjiva Record**
May 27, 2025	Integrated Medical Systems → Hologic, Inc.	"ASSY PWR DIST DRAWER"	9022.90.6000	Ex. 41, Row 505
Dec. 10, 2020	Hologic Australia (Pty) Ltd. →	"SPARE PARTS … HS CODE 902214"	9022.14	Ex. 41, Row 1899

[8] HTS 9022: "Apparatus based on the use of X-rays or of alpha, beta, gamma or other ionizing radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus, X-ray tubes and other X-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like; parts and accessories thereof." Exhibit 35.

[redacted]

	Hologic, Inc.			
May 17, 2025	Hologic Australia & NZ → United States	"MEDICAL DEVICES - DETECTORS AND MONITORS"	N/A	Ex. 41, Row 525
July 1, 2026	MD Healthcare Co., Ltd. → Warehouse Logistics Inc. (Container marked for Hologic, Newark, DE Field Returns)	"RETURN DEFECTIVE IMAGE RECEPTOR"	N/A	Ex. 41, Row 9

81. Hologic markets and offers the Accused Products, including the Envision® Mammography Platform, for sale throughout the United States, including through its website, and unveiled the Envision® platform in the United States at the December 2024 annual meeting of the Radiological Society of North America. *See* Exhibits 20, 22. The Envision® Mammography Platform is an FDA-approved mammography system (PMA No. P080003/S009, approved July 5, 2024). *See* Exhibit 21, at 6–7. On information and belief, Hologic has delivered, installed, and/or placed Envision® Mammography Platform systems with customers and clinical sites in the United States, including the United States sites participating in Hologic's prospective multicenter clinical evaluation of the Envision® platform. *See* Exhibit 42.

VIII. HARMONIZED TARIFF SCHEDULE NUMBERS

82. The Accused Products are classified under at least heading 9022 of the Harmonized Tariff Schedule of the United States, and in particular under subheading 9022.14.00 (apparatus based on the use of X-rays, for medical uses). The foreign-manufactured components and parts incorporated into the Accused Products are classified under at least subheadings 9022.30.00 (X-ray tubes), 9022.90.60 (parts and accessories of apparatus based on the use of X-rays), and 8542.31 or 8542.39 (electronic integrated circuits). These classifications are

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exemplary in nature and not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

IX. THE DOMESTIC INDUSTRY RELATING TO THE '894 PATENT

83. A domestic industry, as defined by Section 337(a)(2) and (3), exists or is in the process of being established in the United States through Siemens Healthineers' investments in plant, equipment, labor, and capital directed toward the research and development, manufacturing, marketing, sales, warehousing, distribution, installation, servicing, training, education, and customer support activities related to Siemens Healthineers' MAMMOMAT B.brilliant® system (the "Domestic Industry Product").

84. Siemens Healthineers' domestic industry reflects a long-standing commitment to the technology of the '894 Patent. The Domestic Industry Product embodies flying-focus tomosynthesis technology that Siemens Healthineers has been licensed to practice under the '894 Patent since the patent was filed and now owns. *See supra* Section II, ¶ 16; Section V; *see also* Conf. Exhibits 45C, 62C. Siemens Healthineers' substantial and continuing United States investments in the Domestic Industry Product, detailed below, are thus directed to technology that Siemens Healthineers has long had an interest in. *See* Conf. Exhibit 15C, at ¶¶ 8, 11–12, 14.

A. Technical Prong

85. The following Domestic Industry Product is protected by at least one claim of the '894 Patent:

- MAMMOMAT B.brilliant®[9]

[9] The identification of the MAMMOMAT B.brilliant® system is intended to be exemplary. Siemens Healthineers USA reserves the right to identify additional domestic industry mammography systems that practice the asserted claims.

[redacted]

86. A claim chart applying exemplary independent claims 1 and 10 of the '894 Patent to the MAMMOMAT B.brilliant® is attached as Confidential Exhibit 7C.[10]

B. Economic Prong

87. There is a domestic industry as defined under 19 U.S.C. § 1337(a)(3)(A), (B), and (C), comprising past and continuing significant and substantial investments made in the United States by Siemens Healthineers in plant and equipment, and in the employment of labor and capital towards manufacturing, marketing, sales, installation, servicing, training and education, warehousing, distribution, and customer support of the Domestic Industry Product in the United States, as well as substantial investments in the exploitation of the '894 Patent through research and development directed to the Domestic Industry Product. Siemens Healthineers' significant and substantial investments include at least those that are detailed in the Declaration of Philipp Schmidt (Confidential Exhibit 15C).

88. At all times relevant to the investments described in this section, each of Siemens Healthineers USA and Siemens Healthineers AG has been either the owner of, or a licensee under, the '894 Patent, so the investments of both count toward the domestic industry requirement. *See* Conf. Exhibit 15C, at ¶ 5; Conf. Exhibit 62C. Consistent with the Declaration of Philipp Schmidt, this section refers to those investments collectively as investments by Siemens Healthineers. *See* Conf. Exhibit 15C, at ¶ 4.

1. Investments in Labor and Capital (19 U.S.C. § 1337(a)(3)(B))

89. By virtue of its employment of personnel in its teams, manufacturing, and supporting its MAMMOMAT B.brilliant® system, Siemens Healthineers has made and

[10] The Domestic Industry Product is protected by additional claims of the '894 Patent, and Siemens Healthineers USA may establish the technical prong of the domestic industry requirement through claims other than those explicitly charted.

[redacted]

continues to make significant investments in the United States in the employment of labor directed to the Domestic Industry Product, in the form of both employee compensation (e.g., salaries and benefits) and fees paid to outside contractors and consultants. Conf. Exhibit 15C, at ¶¶ 15, 23.

90. Siemens Healthineers engages in the following activities in the United States for the Domestic Industry Product: (a) manufacturing ("Manufacturing"); (b) marketing, sales, warehousing, and distribution (collectively, "Commercialization"); (c) post-sale customer support activities, including installation, servicing, training, and education (collectively, "Customer Support"); and (d) research and development ("R&D")[11]. These expenditures include employment of labor and capital and expenditures on plant and equipment. *Id*. at ¶¶ 16, 33.

91. Manufacturing activities for the Domestic Industry Product include the manufacture of the MAMMOMAT B.brilliant® system. *Id*. at ¶ 18. Siemens Healthineers employs personnel at its Hoffman Estates, Illinois manufacturing facility that manage regulatory affairs and FDA compliance, quality assurance, and finances for the manufacture of the MAMMOMAT B.brilliant®. *Id*. Additional employees manage the upkeep of the facility. *Id*.

92. Siemens Healthineers is expanding, and plans to further expand, its United States manufacturing operations relating to the Domestic Industry Product. As noted above, Siemens Healthineers has recently transferred manufacturing activities relating to its MAMMOMAT B.brilliant® mammography systems to the United States, and it plans to continue increasing its United States manufacturing footprint, personnel, and capital investments directed to the Domestic Industry Product. *Id.* at ¶¶ 12, 37. These ongoing and planned expansions will further

[11] Siemens Healthineers' investments in R&D are described in the exploitation section below. *See infra* Section IX.B.3.

[redacted]

increase Siemens Healthineers' domestic investments in plant, equipment, labor, and capital directed to the manufacture of the Domestic Industry Product. *Id.*

93. Commercialization activities for the Domestic Industry Product include Siemens Healthineers' marketing, advertising, warehousing, sales and distribution of the Domestic Industry Product in the United States. Siemens Healthineers employs personnel at its Malvern, Pennsylvania headquarters and throughout the United States, who perform marketing, advertising and sales work relating to the Domestic Industry Product. *Id*. at ¶ 19. Siemens Healthineers also invests in third-party contractors who perform various warehousing and shipping activities involving the Domestic Industry Product. *Id*. at ¶ 22.

94. Customer Support for the Domestic Industry Product includes installation, servicing, training machine operators, and customer education. Siemens Healthineers offers warranty coverage and service agreements for its mammography systems, including preventive maintenance, troubleshooting, repairs, software support, and replacement parts. *Id*. at ¶ 20. Siemens Healthineers employs U.S.-based field service engineers who service and maintain the MAMMOMAT B.brilliant® machines at customer sites, as well as additional U.S.-based representatives who support installation. *Id*.

95. Siemens Healthineers also offers equipment and clinical education, including training associated with newly installed systems, software and hardware upgrades, and clinical workflows. *Id*. Siemens Healthineers employs representatives, including members of its Women's Health education team, who provide education and training from Siemens Healthineers' Education and Development Center ("EDC") in Cary, North Carolina, and support at customer locations. *Id*.

[redacted]

96. Additionally, as part of Siemens Healthineers' efforts to provide mammography services to women in underserved communities, it invests in mobile mammography services.[12] Conf. Exhibit 15C, at ¶ 21. To support the hospitals and organizations that provide mobile mammography using the Domestic Industry Product, Siemens Healthineers' representatives and other marketing and sales personnel support these mobile mammography services, including the screening and diagnostic mammograms performed from inside the trucks. *Id.*

97. Siemens Healthineers' investments in labor and capital directed to the Domestic Industry Product are further set forth in the Declaration of Philipp Schmidt. *Id.* at ¶¶ 15–24.

2. Investments in Plant and Equipment (19 U.S.C. § 1337(a)(3)(A))

98. Siemens Healthineers has made and continues to make significant investments in the United States in plant and equipment directed to the manufacturing, marketing, sale, distribution, installation, servicing, training, and post-sale support of the Domestic Industry Product. Conf. Exhibit 15C, at ¶ 25.

99. Siemens Healthineers makes regular investments in the form of rent, ownership, and maintenance of its domestic facilities. *Id*. at ¶ 26. These facilities are used to conduct Siemens Healthineers' operations, including those directed to the Domestic Industry Product. *Id*. For example, Siemens Healthineers leases its Malvern, Pennsylvania headquarters that totals approximately 126,000 square feet, and has invested to upgrade and refurbish the facility. *Id*. Siemens Healthineers USA's headquarters facility is shown below:

[12] Siemens Healthineers' mobile mammography services include installation of the Domestic Industry Product in customized trucks that can reach women in urban or rural communities without access to hospitals with mammography equipment. *See* Exhibit 17.

[redacted]



100. Siemens Healthineers also leases its Cary, North Carolina EDC, which serves as its primary hub for imaging and laboratory diagnostic equipment training, that totals approximately 68,000 square feet, and it has invested to upgrade and refurbish the facility. *Id*. Siemens Healthineers' EDC is shown below:



101. Siemens Healthineers also owns its Hoffman Estates, Illinois manufacturing facility that totals approximately 382,000 square feet, and it has invested to upgrade and

[redacted]

refurbish the facility. *Id*. Siemens Healthineers' Hoffman Estates manufacturing facility is shown below:



102. Siemens Healthineers also leases its Memphis, Tennessee World Distribution Center managed by DHL Supply Chain that totals approximately 260,000 square feet, and it has invested to upgrade and refurbish the facility. *Id*. Siemens Healthineers' Memphis World Distribution Center is shown below:

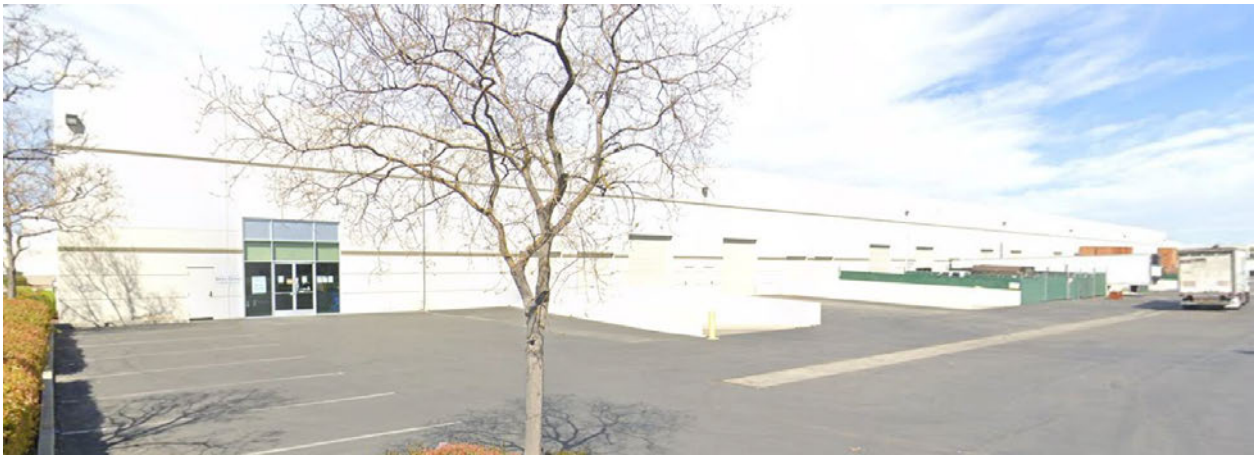


103. Siemens Healthineers also leases two major coastal distribution "mega depots" managed by GXO Logistics in Dayton, New Jersey and Manteca, California, which, together with the Memphis World Distribution Center, total more than 300,000 square feet, and it has invested to upgrade and refurbish these facilities.[13] *Id*. Siemens Healthineers' east and west coast mega depots are shown below:

[13] Siemens Healthineers also stores spare parts for the Domestic Industry Product at an additional nineteen locations throughout the United States. *Id*. at ¶ 26.

[redacted]





104. Siemens Healthineers also makes regular domestic investments in equipment by acquiring, purchasing, and owning a variety of equipment and assets, both physical and electronic, to support its U.S.-based operations and the Domestic Industry Product. *Id*. at ¶ 28. For example, Siemens Healthineers has in its Hoffman Estates, Illinois facility a variety of manufacturing and quality-assurance equipment used in the manufacture of the Domestic Industry Product. *Id*. Furthermore, throughout its United States operations, it has training and instructional equipment, tools, computers, parts inventories, and software used to support the installation, servicing, training, and operation of the Domestic Industry Product. *Id*. Siemens Healthineers' investments in plant and equipment for the Domestic Industry Product are further set forth in the Declaration of Philipp Schmidt. *Id.* at ¶¶ 25–29.

[redacted]

3. Investments in the Exploitation of the '894 Patent Through Research and Development (19 U.S.C. § 1337(a)(3)(C))

105. Siemens Healthineers has also made and continues to make substantial investments in the United States in the exploitation of the '894 Patent through research and development directed to the Domestic Industry Product. Conf. Exhibit 15C, at ¶ 30.

106. Siemens Healthineers' United States-based R&D personnel conduct collaborative research projects with United States hospitals, universities, and academic medical centers to refine and further improve the MAMMOMAT B.brilliant® system, including research directed to the features protected by the '894 Patent. *Id.* at ¶ 31. Siemens Healthineers' investments in exploitation of the '894 Patent through R&D are further set forth in the Declaration of Philipp Schmidt. *Id.* at ¶¶ 30–32.

4. Significance of Siemens Healthineers' Domestic Investments

107. Viewed holistically, a significant and substantial portion of Siemens Healthineers' Women's Health activities, which include manufacturing, installation, servicing, marketing, sales, warehousing, training, education, research and development, and distribution of the Domestic Industry Product and support for this product, takes place in the United States. *Id*. at ¶¶ 14–33. Siemens Healthineers' domestic investments and activities relating to the Domestic Industry Product are significant and substantial under Section 337. *Id*. at ¶¶ 33–36. Moreover, they are significant and substantial both in absolute terms and relative to Siemens Healthineers' overall Women's Health operations in the United States and globally. *Id*. at ¶¶ 34–36. Siemens Healthineers' investments in the Domestic Industry Product are vital to Siemens Healthineers' business with respect to this product and represent significant added value to Siemens Healthineers' Women's Health business as a whole. *Id*. at ¶ 35.

[redacted]

5. Domestic Industry in the Process of Being Established (19 U.S.C. § 1337(a)(2))

108. To the extent the Commission determines that Siemens Healthineers' existing investments described above have not yet established a domestic industry, Siemens Healthineers is in the process of establishing a domestic industry with respect to the '894 Patent, per 19 U.S.C. § 1337(a)(2).[14] For example, Siemens Healthineers has made, and continues to make, substantial domestic investments to establish and expand its United States manufacturing of the Domestic Industry Product, including by transferring MAMMOMAT B.brilliant® manufacturing operations to the United States and dedicating additional plant, equipment, labor, and capital to those operations. *Id.* at ¶¶ 12, 18, 27–28, 37; *see also* Exhibit 36. Siemens Healthineers is likewise expanding its United States research and development directed to the Domestic Industry Product, including through additional planned research collaborations. Conf. Exhibit 15C, at ¶ 38. Siemens Healthineers has thus taken tangible steps toward establishing and expanding an industry in the United States directed to the Domestic Industry Product that practices the '894 Patent, and there is a significant likelihood that Siemens Healthineers USA will satisfy the domestic industry requirement in the near future through these continuing and expanding investments. Conf. Exhibit 15C, at ¶¶ 12, 18, 27–28, 37–38.

X. RELATED LITIGATION

109. Siemens Healthineers USA has asserted the '894 Patent against Hologic in the United States District Court for the District of Delaware, *Siemens Medical Solutions USA, Inc. v. Hologic, Inc.*, No. 1:26-cv-01460 (complaint filed Nov. 13, 2026). That civil action has commenced recently, and Hologic has yet to answer Siemens Healthineers USA's complaint.

[14] These allegations are pleaded in the alternative, and Siemens Healthineers USA maintains that the allegations above, along with the accompanying Declaration of Philipp Schmidt, show that a domestic industry already exists under 19 U.S.C. § 1337(a)(3).

[redacted]

110. In addition, Siemens Healthineers AG and Hologic have been involved in litigation at the European Patent Office (appeal T 1762/21) and the Unified Patent Court, *Hologic, Inc. v. Siemens Healthineers AG et al.*, UPC_CFI_758/2024, where Siemens Healthineers AG relied upon the '894 Patent's European counterpart, EP2262428B1, and its published international application, WO 2009/122328 A1, as part of its defense.

111. Excluding the two actions above, the unfair methods of competition and unfair acts alleged in this Complaint, including subject matter thereof, have not been the subject of any other court or agency litigation, or of any arbitration.

XI. RELIEF REQUESTED

112. Siemens Healthineers USA respectfully requests that the Commission:

(a) Institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to Hologic's violations arising from the importation into the United States, sale for importation, and/or the sale within the United States after importation of Hologic's Accused Products—including the Envision® Mammography Platform—that infringe one or more claims of the '894 Patent;

(b) Schedule and conduct a hearing pursuant to Section 337(c) for the purposes of (i) receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and (ii) following the hearing, determining that there has been a violation of Section 337;

(c) Issue a permanent limited exclusion order directed to products manufactured, imported, sold for importation and/or sold after importation by or on behalf of Hologic, its subsidiaries, related companies, and agents pursuant to 19 U.S.C. § 1337(d) excluding entry into

[redacted]

the United States of Hologic products that infringe one or more claims of the '894 Patent, including, for example, the Envision® Mammography Platform;

(d) Issue a permanent cease and desist order pursuant to 19 U.S.C. § 1337(f) prohibiting Hologic, its domestic subsidiaries, related companies, and agents from engaging in the importation, sale for importation, marketing and/or advertising, distribution, installing, testing, servicing, repairing, supplying spare parts, offering for sale, sale, use after importation, sale after importation, or any other commercialization within the United States of Hologic's products that infringe one or more claims of the '894 Patent, including, for example, the Envision® Mammography Platform;

(e) Impose a bond upon importation of Hologic's products that infringe one or more claims of the '894 Patent, including, for example, the Envision® Mammography Platform, during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(j); and

(f) Issue such other and further relief as the Commission deems just and proper.

Dated: November 16, 2026

Respectfully submitted,

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