UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUJIFILM Corporation *et al.*

Petitioners

v.

Hologic, Inc.

Patent Owner

CASE: Unassigned

Patent No. 7,123,684

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 7,123,684

PETITIONERS' EXHIBIT LIST

Ex. 1001 Declaration of Dr. Christopher Daft

Ex. 1002 Curriculum Vitae of Dr. Christopher Daft

Ex. 1003 U.S. Patent No. 7,123,684 to Zhenxue Jing, et al. ("the '684 Patent")

Ex. 1004 Patent File History for the '684 Patent

Ex. 1005 United States Patent No. 7,443,949 to Kenneth F. Defreitas et al. ("Defreitas")

Ex. 1006 United States Patent No. 5,872,828 to Loren T. Niklason et al. ("Niklason")

Ex. 1007 United States Patent Application Publication No. US 2001/0038679, identifying Serge Muller et al. as named inventors ("Muller")

Ex. 1008 Japanese Patent Application Publication No. S64-46436 identifying Masatsugu Kawamata as inventor ("Kawamata")

Ex. 1009 Certified translation of Kawamata

Ex. 1010 Japanese Patent Application Publication No. H08-186762 identifying Shinichi Yamada and Seiichiro Nagai as inventors ("Yamada")

Ex. 1011 Certified translation of Yamada

Ex. 1012 Portions of the Patent File History for Defreitas

Ex. 1013 International Publication Number WO 03/037046 A2 (publication of Defreitas PCT application)

Ex. 1014 Assignment of Assignors' Interest for Application 10/305,480 (which issued as the '684 Patent), United States Patent Office Reel/frame 014202/0430

Ex. 1015 Assignment of Assignors' Interest for Application 10/496,049 (which issued as Defreitas), United States Patent Office Reel/frame 015887/0928 and 018555/0314

Ex. 1016 Mammography Quality Control Manual, American College of Radiology (1999)

Ex. 1017 "Correspondence between different view breast X-rays using a simulation of breast deformation" Yasuyo Kita, et al., published in Proceedings of the 1998 IEEE Computer Society Conference on Computer Vision and Pattern Recognition

Ex. 1018 "Automatic breast region extraction from digital mammograms for PACS and telemammography applications" by S.L. Lou et al. published in Computerized Medical Imaging and Graphics 2000; 24:205-220 ("Lou")

Ex. 1019 Hologic, Inc. Eighth Supplemental Objections and Responses to Respondents' First Set of Interrogatories to Complainant Hologic, Inc., Revised Exhibit 1, U.S. International Trade Commission Investigation No. 337-TA-1063, dated January 5, 2018

Ex. 1020 "Digital Tomosynthesis in Breast Imaging," Loren T. Niklason, PhD, et al., Radiology 1997; 205:399-406

Ex. 1021 Hologic, Inc. Eighth Supplemental Objections and Responses to Respondents' First Set of Interrogatories to Complainant Hologic, Inc., Revised Exhibit 2, U.S. International Trade Commission Investigation No. 337-TA-1063, dated January 5, 2018

Ex. 1022 Jerrold T. Bushberg et al., The Essential Physics of Medical Imaging (2d ed. 2002) (excerpts)

Ex. 1023 Ingrid Reiser & Stephen Glick, Tomosynthesis Imaging (2014) (excerpts)

Ex. 1024 "Human observer detection experiments with mammograms and power-law noise," Arthur E. Burgess et al., published in Medical Physics 2001; 28:419-437

Ex. 1025 S. Vedantham et al., "Digital Breast Tomosynthesis: State of the Art," published in Radiology 2015; 277:663-684

Ex. 1026 H.K. Huang, PACS and Imaging Informatics: Basic Principles and Applications (2d ed. 2010) (excerpt)

TABLE OF CONTENTS

I. INTRODUCTION

Petitioners respectfully request *inter partes* review of claims 11, 29, 33, and 41 (the "Challenged Claims") of U.S. Patent No. 7,123,684 ("the '684 Patent") (Ex. 1003).

X-ray mammography systems take mammogram images of a patient's breast to screen for breast cancer and other pathologies. To take a mammogram, the patient's breast is compressed with a paddle (to improve image quality) and irradiated from one or more angles. As the '684 Patent acknowledges, the breast often would only take up part of the resulting image because the breast often was smaller than the image receptor—particularly when using a mammography machine with a digital image receptor. The portion of the image outside of the breast typically was not useful. Transmitting and storing that excess portion wasted resources.

The '684 Patent proposes, and the Challenged Claims encompass, a simple solution to this problem: to use information about the breast compression paddle, derived automatically, "to in effect crop the resulting breast image before transmitting and/or storing and/or formatting." Ex. 1003, 5:65-6:2. That is, the portion of the image under the paddle (encompassing the breast) is kept, the rest is discarded. The Challenged Claims are directed to this broad overall concept, not some clever (or even specific) means of achieving it. The '684 Patent says little else about this

alleged invention or its implementation—the entire textual description of this "reduced field of view" image concept takes up less than one column of the specification, even counting the description of unclaimed embodiments. Likewise, the Challenged Claims do not require any specific means of "automatically deriv[ing] information" about the compression paddle or any specific means of creating a "reduced field of view image" based on that information.

But this broad overall concept was well-known in the art. Petitioners present three independent arguments, each of which renders the Challenged Claims unpatentable. The first is based on an earlier patent (Defreitas) presently assigned to the same Patent Owner ("Hologic"), but which qualifies as prior art for both anticipation and obviousness purposes. In pending litigation, *Patent Owner has not contested that Defreitas discloses all elements* of (i.e., anticipates) two Challenged Claims; the only missing element of the other Challenged Claims is to apply Defreitas to a specific known type of mammography called tomosynthesis, an obvious application. The second and third arguments are based on the work of two medical imaging leaders—GE and Toshiba. Like the Challenged Claims, these references disclose automatically determining information about the paddle to obtain and then use a reduced field of view image defined by the paddle.

For these reasons, and as described in detail below, the Board should institute *inter partes* review of the '684 Patent and cancel the Challenged Claims.

II. 37 C.F.R. § 42.8: MANDATORY NOTICES

A. 37 C.F.R. § 42.8(b)(1): Real Parties-in-Interest

The following are the Petitioners and real parties-in-interest: FUJIFILM Corporation; FUJIFILM Medical Systems USA, Inc.; and FUJIFILM Techno Products Co., Ltd.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

To the best knowledge of Petitioners, the '684 Patent is involved in the following litigations and matters:

Case Name	Case No.	Court	Filed
In the Matter of Certain X-Ray Breast Imaging Devices and Components Thereof	337-TA-1063	U.S. International Trade Commission	June 28, 2017
Hologic, Inc., v. FUJIFILM Medical Systems USA, Inc., FUJIFILM Corporation, and FUJIFILM Techno Products Co., Ltd.	3:17-cv-1056	United States District Court for the District of Connecticut	June 26, 2017

C. 37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4): Lead and Back-up Counsel and Service Information

Petitioners provide the following designation of counsel:

Lead Counsel	Back-up Counsel
T. Vann Pearce, Jr. Reg. No. 58,945 ORRICK, HERRINGTON & SUTCLIFFE LLP 1152 15th Street, N.W. Washington, DC 20005-1706 Telephone: (202) 339-8400 Facsimile: (202) 339-8500 vpearce@orrick.com	Christopher J. Higgins Reg. No. 66,422 ORRICK, HERRINGTON & SUTCLIFFE LLP 1152 15th Street, N.W. Washington, DC 20005-1706 Telephone: (202) 339-8400 Facsimile: (202) 339-8500 chiggins@orrick.com

Petitioners submit Powers of Attorney with this Petition. Please address all correspondence to lead and back-up counsel. Petitioners consent to service by email at: **FUJIFILM-HologicIPR@orrick.com**

III. 37 C.F.R. § 42.104(a): GROUNDS FOR STANDING

Petitioners certify that the '684 Patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified in this petition. Petitioners

also certify that this Petition for *Inter Partes* Review is timely filed under 35 U.S.C. § 315(b).

IV. 37 C.F.R. § 42.104(b): IDENTIFICATION OF CHALLENGE

A. 37 C.F.R. § 42.104(b)(1): Claims for Which IPR is Requested

Claims 11, 29, 33, and 41 are challenged in this Petition.

B. 37 C.F.R. § 42.104(b)(2): Identification of Prior Art and Asserted Grounds for Which IPR is Requested

The one-year time bar under pre-AIA 35 U.S.C. §102(b) is measured from the effective U.S. filing date of the '684 Patent, which is no earlier than November 27, 2002, the filing date of the application leading to the '684 Patent.

Petitioners request *inter partes* review in view of the following prior art references:

- United States Patent No. 7,443,949, titled "Mammography system and method employing offset compression paddles, automatic collimation, and retractable anti-scatter grid," issued to Kenneth F. Defreitas et al. as named inventors ("Defreitas") (Ex. 1005);
- United States Patent No. 5,872,828, titled "Tomosynthesis system for breast imaging," issued to Loren T. Niklason et al. as named inventors ("Niklason") (Ex. 1006);
- United States Patent Application Publication No. US 2001/0038679, titled "Radiological imaging device, method and program of control associated

with the device," identifying Serge Muller et al. as named inventors ("Muller") (Ex. 1007);

- Japanese Patent Application Publication No. S64-46436, titled "Mammography apparatus," identifying Masatsugu Kawamata as inventor and Toshiba Corporation as applicant ("Kawamata") (Ex. 1008 - original) (Ex. 1009 - certified translation);
- Japanese Patent Application Publication No. H08-186762, titled "Mammography apparatus," identifying Shinichi Yamada and Seiichiro Nagai as inventors and Toshiba Medical Engineering KK and Toshiba Corporation as applicants ("Yamada") (Ex. 1010 - original) (Ex. 1011 - certified translation).
- The '684 patent's admissions regarding what was known in the prior art, specifically the statements at 1:14-2:30 (the "Admitted Prior Art").

None of Petitioners' references, except for Niklason, were considered during the '684 Patent's prosecution, nor are they cumulative of the prior art considered during prosecution. As discussed further below, 35 U.S.C. § 325(d) does not affect consideration of the grounds involving Niklason. *See infra* 35-36. 35 U.S.C. § 325(d) also does not apply to Defreitas or arguments based on Defreitas. The provisional application and PCT application to which Defreitas claims priority are referenced briefly in the '684 Patent's specification. Ex. 1003, 1:39-44. But

neither these applications, nor any published version of them, nor Defreitas itself, are listed as "References Cited" on the face of the '684 Patent. Ex. 1003. And nothing in the '684 Patent's prosecution history suggests that Patent Owner presented, or the Examiner considered, Defreitas or its predecessor applications as prior art. *See generally* Ex. 1004.

Ground 1: Claims 11 and 41 are unpatentable as anticipated by Defreitas.

Ground 2: Claims 29 and 33 are unpatentable as obvious over Defreitas in view of Niklason.

Ground 3: Claims 11 and 41 are unpatentable as obvious over Muller in view of the Admitted Prior Art.

Ground 4: Claims 29 and 33 are unpatentable as obvious over Muller in view of the Admitted Prior Art and Niklason.

Ground 5: Claims 11 and 41 are unpatentable as obvious over Kawamata in view of Yamada.

Ground 6: Claims 29 and 33 are unpatentable as obvious over Kawamata in view of Yamada and Niklason.

A detailed explanation of how each document qualifies as prior art follows:

Defreitas qualifies as prior art under pre-AIA 35 U.S.C. § 102(e). In relevant part, that statute defines as prior art: "a patent granted on an application for patent by another filed in the United States before the invention by the

application for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language." Defreitas meets all requirements of this statute.

Defreitas is "a patent granted on an application for patent ***by another***" (emphasis added). "A different inventive entity is prima facie evidence that the reference is 'by another.'" MPEP 2136.04(II). "The inventive entity is different if not all inventors are the same." MPEP 2136.04(III). Defreitas and the '684 Patent each name five inventors. Four of these named inventors are completely different across the two patents; accordingly, Defreitas and the '684 Patent have different inventive entities and thus Defreitas is "by another."[1]

Defreitas is "before the invention by the applicant for patent." Defreitas issued as a U.S. patent on October 28, 2008, from an international patent application filed under the Patent Cooperation Treaty on October 17, 2002. Ex. 1005. The Defreitas PCT application designated the United States and was published in English on May 1, 2003. Ex. 1013. Thus, the Defreitas PCT

[1] The lone overlapping inventor was added to Defreitas by a last-minute, post-allowance petition to correct inventorship. *See* Ex. 1012.

application "shall have the effects for the purposes of this subsection of an application filed in the United States" under §102(e). The Defreitas PCT application filing date of October 17, 2002, predates the November 27, 2002, filing date—and presumptive inventive date—of the '684 Patent's application.

Thus, Petitioners have demonstrated that Defreitas is prior art to the Challenged Claims under §102(e), and may be used for both anticipation and obviousness purposes. Patent Owner bears the burden of producing evidence of prior invention. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015). Furthermore, Patent Owner bears the burden of producing evidence that Defreitas is not available as an obviousness reference under pre-AIA § 103(c). *See, e.g., Global Tel*Link Corp. v. Securus Techs., Inc.*, IPR2014-00825, Paper 36 at 11 (P.T.A.B. Dec. 2, 2015) ("Petitioner satisfied its burden of production by arguing in its Petition that [the reference] was prior art under § 102(e) and, in combination with one or more other prior art references, would have rendered claims 1–20 obvious at the time the invention was made under § 103(a). … The burden of production then shifted to Patent Owner to argue or produce evidence that [the reference] was not prior art."). If Patent Owner attempts to swear behind Defreitas in its Preliminary Response, or otherwise produce evidence allegedly showing that Defreitas is not prior art for anticipation

or obviousness purposes, then Petitioners expect to request leave to file a Reply to address Patent Owner's evidence and argument.

Although Petitioners have met their burden of production already, Petitioners note that the Patent Office's public assignment records reflect that the '684 Patent inventors did not execute their assignments until June 2003, and the Defreitas inventors did not do so until October 2004 or November 2006. Exs. 1014 and 1015. All of those assignments were executed well after the effective filing date of the '684 Patent. *See, e.g.*, *Indus. Tech. Res. Inst. v. Pac. Biosciences of Cal., Inc.*, 640 F. App'x 871, 883 (Fed. Cir. 2016) ("[E]vidence of common ownership by assignment after the application filing date does not establish common ownership or an obligation to assign ownership *at the time of the invention*.").

Niklason issued as a U.S. patent on February 16, 1999, more than one year before the effective filing date of the '684 Patent. Niklason is prior art at least under pre-AIA 35 U.S.C. § 102(b).

Muller is a U.S. patent application publication that published on November 8, 2001, more than one year before the effective filing date of the '684 Patent, and is prior art at least under pre-AIA 35 U.S.C. § 102(b).

Kawamata is a Japanese patent application publication that lists on its face a "Publication date" of February 20, 1989, more than one year before the effective

filing date of the '684 Patent. Kawamata is prior art at least under pre-AIA 35 U.S.C. § 102(b).

Yamada is a Japanese patent application publication that lists on its face a "Publication date" of July 16, 1996, more than one year before the effective filing date of the '684 Patent. Yamada is prior art at least under pre-AIA 35 U.S.C. § 102(b).

The **Admitted Prior Art** are statements from the "Background" of the '684 Patent describing characteristics of "typical[]" X-ray mammography systems, and known proposals for improving upon such systems. The Board may properly consider admissions regarding the prior art found in a challenged patent in an obviousness analysis as probative evidence of the scope and content of the prior art and/or the level of skill in the art, particularly where, as here, the admissions are combined with a patent or printed publication. *See, e.g., Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, Case IPR2014-00309, Paper 83 at 20-22 (P.T.A.B. Mar. 23, 2014).

C. Level of Ordinary Skill in the Art

A person of ordinary skill in the field as of the '684 Patent's effective filing date would have a Master's Degree or Ph.D in physics, electrical engineering, or a related field and would also have at least 2 years of experience in the field of medical imaging. Ex. 1001, ¶ 42. Alternatively, someone with a bachelor's degree

and at least 7 years of experience in the field of medical imaging could also be considered one of ordinary skill in the art. *Id.* A person of ordinary skill in the art would have had a basic understanding of mammography or medical x-ray imaging systems, including common features of such systems at the time of the invention like the use of digital image receptors, compression paddles, and collimation, as well as the different types of mammograms commonly obtained and the purposes for which they were obtained. *Id.* ¶ 43. Furthermore, the Admitted Prior Art would have been known to a person of ordinary skill in the art. *Id.*; *see* Ex. 1003, 1:14-2:30. In related litigation, Hologic has contended that a person of ordinary skill in the art would have had an undergraduate or equivalent degree in engineering or physics or a related discipline and 2-4 years of working experience in the field of mammography or digital x-ray medical imaging systems. The Challenged Claims are unpatentable on the Grounds set forth herein under either definition. Ex. 1001, ¶ 45.

D. 37 C.F.R. § 42.104(b)(3): Claim Construction

The Patent Office gives a claim subject to *inter partes* review "its broadest reasonable construction in light of the specification of the patent in which it appears" to one of ordinary skill in the art. 37 C.F.R. §§ 42.100(b) and 42.103(b)(3); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1281 (Fed. Cir. 2015). Petitioners expressly reserve their right to advance different constructions

in litigation before the U.S. International Trade Commission ("ITC") or in district court, which employ a different claim construction standard.

For purposes of this proceeding only, Petitioners propose adopting, as the broadest reasonable interpretation, the following claim construction proposed by the Commission Investigative Staff counsel in the related ITC litigation referenced above (in that litigation, Hologic has indicated a "willing[ness] to agree" to this construction):

Term	Broadest Reasonable Interpretation
"automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby define a reduced field of view image, wherein said [outline/rectangular region] is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging, said [outline/rectangular region] encompasses an entirety of the	Plain and ordinary meaning, except that "reduced field of view" should be construed as "field of view smaller than the entire field of view of an imaging receptor"

patient's breast in the breast image, and the reduced field of view is defined based on said [outline/rectangular region]" (All Challenged Claims)	

In addition, Petitioners propose clarifying the scope of two claims terms under the broadest reasonable interpretation standard in the ways addressed below:

"processing, transmission, and/or archiving" (Claims 11 and 41)	May be satisfied by any one or more of processing, transmission, or archiving
"the reduced field of view is defined based on said [outline/rectangular region]" (All Challenged Claims)	Encompasses either pre- or post-acquisition reduction of the field of view.

The term "and/or" is disjunctive and requires only one of transmission, processing, or archiving. *See, e.g.*, Decision on Appeal, *Ex Parte Gross*, Appeal No. 2011-004811, 2013 WL 6907805, at *2 (P.T.A.B. Dec. 31, 2013).

The Challenged Claims' language is agnostic on whether the "reduced field of view image" is defined before or after the image is acquired, and is broad enough to encompass either scenario. The only temporal requirement in the Challenged Claims is that "*said* reduced field of view image" is subject to further

"processing," "transmission," and/or "archiving." Thus, the "said reduced field of view image" must exist before the processing/transmission/archiving, but otherwise the Challenged Claims do not delineate whether the field of view is reduced before acquiring the image or afterwards. This accords with the apparent purpose of the alleged invention to "eliminat[e] from storage image areas that do not contain an image of the breast." Ex. 1003, 2:27-28.

Therefore, if Patent Owner argues against unpatentability based on the theory that the Challenged Claims do not cover post-acquisition processing, such argument would be inconsistent with the broadest reasonable interpretation of the "reduced field of view image" term and the rest of the Challenged Claims' language. Indeed, the '684 Patent itself describes the alleged invention as "cropping" an image, that is, processing an image after it has been acquired, to obtain a reduced field of view image which is then transmitted, stored, or formatted. Ex. 1003, 5:65-6:2. Nonetheless, even under such an incorrect construction, the Challenged Claims would be unpatentable in view of at least Grounds 1-2 and 5-6, as further demonstrated below.

E. 37 C.F.R. § 42.104(b)(4): How the Claims Are Unpatentable

The requested review of patentability of the Challenged Claims is governed by statutory provisions of 35 U.S.C. §§ 102 and 103 that were in effect before March 16, 2013. The specific grounds for review and an explanation of why the

challenged claims are unpatentable, including identification of where each element of each claim is found in the prior art, are provided in Section V.

F. 37 C.F.R. § 42.104(b)(5): Evidence Supporting Challenge

The Declaration of Dr. Christopher Daft (Ex. 1001) and other supporting evidence in the Exhibit List are filed herewith. Dr. Daft's background and qualifications, and the information provided to him, are discussed in Ex. 1001, ¶¶ 1-8, 16, 44, and Ex. 1002.

V. THERE EXISTS A REASONABLE LIKELIHOOD THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Technological Background and Description of the Alleged Invention of the '684 Patent

The '684 Patent relates to the field of mammography, which is a type of radiographic examination designed to detect breast pathology, and particularly breast cancer. Ex. 1003, 1:8-10; Ex. 1001, ¶ 18. Mammography is conducted for two general purposes: (1) screening, which is a routine examination of patients with no breast symptoms, intended to detect early signs of cancer; and (2) diagnostic, which is used when an abnormality or problem is reported by the patient or found during a screening mammogram or other medical examination. Ex. 1001, ¶¶ 24-25.

Of particular interest here, in a screening mammogram both breasts may be and often would be imaged in their entirety, with two different views of each breast, as Dr. Daft explains. *Id.* ¶¶ 26-28. Imaging the entire breast comports with

the purpose of screening mammograms—to search for suspicious tissue in asymptomatic patients. *Id.* ¶¶ 26-28, 114. Numerous documents around the time of the '684 Patent's alleged invention and earlier reflect screening mammograms encompassing the entirety of the patient's breast. For instance, guidelines published by the American College of Radiology in 1999 stated that the "primary goal" was to image "the maximum amount of breast tissue in a single view." Ex. 1016 at 34; Ex. 1001, ¶ 28. A 1998 paper cited by the examiner during the '684 Patent's prosecution described and showed in images how a patient's full breast is compressed and imaged during screening mammography. Ex. 1017 at 1-2, 4, 6-7; Ex. 1001 ¶ 26. And a paper published in an industry journal from 2000 ("Lou") also describes and shows screening mammograms imaging a patient's entire breast. Ex. 1018; Ex. 1001, ¶ 27.

Mammography has existed for more than a century. Following the discovery of x-rays in 1895, the first attempts to apply the technology to identify breast cancer were made in 1913. The diagnostic value of mammography has been acknowledged since 1930, and the technology developed steadily over the second half of the twentieth century. Ex. 1001, ¶¶ 19-23.

As the '684 Patent explains, modern mammography machines typically have a common set of components: "an x-ray source mounted at one end of a rotatable c-arm assembly and an image receptor at the other. Between the x-ray source and

the image receptor is a device for compressing and immobilizing a breast." Ex. 1003, 1:14-18; *accord* Ex. 1001, ¶ 29. These systems "often have provisions for partly or fully automating the selection of appropriate technic factors for an x-ray exposure," such as the current or the exposure time. Ex. 1003, 1:45-49. The x-ray beam can also be targeted to an appropriate size and direction, so as to reach only the tissue being imaged, through the use of collimators—an arrangement of lead shutters that restrict the x-ray beam to the desired area and direction. Ex. 1001, ¶ 31. The image receptor only creates an image where the x-ray beam strikes. *Id.* ¶ 32. Thus, collimating the x-ray beam also reduces the area of the resulting image to match the area covered by the beam, typically less than the full field of view of the image receptor. *Id.* Radiation targeting can also be achieved from the opposite direction, through use of an anti-scatter grid placed between the compressed breast and the imaging receptor. These grids allow only x-rays that have traveled in a straight line from the source to pass through to the imaging receptor, and to prevent the passage of scattered radiation that can cause loss of contrast in the image. Ex. 1001, ¶ 29.

One of the technological advances of the late twentieth century affected the image receptor. Older mammography machines had used film to develop the image. The '684 Patent acknowledges, however, that "[n]ew mammography systems are now being introduced to use digital image receptors in place of screen-film,

and have many well recognized advantages." Ex. 1003, 1:32-34. In fact, in 1999—three years before the '684 Patent's application was filed—GE had introduced the first commercially available digital mammography system. Ex. 1001, ¶ 23.

Another technological advance that occurred in the 1990s and early 2000s was the use of tomosynthesis, a three-dimensional type of mammography that acquired multiple images of the breast which were digitally reconstructed to allow radiologists to see each "slice" of tissue more clearly. Ex. 1003, 1:62-2:5; Ex. 1001, ¶ 33. Tomosynthesis is useful for reducing both false negatives and false positives in breast cancer detection. Ex. 1001, ¶ 33. Although the concepts behind tomosynthesis, and its benefits for mammography, had long been known, it did not become commercially viable until the late 1990s, with the availability of digital imaging detectors capable of rapidly reading out multiple images. *Id.* ¶ 34.

Against this background, the '684 Patent purports to provide improvements in three areas of mammography: (1) controlling radiation exposure by using an estimate of the thickness and density of the compressed breast; (2) adapting mammography machines to allow the use of tomosynthesis in combination with an anti-scatter grid; and (3) using an effective image size smaller than the full image re-

ceptor area in order to achieve efficiencies in transmission and storage of x-ray images. Ex. 1003, 2:37-50. The Challenged Claims all relate to the third alleged improvement of the '684 Patent. Ex. 1003, Claims 11, 29, 33, 41; Ex. 1001, ¶ 36.

The third alleged improvement—reducing effective image size—addresses a problem arising from the development of digital mammography. Digital mammography requires fine spatial resolution, resulting in large file sizes. *See* Ex. 1001, ¶¶ 33, 54. The problem is compounded with tomosynthesis, where multiple images are digitally added together. *Id.* ¶ 35. These large digital files are more difficult to process, send, and store, and digital mammography places severe performance demands on the picture archiving and communications systems ("PACS") used in medical facilities to share, analyze, and archive radiological images. *Id.* ¶¶ 35, 66-67; Ex. 1018 at 205-06. Yet digital mammogram images often contain large portions of pixels that carry no diagnostic information. This is in part because, unlike film-screen cassettes, digital imaging receptors tend to come in one size that is large enough to accommodate all patients and therefore may be much larger than the particular patient's breast being examined. Ex. 1001, ¶ 30; *see also* Ex. 1003, 5:43-51 & Fig. 5. Accordingly, the '684 Patent identifies an "object" of "improv[ing] the efficiency of x-ray image storage and transmission, particularly for mammography images, by selective use of decreased effective image size." Ex. 1003, 2:46-50.

Researchers had recognized this problem before the '684 Patent, and had also recognized that it could be ameliorated by discarding the useless background pixels and storing only the relevant data. The '684 Patent itself admits that this problem was known and describes one proposed solution, which the '684 Patent contends was limited to a specific type of x-ray beam. Ex. 1003, 2:16-30; Ex. 1001, ¶ 37. Lou also describes this problem and details proposed solutions. Ex. 1018; Ex. 1001, ¶ 67-69.

The '684 Patent depicts this problem in Figure 5, in which "the image **46** of a breast is within a notional rectangular outline **48** (reduced field of view) that is much smaller than the field of view **50** of receptor **12***c*." Ex. 1003, 5:46-49. It purports to solve the problem by using "only the information within the reduced field of view"—that is, the "outline"—that contains the breast image, and discarding any information outside that outline. *Id.*, 5:51-54.

The '684 Patent offers only a high-level, two-paragraph-long sketch of how to solve the problem. *Id.*, 5:58-6:39; Ex. 1001, ¶¶ 38-40. It explains that the relevant outline can be determined in three possible ways, which may be used alone or in combination: (1) automatically determining (by use of an "encoder") the size and position of the compression paddle selected, "so as to match the size and position on receptor **12***c* of the breast being x-rayed"; (2) using "image analysis, such as analysis involving edge detection"; and (3) having the health professional enter

the size and position of the outline through a keyboard based on viewing the full image displayed on a monitor. Ex. 1003, 5:58-6:9, 6:17-21. The '684 Patent provides little detail about how the outline is used to reduce the size of the image. When the outline is generated automatically based on information about the compression paddle, the patent states that "the result [can be] used to in effect crop the resulting breast image before transmitting and/or storing and/or formatting it for transmission or storage." *Id.*, 5:66-2. The patent also describes an arrangement in which a "calculator **58**" determines the outline, which is then "displayed at **60**, e.g., as an outline **48** in an image such as illustrated in FIG. **5**, for the health professional to confirm or modify, e.g. through manual entries." *Id.*, 6:29-35 & Fig. 6.

B. Prosecution History of the '684 Patent

The application that led to the '684 Patent started with five claims that are a far cry from the claims of the issued patent. Ex. 1004, 15-16. The exception—claim 11—began as dependent claim 9 to original claim 3. *Id.*, 60-61. It recited many of the key elements of issued claim 11. *Id.* The examiner rejected claim 9 (and independent claim 3) as anticipated by Chichereau (U.S. Patent No. 6,556,655). *Id.*, 86.

In response, the applicants amended claim 3 (and therefore dependent claim 9) to require that the "outline encompasses *an entirety of the patient's breast* in the breast image and the reduced field of view is defined based on said outline." *Id.*,

110 (emphasis added). The inventors argued that Chichereau merely created a "zone of interest" in a pre-exposure image, and that this zone of interest (1) did not involve an "outline" and (2) did not encompass the entire breast, because it was "specified by the frame of the compression pad," and the type of spot-compression pad used in Chichereau "does not span the full extent of the breast." *Id.*, 119-120.

Nonetheless, the examiner continued to reject claims 3 and 9, finding the former anticipated by a new reference, Rogers (U.S. Patent No. 6,091,841), and the latter obvious in view of Rogers combined with Chichereau. *Id.*, 136-37, 140.

In response, the applicants (1) moved the limitations from claim 3 into claim 9; (2) relabeled claim 9 as an independent claim; and (3) modified the "automatically selecting an outline" limitation—into the form that currently appears in claim 11. *Id.*, 151. They argued that Rogers did not disclose automatically selecting an outline based on information about the compression paddle, and again asserted that Chichereau did not involve an outline (or a reduced field of view image) that encompassed the entirety of the patient's breast. *Id*., 158-60.

The examiner allowed claim 9 in this revised format, stating:

> [The] prior art does not disclose or fairly suggest a mammography method including automatically selecting an outline that encompasses a breast image to thereby define a reduced field of view image, wherein said outline is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray

> imaging, said outline encompasses an entirety of the patient's breast in the breast image, and the reduced field of view is defined based on said outline, in combination with all the limitations in the claim.

Id., 192.

The examiner's reasoning is unclear in light of the examiner's other statements and actions. The examiner continued to reject claim 3. *Id.*, 185. The only element claim 9 adds to claim 3 is the use of automatically derived information about the compression pad to select the outline. The examiner had previously found that Chichereau supplied this missing piece, and the reasons for allowance provide no insight into why the examiner (apparently) changed his mind.

Whatever the reason, once claim 9 was allowed, the applicant added a slew of new independent and dependent claims that, it asserted, "are allowable for at least the reasons that claim 9 is allowable." *Id.*, 63. These claims—numbered 53-68 in the application—include the three remaining Challenged Claims, all of which were allowed without any further rejections by the examiner. *Id.*, 273-74; *see also id.*, 281 (mapping application claims 53, 57, and 65 to issued claims 29, 33, and 41, respectively).

C. Summary of Unpatentability Arguments

This Petition demonstrates the unpatentability of the Challenged Claims based on three primary references: Defreitas, Muller, and Kawamata. Grounds 1-2 are based on Defreitas, Grounds 3-4 are based on Muller, and Grounds 5-6 are

based on Kawamata. The three base references disclose most if not all elements of claims 11 and 41, but differ somewhat in their teachings and thus are not redundant. Defreitas anticipates these claims. Muller discloses all aspects of these claims explicitly but for the requirement that the reduced field of view image encompasses the entirety of the patient's breast in the breast image, which is inherent in Muller or at least obvious in view of Muller, particularly when considering the Admitted Prior Art. Kawamata discloses (expressly or inherently) each element except the final element requiring processing, transmission, or archiving of the image; these well-known concepts are taught in (and would have been obvious in view of) Yamada, a reference from the same company and describing the same general system as Kawamata.

Claims 29 and 33 are similar to claims 11 and 41, just adding a limitation directed to implementing the claimed inventions in tomosynthesis, a well-known type of mammography. Niklason was a seminal patent describing a tomosynthesis. As described in detail below, a person of ordinary skill in the art would have found it obvious to combine Niklason's description of tomosynthesis with the teachings applicable to claims 11 and 41 based on Defreitas, Muller, or Kawamata in a way that would have rendered obvious claims 29 and 33.

D. Common Claim Elements of the Challenged Claims

Independent claims 11, 29, 33, and 41 share many common elements, as reflected in the claim listing appended to this Petition. Common elements of the claims will be addressed together in the sections below.

E. Ground #1: Claims 11 and 41 are Anticipated by Defreitas

1. Defreitas

Defreitas describes a system and method of mammography "that overcomes known disadvantages of proposals involving the otherwise desirable use of flat panel, digital x-ray receptors." Ex. 1005, 2:30-33. The "Background" sections of Defreitas and the '684 Patent are quite similar, in fact identical in places, in their descriptions of existing mammography machines and the state of the art. *Compare* Ex. 1003, 1:14-44, *with* Ex. 1005, 1:14-51.

In relevant part, the Defreitas system allows for the use of different sized compression paddles that can be selected to "match both the size and position of the patient's breast," and it further discloses automatically collimating the x-ray beam based on "the size and position of the compression paddle," "preferably in response to information that is automatically sensed." Ex. 1005, 2:34-45; Ex. 1001, ¶ 52. This collimation creates an image that is smaller than the full field of view of the digital imaging receptor, and Defreitas describes how that image can be processed and transmitted. Ex. 1005, 3:16-20.

As explained in the claim analysis below, Defreitas discloses all limitations of independent claims 11 and 41, in combination, as claimed. Indeed, in related litigation, Hologic has not contested that Defreitas does so. Ex. 1019 (excerpt from Hologic's January 5, 2018 interrogatory response, responding to Petitioners' claim chart for Defreitas, stating only that Defreitas is "[n]ot prior art" as to claims 11 and 41; the only element of the Challenged Claims allegedly "[n]ot disclosed or suggested" is the tomosynthesis element of claim 29). As explained above, Hologic's sole argument as to claims 11 and 41—that Defreitas is not prior art—is incorrect. *See supra* 7-10.

The only difference between independent claim 11 and independent claim 41 is that, each time the former refers to an "outline," the latter refers instead to a "rectangular region." The claims are analyzed together and, where appropriate, a separate discussion of the more generic "outline" versus the more specific "rectangular region" is provided.

2. Independent Claims 11 and 41

a. [a] A mammography method comprising

The preambles of claims 11 and 44 recite "a mammography method comprising." To the extent the preamble is a limitation, Defreitas discloses this limitation. Defreitas is directed to a "Mammography System and Method." *See also* Ex. 1005, Abstract, 2:30-33, Figs. 1-2; Ex. 1001, ¶ 74.

b. [b] Providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor

Claims 11 and 41 recite "providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor."

Defreitas discloses a method for collimating the x-ray beam according to the size and position of the paddle selected, so as to illuminate only an area of the digital receptor large enough to encompass the breast (or the portion of the breast being examined). As Defreitas makes clear, and a person of ordinary skill in the art would understand from Defreitas, this creates an image of the breast that is smaller than the full field of view of the receptor. E.g., Ex. 1005, 3:54-64 ("With suitable collimation by collimators **40** . . . beam **30** from source **1** images the breast onto receptor **5** and the resulting electronic image information is transmitted to a viewing station **22** (FIG. **2**). . . . Preferably, the collimation is such that beam **30** illuminates an area of receptor **5** just large enough to show the image of breast **3**, or at least a selected part thereof."); *see also id.*, 2:40-45; 3:41-46; Ex. 1001, ¶¶ 31-32, 76.

Furthermore, Defreitas discloses (as a person of ordinary skill in the art would have known) that a patient's breast may be (and often would be) smaller than the digital image receptor's full field of view, given that flat-panel digital receptors normally came in just one size which was comparable to larger size screen-

film cassettes used with larger breasts. Ex. 1005, 1:26-35, 1:38-44, 1:67-2:7; Ex. 1001, ¶ 75.

c. [c] Automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby define a reduced field of view image

Claims 11 and 41 recite "automatically selecting an outline"—or "automatically selecting a rectangular region," in the case of claim 41—"that encompasses the breast image to thereby define a reduced field of view image."

As discussed above, Defreitas discloses the use of collimators to restrict the x-ray illumination (and therefore the resulting image) to a defined area that is smaller than the full field of the digital receptor—preferably, it is "just large enough to show the image of breast **3**, or at least a selected part thereof"—thereby defining a reduced field of view image encompasses the breast image. *See supra* Section V.E.2.b.

Defreitas further explains that this collimation (and hence the outline or rectangular region of the image) can be achieved automatically using "an auto-collimation control to adjust the collimation of beam **30**." Ex. 1005, 4:19-20; *see also id.*, Fig. 2 (depicting auto-controls **1a**), 2:40-45 ("Another [object of the disclosed system and method] is to provide automated collimation control that changes x-ray beam collimation in accordance with one or more of the size and position of the

compression paddle … preferably in response to information that is automatically sensed."); Ex. 1001, ¶ 79; *infra* Section V.E.2.d.

For purposes of claim 41, Defreitas discloses that the breast image defined by this automatic collimation process "is typically rectangular." Ex. 1005, 3:61; Ex. 1001, ¶ 79.

d. [d] Wherein said [outline/rectangular region] is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging

Claims 11 and 41 recite "wherein said outline"—or, in the case of claim 41, "said rectangular region"—"is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging."

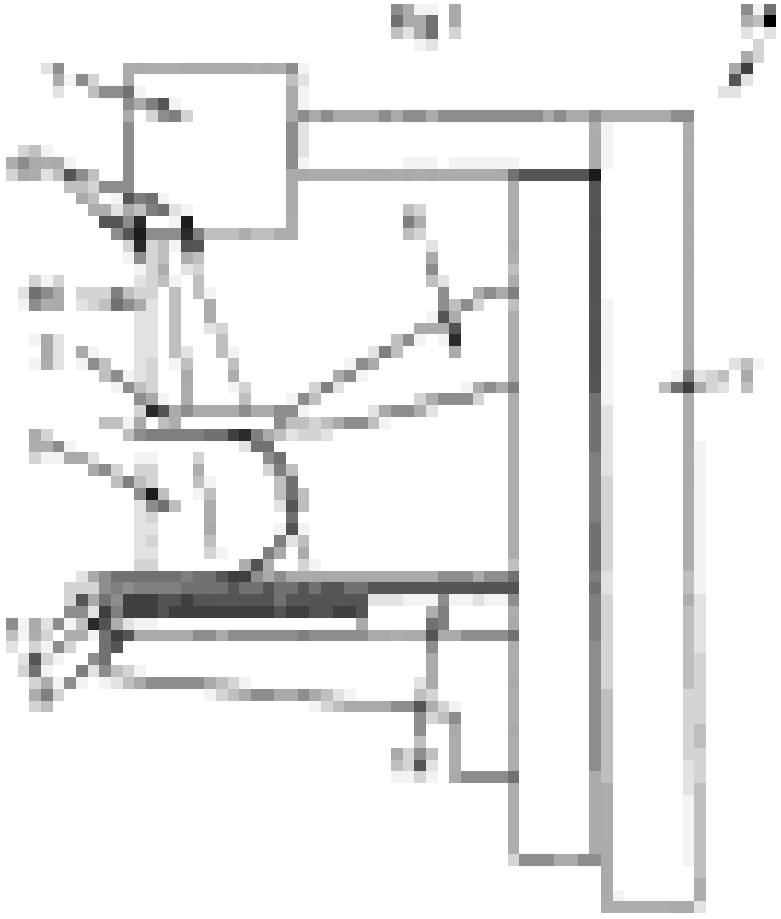
Defreitas discloses a number of ways in which the x-ray source can be collimated to focus specifically on the area of interest—namely, the portion of the imaging receptor that contains the breast or the portion being studied. E.g., Ex. 1005, 4:49-63. And, just like the '684 Patent, one of those ways is to derive the outline area (or rectangular region) automatically based on information about the compression paddle that the health professional has selected to compress the breast. Ex. 1001, ¶ 81. "The system can include a collimation control responsive to information regarding one or more of the size of the paddle, its location along the beam, its location relative to the proximal edge of the receptor…. This information can come from appropriate sensors." Ex. 1005, 3:5-10.

Defreitas makes clear that "the health professional selects a paddle **2** that is suitable in size and perhaps in shape to the breast to be imaged . . . and installs the selected paddle **2**" by attaching it to the mammography device and positioning it appropriately. *Id.*, 5:11-20; Ex. 1001, ¶ 81. Selecting a paddle to match the size of the patient's breast avoids problems that may arise from using a paddle that is either too large or too small. Ex. 1005, 1:26-35, 1:47-51, 1:67-2:7, 2:34-35, 5:11-13. Thus, just as the breast is smaller than the full field of view of the image receptor, so too is the paddle. Ex. 1001, ¶ 81. Defreitas explains that "[t]he auto-collimation control can be an arrangement sensing size and/or the position of one or more of breast **3**, *paddle **2***, and tray **11**, using respective sensors and automatically adjusting collimators **40** to confine beam **30** to the required cross-section and position." Ex. 1005, 4:35-39 (emphasis added). In other words, one option is to use "sensors S that keep track of the size and position of paddle **2**" in order to provide information to the auto-controls, including the auto-collimation control that selects the outline of the area to be imaged. *Id.*, 4:49-52; *see also id.*, Fig. 2 (depicting multiple sensors S); Ex. 1001, ¶ 81.

e. [e] Said [outline/rectangular region] encompasses an entirety of the patient's breast in the breast image

Claims 11 and 41 recite that "said outline"—or, in the case of claim 41, "said rectangular region"—"encompasses an entirety of the patient's breast in the breast image."

In Defreitas, the image outline area (which is often rectangular) provided by the automatic collimation can correspond to the entirety of the patient's breast in the breast image. Ex. 1001, ¶¶ 83-87. Defreitas discloses that, "[p]referably, the collimation is such that beam **30** illuminates an area of receptor **5** *just large enough to show the image of breast **3***." Ex. 1005, 3:61-63 (emphasis added); *see also id.*, 3:41-47. These two passages refer to "patient's breast 3" in Figures 1 and 2, which show that "patient's breast 3" refers to the complete breast rather than a portion thereof (see also Ex. 1001, ¶ 85):



Multiple times, Defreitas discusses how the operator will select a compression paddle to match the size of the patient's breast. E.g., Ex. 1005, 1:47-51, 2:34-35, 5:11-13. This is done, as it was with screen-film mammography, "because the use of a small size paddle on a large breast … may not allow full-breast imaging." *Id.*, 1:29-32. In other words, proper matching of paddle size to breast size *does* allow "full-breast" imaging. Ex. 1001, ¶ 84. Because the collimated x-ray beam—and therefore the resulting image area—is defined based on the paddle selected, it will therefore encompass the entirety of the breast in the breast image if (as Defreitas repeatedly contemplates) the entirety of the breast in the breast image is under compression. Ex. 1001, ¶¶ 85-86; *see also supra* Sections V.E.2.b and c.

f. [f] And the reduced field of view is defined based on said [outline/rectangular region]

Claims 11 and 41 recite "and the reduced field of view is defined based on said outline" or, in the case of claim 41, "based on said rectangular region." This portion of claims 11 and 41 essentially restates what was already entailed in the prior language, discussed above, of "automatically selecting an outline [or rectangular region] that encompasses the breast image to thereby define a reduced field of view image." If the outline or rectangular region is selected to define a reduced field of view image, then the reduced field of view image is defined based on said outline or rectangular region. For the same reasons that Defreitas discloses "automatically selecting an outline [or rectangular region] that encompasses the breast

image to thereby define a reduced field of view image," *see supra* Section V.E.2.c, it necessarily discloses the "the reduced field of view image is defined based on said outline" or, for claim 41, "said rectangular region." Ex. 1001, ¶ 88.

g. [g] Using said reduced field of view image for further processing, transmission, and/or archiving

Claims 11 and 41 recite "using said reduced field of view image for further processing, transmission, and/or archiving."

Defreitas discloses that, after the reduced field of view image is taken according to the process discussed above, "the resulting electronic image information is transmitted to a viewing station **22**." Ex. 1005, 3:59-61; *see also id.*, Fig. 2 (depicting viewing station to which the image is transmitted). Defreitas also discloses that, once the image information is transmitted to the viewing station, the system is capable of "processing it" and "displaying" the information as an image or in other forms. *Id.*, 3:16-20. As discussed above in the "Claim Construction" section, Defreitas's disclosures of subsequent transmission and processing of the reduced field of view image are each independently sufficient bases for meeting this element. Ex. 1001, ¶¶ 89-90.

F. Ground #2: Claims 29 and 33 Are Obvious Over Defreitas in View of Niklason

1. Niklason

Niklason describes systems and methods for tomosynthesis x-ray imaging and, like the '684 Patent, focuses particularly on the field of digital mammography.

It teaches a tomosynthesis system that provides resolution in the vertical dimension—thus creating the three-dimensional effect—by rotating the x-ray source in an arc above the breast. But it also preserves the high in-plane resolution of existing mammography systems, by teaching algorithms to transform the image data so that it corresponds to data produced by conventional linear-motion systems and can be analyzed according to known techniques. Ex. 1001, ¶¶ 54, 91-99.

Although Niklason was cited by the examiner during prosecution of the '684 Patent, it was only for the purpose of rejecting application claims that were directed to different subject matter than the Challenged Claims—specifically, claims that included only the anti-scatter grid feature combined with tomosynthesis processing, not a reduced field of view image—and were ultimately withdrawn. *See* Ex. 1004, 47-48, 66, 262. Importantly here, Niklason was never cited in combination with another reference against a claim, like the Challenged Claims, that recited the reduced field of view feature of the alleged invention. Niklason is cited in this petition against different claims and in combination with different primary references than were considered during prosecution. Moreover, the applicant never disputed the point for which Niklason is used here (that a person of ordinary skill in the art would have found it obvious to modify a mammography system to add Niklason's tomosynthesis functionality). Accordingly, the obviousness Grounds including Niklason do ***not*** rely on substantially the same art or arguments previously

considered during prosecution and the discretionary provision of 35 U.S.C. § 325(d) does not counsel against instituting *inter partes* review on these Grounds.

As explained in the claim analysis below, the teachings of Defreitas as modified by the teaching of Niklason, structurally and functionally, meet all limitations of Claims 29 and 33.

2. Independent Claims 29 and 33

Claims 29 and 33 are unpatentable as obvious in light of Defreitas and Niklason.

Limitations [a] through [f] of claims 29 and 33 are identical to limitations [a] through [f] of claims 11 and 41, respectively. Defreitas discloses limitations [a] through [f] of claims 11 and 41, and therefore discloses the corresponding identical limitations of claims 29 and 33. *See supra* Sections V.E.2.a-f and the evidence cited therein.

Only limitation [g] differs between the two sets of claims. Whereas claims 11 and 41 require using the reduced field of view image for further processing, transmission, and/or archiving, claims 29 and 33 specify that the image will be used for "tomosynthesis processing and transmission." This limitation [g] is the only difference between claims 29 and 33 and the primary prior art, Defreitas. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). Niklason discloses this limitation [g], as discussed below (*see infra* Section V.F.3).

A person of ordinary skill in the art would have been motivated to combine the teachings of Defreitas (disclosing elements [a]-[f] of claims 29 and 33) with the teachings of Niklason (disclosing element [g] of claims 29 and 33) in such a way that the resulting combination would yield the entire alleged invention of claims 29 and 33. Starting with Defreitas, its mammography system was ready for improvement by adding the tomosynthesis functionality taught in Niklason and its attendant benefits, and one skilled in the art would have fully understood the benefits of doing so. Digital breast tomosynthesis is a type of mammography (it is often called "3D mammography"). Ex. 1001, ¶ 54. It can improve over the performance of traditional mammography both in terms of reducing missed cancers and reducing false positives. *Id.* ¶¶ 33, 56-57. Niklason's disclosed digital breast tomosynthesis system was widely praised, as reflected in the acclaim for the highly cited "landmark" article by the inventors and their colleagues published in 1997 in the flagship industry journal Radiology (which itself references the Niklason patent). Ex. 1020; Ex. 1001, ¶¶ 55-58, 97.

The converse also is true: a person skilled in the art would have been motivated to make this combination starting with Niklason's tomosynthesis system. Ex. 1001, ¶ 98. As noted above in Section V.A, it was well known that digital mammography, and especially tomosynthesis, created large file sizes that complicated the processing and storage of mammography images. Ex. 1001, ¶¶ 35, 67.

Researchers were actively searching for solutions, and a person of ordinary skill in the art would have understood that applying Defreitas's teaching of reduced field of view images would improve Niklason's system and alleviate this problem. *Id.* ¶ 98.

A person of ordinary skill in the art would have reasonably expected success in this combination of the disclosures of Defreitas and Niklason. *Id.* ¶¶ 99-100. Defreitas and Niklason disclosed the same basic mammography x-ray machine and digital imaging receptor as Niklason. *Id.* ¶ 99. Niklason teaches that a digital imaging processor can "control the emission of x-rays from source **12** such as by techniques known in the art." Ex. 1006, 4:10-12. The collimation process taught by Defreitas is one such known technique. Ex. 1001, ¶ 100. Nothing in the references or otherwise would have discouraged the combination. *Id.* ¶ 99.

3. [g] Using said reduced field of view image for tomosynthesis processing and transmission

Claims 29 and 33 recite "using said reduced field of view image for tomosynthesis processing and transmission."

Niklason provides improved "systems and methods for tomosynthesis x-ray imaging." Ex. 1006, Abstract. Using a digital x-ray detector and a rotating x-ray source, Niklason generates a series of digital images corresponding to different positions of the source. E.g., *id.*, Abstract, 2:23-38. This image acquisition process is depicted, for example, in Figure 8. In a combination of Defreitas and Niklason,

the acquired images would be "reduced field of view image[s]" by virtue of the automatic collimation process disclosed in Defreitas. Ex. 1001, ¶ 93.

According to Niklason, the acquired images are then subjected to tomosynthesis processing. Niklason discloses an image data processor (Fig. 3, element 10) for this purpose. E.g., Ex. 1006, 2:38-41. (In Figure 8, the processor is depicted as computer **86**, also called "digital processor **86**." *Id.*, 7:26.) The processor first "transforms the image data to a form corresponding to that which would have been generated had the x-ray source moved in a linear motion in a source plane parallel to the image plane, rather than an arc." *Id.*, 2:41-45; *see also id.* 7:24-28, 5:21-26. After transformation, "[t]his new image data is utilized to reconstruct a tomographic plane in the object by a simple shifting and addition of image data sets." *Id.*, 5:26-28; *see also id.*, 5:48-52, 7:30-35; Ex. 1001, ¶ 94.

The images acquired by the digital x-ray receptor are also used for transmission. For example, Niklason explains that the tomosynthesis reconstruction of the acquired images can take place "for example, on a Sun Microsystems Sparc 20 workstation." Ex. 1006, 7:42-44. In that case, the images would necessarily be transmitted from the receptor to the workstation. Ex. 1001, ¶ 95. Similarly, Niklason explains that if the digital image processor does not have a screen, the images can be displayed "on a separate monitor **10***b*," depicted in Figure 4. Ex. 1006,

4:43-45. In that case, the images would be transmitted from the computer to the monitor for display. Ex. 1001, ¶ 96.

G. Ground #3: Claims 11 and 41 Are Obvious Over Muller in View of the Admitted Prior Art

1. Muller

Muller, like the '684 Patent, relates to improvements in x-ray imaging technology and focuses particularly on mammography, including digital mammography. Ex. 1007, ¶¶ 2, 29-34; Ex. 1001, ¶ 60. Muller is a published patent application; it eventually issued as a patent and was assigned to GE, who made the first commercial digital mammography machine. Ex. 1001, ¶¶ 23, 60. Among other things, Muller provides a method for selecting an area of interest—which is defined by the type of compression plate being used—and optimizing the image quality over that area. Muller accomplishes this optimization by using data from an initial low-dose "scout" exposure before the main exposure. *Id.* ¶ 61. Muller also discloses collimating the x-ray source to correspond to the area of interest, thereby reducing the field of view to the particular area of interest. E.g., *id.*; Ex. 1007, ¶ 108.

2. Independent Claims 11 and 41

Muller discloses or at least suggests all limitations of independent claims 11 and 41, in combination, as claimed, particularly in further view of the Admitted

Prior Art. Indeed, in related litigation, Hologic has not disputed that Muller discloses or suggests all of the limitations of claims 11 and 41 except elements [e] through [g]. Ex. 1021. As explained below, Hologic is wrong. Considering the *Graham* analysis, the only aspect of the Challenged Claims not explicit in Muller is that the disclosed compression element covers the entirety of the breast in the breast image. If not inherent in Muller's disclosures, at minimum this would have been an obvious implementation of Muller's teachings to a person of ordinary skill in the art.

As with Defreitas, below claims 11 and 41 are analyzed together and, where appropriate, a separate discussion of the more generic "outline" versus the more specific "rectangular region" is provided.

a. [a] A mammography method comprising

The preambles of claims 11 and 44 recite "a mammography method comprising." To the extent the preamble is a limitation, Muller discloses this limitation. E.g., Ex. 1007, ¶¶ 2 ("The present invention belongs to the field of radiology intended for study … of certain organs in particular, such as the breasts . . . ."), 56 ("The invention can be applied to a mammography apparatus . . . ."). Ex. 1001, ¶ 102.

b. [b] Providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor

Claims 11 and 41 recite "providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor."

As discussed further below, *see infra* 43-45, Muller discloses identifying a "particular area" based on the compression element selected, and then both collimating the x-ray beam to that particular area and optimizing the image quality over that area. Muller also discloses the use of "compression elements whose compression area is less than the sensitive surface area of the [imaging] detector," that is, the compression paddle is smaller than the entire field of view of the imaging receptor. Ex. 1007, ¶ 106; *see also id.* ¶ 60 (the compression element "can glide horizontally in the slide 19," implying that the paddle is smaller than the receptor); Ex. 1001, ¶ 103. When the compression element is smaller than the full field of view—that is, the surface area of the imaging receptor—then the collimated and optimized image will necessarily occupy less than the receptor's entire field of view. Ex. 1001, ¶ 103; *see also supra* Section V.A (discussing how collimation works); Ex. 1001, ¶¶ 31-32.

c. [c] Automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby define a reduced field of view image

Claims 11 and 41 recite "automatically selecting an outline"—or "automatically selecting a rectangular region," in the case of claim 41—"that encompasses the breast image to thereby define a reduced field of view image."

Muller discloses a calculation unit that, among other things, receives the information from the detection unit that determines the type of compression element being used. Muller discloses multiple examples of a "means for recognition of the compression element" that can be used to automatically derive information about the compression element. Ex. 1007, ¶ 30. The means include a "detection element" that can be either mechanical, magnetic, or optical. *Id.* ¶ 31. Each different compression element also contains a corresponding "coder" of the same type, so that the detection element can recognize the compression element. *Id.* ¶¶ 35-39; *see also id.* ¶¶ 60-61. Information from the detection element is sent to a detection unit, which allows for communication with the calculation unit that drives the collimator and the image optimization processing. E.g., *id.* ¶¶ 61-65; *see also* Ex. 1001, ¶ 106. Muller's disclosure in this regard is substantively identical to that of the '684 Patent. Ex. 1001, ¶ 111.

The calculation unit then "sends the 'compression_element_type' information to a matching table stored in memory and receives from the table . . . 'useful_surface_coordinates' information relating to the surface for which it is of interest to optimize the image quality." Ex. 1007, ¶ 65. This surface "can be the flat lower surface **31** of the contact part **28** of the compression element **25**"—that is, the useful surface is an outline, defined by coordinates, that corresponds to the surface area of the side of the compression element that is in contact with the patient's breast, as a person of ordinary skill in the art would understand. Ex. 1007, ¶ 65; Ex. 1001, ¶ 106. This outline then defines a reduced field of view image; "the calculation unit **40** sends a command to the X-ray source **7** and, in particular, to a collimator . . . to adjust the X-ray beam to the useful surface; in other words, for the area of the organ exposed to x-rays to match the useful surface." Ex. 1007, ¶ 65; Ex. 1001, ¶ 106.

For purposes of claim 41, Muller depicts the use of a rectangular compression paddle. *See* Ex. 1007, Fig. 2 (element 25). Since the outline that defines the reduced field of view image is automatically selected based on the surface of the compression element, a rectangular compression paddle would produce a rectangular region. *Id.* ¶¶ 8, 40; Ex. 1001, ¶¶ 107-108.

d. [d] Wherein said [outline/rectangular region] is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging

Claims 11 and 41 recite "wherein said outline"—or, in the case of claim 41, "said rectangular region"—"is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging."

As discussed above in Section V.G.2.c (citing Ex. 1007 ¶¶ 30-31, 35-39, 69-65 and Ex. 1001, ¶ 106), Muller discloses that the outline (which can be rectangular) defining the reduced field of view image is selected based on information about the useful surface of the compression element. *See also* Ex. 1001, ¶¶ 110-112.

e. [e] Said [outline/rectangular region] encompasses an entirety of the patient's breast in the breast image

Claims 11 and 41 recite that "said outline"—or, in the case of claim 41, "said rectangular region"—"encompasses an entirety of the patient's breast in the breast image."

Muller repeatedly refers to using a compression element with a surface "capable of coming in contact with *an organ*, for example, *the breast of a patient benefitting from a mammography examination*." Ex. 1007, ¶ 59 (emphases added); *see also, e.g.*, *id.* ¶¶ 8, 53. A person of ordinary skill in the art would understand these references to a "breast" or "organ," (and not to *part* of a breast/organ) as referring

to the entire breast/organ. Ex. 1001, ¶ 113. When "the organ" being compressed is an entire breast, as Muller clearly contemplates, the entirety of the breast in the breast image will be encompassed in the outline (or "rectangular region") because the outline is determined based on the size of the compression plate. *Id.* Thus, this element is inherent in Muller. *Id.* ¶ 117.

If Muller does not inherently disclose that the "particular area" of interest can be the entirety of the breast in the breast image, it at least would have been obvious to one of ordinary skill in the art that this would be true. *Id.* A person of ordinary skill in the art would have understood that one type of mammography was screening mammography, in which it often would be the case that the patient's entire breast would be compressed and imaged because screening mammography's purpose is to check an asymptomatic patient. *Id.* ¶ 114; *see also supra* Section V.A (citing Exs. 1016, 1017, and 1018); Ex. 1001, ¶¶ 26-28. In this obvious application of Muller, the "particular area" of interest to the radiologist—and therefore the corresponding outline or rectangular region—would be the entirety of the breast in the breast image (typically a smaller area than the entire digital image receptor). Ex. 1001, ¶ 114. Muller refers to "mammography" generally; nothing in Muller suggests that its teachings would exclude screening mammography, and nothing in Muller or elsewhere suggests that a person of ordinary skill would not

have expected and obtained success in applying Muller's teachings this way. *Id.* ¶¶ 114, 116.

This obviousness analysis is further buttressed by the teachings of the Admitted Prior Art, which elaborate on the motivation one skilled in the art would have to use Muller's system in a way that would meet this claim element. It states that compression paddles "come[] in a variety of sizes to match … the breast size. Such matching is desirable because the use of a small size paddle on a large breast … may not allow full-breast imaging." Ex. 1003, 1:29-32. This matching allows for full-breast imaging, in which the compression paddle covers the full breast. Ex. 1001, ¶ 115. Applying this implementation to Muller's teachings would result in the "particular area" of interest encompassing the entirety of the breast in the breast image. *Id.*; *see also supra* Sections V.G.2.b and c.

f. [f] And the reduced field of view is defined based on said [outline/rectangular region]

Claims 11 and 41 recite "and the reduced field of view is defined based on said outline" or, in the case of claim 41, "based on said rectangular region." This portion of claims 11 and 41 essentially restates what was already entailed in the prior language, discussed above, of "automatically selecting an outline [or rectangular region] that encompasses the breast image to thereby define a reduced field of view image." If the outline or rectangular region is selected to define a reduced field of view image, then the reduced field of view image is defined based on said

outline or rectangular region. For the same reasons that Muller discloses "automatically selecting an outline [or rectangular region] that encompasses the breast image to thereby define a reduced field of view image," *see supra* Section V.G.2.c, it necessarily discloses the "the reduced field of view image is defined based on said outline" or, for claim 41, "said rectangular region." Ex. 1001, ¶ 118.

g. [g] Using said reduced field of view image for further processing, transmission, and/or archiving

Claims 11 and 41 recite "using said reduced field of view image for further processing, transmission, and/or archiving."

Muller discloses this limitation in two separate ways. First, Muller describes a process for taking a first radiological image in order to optimize the image quality over the area of interest. Ex. 1007, ¶¶ 8, 41-52. This initial image is itself collimated to the area of interest—that is, it is a reduced field of view image as described in the Challenged Claims. *Id.* ¶ 65. Muller extensively describes processing this image, for example to adjust brightness and contrast. *Id.* ¶¶ 67-103; Ex. 1001, ¶ 119. The optimization processes conducted on this image are "further processing" as described in the Challenged Claims. Ex. 1001, ¶ 119. Second, Muller describes processing, transmission, and archiving of the main radiological image, which is likewise collimated to produce a reduced field of view image. E.g., Ex. 1007, ¶¶ 3 ("The X-ray receiver is equipped with a digital type x-ray detector to display the image obtained on a video screen and/or to print it."), 34 ("The

device can include a means for . . . storing the type of image determined with the image data"), 64 ("The calculation unit **40** may carry out image processing and will be equipped with memory and software for that purpose."); Ex. 1001, ¶ 120.

Alternatively, if Muller does not explicitly disclose processing, transmitting, and/or archiving the reduced field of view image, these functions would have been easily recognized by an ordinarily skilled artisan at the time as either inherent or obvious (indeed, necessary). Mammography is used to obtain images for medical purposes. To serve those purposes, the images must be processed and transmitted after they are taken so that they can be displayed and analyzed by medical personnel. Ex. 1001, ¶¶ 121-122. And they would typically be archived in standard radiology practice at the time, because the process of evaluating a mammogram image includes comparing the present image of the patient's breast tissue to prior images from earlier mammograms of the same patient. *Id.* ¶ 121.

H. Ground #4: Claims 29 and 33 Are Obvious Over Muller in View of the Admitted Prior Art and Niklason

Claims 29 and 33 are unpatentable as obvious in light of Muller, the Admitted Prior Art, and Niklason.

Muller and the Admitted Prior Art disclose or at least suggest limitations [a] through [f] of claims 11 and 41, and therefore disclose or suggest the corresponding identical limitations of claims 29 and 33, respectively. *See supra* Sections

V.G.2.a-f and the evidence cited therein. As discussed above in Section V.F.3, Niklason discloses the remaining limitation of claims 29 and 33, which specifies that the image will be used for "tomosynthesis processing and transmission."

A person of ordinary skill in the art would have been motivated to combine the teachings of Muller and the Admitted Prior Art (disclosing elements [a]-[f] of claims 29 and 33) with the teachings of Niklason (disclosing element [g] of claims 29 and 33) in such a way that the resulting combination would yield the entire alleged invention of claims 29 and 33. Ex. 1001, ¶¶ 124-126. Muller and the Admitted Prior Art disclose the same essential mammography x-ray machine with a digital imaging receptor as Niklason. *See supra* 39; Ex. 1001, ¶ 126. This system was thus ready for improvement by adding the tomosynthesis functionality taught in Niklason and its attendant benefits. One skilled in the art would have fully understood the benefits of doing so for all the reasons described with respect to the Defreitas-Niklason combination in Section V.F. Ex. 1001, ¶¶ 125-126.

The converse is also true: a person skilled in the art would have been motivated to make this combination starting with Niklason's tomosynthesis system. Ex. 1001, ¶ 125. Muller's teachings of collimation and reduced field of view would improve Niklason's system and alleviate the known problem of large file sizes in digital mammography tomosynthesis, for all the reasons described with respect to the Defreitas-Niklason combination in Section V.F. Ex. 1001, ¶¶ 125-126.

A person of ordinary skill in the art would have reasonably expected success in combining Muller, the Admitted Prior Art, and Niklason in this manner. Ex. 1001, ¶ 126. As noted, Muller and Niklason disclosed the same basic mammography x-ray machine and digital imaging receptor, and Muller's collimation process (like Defreitas's) was one of the "techniques known in the art" mentioned by Niklason. Ex. 1006, 4:10-12; Ex. 1001, ¶ 126; *see supra* Section V.F. The specific implementation of the Admitted Prior Art would have remained consistent with the Muller-Niklason combination as it was with Muller alone. Ex. 1001, ¶ 126. Nothing in the references or otherwise would have discouraged the combination. *Id.*

I. Ground #5: Claims 11 and 41 Are Obvious over Kawamata in View of Yamada

1. Kawamata

Kawamata is a published Japanese patent application from Toshiba Corporation. Kawamata discloses the same basic x-ray mammography machine components as the '684 Patent. Ex. 1009, 279 col.1, 282 Fig.1; Ex. 1001, ¶ 63. Kawamata has the same goal as the Challenged Claims: to improve on such machines by enabling control of the x-ray beam based on the size and shape of the compression element being used. Ex. 1009, 280 col.4; Ex. 1001, ¶ 63. Kawamata's disclosed system detects the particular compression plate selected and then applies a field mask (another name for collimator) to the x-ray source to limit the size of the irradiation field accordingly. This automatic control of the field size ensures that the

x-ray only illuminates the area where the breast is compressed. Ex. 1009, 280 col.5; Ex. 1001, ¶ 63. Accordingly, Kawamata's disclosed x-ray beam control allows a reduction in the size of the acquired data. Ex. 1001, ¶ 63.

2. Yamada

Yamada is another published Japanese patent application from Toshiba Corporation and affiliated entity Toshiba Medical Engineering KK. Like Kawamata, this application relates to x-ray mammography machines and describes the same basic x-ray mammography system as Kawamata. Ex. 1011, ¶ 1 & Fig. 2; Ex. 1001, ¶ 65. Since it is later in time, Yamada focuses more particularly on the newer digital mammography technology, like the type discussed in the '684 Patent. Ex. 1011, ¶¶ 59, 21-22, 61-62, 66, & Fig. 14; Ex. 1001, ¶ 65. It therefore discusses in more detail the type of processing, transmission, and archiving that are used with this technology, including the PACS systems described above. E.g., Ex. 1011, ¶¶ 26, 116-120; Ex. 1001, ¶ 65.

Collectively, Kawamata and Yamada are referred to herein as "the Toshiba references."

3. Independent Claims 11 and 41

A person of ordinary skill at the time of the alleged invention would have been motivated to combine the Toshiba references. Both references describe Toshiba's mammography systems, with Yamada (the later reference) detailing

technological advances that had occurred since Kawamata was filed, including advances specific to digital mammography. Ex. 1001, ¶¶ 65, 128; *see also, e.g.*, Ex. 1011, ¶¶ 7, 26, 45. Combining these two compatible references would allow a person of ordinary skill to achieve the advantageous features of both. Ex. 1001, ¶ 128. For example, a person of ordinary skill in the art would have been motivated to upgrade Kawamata's image detector with a more modern digital image detector like Yamada's, and to further implement Yamada's picture archiving and communication system ("PACS") which, as Yamada explains, became useful as a result of "progress in the digitalization of images." *Id.* ¶¶ 128-129; Ex. 1011, ¶ 26. A person of ordinary skill would be motivated to combine Kawamata's teaching of automatically deriving information about the compression paddle in order to drive field masks that collimate the x-ray beam—and thereby create a reduced field of view image—with Yamada's teaching about processing, transmission, and archiving of images. As discussed above, *see supra* 20-21, a smaller effective image size such as that created by Kawamata is particularly advantageous in the digital mammography system described in Yamada, given the need to process, transmit, and store the relatively large data files produced by digital mammography in a PACS. Ex. 1001, ¶ 128.

As explained in the claim analysis below, the combination of Kawamata and Yamada discloses all limitations of independent claims 11 and 41, in combination,

as claimed. As with the foregoing, claims 11 and 41 are analyzed together and, where appropriate, a separate discussion of the more generic "outline" versus the more specific "rectangular region" is provided.

a. [a] A mammography method comprising

The preambles of claims 11 and 44 recite "a mammography method comprising." To the extent the preamble is a limitation, Kawamata discloses this limitation. E.g., Ex. 1009 at 279, col.1 ("A mammography apparatus to perform mammography . . . .); Ex. 1001, ¶ 130.

b. [b] Providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor

Claims 11 and 41 recite "providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor."

Kawamata describes "[a] mammography apparatus to perform mammography by placing the breast of the test subject on an imaging platform having a detection means, compressing the breast using a compression plate . . . and irradiating the breast using an X-ray source that is provided facing said detection means." Ex. 1009, 279, col.1. Kawamata uses lead field masks to collimate the x-ray beam based on the size and shape of the compression plate selected; the resulting image of the patient's breast will therefore match the size and shape of the compression plate as well. E.g., *id.* at 281 col.9-10; *see also id.* at 280 col.5 (describing how

"the X-ray irradiation field will always match the size of the compression plate"); Ex. 1001, ¶ 131. A patient's breast may be (and often would be) smaller than the digital image receptor's full field of view. Ex. 1001, ¶ 132; *see infra* 59. This would be the case in the combination of Kawamata and Yamada, updating Kawamata's image receptor to the more modern digital image receptor like Yamada's. Ex. 1001, ¶¶ 128-129, 132; *see infra* 59. Whenever the compression plate is smaller than the full size of the detection means, the resulting image will be as well. Ex. 1001, ¶ 132; *see also supra* Section V.A (discussing how collimation works); Ex. 1001, ¶¶ 31-32.

c. [c] Automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby define a reduced field of view image

Claims 11 and 41 recite "automatically selecting an outline"—or "automatically selecting a rectangular region," in the case of claim 41—"that encompasses the breast image to thereby define a reduced field of view image."

As discussed in the previous section, Kawamata uses field masks to define an area that encompasses the breast image and is smaller than the full imaging receptor. The reference explains that "[i]rradiation field restriction masks 15, 16, and 17 of diaphragm mechanism 14" will be moved into the correct position based on the detected size of the compression plate selected, "automatically resulting in an X-ray irradiation field that matches the compression plate size." Ex. 1009, 281

col.10-282 col.11; *see also* Ex. 1001, ¶¶ 134-135. This automatically selected outline encompasses the breast image described above in limitation [b] and defines the reduced field of view image. Ex. 1001, ¶ 135.

For purposes of claim 41, Kawamata discloses that the breast image defined by the field mask process is a rectangular region. For example, Figure 3 (reproduced below) shows the irradiation field control mask consisting of elements 15-18, which form a rectangular region that defines the reduced field of view image. Ex. 1009 at 283; Ex. 1001, ¶ 136.

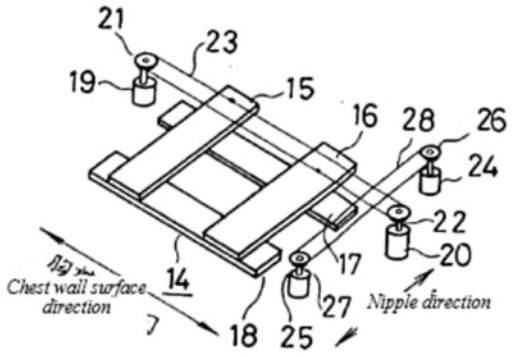


Figure 3

d. [d] Wherein said [outline/rectangular region] is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging

Claims 11 and 41 recite "wherein said outline"—or, in the case of claim 41, "said rectangular region"—"is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging."

As noted above, Kawamata automatically derives the size and shape of the compression plate selected and uses this information to select the proper positioning of the field masks that define the outline (or rectangular region). Kawamata discloses the use of "compression plate size detection means," which can be, for example, a "linear potentiometer **9**" located at the attachment point of the compression plate to the mammography machine. Ex. 1009, 281 col.8-9; Ex. 1001, ¶ 138. This works as follows: each different size of compression plate has a different length shaft **11**, such that a slider **13** attached to the shaft causes variation in the resistance of linear potentiometer **9** based on where it makes sliding contact with the potentiometer. Ex. 1009, 280 col.6-281 col.7; *see also id.* at 283, Fig. 2; Ex. 1001, ¶¶ 138-139. In turn, the linear potentiometer sends a signal to the circuit controlling the irradiation field masks to collimate the x-ray irradiation field based on this automatically detected information about the compression plate size. Ex. 1009, 281 col.8-10; Ex. 1001, ¶ 139.

e. [e] Said [outline/rectangular region] encompasses an entirety of the patient's breast in the breast image

Claims 11 and 41 recite that "said outline"—or, in the case of claim 41, "said rectangular region"—"encompasses an entirety of the patient's breast in the breast image."

Kawamata repeatedly refers to compressing "the breast" with a compression plate. E.g., Ex. 1009 at 279 col.1 ("A mammography apparatus to perform mammography by placing the breast of the test subject on an imaging platform having a detection means, compressing the breast using a compression plate that can move in the vertical direction and irradiating the breast using an X-ray source . . . ."); *id.* at 279 col.2 ("The present invention relates to a mammography apparatus to compress the breast of the test subject that is placed on top of an imaging platform . . . ."); *id.* at 280 col.6 (describing how the compression plate arrangement "enable[s] compression of the breast of the test subject"). A person of ordinary skill in the art would understand these references to a "breast" or "organ," (and not to *part* of a breast/organ) as referring to the entire breast/organ. Ex. 1001, ¶¶ 113, 141.

Kawamata also repeatedly states that the compression plate may be "selected based on the application region of the breast" and is of "a size and shape that matches the application region of the breast of the test subject." Ex. 1009, 280 col.4, 281 col.9. It is inherent from these discloses that (a) the "application region

of the breast" could encompass the entire breast, and (b) that the "size and shape" of a compression plate "that matches" the entire breast would be a plate that would encompass the entire breast. Ex. 1001, ¶ 142. At the very least, these two points would have been obvious to a person of ordinary skill in the art. *Id.* ¶¶ 142-144.

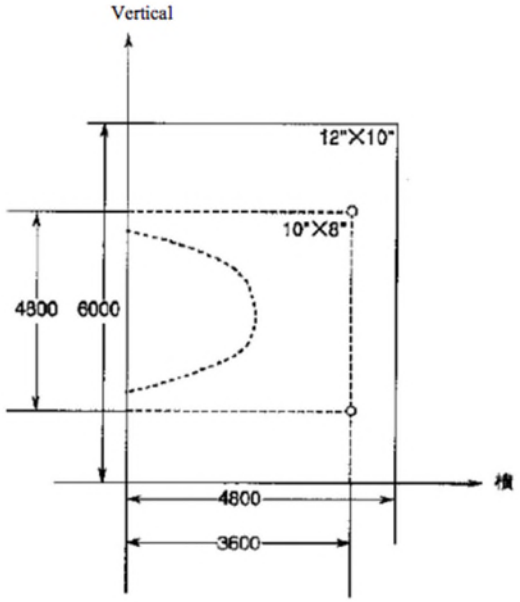
Specifically, as to point (a), Kawamata refers to "mammography" generally. A person of ordinary skill in the art would have understood that one type of mammography was screening mammography, and that the "application region" of interest to the radiologist in a screening mammogram often would be the entirety of the breast in the breast image. Ex. 1001, ¶¶ 24, 26-28, 143. Nothing in Kawamata suggests excluding screening mammography. *Id.* As to point (b), a person of ordinary skill in the art would understand that the compression plate in this scenario typically would encompass the entire breast (typically a smaller area than the entire digital image receptor), and would follow Kawamata's express direction to select a compression plate with a "size" that "matches" the breast. *Id.* ¶¶ 26-28, 144.

When the entire breast is compressed, the entire breast image also will be encompassed within the outline (or "rectangular region") that is defined based on the size of the compression plate. *Id.* ¶ 145; *see also supra* Sections V.I.2.b and c.

Finally, this element is further obvious when considering Kawamata's disclosures in view of Yamada's. Yamada repeatedly depicts the entirety of a pa-

tient's breast with the breast image, for example in Fig. 61, reproduced below, reflecting that including the entirety of the breast in the breast image was one use of the systems described in Kawamata and Yamada (*see* Ex. 1011; Ex. 1001, ¶ 146):

(Figure 61)



A person of ordinary skill in the art would have reasonably expected success in using the Kawamata mammography system to compress and thus create a reduced field of view image encompassing the entirety of the patient's breast in the breast image. Ex. 1001, ¶ 147. As noted above, screening mammography is common, and nothing in Kawamata or otherwise suggests that it could not be applied successfully to screening mammography. *Id.* ¶¶ 143, 147.

f. [f] And the reduced field of view is defined based on said [outline/rectangular region]

Claims 11 and 41 recite "and the reduced field of view is defined based on said outline" or, in the case of claim 41, "based on said rectangular region." This portion of claims 11 and 41 essentially restates what was already entailed in the prior language, discussed above, of "automatically selecting an outline [or rectangular region] that encompasses the breast image to thereby define a reduced field of view image." If the outline or rectangular region is selected to define a reduced field of view image, then the reduced field of view image is defined based on said outline or rectangular region. For the same reasons that Kawamata discloses "automatically selecting an outline [or rectangular region] that encompasses the breast image to thereby define a reduced field of view image," *see supra* Section V.I.2.c, it necessarily discloses the "the reduced field of view image is defined based on said outline" or, for claim 41, "said rectangular region." Ex. 1001, ¶ 149.

g. [g] Using said reduced field of view image for further processing, transmission, and/or archiving

Claims 11 and 41 recite "using said reduced field of view image for further processing, transmission, and/or archiving."

As discussed above, Kawamata discloses a process for obtaining mammography images using a reduced field of view that is defined automatically based on

the size of the compression plate selected to compress the patient's breast. Ex. 1001, ¶ 150.

Yamada describes in detail a picture archiving and communication system (PACS) that is used for "archiving, communicating, and displaying the medical images . . . generated within a hospital." Ex. 1011, ¶ 26. Yamada discloses using a PACS "to manage mammogram images obtained using mammography." *Id.* ¶ 33; *see also, e.g.*, *id.*, ¶¶ 83, 184, 202; Ex. 1001 ¶ 151. Yamada discloses in detail how images are "transmitted by the image collection apparatus," "archived in a database," and various "post-processing for the images." Ex. 1011, ¶¶ 26, 65, 83, 116-120, 132, 134, & Fig. 44; Ex. 1001, ¶ 152. Thus, Yamada discloses this element, and the combination of Kawamata and Yamada discloses every element of claims 11 and 41. Ex. 1001, ¶ 153. For the reasons described above, this combination would have been obvious to a person of ordinary skill in the art.

J. Ground #6: Claims 29 and 33 Are Obvious Over Kawamata in View of Yamada and Niklason

Claims 29 and 33 are unpatentable as obvious in light of Kawamata, Yamada, and Niklason.

The combination of the two Toshiba references discloses or at least suggests limitations [a] through [f] of claims 11 and 41, and therefore discloses the corresponding identical limitations of claims 29 and 33, respectively. *See supra* Sections V.I.2.a-f and the evidence cited therein. As discussed above in Section

V.F.3, Niklason discloses the remaining limitation of claims 29 and 33, which specifies that the image will be used for "tomosynthesis processing and transmission."

A person of ordinary skill in the art would have been motivated to combine the teachings of the Toshiba references (disclosing elements [a]-[f] of claims 29 and 33) with the teachings of Niklason (disclosing element [g] of claims 29 and 33) in such a way that the resulting combination would yield the entire alleged invention of claims 29 and 33. Ex. 1001, ¶¶ 154-156. The Toshiba references disclose the same essential mammography x-ray machine with a digital imaging receptor as Niklason. *See supra* 51-52; Ex. 1001, ¶ 156. This system was thus ready for improvement by adding the tomosynthesis functionality taught in Niklason and its attendant benefits. One skilled in the art would have fully understood the benefits of doing so for all the reasons described with respect to the Defreitas-Niklason combination in Section V.F. Ex. 1001, ¶¶ 155-156.

The converse is also true: a person skilled in the art would have been motivated to make this combination starting with Niklason's tomosynthesis system. Ex. 1001, ¶¶ 155-156. Kawamata's teachings of collimation and reduced field of view would improve Niklason's system and alleviate the known problem of large file sizes in digital mammography tomosynthesis, for all the reasons described with respect to the Defreitas-Niklason combination in Section V.F. Ex. 1001, ¶ 155.

A person of ordinary skill in the art would have reasonably expected success in combining the Toshiba references and Niklason in this manner. *Id.* ¶ 156. As noted, the Toshiba references and Niklason disclosed the same basic mammography x-ray machine and digital imaging receptor, and Kawamata's collimation process (like Defreitas's) was one of the "techniques known in the art" mentioned by Niklason. *Id.*; Ex. 1006, 4:10-12; *see supra* Section V.F. Nothing in the references or otherwise would have discouraged the combination. Ex. 1001, ¶ 156.

VI. CONCLUSION

As demonstrated above, a reasonable likelihood exists that the Challenged Claims are unpatentable. Accordingly, Petitioners respectfully request *inter partes* review of the Challenged Claims.

Dated: January 26, 2018

Respectfully submitted,

By: / T. Vann Pearce, Jr. /

T. Vann Pearce, Jr.
Lead Counsel for FUJIFILM Corporation;
FUJIFILM Medical Systems USA, Inc.;
and FUJIFILM Techno Products Co., Ltd.
Petitioners

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,123,684, including all Exhibits and the Powers of Attorney, was served on January 26, 2018, via Express Mail directed to the attorney of record for the patent at the following address:

Merchant & Gould – Hologic
P.O. Box 2903
Minneapolis, MN 55402

A courtesy copy is also being served by electronic mail to Hologic's litigation counsel at:

HologicITC@apks.com

/ T. Vann Pearce, Jr. /

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for FUJIFILM Corporation, FUJIFILM Holdings America Corporation, and FUJIFILM North America Corporation, and lead counsel for Petitioners, declares that the argument section of this Petition (Sections I and III-VI) has a total of 13,889 words, according to the word count tool in Microsoft Word™.

/ T. Vann Pearce, Jr. /

APPENDIX: CLAIM LISTING (37 C.F.R. § 42.24)

Independent claims 11 and 41 (the non-tomosynthesis claims) and independent claims 29 and 33 (the tomosynthesis claims), respectively, are listed in the tables below. Text in red indicates variations among the four independent claims.

	Claim 11	Claim 41
A	A mammography method comprising:	A mammography method comprising:
B	providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor;	providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor;
C	automatically selecting an outline that encompasses the breast image to thereby define a reduced field of view image,	automatically selecting a rectangular region that encompasses the breast image to thereby define a reduced field of view image,
D	wherein said outline is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging,	wherein said rectangular region is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging,
E	said outline encompasses an entirety of the patient's breast in the breast image,	said rectangular region encompasses an entirety of the patient's breast in the breast image,

F	and the reduced field of view is defined based on said outline; and	and the reduced field of view is defined based on said rectangular region; and
G	using said reduced field of view image for further processing, transmission, and/or archiving.	using said reduced field of view image for further processing, transmission, and/or archiving.

	Claim 29	**Claim 33**
A	A mammography method comprising:	A mammography method comprising:
B	providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor;	providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor;
C	automatically selecting an outline that encompasses the breast image to thereby define a reduced field of view image,	automatically selecting a rectangular region that encompasses the breast image to thereby define a reduced field of view image,
D	wherein said outline is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging,	wherein said rectangular region is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging,
E	said outline encompasses an entirety of the patient's breast in the breast image,	said rectangular region encompasses an entirety of the patient's breast in the breast image,

F	and the reduced field of view is defined based on said outline; and	and the reduced field of view is defined based on said rectangular region; and
G	using said reduced field of view image for tomosynthesis processing and transmission.	using said reduced field of view image for tomosynthesis processing and transmission.