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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUJIFILM CORPORATION,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

Case IPR2018-00538
Patent 7,123,684 B2

Before MEREDITH C. PETRAVICK, BRIAN J. McNAMARA, and MATTHEW S. MEYERS, *Administrative Patent Judges*.

MEYERS, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review

35 U.S.C. § 314(a)

I. INTRODUCTION

A. OVERVIEW

FUJIFILM Medical Systems USA, Inc., FUJIFILM Corporation, and FUJIFILM Techno Products Co., Ltd. (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 11, 29, 33, and 41 of U.S. Patent No. 7,123,684 B2 (Ex. 1003, "the '684 patent"). Pet. 1. Hologic, Inc. ("Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp."), to which we authorized Petitioner to file a Reply (Paper 10, "Pet. Reply").

Section 314(a) of Title 35 of the United States Code provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the Petition, the Preliminary Response, and Petitioner's Reply, for the reasons explained below, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail with respect to any of the challenged claims.

Accordingly, we decline to institute an *inter partes* review.

B. RELATED PROCEEDINGS

Petitioner indicates that the '684 patent is involved in: *In the Matter of Certain X-Ray Breast Imaging Devices and Components Thereof*, Investigation No. 337-TA-1063 in the U.S. International Trade Commission and *Hologic, Inc., v. FUJIFILM Medical Systems USA, Inc., Ltd.*, No. 3:17-

cv-1056 in the United States District Court for the District of Connecticut. Paper 1, 3.

C. THE '684 PATENT

The '684 patent relates to X-ray mammography using digital image receptors. Ex. 1003, 1:14–44. The '684 patent acknowledges that conventional mammography systems "have provisions for partly or fully automating the selection of appropriate technic factors for an x-ray exposure, such as one or more of kVp (the x-ray tube accelerating potential), mA (x-ray tube current), and exposure time." *Id.* at 1:45–49. The '684 patent describes that

> one known approach for use with digital flat panel image receptors is to take a short, low x-ray dosage pre-exposure after the breast has been compressed, and then take an imaging exposure while the breast remains immobilized, using technic factors based on measurements taken with the same receptor in the pre-exposure.

Id. at 1:56–61. The '684 patent further describes that it is known to transmit and store mammography images. *Id.* at 2:16–20. However, the '684 patent identifies that known processes are inefficient because "in many if not most cases, the breast takes up only a part of the image taken with flat panel digital receptors such that an imaginary rectangle that envelops the image of the breast is smaller than the field of view of the receptor." *Id.* at 2:21–24.

To address this drawback, the '684 patent discloses "transmit[ting] and stor[ing] only a portion of the field of view" of the digital receptor by defining a "reduced field of view area **48**" using various methods. *Id.* at 5:58–6:10; *see id.* at Fig. 6, elements 52, 54, 56. In effect, the '684 patent

discloses "crop[ping] the resulting breast image before transmitting and/or storing and/ or formatting it for transmission or storage." *Id.* at 5:65–6:2. Reproduced below is Figure 5 of the '684 patent.

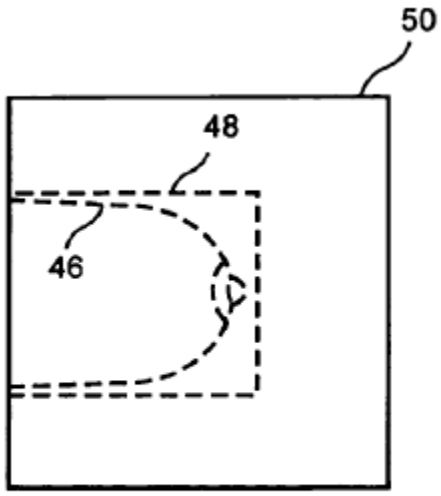

FIG. 5

FIG. 5 illustrates selection of a decreased size mammography image for storage and transmission.

Figure 5 depicts field of view 50 of flat panel x-ray image receptor 12*c* along with breast image 46, which is within reduced field of view 48. *Id.* at 5:41–48.

D. ILLUSTRATIVE CLAIMS

Petitioner challenges claims 11, 29, 33, and 41 of the '684 patent. Each of claims 11, 29, 33, and 41 are independent. Independent claim 11 is illustrative of the challenged claims, and is reproduced below:

11. A mammography method comprising:

providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor;

automatically selecting an outline that encompasses the breast image to thereby define a reduced field of view image, wherein said outline is selected based on automatically derived information about a compression paddle selected to compress the breast for x-ray imaging, said outline encompasses an entirety of the patient's breast in the breast image, and the reduced field of view is defined based on said outline; and

using said reduced field or view image for further processing, transmission, and/or archiving.

E. EVIDENCE AND ASSERTED GROUNDS OF UNPATENTABILITY

Petitioner challenges the claims on the following grounds:

Claims	Basis	Reference(s)
11 and 41	§ 102(b)	Defreitas[1]
29 and 33	§ 103(a)	Defreitas and Niklason[2]
11 and 41	§ 103(a)	Muller[3] and Admitted Prior Art[4]
29 and 33	§ 103(a)	Muller, Admitted Prior Art, and Niklason
11 and 41	§ 103(a)	Kawamata[5] and Yamada[6]

[1] U.S. Patent No. 7,443,949 B2, issued Oct. 28, 2008 (Ex. 1005; "Defreitas").

[2] U.S. Patent No. 5,872,828, issued Feb. 16, 1999 (Ex, 1006; "Niklason").

[3] U.S. Patent Application Publication No. US 2001/0038679 A1, published Nov. 8, 2001 (Ex. 1007; "Muller").

[4] "'Background' of the '684 patent describing characteristics of 'typical[]' X-ray mammography systems, and known proposals for improving upon such systems" (Ex. 1003; "Admitted Prior Art").

[5] Japanese Patent Application Publication No. S64-46436, published February 20, 1989 (Ex. 1009; "Kawamata").

[6] Japanese Patent Application Publication No. H08-186762, published July 16, 1996 (Ex. 1011; "the '762 publication").

Claims	Basis	Reference(s)
29 and 33	§ 103(a)	Kawamata, Yamada, and Niklason

Pet. 5–11. Petitioner relies upon a Declaration of Dr. Christopher Daft. Ex. 1001.

II. ANALYSIS

A. CLAIM INTERPRETATION

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach). For the purposes of this decision, and on this record, we determine that only the following claim element needs explicit interpretation. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

Petitioner proposes clarifying the scope of two claim terms: "processing, transmission, and/or archiving," as recited by claims 11 and 41, and "the reduced field of view is defined based on said [outline/rectangular region]." Pet. 14–15. Under the broadest reasonable interpretation standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as they would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). In interpreting claims, care must be exercised, as there is a fine line between interpreting claims in light of the specification, and reading limitations into the claims from the specification.

Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1186–87 (Fed. Cir. 1998). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

For the purposes of this Decision, we discern that only the following terms require construction.

1. "reduced field of view"

Petitioner asserts that the term "'reduced field of view'" should be construed as 'field of view smaller than the entire field of view of an imaging receptor.'" Pet. 13. Patent Owner does not oppose Petitioner's proposed construction. We find Petitioner's construction to be consistent with the use of the term in the'684 patent. The '684 patent discloses that "the image of the breast lies within a rectangle that is smaller than the field of view, as illustrated in FIG. 5, where the image of a breast is within a notional rectangular outline **48** (reduced field of view) that is much smaller than the field of view **50** of receptor **12***c*." Ex. 1003 5:44–49. Thus, we construe "reduced field of view" as a "field of view smaller than the entire field of view of an imaging receptor."

2. "reduced field of view image"

Petitioner asserts that the "reduced field of view image" should be construed as "[e]ncompass[ing] either pre- or post-acquisition reduction of the field of view." Pet. 14. Petitioner asserts this construction is proper because "[t]he Challenged Claims' language is agnostic on whether the 'reduced field of view image' is defined before or after the image is acquired, and is broad enough to encompass either scenario." *Id.* Petitioner

acknowledges the claims include some temporal order, i.e., "'said reduced field of view image' must exist before the processing/transmission/archiving," is required by the claims, but Petitioner argues that the claims "do not delineate whether the field of view is reduced before acquiring the image or afterwards." *Id.* at15.

Patent Owner disagrees, asserting that "all Challenged Claims clearly require the 'reduced field of view' to be defined ***after*** a first image is 'provided' (and therefore in existence)" (Prelim. Resp. 18), and thus, that the claims require an implicit order based on both logic and antecedent basis. *Id.* at 16–17 (citing *Mformation Technologies, Inc. v. Research-in-Motion Ltd.*, 764 F.3d 1392 (Fed. Cir. 2014); *Wi- Lan, Inc. v. Apple, Inc.*, 811 F.3d 455 (Fed. Cir. 2016)). More particularly, Patent Owner asserts that "[a]ll Challenged Claims require 'providing ***an image of a patient's breast*** that occupies less than the entire field of view of an imaging receptor' and "automatically selecting a[n outline/rectangular region] that encompasses ***the breast image*** to thereby define a reduced field of view image[.]" *Id.* at 17.

As a general rule, "[u]nless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed.Cir.2001). However, "a claim requires an ordering of steps when the claim language, as matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires an order of steps." *Mformation Techs.*, 764 F.3d at 1398–99 (internal citation and quotation marks omitted); *see also Function Media, LLC v. Google, Inc.*, 708 F.3d 1310, 1320 (Fed. Cir. 2013) (concluding that a claim that recites

"processing" an "electronic advertisement" necessarily indicates that "the creation of the ad must happen before the processing begins"). A method claim can also require a specific order implicitly, for example, if the language of a claimed step refers to the completed results of the prior step. *E–Pass Techs., Inc. v. 3Com Corp.*, 473 F.3d 1213, 1222 (Fed. Cir. 2007).

Independent claim 11[7] is directed to a mammography method, comprising the following steps in the order as written : (1) "providing an image of a patient's breast"; (2) "selecting an outline that encompasses the breast image to . . . define a reduced field of view image"; and (3) "using said reduced field of view image for further processing, transmission, and/or archiving." *See* Ex. 1003, 7:26–38; *see id.* at 9:18–30; 9:44–57; 10:36–49.

The claim term "an image of a patient's breast" recited in step 1 provides antecedent basis for "the breast image" recited in step 2. Claim 11 further recites that the recited "image of a patient's breast" "occupies less than the entire field of view of an imaging receptor." Step 2 of claim 11 recites "automatically selecting an outline that encompasses the breast image to thereby define a reduced field of view image." Step 2 is performed after step 1 because step 2 requires selecting an outline from the image recited in step 1. *See Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc.*, 152 F.3d 1368, 1375–76, (Fed. Cir. 1998) (holding that the steps of a method claim had to be performed in their written order because each subsequent step referenced something indicating the prior step had been performed). Furthermore, step 2 is a product of step 1—a breast image is provided before

[7] Although differences exists between claims 11, 29, 33, and 41, these difference do not alter the order of the steps.

"a reduced field of view image" can be defined. *See also E–Pass Techs.*, 473 F.3d at 1222; *see also Loral Fairchild Corp. v. Sony Elecs. Corp.*, 181 F.3d 1313, 1321 (Fed. Cir. 1999) (holding that the claim language itself indicated that the steps had to be performed in the order written because the second step required the alignment of a second structure with a first structure formed by the prior step).

To interpret otherwise, it would mean the term "an image of a patient's breast" recited in step 1 refers to the same breast image recited in step 2.[8] Furthermore, step 1 would have no relationship with the other steps in the mammography method. For these reasons, we are not persuaded that step 2 can be performed "before or after the image is acquired," as Petitioner asserts. *See Microsoft Corp., v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed.Cir.2015) (Claims should not be construed "so broadly that [their] constructions are unreasonable under general claim construction principles."

The language of claim 11 also requires the remaining step 3 to be performed in the order written. Notably, step 3 necessarily occurs after step 2 because step 3 uses the "reduced field of view image" defined in step 2 for "further processing, transmission, and/or archiving," as recited by claims 11 and 41, and "tomosynthesis processing and transmission," as recited by claims 29 and 33. *See Loral Fairchild*, 181 F.3d at 1321.

[8] We note that throughout the prosecution history of the '684 patent, the Examiner made approximately 37 objections to the claims for "informalities, which appear to be minor draft errors including lack of antecedent basis and grammatical problems" (*see* Ex. 1004, 84–85, 234–235), but did not identify any issue related to the aforementioned claims.

The Specification also supports the recited steps being performed in the order written. For example, the '684 patent discloses that its mammography system uses a relatively large field-of-view receptor, but is able "[t]o save on transmitting and storing the breast image" by discarding information outside of the reduced field of view. Ex. 1003, 5:41–54. The '684 patent further discloses, "[i]f there is any significant information outside outline **48**, only that information **55** can be attached to the information for the image portion inside outline **48**." *Id.* at 5:54–57. The '684 patent still further discloses that "[t]he size and position of paddle **12***e* can be automatically determined, and the result used to in effect crop the resulting breast image before transmitting and/or storing and/or formatting it for transmission or storage." *Id.* at 5:65–6:2.

For the foregoing reasons, we determine that claims 11, 29, 33, and 41 require the recited steps be performed in the order written. We are not persuaded by Petitioner's assertion that the claims are "agnostic on whether the 'reduced field of view image' is defined before or after the image is acquired, and is broad enough to encompass either scenario" (Pet. 14). We agree with Patent Owner that the claims "require the 'reduced field of view' to be defined ***after*** a first image is 'provided' (and therefore in existence)." Prelim. Resp. 18.

3. Remaining Claim Terms

We have given all remaining claim terms their ordinary and customary meaning, and determine that it is not necessary to make that meaning explicit for any other term. *See Vivid Techs.,* 200 F.3d at 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

B. LEVEL OF SKILL IN THE ART

Regarding the level of skill in the art, Petitioner asserts

> [a] person of ordinary skill in the field as of the '684 Patent's effective filing date would have a Master's Degree or Ph.D[.] in physics, electrical engineering, or a related field and would also have at least 2 years of experience in the field of medical imaging. Ex. 1001, ¶ 42. Alternatively, someone with a bachelor's degree and at least 7 years of experience in the field of medical imaging could also be considered one of ordinary skill in the art.

Pet. 11–12 (citing Ex. 1001 ¶ 42). Patent Owner disagrees to some extent with Petitioner's assessment, but states "there is no meaningful difference between these definitions for purposes of the present proceeding." Prelim. Resp. 15.

In view of Patent Owner's acknowledgement, that there is no meaningful difference between its definition of one of ordinary skill and that proposed by Petitioner, we adopt Petitioner's definition. We also note that the level of ordinary skill in the art is reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Thus, the distinctions between Petitioner and Patent Owner's proposed definitions of one of ordinary skill would not alter our decision to deny institution in the present proceeding.

III. PATENTABILITY

A. ANTICIPATION BY DEFREITAS – GROUND 1

Petitioner asserts that claims 11 and 41 are anticipated by Defreitas. Pet. 26–34 (citing Exs. 1001, 1003, 1005, 1019). Patent Owner responds to Petitioner's assertions. Prelim. Resp. 18–30 (citing Exs. 1001, 1003, 1005, 1007, 1016, 1018, 1022, 2001).

1. Overview of Defreitas

Defreitas is directed to a digital mammography system that employs flat panel receptors. Ex. 1005, 1:8–10. More particularly, Defreitas discloses that its system employs "compression paddles that match both the size and position of the patient's breast relative to the proximal edge of a digital x-ray image receptor so as to improve image quality, patient comfort and the ability of the health professional to position the breast optimally for imaging." *Id.* at 2:34–39. Defreitas further discloses "automated collimation control" that is "responsive to information regarding one or more of the size of the paddle, its location along the beam, its location relative to the proximal edge of the receptor, a desired field of view, magnification parameters, and the like." *Id.* at 3:5–11. Defreitas also discloses, "[a]ny desired further lateral adjustment can be made by sliding paddle **2** along the direction of the proximal edge **5***a*, before or during compressing the breast for taking an image." *Id.* at 5:17–20.

2. Independent claims 11 and 41

Petitioner asserts that Defreitas anticipates claims 11 and 41 of the '684 patent. Pet. 26–34 (citing Exs. 1001, 1003, 1005, 1019). Patent Owner disagrees. Prelim. Resp. 18–30 (citing Exs. 1001, 1003, 1005, 1007, 1016, 1018, 1022, 2001). In particular, Patent Owner asserts that Petitioner does not adequately establish that Defreitas discloses a "reduced field of view image," as required by claims 11 and 41. Prelim. Resp. 18–28; *see also id.* at 1–5. We agree with Patent Owner.

Independent claims 11 and 41 recite, "automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby

define a reduced field of view image." To address this limitation, Petitioner asserts

> Defreitas discloses the use of collimators to restrict the x-ray illumination (and therefore the resulting image) to a defined area that is smaller than the full field of the digital receptor—preferably, it is "just large enough to show the image of breast **3**, or at least a selected part thereof"—thereby defining a reduced field of view image encompass[ing] the breast image."

Pet. 29 (citing Ex. 1005, 1:26–35, 1:38–44, 1:67–2:7, 3:54–64, 2:40–45, 3:41–46; Ex. 1001 ¶¶ 31–32, 75–76). Petitioner also asserts that this collimation "can be achieved automatically using an auto-collimation control to adjust the collimation of beam **30**." Pet. 29–30 (citing Ex. 1005, 4:19–20, 2:40–45, Fig. 2; Ex. 1001 ¶ 79). Petitioner further asserts "that the breast image defined by this automatic collimation process 'is typically rectangular.'" Pet. 30 (citing Ex. 1005, 3:61; Ex. 1001 ¶ 79).

In response, Patent Owner asserts that "collimation alone does not—and cannot—result in a 'reduced field of view image' within the meaning of the '684 Patent." Prelim. Resp. 1. Patent Owner acknowledges that "collimation directs X-ray beams to a specific area," but argues that "it does not prevent the digital detector from picking up data in areas outside the area of collimation." Prelim. Resp. 4 (citing Ex. 1022, 5; Ex., 1018, 3). According to Patent Owner, "Fujifilm's expert, Dr. Daft, has admitted that there [are] data received by the portion of the detector outside the field of collimation." Prelim. Resp. 4, 26–27 (citing Ex. 2001, 582:22–585:11, 588:24–590:10; 635:25–6:37:18).

Petitioner disagrees with Patent Owner's assessment of Dr. Daft's testimony. Pet. Reply 1–5 (citing Exs. 1005, 1011, 1027, 2001). Instead, Petitioner asserts that Dr. Daft

> explained again that collimation creates a reduced field of view image (Ex. 2001, 583:16–584:4, 636:3–6); the "image is only in the portion of the detector that was illuminated by the x-rays," (*Id*., 589:5–7, *see also* 584:19–23, 589:12–20, 636:14–15), and the rest of the detector only receives noise generated by the circuitry or scatter—"meaningless numbers"—not an image (*Id*., 583:21–584:1, 589:8–21, 636:14–17).

Pet. Reply 2. Thus, Petitioner asserts that "Dr. Daft's testimony confirms that collimation, as taught in the prior art, 'define[s] a reduced field of view image[]'" (Pet. Reply 1 (emphasis omitted)) because Dr. Daft testified that "'there is no image created outside of the collimated x-ray beam.'" Pet. Reply 1 (citing Ex. 1027, 133 Q. 403). We do not agree.

We find the full-context of Dr. Daft's statement to be relevant. Dr. Daft stated

> [i]n the scenario described by Defreitas and other prior art, the mammography system provides a collimated area that is some subset of the image receptor's area. The diagnostic image is confined to that collimated area. Outside of that area, the detector will receive scattered radiation and noise; there is no diagnostic value to the information in that area. So there is no image created outside of the collimated x-ray beam because there is no clinical value to that area. It is only noise and scatter: random numbers with no value.

Ex. 1027, 133 Q. 403. Dr. Daft's testimony fails to support Petitioner's assertion that "collimation . . . 'define[s] a reduced field of view image[]'" (Pet. Reply 1 (emphasis omitted); *see* Pet. 28–30). Dr. Daft's testimony identifies that it is "[t]he diagnostic image [that] is confined to that collimated area" (Ex. 1027, 133 Q. 403), but on this record, Petitioner has failed to establish that "[t]he diagnostic image" constitutes a "reduced field of view **image**" (emphasis added) within the meaning of each of the challenged claims. Dr. Daft further states, "there is no image created outside

of the collimated x-ray beam because there is no clinical value to that area." Ex. 1027, 133 Q. 403; *see also id.* at 134 Q. 404. Regardless of whether there is "clinical value" or not, Dr. Daft acknowledges that the detector does, in fact, "receive scattered radiation and noise" (*id.*), which we agree with Patent Owner, would generate pixel data. Prelim. Resp. 23–25 (citing Exs. 1007, 1018, 1022). Thus, we agree with Patent Owner that "collimation alone does not—and cannot—result in a "reduced field of view **image**" within the meaning of the '684 Patent." Prelim. Resp. 1 (emphasis added).

In this context, Patent Owner asserts that Petitioner has not shown sufficiently that Defreitas discloses a "reduced field of view image" created by

> a process whereby a region of a first image (i.e., "entire field of view image") is defined and the pixel data from sections of that first image outside that region (i.e., the "reduced field of view") are excluded or discarded (e.g., cropped) from the first image to form a second image (i.e., "reduced field of view image").

Prelim. Resp. 20–21 (citing Ex. 1003, 5:65–6:2, 7:26–38) (emphases omitted). More particularly, Patent Owner argues, "Defreitas simply does not discuss the removal or exclusion of any data outside the reduced field of view and therefore could not be describing a 'reduced field of view image.'" Prelim. Resp. 22. We agree with Patent Owner.

We agree with Patent Owner that "[a]lthough collimation will restrict a majority of the X-ray beam to one region of the digital detector, the machine will still read out data from the entire area of the detector." Prelim. Resp. 23 (citing Ex. 1022, 5). Defreitas "employ[s] compression paddles that match both the size and position of the patient's breast" and "provide[s] automated collimation control that changes x-ray beam collimation in

accordance with one or more of the size and position of the compression paddle and of the breast." Ex. 1005, 2:34–35, 2:40–43. As Patent Owner points out, however, "Defreitas describes a process of taking a [cranio-caudal] image, thereby generating a breast image that is 'typically rectangular,' but this image undergoes no processing that would remove any image data." Prelim. Resp. 22 (citing Ex. 1005, 3:54–67).

Furthermore, as discussed above, we determine that claims 11, 29, 33, and 41 require the recited steps be performed in the order written. As we noted in our discussion of claim 11, defining a reduced field of view image by automatically selecting an outline that encompasses the breast image in the first step is different from providing an image of the patient's breast that occupies less than the entire field of view in the second step. Turning to Petitioner's analysis of Defrietas, it is unclear how the "collimated area that is some subset of the image receptor's area" (*see* Pet. Reply 1 (citing Ex. 1027, 133 Q. 403)), which Petitioner asserts "define[s] a reduced field of view image[]" (Pet. Reply 1), as recited in the second step, is different from the "image of a patient's breast that occupies less than the entire field of view of an imaging receptor," as provided in the first step of each of the challenged claims. *See* Pet. 28–29 (citing Ex. 1005, 1:26–35, 1:38–44, 1:67–2:7, 2:40–45, 3:41–46, 3:54–64, Ex. 1001 ¶¶ 31–32, 75–76).

Petitioner relies on the description in Defreitas of "the use of collimators to restrict the x-ray illumination (and therefore the resulting image) to a defined area that is smaller than the full field of the digital receptor" (Pet. 29; *see also id.* at 28–29) as disclosing both the "image of a patient's breast" provided in the first step and the "reduced field of view image" defined in the second step of each of the challenged claims. For this

reason, agree with Patent Owner that the image formed from collimation in Defreitas is not the same as the "reduced field of view image" required by the challenged claims.

For the above reasons, we determine that Petitioner fails to show a reasonable likelihood that Defreitas discloses a "reduced field of view image," and therefore has not shown a reasonable likelihood of prevailing on its assertion that Defreitas anticipates claims 11 and 41.

B. OBVIOUSNESS OVER DEFREITAS AND NIKLASON – GROUND 2

Petitioner asserts that claims 29 and 33[9] are obvious over Defreitas and Niklason. Pet. 34–40 (citing Exs. 1001, 1004, 1006, 1020). Patent Owner responds to Petitioner's assertions. Prelim. Resp. 30–35 (citing Exs. 1003, 1006, 1020, 1022).

1. Overview of Niklason

Niklason is directed to a "method for tomosynthesis x-ray imaging." Ex. 1006, 2:24–25. Niklason discloses that its "x-ray source and detector are disposed on opposite sides of an object region disposed about an object plane parallel to the image plane" and "[a]s the source moves along the arc, the detector generates for a succession of points along the arc, a corresponding succession of image data sets, each set being representative of the intensity of x-rays incident on the detector for the then current position

[9] Claims 29 and 33 are substantially similar to claims 11 and 41. The primary difference between the two sets of claims lies in the last limitation of each of the challenged claims. Claims 11 and 41 require using the reduced field of view image for further processing, transmission, and/or archiving, whereas claims 29 and 33 specify that the image will be used for "tomosynthesis processing and transmission."

of the source." *Id.* at 2:34–38. After processing, Niklason discloses that "[t]he resultant image data thus corresponds in form to that produced by a conventional linear motion . . . so that conventional techniques may be used to produce a final representation of the x-ray absorption of the object region." *Id.* at 2:45–49. Niklason further discloses that tomosynthesis images can be transmitted from its imaging system to a workstation. *Id.* at 7:42–46.

2. Independent claims 29 and 33

Petitioner asserts that claims 29 and 33 are obvious over the combination of Defreitas and Niklason. Pet. 34–40. Petitioner asserts

> [a] person of ordinary skill in the art would have been motivated to combine the teachings of Defreitas (disclosing elements [a]–[f] of claims 29 and 33) with the teachings of Niklason (disclosing element [g] of claims 29 and 33) in such a way that the resulting combination would yield the entire alleged invention of claims 29 and 33.

Pet. 37. However, Petitioner does not allege that Niklason addresses the deficiencies identified in connection with Defreitas, as discussed above. In particular, Petitioner does not explain how the addition of Niklason would have rendered obvious a mammography method including the first step of "providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor" and then, as a second step, "automatically selecting an [outline/rectangular region] that encompasses the breast image to thereby define a reduced field of view image." Therefore, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing in showing that claims 29 and 33 would have been obvious over the combination of Defreitas and Niklason.

C. OBVIOUSNESS OVER MULLER AND ADMITTED PRIOR ART – GROUND 3

Petitioner asserts that claims 11 and 41 are obvious over Muller and Admitted Prior Art. Pet. 40–49 (citing Exs. 1001, 1003, 1007, 1016–1018, 1021). Patent Owner responds to Petitioner's assertions. Prelim. Resp. 35–43 (citing Exs. 1003, 1007, 1022).

1. Overview of Muller

Muller is directed to an automated radiological imaging device that seeks to reduce radiography errors and improve the quality of images obtained. Muller ¶¶ 2, 5–7. Muller's device "can be applied to a mammography apparatus using a screen-film pair (inside a cassette) as well as an apparatus using a digital detector." *Id.* ¶ 56. Muller's device utilizes a compression element or ball, which includes a means for recognition, and is used for "control of exposure time as a function of the signal." *Id.* ¶¶ 35, 57. Muller discloses that compression element or ball 25 can cooperate with slide 19 and glide horizontally. *Id.* ¶¶ 59–60. Muller discloses that its device provides image optimization processing that optimizes brightness and contrast within a specific area of the image. *Id.* ¶ 66.

Muller further discloses obtaining a "pre-exposure image" using a very low X-ray dose on the densest area of the part of the breast in order to estimate the exposure time. *Id.* ¶ 106. More particularly, Muller discloses

> [w]ithout a priori knowledge of the compression element used, the search of that area is carried out over the entire surface of the image. With a priori knowledge of the compression element used, and knowing the mechanical thickness of compression and the geometric enlargement factor used, a search area can be deduced therefrom on the pre-exposure image, limited to the useful part of the compression element used. This is particularly

> of interest for compression elements whose compression area is less than the sensitive surface area of the detector.

Id. ¶ 106. Muller also discloses, "[k]nowledge of the compression ball or element used makes it possible to control the X-ray collimator located at the outlet of the X-ray tube, for the purpose of limiting the irradiated area of the object studied." *Id.* ¶ 108. In this regard, Muller discloses that "[c]ollimation can be chosen as a function of the shape or size of the compression ball, according to the size of the ball±N cm in each dimension, the table unequivocally connecting the compression ball used and the collimator opening, etc." *Id.* ¶ 109. Muller further discloses a displaying and storing the image in a computer file. *Id.* ¶ 34.

2. Admitted Prior Art

Petitioner identifies Admitted Prior Art as "statements from the 'Background' of the '684 Patent describing characteristics of 'typical[]' X-ray mammography systems, and known proposals for improving upon such systems." Pet. 11. Petitioner asserts that Admitted Prior Art discloses "that compression paddles 'come[] in a variety of sizes to match . . . the breast size. Such matching is desirable because the use of a small size paddle on a large breast . . . may not allow full-breast imaging.'" Pet. 47 (citing Ex. 1003, 1:29–32).

3. Independent claims 11 and 41

Petitioner asserts that the combination of Muller and Admitted Prior Art discloses or suggests the subject matter of claims 11 and 41 of the '684

patent.[10] Pet. 40–49 (citing Exs. 1001, 1003, 1007, 1016–1018, 1021). Patent Owner disagrees. Prelim. Resp. 35–43 (citing Exs. 1003, 1007, 1022). In particular, Patent Owner asserts that Petitioner does not adequately establish that the combination of Muller and Admitted Prior Art discloses or suggests a "reduced field of view image," as required by claims 11 and 41. Prelim. Resp. 35–39; *see also id*. at 1–5. We agree with Patent Owner.

Independent claims 11 and 41 recite "automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby define a reduced field of view image." To address this limitation, Petitioner asserts

> Muller discloses a calculation unit that, among other things, receives the information from the detection unit that determines the type of compression element being used. Muller discloses multiple examples of a "means for recognition of the compression element" that can be used to automatically derive information about the compression element.

Pet. 43 (citing Ex. 1007 ¶¶ 30, 35–39, 60–61, 61–65; Ex. 1001 ¶ 106). Once the compression element is recognized, Petitioner asserts that this forms "an outline, defined by coordinates, that corresponds to the surface area of the side of the compression element that is in contact with the patient's breast" (Pet. 44 (citing Ex. 1007 ¶ 65)), and

> [t]his outline then defines a reduced field of view image; "the calculation unit **40** sends a command to the X-ray source **7** and,

[10] More particularly, Petitioner asserts "Muller discloses all aspects of these claims explicitly but for the requirement that the reduced field of view image encompasses the entirety of the patient's breast in the breast image, which is inherent in Muller or at least obvious in view of Muller, particularly when considering the Admitted Prior Art." Pet. 25.

> in particular, to a collimator . . . to adjust the X-ray beam to the useful surface; in other words, for the area of the organ exposed to x-rays to match the useful surface.

Pet. 44 (citing Ex. 1007 ¶ 65; Ex. 1001 ¶¶ 107–108). Petitioner further asserts that Muller depicts the use of a rectangular compression paddle (Pet. 41 (citing Ex. 1007, Fig. 2 (element 25)), and because the outline that defines the reduced field of view image is automatically selected based on the surface of the compression element, a rectangular compression paddle would produce a rectangular region." Pet. 44 (citing Ex. 1007 ¶¶ 8, 40; Ex. 1001 ¶¶ 107–108).

Patent Owner disagrees, and asserts that Petitioner "again relies on collimation of the x-ray beam to define the 'reduced field of view image.'" Prelim. Resp. 36. We agree with Patent Owner.

As discussed in connection with Ground 1, Petitioner has not established that collimating the x-ray beam to an area of the digital detector discloses or suggests "defin[ing] a reduced field of view **image**" (emphasis added), as required by each of the challenged claims. With respect to Ground 3, Petitioner asserts that Muller discloses a "reduced field of view image" that constitutes "an outline, defined by coordinates, that corresponds to the surface area of the side of the compression element that is in contact with the patient's breast." Pet. 44 (citing Ex. 1007 ¶ 65; Ex. 1001 ¶ 106). As Patent Owner points out, however, the cited portions of Muller do not disclose or suggest "the exclusion or deletion of data to generate a 'reduced field of view image.'" Prelim. Resp. 36.

Muller discloses using an x-ray collimator for limiting the irradiated area of an object. Ex. 1007 ¶ 108. Muller seeks to reduce radiography errors and improve the quality of images obtained by optimizing image

quality over a particular area defined by its compression element. *Id.* ¶¶ 2, 5–8. Muller describes obtaining a "pre-exposure image" using a very low X-ray dose on the densest area of the part of the breast in order to estimate the exposure time. *Id.* ¶ 106. In this way, Muller discloses, "[a] possible optimization of exposure is thus avoided on an area outside the particular area defined by the compression element, which would have the effect of degrading exposure of the part of the breast under compression, which is the part of interest to the radiologist." *Id.* ¶ 107. That is, Muller discloses that pixel data outside the field of collimation is present and avoided during image optimization. *Id.* However, as discussed above with respect to Ground 1, Petitioner relies on "a collimator . . . to adjust the X-ray beam to the useful surface" (Pet. 44; *see also id.* at 42) as disclosing both the "image of a patient's breast" provided in the first step and the "reduced field of view image" defined in the second step of each of the challenged claims. For this reason, we agree with Patent Owner that the image formed from collimation in Muller is not the same as the "reduced field of view **image**" (emphasis added) required by the challenged claims.

For the above reasons, we determine that Petitioner has not show a reasonable likelihood that Muller and Admitted Prior Art discloses or suggests a "reduced field of view image," and therefore has not shown a reasonable likelihood of prevailing on its assertion that Muller and Admitted Prior Art renders obvious claims 11 and 41.

D. OBVIOUSNESS OVER MULLER, ADMITTED PRIOR ART, AND NIKLASON – GROUND 4

Petitioner asserts that claims 29 and 33 are obvious over Muller, Admitted Prior Art, and Niklason. Pet. 49–51 (citing Exs. 1001, 1006,

1020). Patent Owner responds to Petitioner's assertions. Prelim. Resp. 43–45 (citing Exs. 1006, 1007, 1020, 1022).

1. Independent claims 29 and 33

Petitioner asserts that claims 29 and 33 are obvious over the combination of Muller, Admitted Prior Art, and Niklason. Pet. 49–51. Petitioner asserts that the combination of Muller and Admitted Prior Art discloses or suggests every limitation of claims 29 and 33 except for "using said reduced field of view image for tomosynthesis processing and transmission." Pet. 49. Petitioner takes the position

> [a] person of ordinary skill in the art would have been motivated to combine the teachings of Muller and the Admitted Prior Art (disclosing elements [a]–[f] of claims 29 and 33) with the teachings of Niklason (disclosing element [g] of claims 29 and 33) in such a way that the resulting combination would yield the entire alleged invention of claims 29 and 33.

Pet. 50 (citing Ex. 1001 ¶¶ 124–126). However, Petitioner does not allege that Niklason addresses the deficiencies identified in connection with Muller and Admitted Prior Art, as discussed above. In particular, Petitioner does not explain how the addition of Niklason would have rendered obvious a mammography method including the steps of "providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor" and then "automatically selecting an [outline/rectangular region] that encompasses the breast image to thereby define a reduced field of view image." Therefore, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing in showing that claims 29 and 33 would have been obvious over the combination of Muller, Admitted Prior Art, and Niklason.

E. OBVIOUSNESS OVER KAWAMATA AND YAMADA – GROUND 5

Petitioner asserts that claims 11 and 41 are obvious over Kawamata and Yamada. Pet. 51–62 (citing Exs. 1001, 1009, 1011). Patent Owner responds to Petitioner's assertions. Prelim. Resp. 45–52 (citing Exs. 1001, 1003, 1009, 1011, 1020, 1022).

1. Overview of Kawamata

Kawamata is directed to a mammography apparatus which includes a vertically moving compression plate, a compression plate size detection means, and

> an irradiation field mask drive means to drive the irradiation field mask of said diaphragm mechanism and to control the irradiation field to ensure a predetermined opening section of the diaphragm mechanism based on the size of the compression plate when the size of the compression plate is detected by this compression plate size detection means.

Ex. 1009 at 280, cols. 3–4. Kawamata identifies that in conventional mammography,

> it is necessary to prepare the compression plates of multiple sizes and shapes in advance according to the application region of the breast, imaging technique and film size for use, and it is also necessary to have a large number of X-ray radiation tubes with different sizes and shapes according to the type of compression plate.

Id. at 279–280, cols. 2–3. Kawamata further identifies that the need to select the size and shape of the compression plate along with the corresponding radiation tubes requires a great deal of time and labor, and may lead to imaging errors. *Id.* at 280, col. 3. To address this need, Kawamata discloses that its mammography apparatus "enable[s] the appropriate restriction of the X-ray irradiation field without using an X-ray radiation tube even if the size

and shape of the compression plate changes." *Id.* Kawamata further discloses that its apparatus

> automatically restrict[s] the X-ray irradiation field regardless of the size of the compression plate, eliminating the conventional time and labor required to replace the X-ray radiation tube and making it possible to perform good X-ray imaging because the X-ray irradiation field will always match the size of the compression plate.

Id. at 280, col. 5.

2. Yamada

Yamada is directed to a digital mammography detection system. Ex. 1011 ¶ 21. Yamada describes, *inter alia*, "a medical picture archiving and communication system (PACS)" which aids in "archiving, communicating[,] and displaying" mammogram images. *Id.* ¶¶ 26, 33.

3. Independent claims 11 and 41

Petitioner asserts that the combination of Kawamata and Yamada discloses or suggests the subject matter of claims 11 and 41 of the '684 patent. Pet. 51–62 (citing Exs. 1001, 1004, 1006, 1020). Patent Owner disagrees. Prelim. Resp. 45–52 (citing Exs. 1001, 1003, 1009, 1020, 1022). In particular, Patent Owner asserts that Petitioner does not adequately establish that Kawamata and Yamada discloses or suggests a "reduced field of view image," as required by claims 11 and 41. Prelim. Resp. 45–48; *see also id.* at 1–5. We agree with Patent Owner.

Independent claims 11 and 41 recite, "automatically selecting [an outline/a rectangular region] that encompasses the breast image to thereby define a reduced field of view image." To address this limitation, Petitioner asserts Kawamata "explains that '[i]rradiation field restriction masks 15, 16,

and 17 of diaphragm mechanism 14' will be moved into the correct position based on the detected size of the compression plate selected, 'automatically resulting in an X-ray irradiation field that matches the compression plate size.'" Pet. 55 (citing Ex. 1009, 281 col. 10 – 282 col. 11; Ex. 1001 ¶¶ 134–135). Petitioner takes the position that "[t]his automatically selected outline encompasses the breast image" acquired by collimating the x-ray beam based on the size and shape of the compression plate selected, and thus defines the reduced field of view image. Pet. 56 (citing Ex. 1001 ¶ 135). With respect to claim 41, Petitioner asserts that the breast image defined by Kawamata's "field mask process is a rectangular region." Pet. 54–56 (citing Ex. 1009, 281, col. 9–10, Fig. 3; Ex. 1001 ¶¶ 135–136).

Patent Owner disagrees, and asserts that Petitioner once again relies on collimation of the x-ray beam to define the "reduced field of view image." Prelim. Resp. 46. We agree with Patent Owner.

As discussed in connection with Grounds 1 and 3, Petitioner has not established that collimating the x-ray beam to an area of the digital detector discloses or suggests "defin[ing] a reduced field of view **image**" (emphasis added), as required by each of the challenged claims. With respect to Ground 5, Petitioner asserts that Kawamata discloses a "reduced field of view image" that corresponds to "an X-ray irradiation field that matches the compression plate size" (Pet. 55 (citing Ex. 1009, 281 col. 10–282 col. 11; Ex. 1001 ¶¶ 134–135)), i.e., the breast image defined by the field mask process. Pet. 56. Petitioner relies on the collimation of the X-ray beam in Kawamata to define the "reduced field of view image" and relies on Yamada only to the extent it discloses "processing, transmission, and/or archiving of images." *See* Pet. 61–62. However, similar to Grounds 1 and 3, Petitioner

relies on the use of lead field masks to collimate the x-ray beam (Pet. 55–56; *see also id.* at 54–55) as disclosing both the "image of a patient's breast" provided in the first step and the "reduced field of view image" defined in the second step of each of the challenged claims. For this reason, we agree with Patent Owner that Petitioner has failed to establish that the image formed by Kawamata's field masks discloses or suggests the "reduced field of view **image**" (emphasis added) required by the challenged claims.

For the above reasons, we determine that Petitioner has not shown a reasonable likelihiood that the combination of Kawamata and Yamada discloses or suggests a "reduced field of view image," and therefore has not shown a reasonable likelihood of prevailing on its assertion that the combination of Kawamata and Yamada rednders obvious claims 11 and 41.

F. OBVIOUSNESS OVER KAWAMATA, YAMADA, AND NIKLASON – GROUND 6

Petitioner asserts that claims 29 and 33 are obvious over Kawamata, Yamada, and Niklason. Pet. 62–64 (citing Exs. 1001, 1006). Patent Owner responds to Petitioner's assertions. Prelim. Resp. 52–53 (citing Ex. 1020).

1. Independent claims 29 and 33

Petitioner asserts that claims 29 and 33 are obvious over the combination of Kawamata, Yamada, and Niklason. Pet. 62–64. Petitioner asserts that the combination of Kawamata and Yamada discloses or suggests every limitation of claims 29 and 33 except for "using said reduced field of view image for tomosynthesis processing and transmission." Pet. 62–63. Petitioner takes the position

> [a] person of ordinary skill in the art would have been motivated to combine the teachings of the Toshiba references

> (disclosing elements [a]–[f] of claims 29 and 33) with the teachings of Niklason (disclosing element [g] of claims 29 and 33) in such a way that the resulting combination would yield the entire alleged invention of claims 29 and 33.

Pet. 63 (citing Ex. 1001 ¶¶ 154–156). Petitioner, however, does not allege that Niklason addresses the deficiencies identified in connection with Kawamata and Yamada, as discussed above. In particular, Petitioner does not explain how the addition of Niklason would have rendered obvious a mammography method including the first step of "providing an image of a patient's breast that occupies less than the entire field of view of an imaging receptor" and then, as a second step, "automatically selecting an [outline/rectangular region] that encompasses the breast image to thereby define a reduced field of view image." We, therefore, conclude that Petitioner has not shown reasonable likelihood that claims 29 and 33 would have been obvious over the combination of Kawamata, Yamada, and Niklason.

IV. CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to any challenged claim of the '684 patent on any of the challenged grounds. Accordingly, we do not institute *inter partes* review.

V. ORDER

For the reasons given, it is:

ORDERED that the Petition is *denied*.

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