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. 7,831,296

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 7,831,296

PETITIONERS' EXHIBIT LIST

Ex. 1001 Declaration of Dr. John Allison

Ex. 1002 Curriculum Vitae of Dr. John Allison

Ex. 1003 U.S. Patent No. 7,831,296 ("the '296 Patent").

Ex. 1004 Patent File History for the '296 Patent

Ex. 1005 U.S. Patent No. 7,123,684 ("the '684 Patent")

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

Ex. 1007 *Development and Clinical Evaluation of Tomosynthesis for Digital Mammography* by Daniel B. Kopans, M.D. ("Kopans")

Ex. 1008 *Tomosynthesis Breast Imaging: Early Detection and Characterization of Breast Cancer* by Leena M. Hamberg, PhD ("Hamberg")

Ex. 1009 U.S. Patent Application Publication No. 2002/0090055 naming Albert Zur, et al. as inventors ("Zur")

Ex. 1010 U.S. Patent No. 4,613,982 to Dornheim, et al. ("Dornheim")

Ex. 1011 U.S. Patent No. 6,632,020 to Kaufhold, et al. ("Kaufhold")

Ex. 1012 E-mail dated November 1, 2017 from Carol E. Jacobsen, Chief, Customer Support Division, Directorate of User Services, Defense Technical Information Center

Ex. 1013 Archived copies of public webpages, dated August 2000, on the Defense Technical Information Center's website obtained from the Internet Archive

Ex. 1014 Archived copies of public webpages, dated August 2000, on the website of National Technical Information Services ("NTIS") obtained from the Internet Archive

Ex. 1015 Affidavit of Christopher Butler, Office Manager of the Internet Archive, dated December 28, 2017

Ex. 1016 Print out of web page showing search results for Kopans in the NTIS collection

Ex. 1017 U.S. Patent No. 8,452,379 (the "'379 Patent")

Ex. 1018 Bushberg JT, Seibert JA, Leidholdt EM and Boone JM, The Essential Physics of Medical Imaging, 2nd edition. Philadelphia, PA: Lippincott Williams & Wilkins 2002 (excerpts)

Ex. 1019 "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. 1020 Instrumentarium Imaging, "Diamond Breast Care," copyright 2003

Ex. 1021 "Digital Tomosynthesis in Breast Imaging," Loren T. Niklason, PhD, et al., Radiology 1997; 205:399-406 ("Niklason")

Ex. 1022 Dobbins, J.T., Godfrey, D.J., "Digital x-ray tomosynthesis: Current state of the art and clinical potential," Phys. Med. Biol. 2003 Vol. 48:R65-R106

Ex. 1023 Japanese Patent Application Publication No. H08-186762 identifying Shinichi Yamada and Seiichiro Nagai as inventors ("Yamada")

Ex. 1024 Certified translation of Yamada

Ex. 1025 U.S. Patent No. 6,751,285 to Jeffrey Wayne Eberhard ("Eberhard")

Ex. 1026 U.S. Patent No. 6,611,575 to Abdalmajeid Musa Alyassin, et al. ("Alyassin")

Ex. 1027 S. Vedantham et al., "Digital Breast Tomosynthesis: State of the Art," Radiology 277(3), 663-684

Ex. 1028 Ingrid Reiser & Stephen Glick, Tomosynthesis Imaging (2014) (excerpts)

Ex. 1029 U.S. Patent No. 4,542,521 to Hahn, et al. ("Hahn")

Ex. 1030	U.S. Patent No. 6,434,218 to Matsumoto ("Matsumoto")
Ex. 1031	Japanese Utility Model Patent Publication No. S58-16640, identifying Shigekazu Hara et al. as inventors ("Hara")
Ex. 1032	Certified translation of Hara
Ex. 1033	Declaration of Frances Cheever, dated February 14, 2018

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I. INTRODUCTION

Petitioners respectfully request *inter partes* review of claims 23-25, 33, 35, 36, 39, 40, 42, and 44 (the "Challenged Claims") of U.S. Patent No. 7,831,296 ("the '296 Patent") (Ex. 1003).

The Challenged Claims are directed to x-ray mammography systems capable of performing a particular technique called digital breast tomosynthesis ("DBT"). By the '296 Patent's effective filing date, DBT had been described in numerous patents, papers, and other printed publications, and real-world combination DBT/mammography machines had existed for years.

In particular, through the work of Dr. Daniel Kopans and Dr. Loren and Laura Niklason, the first operable DBT machine was designed, built, and installed at Massachusetts General Hospital ("MGH") in the late 1990s. This prototype and a subsequent MGH prototype were modified GE mammography machines. Drs. Kopans's and Niklason's work was described in numerous patents and printed publications, including U.S. Patent No. 5,872,828 and two public reports to the U.S. Army Medical Research and Materiel Command, all of which are prior art to the '296 Patent and form the basis of this Petition.

The '296 Patent ***admits*** that a DBT "laboratory unit is believed to have been installed at the Massachusetts General Hospital (more than a year before the filing date hereof)," Ex. 1003, 1:64-2:1, but the applicants did not disclose that system's

details or submit to the Patent Office documentation (such as the prior art cited here) describing that system. The Challenged Claims are directed to a purportedly "commercially available" (Ex. 1003, 2:22-25) version this existing system, as the '296 Patent admits. But the MGH prototypes had all the components and all the capabilities claimed in the Challenged Claims (except one dependent claim which claims a well-known variant on one component of the system). The three core prior art documents described in this petition disclose those components and capabilities, and also disclose the element purportedly missing from the prior art of record during prosecution.

For these reasons, and as described in detail below, the Board should institute *inter partes* review of the '296 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 '296 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

Further, Petitioners are filing an additional petition for *inter partes review* of the following patent, which resulted from a divisional application of the '296 Patent's application and claims similar subject matter: U.S. Patent No. 8,452,379 (the "'379 Patent"). Petitioners also have filed a petition for *inter partes* review of U.S. Patent No. 7,123,684 (the "'684 Patent"), IPR2018-00538. The '296 Patent's application nominally is a continuation-in-part of the '684 Patent's application,

though as discussed below the '296 Patent describes and claims entirely different subject matter than the '684 Patent.

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 '296 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 23-25, 33, 35, 36, 39, 40, 42, and 44 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

1. Identification of Prior Art

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

- U.S. Patent No. 5,872,828, titled "Tomosynthesis System for Breast Imaging," naming Loren Niklason, Laura Niklason, and Daniel Kopans as inventors and assigned to The General Hospital Corporation, Boston, MA ("Niklason") (Ex. 1006)
- *Development and Clinical Evaluation of Tomosynthesis for Digital Mammography* by Daniel B. Kopans, M.D. of The General Hospital Corporation, Boston, MA, dated October 2000 ("Kopans") (Ex. 1007)
- *Tomosynthesis Breast Imaging: Early Detection and Characterization of Breast Cancer* by Leena M. Hamberg, PhD of The General

Hospital Corporation, Boston, MA, dated July 2000 ("Hamberg") (Ex. 1008)

- U.S. Patent Application Publication No. 2002/0090055, titled "Digital X-Ray Bucky Including Grid Storage," naming Albert Zur et al. as inventors ("Zur") (Ex. 1009)
- U.S. Patent No. 4,613,982, titled "Radiodiagnostic Apparatus for Mammograms," naming Hans-Peter Dornheim and Edmund Saffer as inventors ("Dornheim") (Ex. 1010); and
- U.S. Patent No. 6,632,020, titled "Method and apparatus for calibrating an imaging system," naming John Patrick Kaufhold et al. as inventors ("Kaufhold").

None of these references were considered by the Patent Office during prosecution of the '296 Patent, nor are they cumulative of the prior art considered by the Patent Office. None of these references is listed on the '296 Patent's face as "References Cited" and none are mentioned in the '296 Patent's file history. *See generally* Ex. 1004.

2. Asserted Grounds

Ground 1: Claims 23-25, 33, 35, 39, 40, 42, and 44 are unpatentable as obvious over Niklason in view of Kopans and Hamberg.

Ground 2: Claims 23-25, 33, 35, 39, 40, 42, and 44 are unpatentable as obvious over Niklason in view of Kopans, Hamberg, and Zur.

Ground 3: Claims 23-25, 33, 35, 39, 40, 42, and 44 are unpatentable as obvious over Niklason in view of Kopans, Hamberg, and Dornheim.

Ground 4: Claim 36 is unpatentable as obvious over Niklason in view of Kopans, Hamberg, and Kaufhold.

Ground 5: Claim 36 is unpatentable as obvious over Niklason in view of Kopans, Hamberg, Zur, and Kaufhold.

Ground 6: Claim 36 is unpatentable as obvious over Niklason in view of Kopans, Hamberg, Dornheim, and Kaufhold.

3. How Each Reference Qualifies As Prior Art

a. Effective Filing Date and § 102(b) Critical Date

The one-year time bar under pre-AIA 35 U.S.C. § 102(b) is measured from the '296 Patent's effective U.S. filing date. In an *inter partes* review proceeding, once the Petitioner identifies prior art, the patent owner bears the burden of producing evidence that the Challenged Claims are entitled to the effective filing date of an earlier patent application. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015); *Core Survival, Inc. v. S & S Precision, LLC*, PGR2015-00022, Paper 8 at 7-9 (P.T.A.B. Feb. 19, 2016).

The ’296 Patent’s application (No. 10/723,486, the “’486 Application”) was filed on November 26, 2003. The ’486 Application was filed without claiming priority to any application. Ex. 1004 at 2. Later during prosecution the applicants designated the ’486 Application as a continuation-in-part of an earlier application filed on November 27, 2002 (No. 10/305,480, the “’480 Application,” which eventually issued as the ’684 Patent). *Id.* at 179. But the two applications had completely different disclosures, such that the subject matter of the Challenged Claims was not disclosed in the ’480 Application. *Compare* Ex. 1004, 10-41 (’486 Application specification) *with* Ex. 1005 (’684 Patent). In the pending U.S. International Trade Commission (“ITC”) litigation, Patent Owner (“Hologic”) has not asserted that any Challenged Claims are entitled to the effective filing date of the ’480 Application.

Therefore, the ’296 Patent’s earliest effective filing date is November 26, 2003, and the “Critical Date” for § 102(b) purposes is November 26, 2002.

b. Niklason

Niklason issued as a U.S. patent on February 16, 1999, before the Critical Date. Niklason thus is prior art at least under pre-AIA 35 U.S.C. § 102(b).

c. Kopans and Hamberg

Kopans and Hamberg meet the standard for public accessibility to qualify as a printed publication at least under pre-AIA 35 U.S.C. § 102(b). In the related ITC

litigation, Hologic has not contested that Kopans and Hamberg qualify as prior art to the '296 Patent. Although Petitioners do not expect this issue to be disputed, Petitioners nonetheless show in detail below that Kopans and Hamberg were publicly accessible by no later than May 4, 2001. *See* Ex. 1001 (Declaration of Dr. John Allison), ¶¶ 91-110.

To qualify as a printed publication under pre-AIA 35 U.S.C. § 102(b), a reference must be "publicly accessible," which requires a "showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (citation omitted). "If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988).

Kopans and Hamberg state that they were prepared for the U.S. Army Medical Research and Material Command pursuant to a research grant. Ex. 1007 at 1; Ex. 1008 at 1. Kopans and Hamberg include a "Distribution/Availability Statement" stating "Approved for public release; distribution unlimited," and further are marked "Unclassified." Ex. 1007 at 1-2; Ex. 1008 at 1-2.

After submission to the U.S. Army, Kopans and Hamberg were made accessible to the interested public through two U.S. government organizations: the Defense Technical Information Center ("DTIC") and the National Technical Information Service ("NTIS"). DTIC and NTIS each independently provided a sufficient means for Kopans to qualify as a printed publication before the Critical Date.

Regarding DTIC, first, the Chief of the Customer Support Division, Directorate of User Services at DTIC confirmed via e-mail (Ex. 1012) the following information : Kopans "is part of the DTIC Collection, and its accession number is ADA387722. It is labeled on the cover paged and the SF 298 Approved for Public Release. A paper copy was received on March 23, 2001. It was processed through DTIC's Electronic Document Management System (EDMS) and digitally stored on April 4, 2001. This date is also when the citation was available on [DTIC's] website; the full text of the report became available online to the public within 30 days [i.e., May 4, 2001]."[1] The March 23, 2001 date provided by

[1] If Patent Owner objects to the admissibility of this or any other exhibit, those objections would not be a barrier to institution; any evidentiary objections should be addressed during trial. *E.g.*, *IBM Corp. v. Intellectual Ventures I LLC*, IPR2014-

DTIC corresponds to the "20010323" stamped on Kopans's cover in yyyymmdd format. Ex. 1007 at 1; Ex. 1001, ¶ 98. DTIC provided similar information regarding Hamberg, confirming that it was received on March 27, 2001 (as is stamped on the front of Hamberg), stored on April 4, 2001, and the full text was available online to the public by May 4, 2001. Ex. 1012; Ex. 1008 at 1; Ex. 1001, ¶ 99.

While Ex. 1012 alone demonstrates public accessibility through DTIC, archived DTIC webpages further describe how interested persons could search for and obtain documents in the DTIC Collection, like Kopans and Hamberg. Ex. 1013 (Internet Archive webpages)[2]; Ex. 1001, ¶¶ 99-102. In particular, the

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01385, Paper 7 at 8-9 (P.T.A.B. Feb. 11, 2015). In any event, Ex. 1012 is a statement by a U.S. government official in her official capacity about her office's activities and thus qualifies for numerous hearsay exceptions, including Fed. R. Evid. 803(8) and Fed. R. Evid. 807.

[2] As explained in Ex. 1015, an affidavit from the Internet Archive's Office Manager, the webpages in Exs. 1013 and 1014 were archived (and thus existed) on the Internet in August 2000. Ex. 1015 authenticates the documents in Ex. 1014, and Ex. 1033 authenticates the documents in Ex. 1013. The Board has accepted Internet Archive documents supported by such affidavits. *E.g., Creston Elecs., Inc. v.*

webpages describe the DTIC's Public "STINET," a searchable online database of the DTIC collection designed to "help[] the DoD community access pertinent scientific technical information." Ex. 1013 at 1. As an "unclassified unlimited" document, the full text of Kopans and Hamberg would have been available through STINET after they became part of DTIC's collection in May 2001. *Id.*

Anyone could have searched STINET, which was indexed and "highlight[ed] featured material from the collection to make searches easier," and viewed citations to unclassified unlimited documents in DTIC's collection (like Kopans and Hamberg) without registration and free of charge. Ex. 1013 at 7. One skilled in the art, exercising reasonable diligence, thus could have located Kopans and Hamberg by searching STINET by no later than May 4, 2001. Ex. 1001, ¶ 101. Eligible users also could register with DTIC and obtain reports directly from DTIC. Ex. 1013 at 7. A substantial majority of persons interested in the art would have been eligible to register. Ex. 1013 at 3-4; Ex. 1001, ¶¶ 100, 102. And if a particular person was not eligible, he or she could have obtained a copy of Kopans and Hamberg from one of the many people who were eligible because the

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Intuitive Building Controls, Inc., IPR2015-01460, Paper No. 14, at 12-16 (P.T.A.B. Jan. 14, 2016); *America Express Co. v. Lunenfeld*, CBM2014-00050, Paper No. 17, at 34 (P.T.A.B. June 18, 2014).

documents were unclassified. Ex. 1001, ¶ 102. Accordingly, Kopans and Hamberg were sufficiently publicly available through DTIC prior to the Critical Date to qualify as a "printed publication." *Id.*, ¶ 101.

Even if access through DTIC did not satisfy the "public accessibility" standard, Kopans and Hamberg were sufficiently accessible through NTIS. Ex. 1001, ¶¶ 103-108. DTIC's webpages specifically directed users not eligible for DTIC registration to obtain unclassified/unlimited documents from NTIS, to whom DTIC provided such documents "for dissemination to the public." Ex. 1013 at 6; Ex. 1012. NTIS, "our nation's largest central source for government-sponsored scientific, technical, engineering, and related business information," "facilitates public access to Federal information," according to archived copies of NTIS webpages from August 2000. Ex. 1014 (webpages) at IA000029, 32; Ex. 1015. NTIS was directed to those skilled in the art. Ex. 1014, IA000032; Ex. 1001, ¶ 105.

Anyone could perform "detailed subject searches through the NTIS Government Research Center's online databases" or search through the NTIS website via an online query engine. Ex. 1014 at IA000030, 38. NTIS also had "a print-on-demand system." *Id.* at IA000034. Accordingly, interested members of the public, exercising reasonable diligence, could have searched for and obtained documents in NTIS's collection. Ex. 1001, ¶ 107.

The evidence shows that Kopans and Hamberg were received by NTIS from DTIC and added to NTIS's collection (and thus, publicly accessible) long before the Critical Date. Ex. 1001, ¶¶ 107-108. Per DTIC's practice at the time, Kopans and Hamberg would have been sent to NTIS within two weeks of receipt by DTIC, after which time NTIS would have added Kopans and Hamberg to its collection. Ex. 1012; Ex. 1013 at 4. Furthermore, Kopans and Hamberg remains available by searching NTIS's databases, which show a "Publication Year" of 2000 for both documents. Ex. 1016; Ex. 1001, ¶ 106. At minimum, this evidence establishes a "reasonable likelihood" that Kopans and Hamberg were part of NTIS's collection by the Critical Date.

d. Zur

Zur is a U.S. patent application publication that was published on July 11, 2002, before the Critical Date. Ex. 1009. Zur is prior art to the '296 patent at least under pre-AIA 35 U.S.C. § 102(b).

e. Dornheim

Dornheim is a U.S. patent that issued on September 23, 1986, before the Critical Date. Ex. 1010. Dornheim is prior art to the '296 patent at least under pre-AIA 35 U.S.C. § 102(b).

f. Kaufhold

Kaufhold is a U.S. patent that issued on October 14, 2003 from a patent application filed on October 12, 2001. Ex. 1011. Kaufhold is prior art to the '296 patent at least under pre-AIA 35 U.S.C. § 102(a) and (e).

C. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA"), at the '296 Patent's effectively 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, ¶ 77. 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 POSITA 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.*, ¶ 79. Furthermore, the '296 Patent's "Background" section describes prior art that a POSITA would have known. *Id.*; Ex. 1003, 1:19-2:21. The '296 Patent also states that it is "known in the art, [that anti-scatter] grid 108 can be made to move relative to the

x-ray beam during the taking of a set of image data." Ex. 1003, 9:35-37; Ex. 1001, ¶ 79.

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, ¶ 80.

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 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 constructions (key portions emphasized):

Term	**Broadest Reasonable Interpretation**
"the x-ray dose for said mammogram position is similar to a dose used for a ***conventional*** mammogram" (Claim 23)	"the x-ray dose for the mammogram position is similar to the dose that would have been used for a conventional mammogram ***at the time of filing***"

"A claim cannot have different meanings at different times; its meaning must be interpreted as of its effective filing date." *PC Connector Solutions. LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1363 (Fed. Cir. 2005); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1333 (Fed. Cir. 2005) (en banc) (claim term meaning is judged "as of the effective filing date of the patent application."). Accordingly, the broadest reasonable interpretation of a "conventional" mammogram dose should refer to the dose "at the time of filing." *See Catch Curve, Inc. v. Venali, Inc.*, 2010 WL 270889, *3 (Fed. Cir. 2010) ("conventional" means at the time of filing, not at the time of alleged infringement).

Even if this term's meaning is viewed as changing over time (to whatever the "customary" dose was at the time), it would not affect the result. The prior art

references disclosed mammography/DBT devices that acquired standard mammogram images using doses for a standard mammogram around the time of the alleged invention of the '296 Patent as discussed further below. Beyond the temporal limitation inherent in "conventional," the '296 Patent provides no specific guidance or limits on what was a "conventional" mammogram dose. Ex. 1003, 2:53-55, 6:13-22; *see* Ex. 1001, ¶ 87 (mammogram dose varies by patient and other conditions).

In addition, Petitioners propose making clear one issue of claim scope under the broadest reasonable interpretation standard: the claimed system is ***not*** required to be configured to capture both a mammogram image and tomosynthesis images during a single compression of the patient's breast. Claim 23 recites "a control configured to selectively energize the source to emit x-rays through the breast support to the imager, while a patient's breast remains immobilized in the breast support at each of said different angular positions." By its plain terms, this element is met when the patient's breast is compressed ("remains immobilized in the breast support") at each imaging position of the x-ray source. In other words, while the x-ray source is emitting x-rays, the patient's breast should remain compressed. While this *could* be accomplished by keeping the breast compressed during an entire exam spanning multiple imaging positions, this is not *necessary*:

compressing the patient's breast separately for each imaging position would also meet the claim language.

Indeed, Hologic expressly characterized this claim during prosecution in a manner consistent with Petitioner's proposed broadest reasonable interpretation: "Moreover, both kinds of images can be taken in a single compression of the patient's breast, ***although in the alternative they can be taken at different compressions or times***." Ex. 1004 at 276 (emphasis added).

Furthermore, the applicants explicitly claimed capturing both mammogram and tomosynthesis images during a single compression of a patient's breast in other claims, like Claim 8 of the '379 Patent (which issued from a divisional application of the '296 Patent's application). Ex. 1017, Claim 8 ("The system as in Claim 6 in which the image data for the mammogram and tomosynthesis positions is acquired during a single compression of a patient's breast"). *See also* '296 patent, claim 1 (reciting "in a single breast compression" in the preamble). No such "single compression" language appears in any Challenged Claims.

Nonetheless, even applying a narrower interpretation requiring the capability to take both mammogram and tomosynthesis images during a single compression, the Challenged Claims are rendered obvious by the Grounds set forth in this Petition, as explained in more detail below.

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

The Declaration of Dr. John Allison, Ex. 1001, and other supporting evidence in the Exhibit List are filed herewith. Dr. Allison's background and qualifications, and the information provided to him, are discussed in Ex. 1001, ¶¶ 1-18, 77-78, 81-83, 140 and Ex. 1002.

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

A. Technology Background and State of the Art

The '296 Patent relates to mammography, a type of radiographic examination designed to detect breast pathology (particularly cancer). Ex. 1003, 1:14-24; Ex. 1001, ¶¶ 19-20. In particular, the '296 Patent relates to combining mammography with tomosynthesis. Ex. 1003, 1:14-16; Ex. 1001, ¶ 19.

In standard screening mammography, x-ray images are taken of each compressed breast from two standard views: the cranial-caudal view, in which the x-ray source is directly above the breast, and the mediolateral-oblique view, which is a side view in which the imaging assembly is rotated 45 degrees. Ex. 1003, 1:27-29; Ex. 1001, ¶ 26. This results in four two-dimensional projection images. Ex. 1001, ¶ 26. Mammography machines at the time included standard parts: an x-ray source, shielding/restrictions on the x-ray beam, a paddle for compressing the patient's breast, and an image detector. *Id.*, ¶¶ 21-25. Full-field digital image

detectors began to replace screen-film detectors in mammography in the late 1990s. *Id.*, ¶ 31.

Digital tomosynthesis is an updated approach to conventional geometric tomography (imaging by sections). Ex. 1001, ¶ 32. Computer tomography ("CT") allowed for three-dimensional imaging of body parts. Tomosynthesis improves on CT by enabling reconstruction of an image from an arbitrary number of planes taken in a single image sequence. *Id.*, ¶¶ 32-33. The term was coined in the 1970s, when a tomosynthesis machine worked in concept but required changing the film between each image and thus was not practical. *Id.*, ¶¶ 34-35.

Tomosynthesis involves taking a series of images from multiple different angles. Ex. 1001, ¶¶ 42-43. The x-ray source rotates as the patient's breast remains under compression. Ex. 1001, ¶¶ 40, 85, 118. The images are then reconstructed digitally to show a single plane (or "slice") of the patient's breast in better detail than each of the single isolated views used in standard mammography. Ex. 1001, ¶¶ 36-37, 41, 146; Ex. 1023 at R95.

The availability of advanced digital detectors enabled researchers at Massachusetts General Hospital ("MGH") to develop the first clinically practical combination mammography/tomosynthesis machines. *Id.*, ¶ 36. This research, led by Drs. Niklason and Kopans, is described in detail in the Niklason, Kopans, and Hamberg prior art documents discussed herein.

The Kopans and Niklason DBT machine was widely hailed as a breakthrough. It was described in a 1997 article in *Radiology*, a flagship industry publication, which has since been cited over 700 times and received recognition. Ex. 1001, ¶¶ 36, 89-90; Ex. 1021 (*Radiology* article). It was also described in the Niklason '828 patent. This research spurred further developments. Some happened at MGH: Drs. Kopans, Niklason, and colleagues created a second, improved prototype, which is described in the Kopans prior art reference. Ex. 1001, ¶ 38. Others joined in: by 2003, over 100 references had been published or patented by a host of leading universities and industry companies describing digital tomosynthesis systems leveraging the MGH work. *Id.*, ¶ 37.

Tomosynthesis and mammogram images are acquired in much the same way. Ex. 1001, ¶¶ 45-47. The only differences are (a) the x-ray dose, which is lower for each tomosynthesis image than each mammogram image (because more images are taken in each session) and (b) the position (an image taken at the usual MLO or CC positions could be used for either mammography or tomosynthesis, while images taken at other angular positions could only be used for tomosynthesis). *Id.* The detector operates in the same manner for both. *Id.* Adjusting dose was not difficult; dose and settings already were changed on a patient-by-patient basis in normal mammograms. *Id.* As discussed further below, early DBT machines (like the two MGH prototypes) were built by modifying

mammography machines, and retained the capability to take mammogram images. Ex. 1001, ¶¶ 36, 48, 148.

At the time, anti-scatter grids were typical mammography machine components. Ex. 1001, ¶ 27. The grids are made of strips of radiation-absorbing material and, when used in mammography, are positioned between the compressed breast and the imaging receptor. *Id.*, ¶ 28. The grids allow only x-rays that have traveled in a straight line from the source to pass through to the imaging receptor preventing the passage of scattered radiation that can cause loss of image contrast. *Id.* When the x-ray source is at an angle to the imaging receptor, however—such as in many tomosynthesis imaging positions—the anti-scatter grid would absorb the primary x-ray beam and prevent proper imaging. Therefore, early tomosynthesis developers recommended removing the anti-scatter grid when taking tomosynthesis images. *Id.*, ¶ 44. Prior art machines included removable anti-scatter grids because some imaging modes (like magnification imaging) could not use the grids. *Id.*, ¶ 29. As discussed further below, grid movement often was motorized and automated; additionally, prior art mammography systems often provided side access allowing an operator to manually reposition the grid without disturbing a patient whose breast was compressed. *Id.*, ¶¶ 29-30.

B. Description of the '296 Patent

The '296 patent's stated purpose was to make a commercially available version of the tomosynthesis breast imaging systems that were admittedly available at the time in clinical and research settings. Ex. 1003, 2:22-27.

The '296 patent begins by listing certain "typical" features of existing mammography machines. Ex. 1003, 1:24-48; Ex. 1001, ¶¶ 50-55. These include an x-ray source which images the breast from the CC and MLO views, an anti-scatter grid, breast compression, and an image receptor (which by this time increasingly was digital instead of film-screen). *Id.* The '296 patent asserts that false negatives and positives in screening mammography remained a problem, and while techniques such as CT, MRI, and ultrasound could help address those problems, they also may have drawbacks. Ex. 1003, 1:49-68; Ex. 1001, ¶ 56.

The '296 Patent also acknowledges: "Digital tomosynthesis has been proposed for x-ray breast imaging, and a laboratory unit is believed to have been installed at the Massachusetts General Hospital (***more than a year before the filing date hereof***)…." Ex. 1003, 1:64-2:4 (emphasis added). The '296 Patent does not describe any further details about this machine or the research done at MGH, nor does it cite any of the published work of Drs. Niklason and Kopans. Ex. 1001, ¶ 57. The patent asserts that "no breast tomosynthesis systems are ***commercially available*** currently for clinical use…." Ex. 1003, 2:22-25 (emphasis added).

While the '296 Patent asserts a "need" for "improved and practical tomosynthesis mammography," Ex. 1003, 2:22-27, it does not describe the particular "improvements" that are needed, nor how its alleged inventions provide those improvements. Ex. 1001, ¶ 58. The alleged invention includes the same components admittedly present in "typical" prior art mammography machines: a digital detector, a rotating C-arm containing an x-ray source, an anti-scatter grid, and equipment for breast compression. Ex. 1003, 2:31-3:38, 4:11-5:43; Ex. 1001, ¶¶ 59-63. The patent also describes, at a high level, processing and display of image data. Ex. 1003, 5:44-58, 6:7-9, 6:38-7:35, Fig. 3; Ex. 1001, ¶¶ 74-76.

The specification states that image data may be taken with or without an anti-scatter grid. Ex. 1003, 3:6-8. But the only description of a movable antiscatter grid, or how such movement is performed, is, in full: "In each of the embodiments of FIGS. 1-2 and FIGS. 7-8, antiscatter grid 108 may be selectively retractable, so that the user may take any selected set of x-ray image data with or without using grid 108. As in known in the art, grid 108 can be made to move relative to the x-ray beam during the taking of a set of image data." Ex. 1003, 9:33-38; Ex. 1001, ¶¶ 64-66. This appears to refer to the well-understood "reciprocating" grid movement to prevent image artifacts, not retracting the grid out of the x-ray beam's path; regardless, it assumes that the method of moving the grid is "known in the art." Ex. 1001, ¶ 67.

Consistent with the Technology Background (*supra* Section V.A), the ’296 Patent does not describe any differences between how the alleged invention acquired tomosynthesis and mammogram images except a difference in source position, and that the tomosynthesis image dose is “less, preferably much less” than the mammogram image dose. Ex. 1003, 5:11-43, 6:9-38; Ex. 1001, ¶¶ 69-71. The patient’s breast may remain immobilized in the same position while tomosynthesis and mammogram images are acquired. Ex. 1003, 6:21-31. The ’296 Patent does not disclose details of how the x-ray source is controlled to apply different doses for mammogram and tomosynthesis images while the patient’s breast remains compressed. Ex. 1001, ¶ 72. Nor does it describe how much time is needed to acquire tomosynthesis and/or mammogram images, or suggest that the patient’s breast must remain compressed for only a limited time; to the contrary, it describes x-ray source motion as “gradual” and states that source motion may be intermittent. Ex. 1003, 4:22-60, 5:32-43, 5:65-68; Ex. 1001, ¶¶ 61 72.

In short, the ‘296 Patent does not suggest that a POSITA would have had any difficulty using a machine that already is capable of both mammography and tomosynthesis to take both mammogram and tomosynthesis images while a patient’s breast remains compressed (with our without grid movement during that procedure). Nor does it describe any systems or methods for overcoming the difficulties (if any) associated with that procedure. Ex. 1001, ¶¶ 68, 73.

C. Prosecution History

During prosecution, original claim 79, which is now challenged claim 23, was rejected as obvious. Ex. 1004, 152-154. In response, the applicant argued that the cited prior art "does not teach a fused mammogram/tomosynthesis system that takes both types of images without the need to release the patient's breast from compression and move the patient to other x-ray equipment." *Id.* at 209-211. The examiner rejected this attempted distinction. *Id.* at 217-226. In response, the applicant amended independent claim 79 to add the limitation "wherein said x-ray source applies an x-ray dose to the patient's breast in each of said tomosynthesis positions that is less than the x-ray dose applied to the breast in said mammogram position, and the x-ray dose for said mammogram position is similar to a dose used for a conventional mammogram." *Id.* at 262. The applicant argued that the cited prior art did not specifically disclose that its dose used for tomosynthesis images was less than the dose used for its mammogram images. *Id.* at 275.

The applicant further characterized the independent claims as follows: "Moreover, ***both kinds of images can be taken in a single compression of the patient's breast, although in the alternative they can be taken at different compressions or times***." *Id.* at 276 (emphasis added). This amendment and argument resulted in allowance. *Id.* at 302.

D. Summary of Unpatentability Arguments

The Niklason patent provides the essential description of the groundbreaking digital mammography/tomosynthesis system, including its ability to acquire images at tomosynthesis angles and dosages and to perform the processing necessary to reconstruct those images into three-dimensional views of a patient's breast. Kopans and Hamberg provide additional details about the MGH team's research, including (in Kopans) an updated second prototype mammography/tomosynthesis machine. Together, these three references disclose each element of each of the Challenged Claims (except claim 36), as discussed below in Section V.E—including the element supposedly missing from the prior art cited during prosecution. It would have been obvious to combine these three references' teachings, which relate to the exact same underlying research project and prototype mammography/tomosynthesis systems.

If these references insufficiently disclose the claimed anti-scatter grid, these claims are nonetheless unpatentable as obvious. Automatically retractable anti-scatter grids were well-known in the art, dating back to the 1980s, including in digital imaging systems (e.g., Zur) and mammography systems (e.g., Dornheim). A POSITA would have found it obvious to supply this routine capability to the combination mammography/tomosynthesis machines disclosed in Niklason, Kopans, and Hamberg. Economic and patient-comfort imperatives

driving towards a more efficient clinical workflow would have motivated such combinations. *See infra* Sections V.F-G.

Finally, dependent claim 36 adds only a trivial limitation—that the x-ray source uses tungsten—which was a well-known design choice and is expressly disclosed in Kaufhold, another prior art patent concerning a mammographic tomosynthesis machine. *See infra* Sections V.H-J.

E. Ground #1: Claims 23-25, 33, 35, 39, 40, 42, and 44 are Obvious Over the Combination of Niklason, Kopans, and Hamberg

1. Niklason

The Niklason patent describes DBT machine that could capture mammogram and tomosynthesis images of a breast. Ex. 1001, ¶ 85. Figure 7 of Niklason illustrates a "General Electric model DMR mammography gantry **71**" modified with a full field digital image receptor (72). Ex. 1006, 6:54-67.

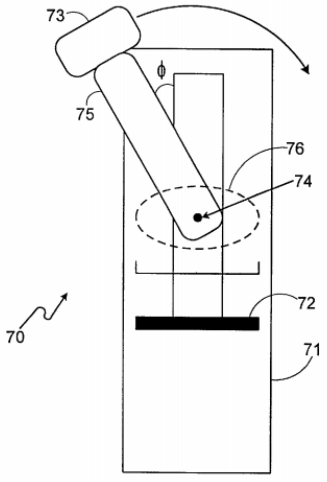


FIG. 7

The x-ray source (73), whose motion can be motorized and computer-controlled, emits energized photons toward the compressed breast and digital detector to produce images. Ex. 1003, 6:65-67; Ex. 1001, ¶¶ 86, 88. This automated movement permitted capture of all the tomosynthesis image views in about 3-5 seconds. Ex. 1003, 8:48-53. The x-ray source (73) could pivot about an axis point (74) between an angular range of ±27 degrees. Ex. 1006, 6:59-63; Figure 6 (below).

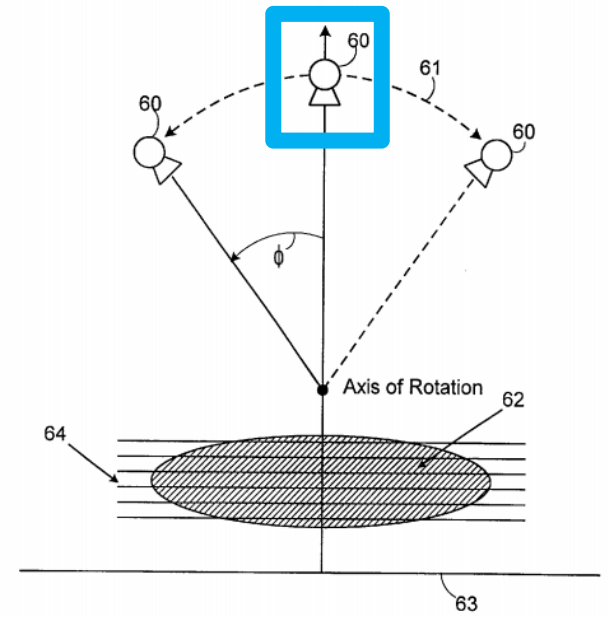


FIG. 6

Notably, Figure 6, and other Figures in Niklason, demonstrate that the mammography/tomosynthesis system could take an image at 0° (shown in the blue box above). This was a standard mammography position. Ex. 1001, ¶ 86.

Niklason teaches that adapting digital tomosynthesis to an existing mammography system, the combination system would retain the capabilities supporting routine mammography imaging. *Id.* at 6:54-67, 8:42-48.

Niklason further describes the *relative* doses for tomosynthesis imaging, taken at angles to either side of center: "the total radiation dose for all the [tomosynthesis] images being equivalent to, or slightly higher than, the dose used for a standard single view mammogram." Ex. 1006, 6:32-36; Ex. 1001, ¶¶ 86-87.

Niklason further described processing the tomosynthesis projection images to display the images on a computer screen. Niklason recognized that applying a shift and add or a backprojection algorithm would make it "possible to reconstruct any plane in the breast that is parallel to the detector." *See id.* at 4:34-6:47.

2. Kopans

Dr. Kopans, who was a co-inventor on the Niklason patent, authored this Annual Report describing the second MGH clinical mammography/tomosynthesis prototype. Ex. 1007 at 5, 49-67; Ex. 1001, ¶ 111. This prototype had the same physical parts as described in Niklason. *Id.* at 5, 10; Ex. 1001, ¶ 112. Kopans also describes the system's software and includes a copy of the prototype's Users Manual, describing in detail how the machine could be operated. Ex. 1007 at 10, 68-84; Ex. 1001, ¶¶ 113-114.

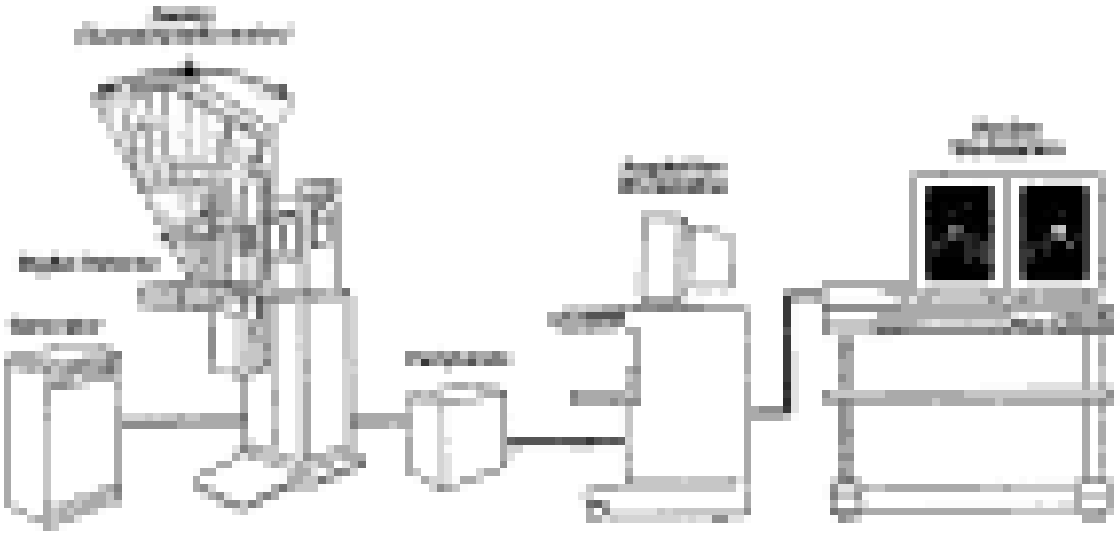
The Users Manual explains that the system was configured to take tomosynthesis or normal mammogram examinations and allowed the user to create imaging acquisition sequences and adjust scan parameters (e.g., dose); this allowed the system to execute a tomosynthesis scan and a mammogram sequentially without disturbing the patient. Ex. 1007 at 75-78; Ex. 1001, ¶¶ 114-115. Once images were captured, the software interface allowed the operator to choose which images to reconstruct and display on the monitor. Ex. 1007 at 80-82; Ex. 1001, ¶ 116.

In addition, Kopans includes results of actual system testing for both mammogram and tomosynthesis images generated by the prototype. Ex. 1007 at 27-34, 49-67; Ex. 1001, ¶ 112. Kopans reports that the system was "performing well and is ready for initial patient imaging." Ex. 1007, at 6. Of particular interest, the system tested both tomosynthesis images and standard mammogram images of the same breast phantom. *Id.* at 56. The tomosynthesis images were obtained without an anti-scatter grid, and the mammogram images were obtained with an

anti-scatter grid. *Id.* at 56-57, 69. Also, "the dose from 11 [tomosynthesis] images spread over 50 degrees with a total mAs of 100 is very close to that from a single exposure [mammogram] at 0 degrees of 100 mAs." *Id.* at 60.

3. Hamberg

Dr. Hamberg, who was working with Drs. Niklason and Kopans, authored this report describing the first MGH mammography/tomosynthesis prototype. Ex. 1008; Ex. 1001, ¶¶ 117-118. Hamberg describes some additional details about that system. Ex. 1008 at 5-8, Figs. 1-2 and 5-8; Ex. 1001, ¶¶ 119-120. For example, Hamberg illustrates the entire system including the review workstation (Ex. 1008 at 5):



The study described in Hamberg was done, in part, to compare mammographic images to tomosynthesis images, while varying parameter settings includ-

ing x-ray dose. Ex. 1008 at 12-15; Ex. 1001, ¶¶ 121-122. Hamberg describes obtaining 2D images with a "full, mammographic dose," and tomosynthesis images using "1/9 of a full dose" for each. Ex. 1008 at 14. The images were then read on a display by a radiologist. *Id.*

4. Motivation to Combine Niklason, Kopans, and Hamberg

A POSITA would find explicit motivations to combine Niklason, Kopans, and Hamberg in the references themselves. These references identify the same researchers, working at the same hospital, on the same underlying project: construction and testing of combination mammography/tomosynthesis machines built from modified GE Senographe DMR mammography machines. Ex. 1001, ¶ 145; Ex. 1006, cover page, 3:67-4:2; Ex. 1007 at 1, 5-6, 10, 18-19, 27-28, 48, 56-57, 61, 63, 71, 72-83; Ex. 1008 at 1, 4, 13-15, 17-20. A POSITA would have been motivated to combine all three documents' teachings to understand the state of the art in combined mammography/tomosynthesis machines and the full capabilities of the systems and methods devised by the MGH research team. Ex. 1001, ¶ 145. And given the MGH team's real-life success developing working devices, a POSITA reasonably would have expected success in combining the disclosures of Niklason, Kopans, and Hamberg in a way that yields the complete subject matter of the claims discussed below. *Id.*, ¶ 150.

More generally, a POSITA would have been motivated to achieve a working tomosynthesis machine to obtain its recognized benefits of improving breast cancer detection while reducing recall and biopsy rates. Ex. 1001, ¶ 146 (citing Ex. 1022 (2003 journal article on tomosynthesis)). A POSITA also would have been motivated to retain standard 2D mammography capability, because it remained the known, accepted, and required mode for breast cancer screening—indeed, this is exactly what companies like GE already had done in adding 3D imaging to 2D mammography machines. *Id.*, ¶¶ 147-148. To do so, a POSITA would have been motivated to look to the work of the MGH research team, given its widespread recognition—as the '296 patent's inventors apparently did themselves. *Id.*, ¶ 149; Ex. 1003, 1:65-2:4.

5. Claim 23

a. A combination mammogram/tomosynthesis system comprising

If claim 23's preamble is a limitation, Niklason, Kopans, and Hamberg disclose a combination mammogram/tomosynthesis system. Ex. 1001, ¶¶ 152-154.

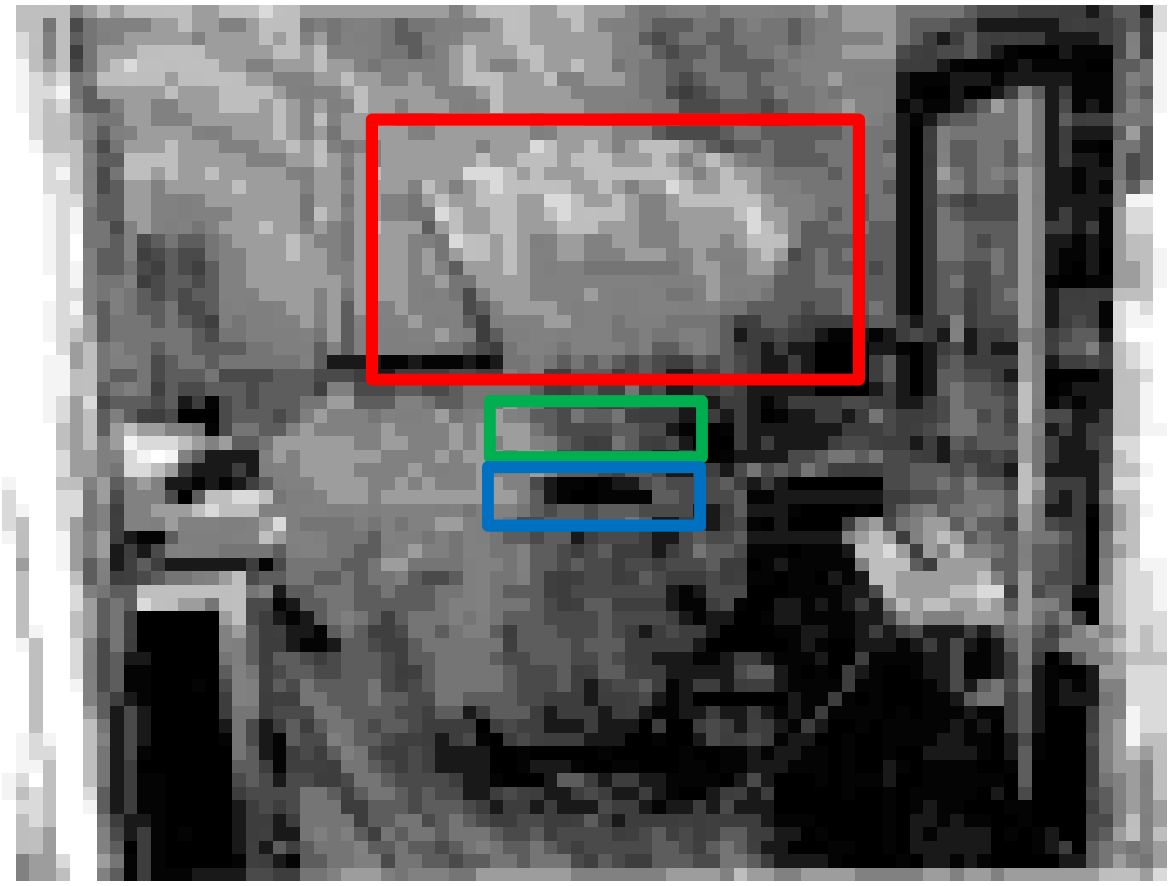
Niklason describes that its machine "will still be completely useable for routine breast imaging, thereby eliminating the need for a dedicated tomosynthesis system." Ex. 1006, 8:37-53; Ex. 1001, ¶ 152. Kopans and Hamberg both describe their systems taking both tomosynthesis images and standard mammogram images

of the same breast phantom. Ex. 1007 at 56, 69; Ex. 1008, 13-15; *see* Ex. 1001, ¶ 153.

b. <u>an x-ray source, a flat panel digital x-ray imager, and a breast support configured to immobilize a patient's breast between the source and the imager</u>

Niklason, Kopans, and Hamberg disclose an x-ray source, a flat panel digital x-ray imager, and a breast support. Ex. 1001, ¶¶ 155-157.

Niklason expressly discloses and depicts these elements. Ex. 1006, 2:23-37, 3:39-51; Fig. 3, 6:28-36 (describing the "stationary breast"), 6:54-67 (describing movement of "x-ray source **73**"), 6:59 (identifying "full-field digital image receptor **72**); Fig. 7; Ex. 1001, ¶ 155. So does Kopans, in this annotated photo of the prototype system (Ex. 1007 at 69):

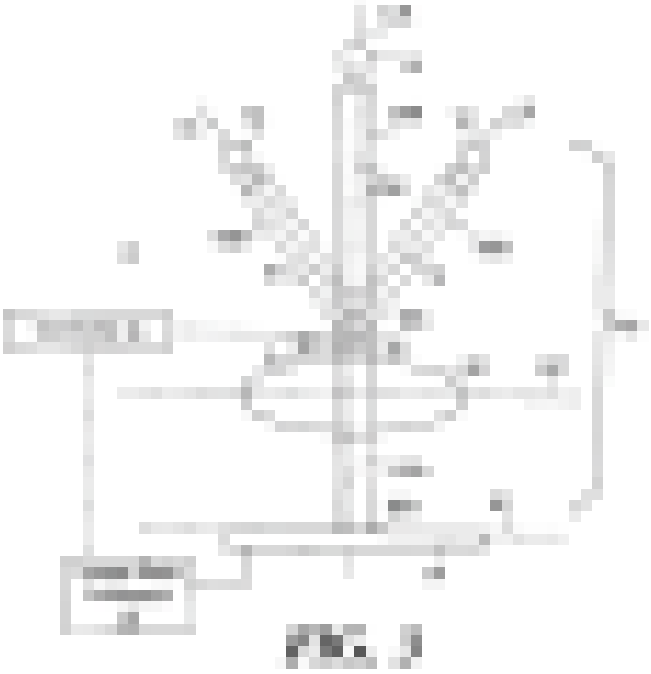


The red box encompasses x-ray shielding over the arc path in which the source is rotated; the blue box is the detector, breast support, and anti-scatter grid (when in place); and the green box is the location for the breast compression paddle. Ex. 1001, ¶ 156; *see also* Ex. 1007 at 16 ("For patient imaging, . . . the breast is compressed").

c. <u>a source support configured to selectively move the source relative to the breast support between different angular positions of the source relative to the breast support;</u>

Niklason, Kopans, and Hamberg each explicitly describe this element. Ex. 1001, ¶¶ 158-162.

Niklason describes support structure 16 which supports and moves x-ray source 12 (Ex. 1006, 3:39-45) with reference to Figure 3, below (Ex. 1001, ¶ 158):



The articulated support structure (16) has two portions: 16A, which remains stationary and perpendicular to the imaging plane, and 16B, which is used to rotate the x-ray source (12). "An actuator **30** is selectively controlled to determine the angle of portion **16**B (and axis B) with respect to portion **16**A (and axis A), in response to control signals from controller **8**." Ex. 1006, 3:61-64. A POSITA would understand that portion 16B—and therefore the x-ray source—can be positioned at any angular location along the arc path depicted in Figure 3, while a patient's breast ("object **20**") remains compressed. Ex. 1001, ¶ 159.

Kopans likewise depicts the tube arm and rotation arc of the x-ray source. Ex. 1007 at 11, 14-16. And it describes performing testing with a preprogrammed

rotation of the source (the tube arm) through a range of between 40 and 50 degrees, taking exposures at 8 or 11 angles within that range. *Id.* at 11-13, 50, 69; *see also* Ex. 1001, ¶ 161.

Hamberg, too, illustrates the x-ray source movement, indicated as "tomo motion" in Figure 1, below (Ex. 1008 at 5):

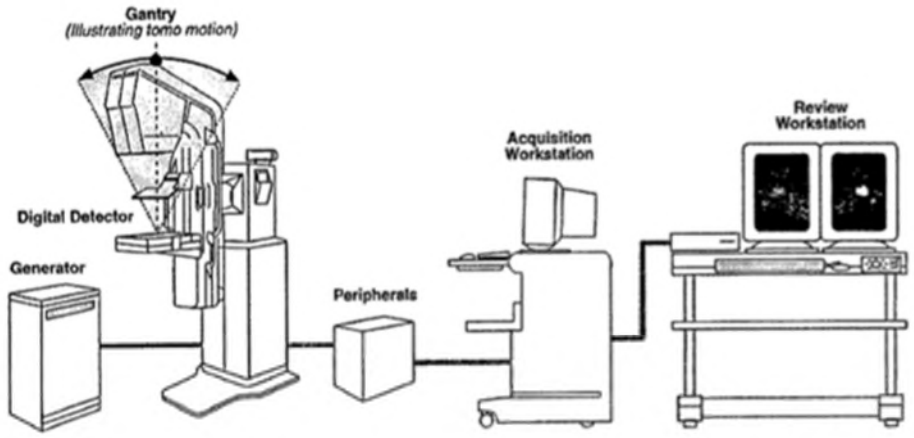


Figure 1. A graphical presentation of the digital tomosynthesis system used in the study. The x-ray source can move in an arc above the full size digital detector plate. During each exposure the x-ray tube is stationary moving to the next position between exposures. 9 views are usually acquired at 9 exposure positions within a 40° arc. Any plane parallel to the detector can be reconstructed from these data.
(*Courtesy of Jeff Eberhard, GE Medical Systems*)

Hamberg describes how "the X-ray source is moved in an arc while the object [i.e., the breast] and the detector are stationary." *Id.* at 4; Ex. 1001, ¶ 160.

d. <u>a control configured to selectively energize the source to emit x-rays through the breast support to the imager, while a patient's breast remains immobilized in the breast support at each of said different angular positions;</u>

The combination of Niklason, Kopans, and Hamberg discloses this element. Ex. 1001, ¶¶163-183.

For the first part of this element ("a control configured to…"), Niklason discloses an "image data processor **10**" that can, among other things, "function to control the emission of x-rays from source **12**" at each selected angular positions. Ex. 1006, 2:32-38, 4:7-11, Figs. 3-4. This processor "may be a conventional digital computer" that includes an "x-ray controller **24**"; the controller can drive other devices, and specifically it "can further command and control irradiation by the x-ray source such as through control signals 29." *Id.*, 4:33-49. A POSITA would understand that controlling the emission of x-rays would require controlling technical settings such as kVp (source voltage), mAs (source current), and target/filter materials, which together determine the spectrum of x-ray energies generated for imaging and the dose. *Id.*, 3:61-64; Ex. 1001, ¶ 163.

Both Kopans and Hamberg disclose automated acquisition images from selected angles along the arc of the x-ray source's movement. Ex. 1007, 12-13; Ex. 1008, 4-8; Ex. 1001, ¶ 165. Kopans provides a set of "scan plans" with radiation parameters; the operator would select a plan to determine the number of angles and the particular technical factors to use in a tomosynthesis scan. (For standard mammography, Kopans explains that the existing controls of the system remained unchanged.) Ex. 1007, 70-71; Ex. 1001, ¶ 164. In addition, the operator could modify a particular scan plan to alter a dose from one source position to another within the scan. Ex. 1007, 75-77; Ex. 1001, ¶ 164.

The second part of the limitation, "while a patient's breast remains immobilized in the breast support at each of said different angular positions," does not require that a system be configured to immobilize a patient's breast *throughout the entire series* of mammogram and tomosynthesis image acquisitions. The broadest reasonable interpretation requires only that the breast be immobilized "at each of said different angular positions"; that is, at each imaging position, the breast should be under compression. *See supra* Section IV.D; Ex. 1001, ¶ 167. As properly construed, this element is disclosed by Niklason, Kopans, and Hamberg for the reasons discussed above and in Section V.E.5.b (*see also* Ex. 1001, ¶¶ 168, 172). And the '296 Patent acknowledges that the need for compression during imaging "in each view" was known and standard in the prior art. Ex. 1003, 1:35-39.

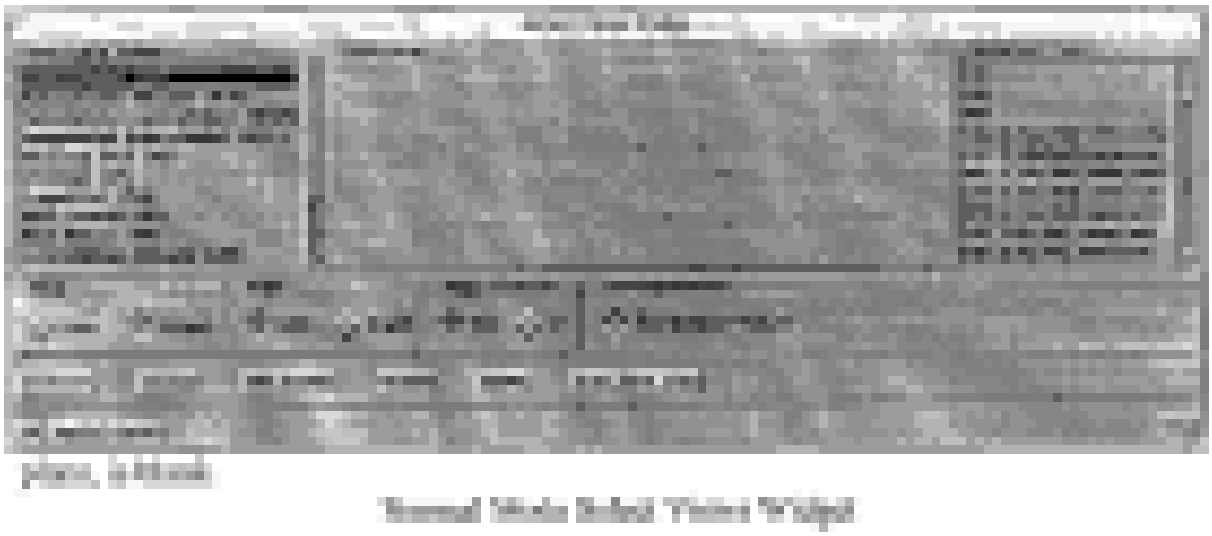
Even if the limitation were construed to require that the breast remain immobilized during the entire scan—a single compression for both mammography and tomosynthesis—the combination of Niklason, Kopans, and Hamberg describe systems that were capable of taking mammogram and tomosynthesis images during a single breast compression, thus meeting this element. Ex. 1001, ¶¶ 169-183.

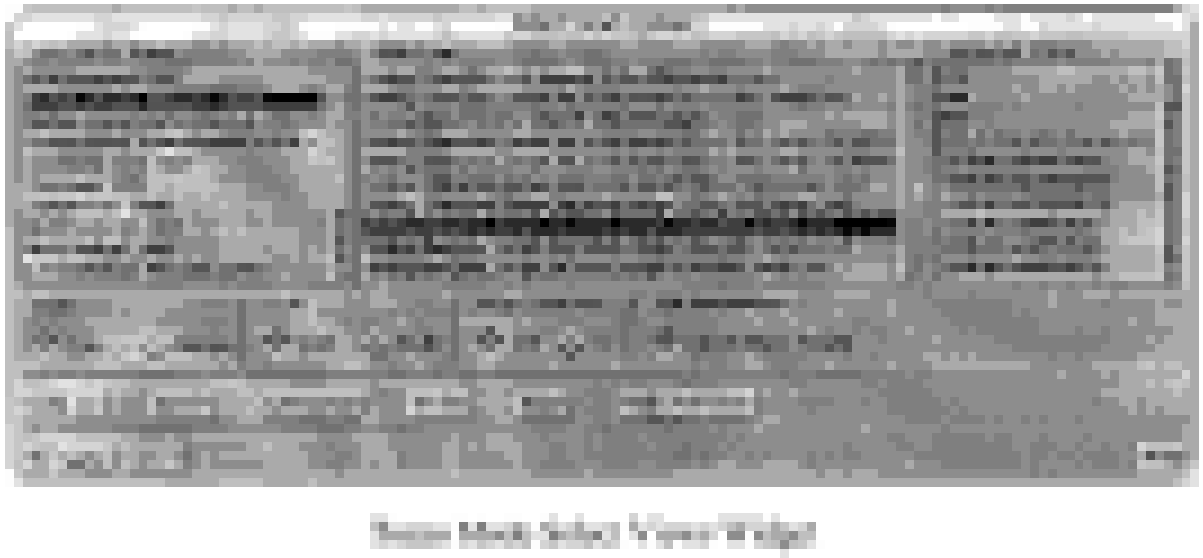
As noted above in Section V.A, the difference between acquisition of mammogram and tomosynthesis images is simply the x-ray source angle with

respect to the receptor and the radiation dose. In standard mammography, the x-ray source is perpendicular to the plane of the image receptor in either the CC or MLO view. In tomosynthesis, a series of images are taken at different angles as the x-ray source moves in an arc relative to the receptor. In addition, the radiation dosage for a mammogram image is higher than that for a tomosynthesis image. *See also* Ex. 1001, ¶ 173. Otherwise, mammogram and tomosynthesis image acquisition is the same, in both the prior art and the '296 patent's description. Section V.A; Ex. 1001, ¶ 173; Ex. 1003, 5:11-43, 6:9-38; Ex. 1001, ¶¶ 69-71.

Accordingly, the systems described in Niklason, Kopans, and Hamberg were configured to perform mammography and tomosynthesis imaging during a single breast compression in two independent ways. *First*, the operator could select a clinical workflow (via the user interface shown in Kopans) that proceeded from mammography to tomosynthesis (or vice versa) without releasing compression. Ex. 1001, ¶¶ 48, 174-175.

Kopans describes how to set up such a workflow. Kopans shows a user interface button to "home" the gantry back to the mammography position. Ex. 1007 at 73, 83; Ex. 1001, ¶ 174. It also depicts the user interface widget with the ability to select between LCC and RCC views (mammography) and various tomosynthesis views. Ex. 1007 at 75; Ex. 1001, ¶ 174.



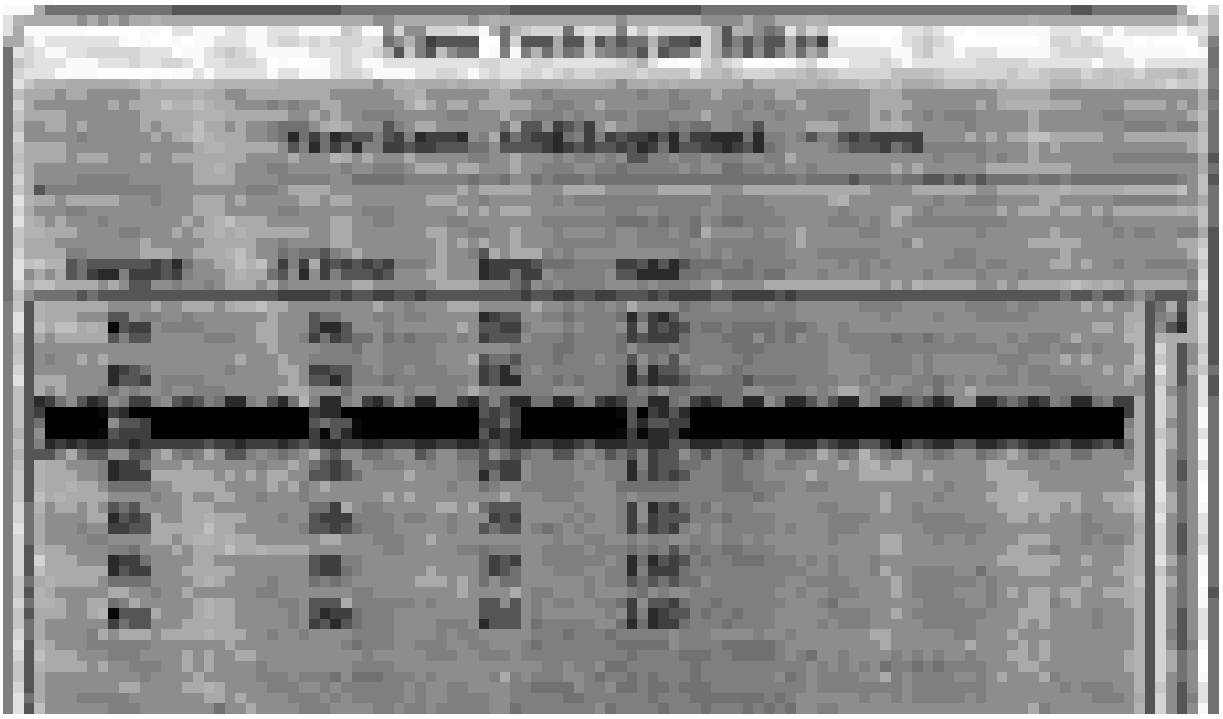


Using this interface, an operator could have selected tomosynthesis and mammography scan settings as two different views, position the patient and apply compression to the breast, perform the tomosynthesis scan, and then perform the mammography scan. Ex. 1001, ¶¶ 170, 175. This sequence required no programming besides using the standard options already included and described in Kopans. *Id.*, ¶ 175. A POSITA would have recognized that this workflow would

permit direct comparison of the mammography and tomosynthesis images, without any inconsistencies produced by repositioning the patient. *Id.*

Hamberg in particular demonstrates how the system could be used for both mammography and tomosynthesis imaging with little modification; it used the same technique settings for each acquisition and simply reduced the exposure time for each tomosynthesis angle. Ex. 1008, 14; Ex. 1001, ¶ 170.

Second, and alternatively, the operator could have used the "asynchronous" scanning mode described in Kopans. Ex. 1001, ¶ 176. For asynchronous scans, the tube moves to the next position, the operator waits for system vibrations to die down, then selects the appropriate buttons to begin the next exposure. Ex. 1007 at 76. Kopans further explains that the system allows for "custom views," in which the technical settings (including the radiation dose) can be modified. *Id.* at 76-79.



Combining these teachings, a POSITA would understand that the operator could create a scan plan in asynchronous mode that included a higher dose at the mammography position (0 degrees) and a lower dose at the tomosynthesis positions. Ex. 1001, ¶ 176. Kopans confirms that the asynchronous mode scan takes place using a single compression; it notes that this mode increases exam time and risks patient movement, which would not be notable if the compression were removed between views. *Id.*; Ex. 1007 at 76-79.

Relevant here, the ’296 patent discloses almost nothing about single compression mammography and tomosynthesis. *See supra* Section V.B. Assuming the ’296 patent itself has an adequate and enabling written description, the prior art’s far more detailed disclosure of how mammography and

tomosynthesis could be performed in a single compression must suffice to disclose or at least suggest this claim element. Ex. 1001, ¶ 177. In particular, the '296 patent says nothing about how long the patient's breast would be compressed, though its disclosure of "gradual" and start-stop x-ray source movement suggests a lengthy procedure. Ex. 1003, 4:22-60, 5:32-43, 5:65-68. In other words, a system is still configured for single compression even if the length of the procedure may cause some patient discomfort. In contrast, Niklason teaches that the tomosynthesis portion of the scan took only 3-5 seconds, with the patient's breast remaining compressed during that timeframe. Ex. 1006, 8:48-53; Ex. 1001, ¶ 172. Adding an image at the mammogram position before or after the tomosynthesis positions would be simple and would not add significant time. Ex. 1001, ¶ 175.

The Challenged Claims are system claims reciting a particular *configuration*; thus, to prove obviousness, Petitioners need not show a disclosure of the prior art systems actually operating according to the claimed configuration. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204-05 (Fed. Cir. 2010); *see also In re Screiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) ("It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.").

But even though the law does not require Petitioners to show that it would have been obvious to actually perform single compression

mammography/tomosynthesis on the Niklason/Kopans/Hamberg systems, that use would in fact have been obvious to a POSITA. Ex. 1001, ¶ 178. A POSITA would have understood the importance, in the clinical setting, of performing mammography efficiently to obtain the best possible diagnostic information in the least amount of time. Ex. 1001, ¶ 179. Obtaining mammography and tomosynthesis images from a single position, allowing for comparison of the two, without recompressing the breast, would serve these goals. *Id.* In contrast, a second, unnecessary breast compression between acquisitions would be completely inefficient and disfavored—increasing patient discomfort and hampering comparative image review due to the introduction of artifacts. *Id.*

Moreover, although the radiologist might want to obtain tomosynthesis images, federal guidelines at the time required standard (2D) mammography imaging as part of a routine screening protocol. *Id.*, ¶ 180. Again, the value of obtaining both views in a single compression would have been obvious to a POSITA. *Id.* And while combining mammography and tomosynthesis would increase the patient's overall radiation dose, a radiologist would view this as an acceptable trade-off in some circumstances, particularly to avoid even higher doses from an unnecessary follow-up or recall examination. *Id.* Kopans's description of its testing procedures also demonstrates how a combination

mammography/tomosynthesis examination could be within a safe radiation dose range. *Id.*, ¶ 181; Ex. 1007 at 59.[3]

Furthermore, keeping the patient's breast immobilized during a series of different imaging angles and modes was well-known in the art to be technically feasible. Ex. 1001, ¶ 182; Ex. 1007 at 75-76. For example, the Yamada Japanese patent publication reference discloses compressing the patient's breast, performing imaging at 0°, and then performing imaging at a range of other angles to obtain "three-dimensional information." Ex. 1024, ¶¶ 154-156; *see* Ex. 1001, ¶ 182.

In sum, the combination of Niklason, Kopans, and Hamberg discloses a control configured to selectively energize the x-ray source at different angular positions, and—even under an unduly narrow reading—discloses or at least suggests the obvious configuration of selectively energizing the x-ray source at the different positions while the breast remains under compression. Ex. 1003, ¶ 183.

[3] The particular approved protocol used in Kopans's early clinical evaluation does not indicate that the prototype could not acquire mammogram and tomosynthesis images in a single compression. Ex. 1001, ¶ 181; Ex. 1007 at 21.

e. <u>wherein at least one of said angular positions is a mammogram position that is the same or similar to a position for a conventional mammogram but others of said positions are tomosynthesis positions that are different from conventional mammogram positions</u>

The combination of Niklason, Kopans, and Hamberg discloses both a mammogram position and tomosynthesis positions. Ex. 1001, ¶¶ 184-187.

Niklason, Kopans, and Hamberg disclose a combination mammography/tomosynthesis system. *See supra* Section V.E.5.a. Niklason takes images at mammogram positions and at tomosynthesis positions. This is shown in Figures 3, 5, 6, 7, and 8, each depicting the arc of the x-ray source's rotation, for example:

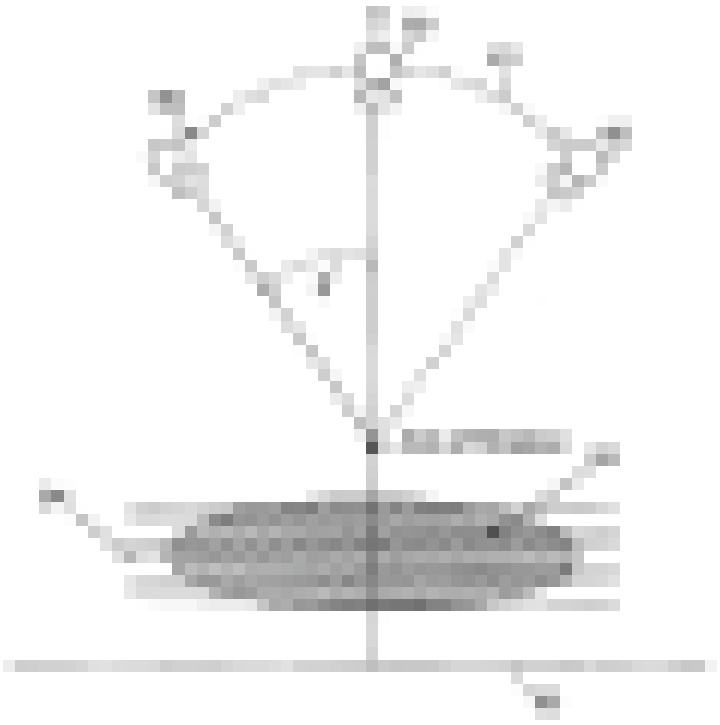


FIG. 6

The center position is a conventional mammogram position; it is the preferred position at which the standard cranio-caudal or mediolateral oblique projection image would be obtained. *See supra* Section V.A; Ex. 1001, ¶ 184. The other positions along the arc, which are different, are tomosynthesis positions. *Id.*; *Ex*. 1003, 6:28-67, 8:39-53.

Kopans likewise explains that the system is configured to take "tomo or non-tomo" examinations, and describes both mammogram and tomosynthesis images taken during evaluations. Ex. 1007 at 27-34, 49-67, 69, 75; Ex. 1001, ¶ 185.

Hamberg describes comparing the results of digital mammographic images (taken at a mammogram position) to digital tomosynthesis images (taken at tomosynthesis positions). Ex. 1008, 14. "2-dimensional images were acquired with a full, mammographic dose (30kV, 63mAs, RhRh), and tomosynthesis data was acquired by using 9 views and 1/9 of a full dose (30kV, 5.6mAs per view, 62 mAs total, RhRh)." *Id.*

As described in prior sections, Niklason, Kopans, and Hamberg each describe the system's ability to position the source at any select location along the arc path, including the 0° (mammogram) position. Ex. 1001, ¶ 185. Also as explained previously and below, the Niklason, Kopans, and Hamberg systems were configured to change technique settings (e.g., dose), permitting them to take both mammogram and tomosynthesis images. *Id.*, ¶ 186.

f. wherein said x-ray source is configured to apply an x-ray dose to the patient's breast in each of said tomosynthesis positions that is less than the x-ray dose applied to the breast in said mammogram position, and the x-ray dose for said mammogram position is similar to a dose used for a conventional mammogram

Each of the three references discloses using a lower x-ray dose for tomosynthesis images. Ex. 1001, ¶¶ 188-191. Niklason discloses that, "[i]n the tomosynthesis methods of the invention, . . . [t]he images obtained at each angle ϕ by the detector **63** are of low radiation dose, with the total radiation dose for all of

the images being equivalent to, or slightly higher than, the dose used for a standard single view mammogram." Ex. 1006, 6:28-36. Meanwhile, the system was "completely useable for routine breast imaging," which a POSITA would understand to mean that the x-ray source could be placed in a mammogram position (as discussed above) and could use a normal (higher) mammogram dose. Ex. 1006, 8:46-47; Ex. 1001, ¶ 188.

Kopans discloses that "the dose from 11 [tomosynthesis] images spread over 50 degrees with a total mAs of 100 is very close to that from a single exposure [mammogram] at 0 degrees of 100 mAs." Ex. 1007 at 60; *see also id.* at 49-50, 56-61; Ex. 1001, ¶ 189. Kopans also describes how "images were made without tomosynthesis" using a dose consistent with conventional mammography. Ex. 1007 at 57.

Hamberg describes acquire nine tomosynthesis images, each at "1/9 of the dose of one normal mammogram." Ex. 1008, 8; Ex. 1001, ¶ 190. Hamberg likewise describes how "2-dimensional images were acquired with a full, mammographic dose (30kV, 63mAs, RhRh)." Ex. 1008, 14.

Thus the x-ray source in the mammography/tomosynthesis systems disclosed in Niklason, Kopans, and Hamberg were configured to apply a conventional mammogram radiation dose in the mammography position and to apply a lower radiation dose in the tomosynthesis positions. Ex. 1001, ¶ 191.

g. an anti-scatter grid configured to be selectively movable in the path of said x-rays from the breast to the imager, said grid being in said path for the mammogram position but being out of said path for at least some of the tomosynthesis positions

Niklason discloses that its system is a modified General Electric Model DMR mammography machine that "will still be completely useable for routine breast imaging, thereby eliminating the need for a dedicated tomosynthesis system." Ex. 1006, 8:45-48. By retaining the ability to perform standard mammography exams, Niklason retained the DMR's ability to use an anti-scatter grid for mammography views. Ex. 1001, ¶ 192. For tomosynthesis images, the antiscatter grid would be removed from the x-ray beam path. *Id.*

Kopans confirms that "for Tomo examinations the Bucky grid, used for scatter reduction, must NOT be used." Ex. 1007 at 69. Kopans describes tests on a breast phantom in which the tomosynthesis images were obtained without a grid in the x-ray path, while the mammogram images were obtained with a grid. *Id.* at 56-57. Kopans also demonstrates how "Grid Status" (either "Grid" or "No Grid") was shown in the user interface. Ex. 1007 at 77; Ex. 1001, ¶¶ 193-194.

Niklason, Kopans, and Hamberg thus disclose this claim element because their described systems were configured such that the grid could be left in the x-ray

path for the mammogram position and withdrawn for the tomosynthesis positions. The Challenged Claims do not require that the system be configured to capture both a mammogram image and tomosynthesis images during a single breast compression. *See supra* Section IV.D. Accordingly, the grid need not be removable while the breast is under compression either. Ex. 1001, ¶¶ 195-196 (describing possible sequences that an operator might employ to use the system in this way).

Even if claim 23 is read to require movement of the grid into/out of the x-ray beam path while the patient's breast remains compressed, the prior art discloses or at least suggests and would have rendered obvious this element. Ex. 1001, ¶ 197. It was common for prior art mammography systems to permit side access to the anti-scatter grid. *Id.* (citing Ex. 1020 at 6-7, describing the Instrumentarium DIAMOND mammography system). This configuration allowed the operator to remove and/or insert the grid during an exam, while the patient's breast was compressed. Ex. 1001, ¶ 197. Furthermore, Niklason disclosed that its invention could be adapted onto any full-field digital mammography system with the appropriate imaging geometry. Ex. 1006, 6:54-59. With a side-access grid, the operator using Niklason's system could manually position the anti-scatter grid in or out of the imaging path for mammography or tomosynthesis (respectively), all during a single breast compression. Ex. 1001, ¶ 198. A POSITA would have been

motivated to modify such existing mammography machines to add the Niklason, Kopans, and Hamberg tomosynthesis functionality for all the reasons described previous in Section V.E.4. *Id.*

Finally, the '296 Patent itself discloses almost nothing about how the anti-scatter grid is moved into and out of position, stating only that it is "may be selectively retractable," "[a]s is known in the art." Ex. 1003, 9:33-38; *see supra* Section IV.B. Assuming that the '296 Patent itself has an adequate and enabling disclosure, then moving the grid into and out of the x-ray beam path during a single compression, if necessary for claim 23, would have been both an obvious modification and within the ability of a POSITA in view of the prior art. Ex. 1001, ¶ 199.

h. <u>a processor configured to use an output of said imager for said mammogram and tomosynthesis positions of the source relative to the immobilized breast to form at least one mammogram image for display and tomosynthesis images of the breast for display</u>

Niklason, Kopans, and Hamberg disclose this element. Ex. 1001, ¶¶ 200-203.

Niklason discloses a processor "programmed to the [sic] process data produced by the detector **14** in response to incident x-rays." Ex. 1003, 4:6-9. The processor "generate[s] an output image signal representative of the x-ray absorption within the object region" by "transform[ing] the image data," including

through the "reconstruction of any tomographic plane of an object region." *Id.* 2:38-58. Niklason's image data processor may be part of digital computer 10' (shown in Figure 4) that "can further include a display section **10***a*; or it can command video on a separate monitor **10***b*." *Id.* 4:34-45. Niklason thus provides multiple options for displaying the mammogram and tomosynthesis images. Ex. 1001, ¶ 200.

Kopans demonstrates how the processor was used to form mammogram and tomosynthesis images for display. Ex. 1007 at 27 (Figures 3.1a ("Digital Mammogram") and 3.1b (Tomosynthesis Slice")). Kopans details how the user interface allows the operator to select the image processing and reconstruction methods and the methods for image conversion and transfer to a workstation for review. *Id.* at 73-83; Ex. 1001, ¶ 201.

Hamberg provides additional detail on the reconstruction algorithms employed by the mammography/tomosynthesis system. Ex. 1008 at 7-8. Hamberg describes how the system was tested in order to "optimize tomosynthesis data acquisition and image reconstruction." *Id.* at 4. To achieve this optimization, both mammogram and tomosynthesis images were obtained on the mammography/tomosynthesis system and processed by a processor on a workstation. *Id.* at 13-14; Ex. 1001, ¶ 202.

6. Claim 24 - The system of claim 23, wherein the control is configured to energize the source to emit a patient x-ray dose for each of the tomosynthesis positions that is much less than the patient x-ray dose for the mammogram position

Niklason, Kopans, and Hamberg disclose this limitation. Niklason, Kopans and Hamberg disclose the total tomosynthesis dose to be equivalent to the dose required for a conventional mammogram, and there are at least 8 tomosynthesis exposures. *See supra* Section V.E.5.f; Ex. 1006, Abstract, 6:13-15, 6:28-36; Ex. 1007 at 49-50, 56-61; Ex. 1008 at Abstract, 2, 4, 8, 11, 14. Under the broadest reasonable interpretation, each of these tomosynthesis position doses would be "much less" than the mammogram position dose, especially considering that the '296 patent itself provides no specific guidance as to what "much less" means. Ex. 1001, ¶¶ 205-206.

7. Claim 25 - The system of claim 23, wherein the control is configured to energize the x-ray source at different angular positions intermittently during a continuous movement of the source relative to the breast covering at least some said positions.

Niklason, Kopans, and Hamberg disclose a control configured to energize the x-ray source as it moves through different angular positions. *See supra* Section V.E.5.d. Niklason teaches that the source movement could be continuous as one possible design choice. Ex. 1006, 4:3-14, 7:47-49; Ex. 1001, ¶ 207. A POSITA

would have been motivated to move the source continuously to solve a known problem (system vibration) with this known solution in prior art to provide the predictable benefit of reduced vibration. *See* Ex. 1001, ¶¶ 208-209.

8. Claim 33 - The system of claim 23, wherein the control is configured to place the source for taking image data for the mammogram position after taking image data for the tomo-synthesis positions.

Niklason, Kopans, and Hamberg disclose a control configured to place the source in the proper imaging position (mammogram or tomosynthesis). *See supra* Sections V.E.5.c-e. The control described by Kopans was a programmable "timing model," configured to allow the operator to choose to acquire a mammogram image with the source positioned in the center position after acquiring a series of tomosynthesis images from different views. Ex. 1007 at 12-13, 71-82. Kopans further describes how the x-ray source was "homed" back to the zero degree position after each exam, thus being placed in the mammogram position. *Id.* at 73; *see also id.* at 73, 79-80, 83 (describing the "Move to Zero Position" button) on the user interface. Thus, Niklason, Kopans, and Hamberg disclose that the x-ray source may be placed in the mammogram position after it has taken image data at the tomosynthesis positions. Ex. 1001, ¶¶ 210-211.

9. Claim 35 - The system of claim 23, wherein the control is configured to energize the source for taking image data for each of the tomosynthesis positions at substantially higher x-ray source kV compared with the kV used for acquiring the image date [sic] at the mammogram position.

The '296 patent describes "higher kVp imaging of the breast…. as between 25 and 50 kVp." Ex. 1003, 8:34-44. Niklason discloses that its tomosynthesis images may be taken at a kVp range of "26-30 kVp." Ex. 1006, 7:36-41. Kopans also discloses taking tomosynthesis images at up to 35 kVp. Ex. 1007 at 64. Kopans and Hamberg purposefully chose higher kVp settings to have more penetrating x-rays for low dose tomosynthesis imaging. *Id*. at 13, 51-53, 57, 59-61; Ex. 1008 at 8.

Niklason, Kopans, and Hamberg thus disclose this claim element. Ex. 1001, ¶¶ 212-213.

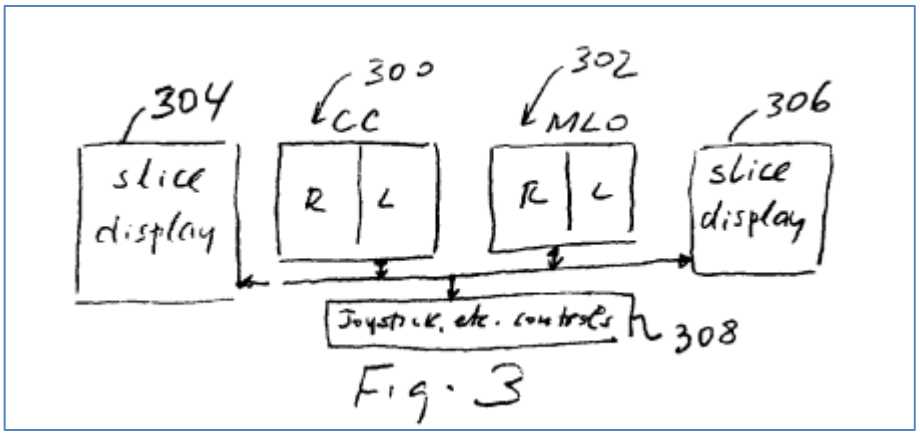
10. Claim 39 - The system of claim 23, wherein the control is configured to move the source through angular positions that extend over a range of no more than 60°.

Niklason, Kopans, and Hamberg each disclose this element. Ex. 1001, ¶¶ 214-215. Niklason describes "allow[ing] imaging at any angle ϕ up to ±27 degrees from the [sic] perpendicular to the detector." Ex. 1006, 7:57-61. Thus the total angular range is 54°, within Claim 39's range. Ex. 1001, ¶ 214. Kopans and Hamberg similarly disclose a range of less than 60 degrees. Ex. 1007 at 75-76

(disclosing range of motion up to 40 or 50°); Ex. 1008, 5 & Fig. 1 (disclosing range of motion of 40°); Ex. 1001, ¶ 214.

11. Claim 40 - The system of claim 23, comprising at least one display configured for displaying the mammogram and tomosynthesis images for concurrent viewing.

As described above in Section V.E.5.h, both Niklason and Kopans discuss processing mammogram and tomosynthesis images for display. The '296 patent describes the "display" as one or more monitors in which images may be viewed. Ex. 1003 at 6:38-7:35; Fig. 3.



Considering that description, and the "at least one" claim language, claim 40 does not require both types of images to be displayed concurrently on the same monitor.

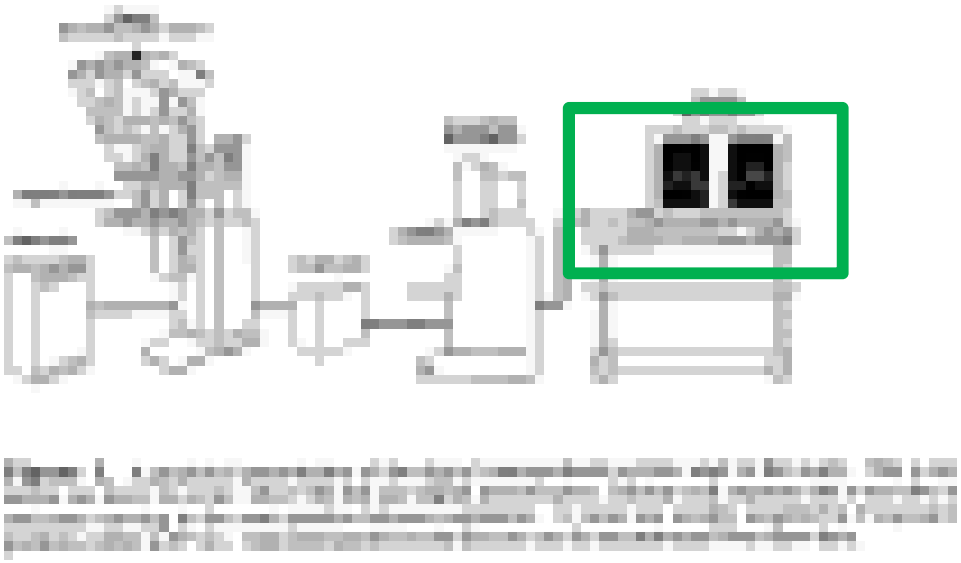
Hamberg discloses a dual-monitor display system configured to display at least two images—such as one mammogram and one tomosynthesis—side-by-side. Ex. 1008 at 5, Fig. 1 ("Review Workstation"). Indeed, comparing mammogram images with tomosynthesis images was a main purpose of Hamberg's research to evaluate whether tomosynthesis was superior to mammograms. *Id.* at 3-5.

Kopans, meanwhile, also discloses a dual monitor display, and provides examples of mammogram and tomosynthesis images that were processed and displayed on the workstation. *See, e.g.,* Ex. 1007 at 30 (showing a tomosynthesis image and a mammogram image); 27-49. Kopans also discloses that the software allows users to select mammogram and tomosynthesis images for display and is capable of storing and retrieving multiple image sets and accessing a multiple frame dataset. *Id.* at 80-83. Side-by-side display of medical images conveying different diagnostic information was a standard practice in diagnostic imaging. Ex. 1001, ¶¶ 39, 216.

Accordingly, Niklason, Kopans, and Hamberg discloses or at least suggests and would have rendered obvious this claim to a POSITA. Ex. 1001, ¶¶ 216-217.

12. Claim 42 - The system of claim 23, comprising at least one display configured for displaying the mammogram and tomosynthesis images on adjacent screens.

As the preceding section describes, the combination of Niklason, Kopans, and Hamberg includes a display configured to display mammogram and tomosynthesis images on adjacent screens, as depicted in Figure 1 of Hamberg:



Ex. 1008 at 5.

For the same reasons described in Section V.E.11, Niklason, Kopans, and Hamberg discloses or at least suggests and would have rendered obvious this claim to a POSITA. Ex. 1001, ¶¶ 216-219.

13. Claim 44 - The system of claim 23, wherein the processor is configured to form tomosynthesis images that represent thick slices of the breast, about 5 to about 10 mm thick.

Niklason, Kopans, and Hamberg disclose this claim element. Ex. 1001, ¶¶ 220-222. Niklason, Kopans, and Hamberg includes a processor configured to form tomosynthesis images. *See supra* Section V.E.5.h. Kopans discloses how the prototype's user interface allowed a user to select a "slice separation." Ex. 1007 at 80-81. This allowed a user to select a slice thickness between 5 and 10 mm in thickness. Ex. 1001, ¶ 221.

F. Ground #2: Claims 23-25, 33, 35, 39, 40, 42, and 44 are Obvious Over the Combination of Niklason, Kopans, Hamberg, and Zur

1. Zur

Zur is published patent application describing an improved anti-scatter grid for x-ray imaging, which would include mammography, and in particular for digital imaging. Ex. 1009, ¶¶ 12-15; Ex. 1001, ¶ 125. In Zur, the Bucky device consists of two chambers: (1) an "active chamber" in which the grid is "positioned upstream of the image detection module **30** in terms of X-ray impingement"—that is, in the x-ray beam path; and (2) a "storage chamber," in which the grid is out of the x-ray path. Ex. 1009, ¶¶ 43-46; Ex. 1001, ¶ 146. Zur explains that the anti-scatter grid's movement through these positions may be "fully or partially motorized using suitable electrically motorized means." Ex. 1009, ¶ 48. Motorizing the process "provide[s] additional ease-of-use." *Id.*; Ex. 1001, ¶ 228. Zur discloses internal sensors connected to external indicator lights that indicate the anti-scatter grid's position, and software implemented in ROM to control the motorized driving means. Ex. 1009, ¶¶ 35, 52; Ex. 1001, ¶ 125.

2. Claim 23

Limitations [a] through [f] and [h] of Claim 23 are obvious in view of Niklason, Kopans, and Hamberg for the reasons explained above. *See supra* Sections V.E.5.a-f and h. Even if the selectively movable anti-scatter grid of element [g] is viewed as not being disclosed or suggested by the combination of

Niklason, Kopans, and Hamberg, it would have been obvious in view of the teachings of Zur combined with the teachings of those three references. In particular, if the Challenged Claims are viewed as requiring automated/motorized movement of the anti-scatter grid, Zur discloses one example of this well-known practice that could easily be adapted into the combination mammography/tomosynthesis system disclosed in Niklason, Kopans, and Hamberg. Ex. 1001, ¶¶ 223-227.

a. <u>an anti-scatter grid configured to be selectively movable in the path of said x-rays from the breast to the imager, said grid being in said path for the mammogram position but being out of said path for at least some of the tomosynthesis positions</u>

As discussed in Section V.E.5.g, Niklason, Kopans, and Hamberg disclose using an anti-scatter grid for mammography imaging positions and removing the anti-scatter grid for tomosynthesis imaging positions. Zur, as explained in Section V.F.1, discloses an anti-scatter grid that can be moved into and out of the imaging path by placing it in an active chamber and a storage chamber (respectively), and further discloses that this process can be automated. *See also* Ex. 1001, ¶¶ 220, 228. Zur specifically discloses selectively movement of the grid between these chambers based on whether one is performing an "X-ray imaging procedure which employs the anti-scatter grid"—such as standard mammography—or an "X-ray imaging procedure which does not employ the anti-scatter grid"—such as

tomosynthesis. Ex. 1009, ¶ 22; Ex. 1001, ¶ 229. Zur also discloses sensors that indicate the position of the anti-scatter grid and software for controlling the grid position. Ex. 1009, ¶¶ 35, 52; Ex. 1001, ¶¶ 230-232.

A POSITA would understand from Zur's teachings that the sensors and software could be used to automatically drive the grid position based on the type of imaging to be performed, and that a specific sequence of grid movements between positions would be predetermined and stored as an executable sequence of instructions stored in ROM. Ex. 1001, ¶ 232. Thus in the combination of Zur with the mammography/tomosynthesis systems disclosed in Niklason, Kopans, and Hamberg, the operator would be able to create a scan that would perform imaging at tomosynthesis positions and doses, automatically move the grid into the x-ray path, then perform imaging at a mammography position and dose—or vice-versa. *Id.* ¶ 233. These sequences could have happened during single breast compression. *Id.*

A POSITA would have been motivated to combine Niklason, Kopans, Hamberg, and Zur to achieve this result. Ex. 1001, ¶¶ 235-247. Motorized and/or automated control of anti-scatter grids was well-known in the art—this concept is disclosed not only in Zur and Dornheim (discussed below), but in numerous other references dating back to the early 1980s. Ex. 1001, ¶¶ 123-136, 236 (citing Exs. 1029-1032). These references span the field of x-ray imaging, including the sub-

field of mammography. *Id.* A POSITA considering a mammography/tomosynthesis system like the ones disclosed in Niklason, Kopans, and Hamberg would have viewed automated grid control as a routine design choice. *Id.*, ¶ 237. They would have looked to Zur in particular given its use of a digital imaging detector. *Id.*, ¶ 238.

Automating the grid movement would have provided benefits in clinical workflow, which is critical to the economics of a medical facility that performs x-ray imaging. *Id.*, ¶¶ 239-241. In mammography specifically, it also would have increased patient comfort by shortening breast compression times. *Id.* This would be particularly important in a combination mammography/tomosynthesis system, in which many images are acquired and the desire to shorten imaging time is more acute. *Id.*

The fact that Niklason, Kopans, and Hamberg do not expressly disclose grid automation does not undermine the obviousness of combining those references with Zur. The MGH research team was focused on building and testing a proto-type system to prove the viability of DBT, and not on producing a polished com-mercial system. *Id.*, ¶ 242; Ex. 1007 at 4. But a POSITA would understand that other common features—not necessary for the evaluation of the new imaging mode—could be implemented later without affecting system performance. Ex. 1001, ¶ 242.

Furthermore, a POSITA seeking to add Zur to the prototype mammography/tomosynthesis system would have reasonably expected success in doing so. No technical or other reason would have discouraged the combination. *Id.*, ¶ 243. Moreover, although physical compatibility is not required for obviousness, *see In re Keller*, 642 F.2d 413, 425 (CCPA 1981), the improved anti-scatter grid disclosed in Zur would have been physically compatible with the Niklason/Kopans/Hamberg systems. The digital Bucky disclosed in Zur could have been placed in the same position as the grid in the prototype system, and the automated extraction and insertion process could take place either in the space between the imaging receptor and the gantry or by taking advantage of the space available in the system upon which the prototype was based. *See* Ex. 1001, ¶¶ 244-246.

Finally, the '296 Patent itself discloses almost nothing about how the selective grid movement is accomplished. *See supra* Section V.E.5.g. Zur discloses far more detail about this process. Assuming that the '296 Patent has an adequate and enabling disclosure, then it cannot be said that a POSITA would have faced undue difficulty in implementing a system configured with a selectively movable grid. Ex. 1001, ¶ 247.

3. Claims 24, 25, 33, 35, 36, 39, 40, 42, and 44

The additional limitations of these dependent claims each are disclosed or at least suggested by and would have been obvious in view of Niklason, Kopans, and

Hamberg. *See supra* Sections V.E.6-13. Accordingly, these claims likewise would have been obvious in view of Niklason, Kopans, Hamberg, and Zur.

G. Ground #3: Claims 23-25, 33, 35, 39, 40, 42, and 44 are Obvious Over the Combination of Niklason, Kopans, Hamberg, and Dornheim

1. Dornheim

Dornheim describes a mammography system able to select between two different recording "stages." Ex. 1010, Abstract. The two stages (8 and 9) are attached to the system in a way that allows them either to swivel about a vertical axis (Figure 1, below) or to rotate around the other components of the system by means of a horizontal axis (Figure 2, below). This system achieves clinical workflow efficiency because the different stages do not have to be detached and reattached. *See* Ex. 1010, 1:17-35.

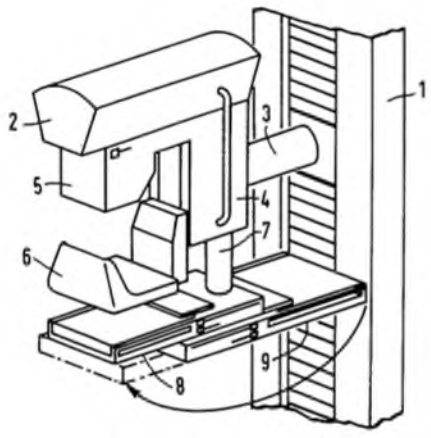


FIG 1

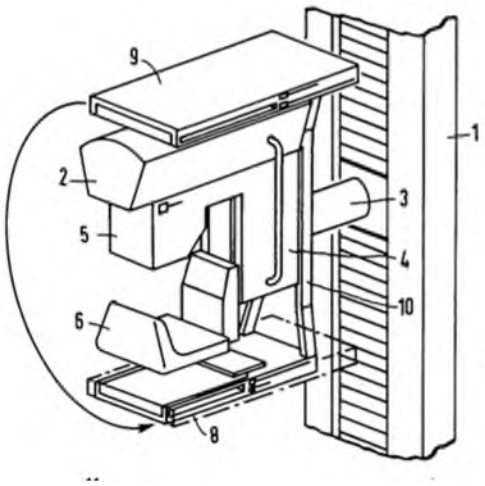


FIG 2

Dornheim "take[s] into account the desire of physicians to make x-ray pictures selectively with or without a scattered-ray grid." Ex. 1010, 1:53-56. Both stages "may be designed so that the scattered-ray grid provided there can be brought into a position in which it is outside the roentgen radiation." *Id.*, 1:56-58. "[S]tages **8** and **9** are designed so that scattered-ray grid **11** can be brought into a position shown in broken lines in which it lies outside the roentgen radiation, so that x-ray pictures without the scattered-ray grid can be produced." *Id.*, 2:43-47, Fig 3:

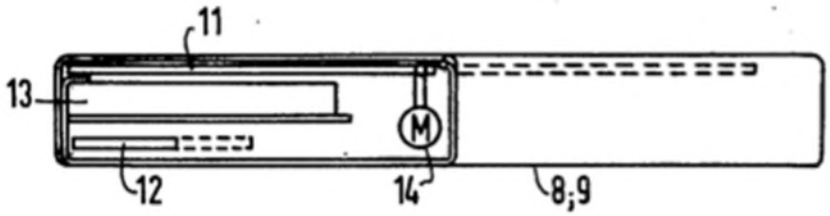


FIG 3

Whatever recording stage is presently in the "recording position" (8) can contain an anti-scatter grid that is selectively withdrawable from the x-ray beam's path. Ex. 1001, ¶¶ 128-130. Dornheim discloses that this selective withdrawal is accomplished automatically; the anti-scatter grid is moved into and out of the recording position "by motor **14**." Ex. 1010, 2:47-50; Ex. 1001, ¶¶ 128-130.

2. Claim 23

Limitations [a] through [f] and [h] of Claim 23 are obvious in view of Niklason, Kopans, and Hamberg for the reasons explained above. *See* Sections V.E.5.a-f and h and the evidence cited therein. Even if the selectively movable anti-scatter

grid of element [g] is viewed as not being disclosed or suggested by the combination of Niklason, Kopans, and Hamberg, it would have been obvious in view of the teachings of Dornheim combined with the teachings of those three references, as discussed below. In particular, if the Challenged Claims are viewed as requiring automated/motorized movement of the anti-scatter grid, Dornheim discloses one example of this well-known practice that could easily be adapted into the combination mammography/tomosynthesis systems disclosed in Niklason, Kopans, and Hamberg. Ex. 1001, ¶¶ 248-252.

a. <u>an anti-scatter grid configured to be selectively movable in the path of said x-rays from the breast to the imager, said grid being in said path for the mammogram position but being out of said path for at least some of the tomosynthesis positions</u>

As discussed in Section V.E.5.g, Niklason, Kopans, and Hamberg disclose using an anti-scatter grid for mammography imaging positions and removing the anti-scatter grid for tomosynthesis imaging positions. Dornheim, as explained in Section V.G.1, discloses an anti-scatter grid that can be moved into and out of the imaging path, and further discloses that this process can be automated through use of a motor. Thus in the combination of Dornheim with the mammography/tomosynthesis system disclosed in Niklason, Kopans, and Hamberg, the operator would be able to create a scan that would perform imaging at tomosynthesis positions and doses, automatically move the grid into the x-ray path, then perform imaging at a

mammography position and dose—or vice-versa. Ex. 1001, ¶¶ 253-257. These sequences could have occurred during a single breast compression.

A POSITA would have been motivated to combine Niklason, Kopans, Hamberg, and Dornheim to achieve this result. Ex. 1001, ¶¶ 258-271. This is true for all the reasons discussed above with respect to Zur. *Id., see supra* Section V.F.2. And a POSITA would have looked to Dornheim in particular because, like the Niklason/Kopans/Hamberg system, it is designed for mammography specifically. Ex. 1001, ¶ 261. A POSITA adding Dornheim to the mammography/tomosynthesis system would have reasonably expected success. Indeed, Dornheim provides a practical solution for the type of permanent imaging detector disclosed in Niklason, Kopans, and Hamberg, because the grid simply moves out of the way and stops, meaning there is no wasted movement, time, or bulk. Ex. 1001, ¶¶ 262, 269. The POSITA would understand that control of the grid could be provided through the software controls discussed in detail in Kopans. Ex. 1001, ¶ 262.

3. Claims 24, 25, 33, 35, 36, 39, 40, 42, and 44

The additional limitations of these dependent claims each are disclosed or suggested by the combination of Niklason, Kopans, and Hamberg. Accordingly, these claims would have been obvious in view of Niklason, Kopans, Hamberg, and Dornheim, for the same reasons already discussed. *See supra* Sections V.E.6-13 and evidence cited therein. Ex. 1001, ¶¶ 272-273.

H. Ground #4: Claim 36 is Obvious over the Combination of Niklason, Kopans, Hamberg, and Kaufhold

1. Kaufhold

Kaufhold describes a method for calibration of a digital imaging system, in particular a "mammographic tomosynthesis" system. Ex. 1011, Abstract, 3:6-15; Ex. 1001, ¶ 138. Kaufhold describes setting image acquisition parameters of this system, including the x-ray anode material; and that "[t]ypical choices for anode materials are a) Molybdenum, b) Rhodium or c) Tungsten." Ex. 1011, 7:4-19; Ex. 1001, ¶ 39.

2. Claim 36: The system of claim 23, wherein the source comprises a Tungsten X-ray target emitting X-rays toward said imager.

This claim is obvious over the combination of Niklason, Kopans, Hamberg, and Kaufhold. Ex. 1001, ¶¶ 274-277; *see supra* Section V.E.4-5 (obviousness of independent claim 23). While Niklason, Kopans, and Hamberg disclose using a Molybdenum or Rhodium x-ray target (i.e., anode), Kaufhold discloses a third "typical" x-ray target choice material: Tungsten. Ex. 1011, 7:4-19; Ex. 1001, ¶ 276. Thus, adding Kaufhold's teaching of a Tungsten x-ray target to the combined disclosures of Niklason, Kopans, and Hamberg yields the subject matter claimed in claim 36. Ex. 1001, ¶ 275.

A POSITA would have view this combination as obvious for several reasons. Given Kaufhold's teaching of Molybdenum, Rhodium, and Tungsten as the

three "typical" x-ray target materials, a POSITA would have viewed substituting Tungsten for the other two materials as a simple substitution of known elements to serve their known purposes with predictable benefits. Ex. 1001, ¶ 277. This is especially true considering that Kaufhold explicitly describes its system as a "mammographic tomosynthesis" device, just like the other three references. *Id.* at 276; Ex. 1011, 3:6-15; *see also* Feig and Yaffe, "Digital Mammography," 18:4 *Radiographics* 893, 897-898 (July-August 1998), *available at* http://pubs.rsna.org/doi/pdf/10.1148/radiographics.18.4.9672974 (describing the use of a Tungsten x-ray tube with digital mammography systems). Furthermore, a POSITA would have understood that Tungsten's properties would make it particularly beneficial in a combination mammography/tomosynthesis system. Ex. 1001, ¶ 277 (citing Ex. 1018).

I. Ground #5: Claim 36 is Obvious over the Combination of Niklason, Kopans, Hamberg, Zur, and Kaufhold

As discussed in Section V.F, an alternative obviousness argument for claim 23 is to combine Niklason, Kopans, and Hamberg with Zur's teachings of anti-scatter grid. Thus, adding Kaufhold's teachings of a Tungsten x-ray target to this combination yields the subject matter of claim 36. This combination would have been obvious for the same reasons as the Niklason, Kopans, Hamberg, and Kaufhold combination discussed in detail in Section V.H. Ex. 1001, ¶¶ 278-281.

J. Ground #6: Claim 36 is Obvious over the Combination of Niklason, Kopans, Hamberg, Dornheim and Kaufhold

As discussed in Section V.G, an alternative obviousness argument for claim 23 is to combine Niklason, Kopans, and Hamberg with Dornheim's teachings of anti-scatter grid. Thus, adding Kaufhold's teachings of a Tungsten x-ray target to this combination yields the subject matter of claim 36. This combination would have been obvious for the same reasons as the Niklason, Kopans, Hamberg, and Kaufhold combination discussed in detail in Section V.H. Ex. 1001, ¶¶ 282-285.

VI. CONCLUSION

Petitioners have demonstrated a reasonable likelihood that the Challenged Claims are unpatentable and respectfully request *inter partes* review of the Challenged Claims.

Dated: February 14, 2018

Respectfully submitted,

By: /T. Vann Pearce, Jr. /

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Petitioners

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,831,296, including all Exhibits and the Powers of Attorney, was served on February 14, 2018, via Federal Express directed to the attorney of record for the patent at the following address:

Merchant & Gould – Hologic
80 South 8th Street, Suite 3200
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 Medical Systems USA, Inc., and FUJIFILM Techno Products Co., Ltd., and lead counsel for Petitioners, declares that the argument section of this Petition (Sections I and III-VI) has a total of 13,978 words, according to the word count tool in Microsoft Word™.

/ T. Vann Pearce, Jr. /