UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VIEWRAY, INC. and VIEWRAY TECHNOLOGIES, INC.
Petitioner,

v.

VARIAN MEDICAL SYSTEMS, INC.,
Patent Owner

Case No.: To Be Assigned
U.S. Patent No. 9,082,520 B2
Title: MULTI LEVEL MULTILEAF COLLIMATORS

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,082,520 B2

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

TABLE OF EXHIBITS

NO.	DESCRIPTION
Ex. 1001	U.S. Patent No. 8,637,841 B2 ("'841 Patent")
Ex. 1002	U.S. Patent No. 9,082,520 B2 ("'520 Patent")
Ex. 1003	Declaration of Dr. Niko Papanikolaou ("Papanikolaou")
Ex. 1004	Declaration of Sylvia D. Hall-Ellis, Ph.D. ("Hall-Ellis Decl.")
Ex. 1005	'841 Patent File History
Ex. 1006	'520 Patent File History
Ex. 1007	U.S. Patent No. 4,463,266 ("Brahme")
Ex. 1008	U.S. Patent No. 4,987,309 ("Klassen")
Ex. 1009	Dai, Jianrong & Cui, Weijie. A finger leaf design for dual layer MLCs. IFMBE Proceedings. 25. 696-699 (2009) ("Dai")
Ex. 1010	Siochi, Ramon Alfredo. "Leakage reduction for the Siemens ModuLeaf," Journal of applied clinical medical physics / American College of Medical Physics. 10, 2 2894 (2009) ("Siochi")
Ex. 1011	Schlegel W., Grosser K.H., Häring P., Rhein B. "Beam Delivery in 3D Conformal Radiotherapy Using Multi-Leaf Collimators," In: Schlegel W., Bortfeld T., Grosu AL. (eds) "New Technologies in Radiation Oncology," Medical Radiology (Radiation Oncology). Springer, Berlin, Heidelberg (2006) ("Schlegel")
Ex. 1012	U.S. Patent No. 6,600,810 ("Hughes")
Ex. 1013	RESERVED

NO.	DESCRIPTION
Ex. 1014	Japanese Patent Application Publication No.: P2002-210026A ("Noguchi") with translation and certificate of translation
Ex. 1015	U.S. Food and Drug Administration. *510(k) Summary for PreScision™ Option*. Silver Spring, MD: FDA, 2009 ("Oncor1")
Ex. 1016	Siemens AG. *Siemens Oncor Brochure*. Muenchen, Germany: Siemens, 2009 ("Oncor2")
Ex. 1017	Varian's Open Claim Construction Brief in District Court
Ex. 1018	ViewRay's Claim Construction Brief in District Court (public version)
Ex. 1019	Varian's Reply Claim Construction Brief in District Court (public version)
Ex. 1020	Excerpts from Varian's Amended '520 Patent Infringement Contentions in the District Court
Ex. 1021	U.S. Patent Application Publication 2006/0198492 ("Noguchi '492")

I. INTRODUCTION

Petitioner ViewRay, Inc. and ViewRay Technologies, Inc. (collectively "ViewRay" or "Petitioner") requests institution of *inter partes* review (IPR) and cancellation of claims 1-3, 5-8, 10, 13, 14 of U.S. Patent No. 9,082,520 ("the '520 Patent," Ex. 1002), owned by Varian Medical Systems, Inc. ("Varian" or "Patent Owner").

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(b)

A. Real parties-in-interest under 37 C.F.R. § 42.8(b)(1)

Petitioners ViewRay, Inc. and ViewRay Technologies, Inc. are the only real parties in interest; there are no other real parties in interest under 35U.S.C.§ 312(a)(2) and 37C.F.R.§ 42.8(b)(1).

B. Related matters under 37 C.F.R. § 42.8(b)(2)

Varian is presently asserting the '520 Patent and U.S. Patent No. 8,637,841 (Ex. 1001) (parent of the '520 Patent) in the U.S. District Court for the Northern District of California, *Varian Medical Systems, Inc. v. ViewRay, Inc. et al.,* 3:19-cv-05697-SI, filed on September 10, 2019.

ViewRay expects to file an IPR petition regarding the '841 Patent shortly.

C. Lead and backup counsel under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel:

Lead Counsel	**Back-Up Counsel**
Howard N. Wisnia (Reg. No. 37,502)	James P. Conley (Reg. No. 52,459)

Wisnia PC	Pillsbury Winthrop Shaw Pittman LLP
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D. Service information under 37 C.F.R. § 42.8(b)(4)

Service of any documents via hand-delivery may be made at the addresses of lead and back-up counsel above with courtesy copies to the email addresses: Howard@wisnialaw.com and ViewRay-VarianIPR@pillsburylaw.com. Petitioner consents to electronic service.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW

This Petition complies with all statutory requirements and requirements under 37 C.F.R. §§ 42.103, 42.104, 42.105 and 42.15.

A. Payment of fees under 37 C.F.R. § 42.103

The undersigned authorizes the Office to Charge Deposit Account No. 033975 for the fee set forth in 37 C.F.R. § 42.15(a) for this Petition for IPR and any additional fees in connection with this Petition.

B. Grounds for standing under 37 C.F.R. § 42.104(a)

Petitioner certifies that the ’520 Patent is available for IPR. Petitioner is not barred or estopped from requesting the present IPR.

C. Identification of challenge under 37 C.F.R. § 42.104(b)

1. Challenged claims under § 42.104(b)(1)

Petitioner requests an IPR trial on and cancelation of claims 1-3, 5-8, 10, 13, and 14 of the ’520 Patent.

2. Claim construction under § 42.104(b)(3)

Petitioner’s proposed claim constructions are set forth in Section V.E., *infra*.

3. Specific statutory grounds under § 42.104(b)(2), supporting evidence and claim-by-claim analysis under § 42.104(b)(4), and exhibit number and relevance of supporting evidence under § 42.104(b)(5)

Petitioner asserts the following grounds under 35 U.S.C. § 103:

- **Ground 1:** Claims 1-3 are unpatentable under 35 U.S.C. § 103 as obvious over Dai (Ex. 1009).[1]
- **Ground 2:** Claims 1-3 are unpatentable under 35 U.S.C. § 103 as obvious over Noguchi (Ex. 1014)[2] alone or in view of Dai (Ex. 1009).

[1] Dai is a printed publication publicly accessible by June 25, 2009 and thus qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103. *See*, Hall-Ellis Decl. (Ex. 1004) ¶¶39-44.

[2] Noguchi is a Japanese patent document publicly accessible by July 30, 2002 and thus qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103.

- **Ground 3:** Claims 5-8, 10, 13, 14 are unpatentable under 35 U.S.C. § 103 as obvious over Noguchi (Ex. 1014) alone or in view of Dai (Ex. 1009), Schlegel (Ex. 1011)[3] and Klassen (Ex. 1008).[4]
- **Ground 4:** Claim 14 is unpatentable under 35 U.S.C. § 103 as obvious over Noguchi (Ex. 1014) in view of Noguchi '492 (Ex. 1021)[5] and Brahme (Ex. 1007),[6] or in the alternative, in further view of Dai (Ex. 1009), Schlegel (Ex. 1011) and Klassen (Ex. 1008).

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[3] Schlegel is a printed publication publicly accessible by November 16, 2004 and thus qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103. *See*, Hall-Ellis Decl. ¶¶52-57.

[4] Klassen is a U.S. Patent published on January 22, 1991 and thus qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103.

[5] Noguchi '492 is a U.S. Patent Application published on September 7, 2006 and thus qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103.

[6] Brahme is a U.S. Patent published on July 31, 1984 and thus qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103.

The grounds are summarized in the following chart:

Ground	Claims	Prior Art under § 103
1	1-3	Dai
2	1-3	Noguchi alone, or Noguchi in view of Dai
3	5, 6-8, 10, 13, 14	Noguchi alone or Noguchi in view of Dai, Schlegel and Klassen
4	14	Noguchi in view of Noguchi '492 and Brahme, or Noguchi in view of Dai, Schlegel, Klassen, Noguchi '492 and Brahme

The prior art is discussed throughout this Petition and the accompanying Declaration of Dr. Niko Papanikolaou (Ex. 1003), including analysis on how each construed claim is unpatentable under each ground. The Petition and Papanikolaou declaration identify by exhibit number the supporting evidence and explain its relevance to the challenge.

IV. BACKGROUND OF THE TECHNOLOGY

A. Radiation therapy and beam collimation

The technology at issue in this IPR relates to radiation therapy, which uses beams of intense energy to target and destroy cancerous tumor cells. The radiation beams may be created by a device called a linear accelerator or "linac." Because a linac's high energy beams can damage all living cells in their path (tumors and healthy tissues alike), it is important to <u>shape</u> the beams to approximate the shape of the tumor. The technology of the '520 patent relates to this type of beam shaping. Papanikolaou ¶31.

Figure 1 of the '520 Patent (reproduced below) depicts a radiotherapy setup, with a radiation source 102 creating a beam of radiation 103 directed toward a treatment area 112. Figure 1 also depicts a collimating device 110 which shapes beam 103 so that it matches the shape of target 112. The target 112 is a tumor within a patient lying on a treatment couch and located near the radiotherapy system's "isocenter" 108. *See, e.g.*, Ex. 1002 ('520 Patent) at 4:10-37. Papanikolaou ¶32.

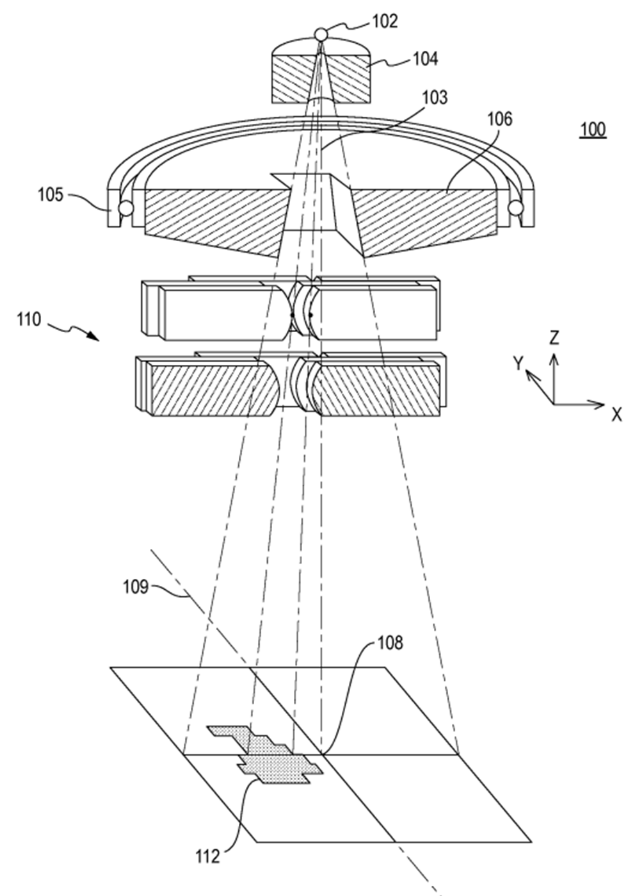
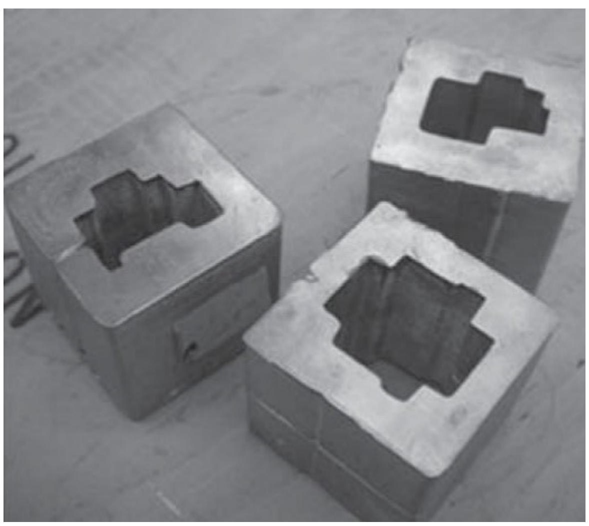
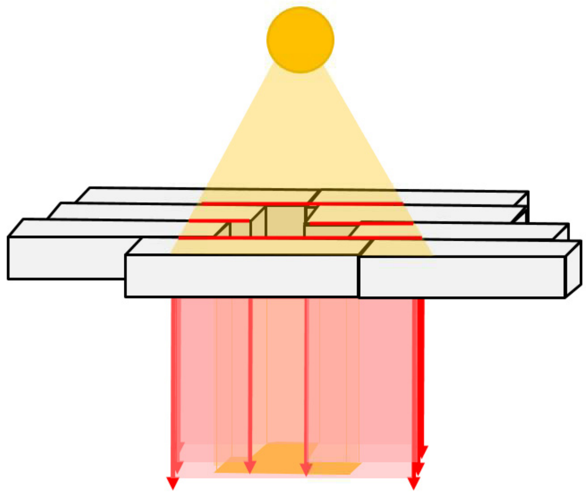


FIG. 1

In the early days of radiotherapy, clinicians would machine cut outs from thick blocks of metal to match the shape of a tumor (below, left) but this was expensive and time-consuming. Around 1965, the multi-leaf collimator or "MLC" was invented (*see, e.g.*, below right). MLCs can be used to create numerous shapes using leaves that can be moved in and out of the radiation beam, thus allowing customizable and quicker therapy. It should be noted that MLCs are sometimes referred to as "diaphragms" and leaves are sometimes referred to as "plates." Papanikolaou ¶33.

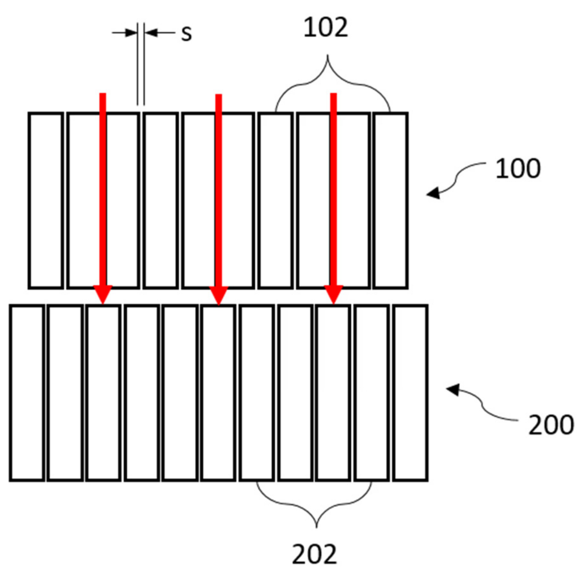


One drawback of multileaf collimators that does not exist with blocks is that radiation can leak <u>between the leaves</u> and strike the patient in unwanted locations (as demonstrated by the red lines and shading in the figure below). This is often referred to as inter-leaf leakage. Papanikolaou ¶34.

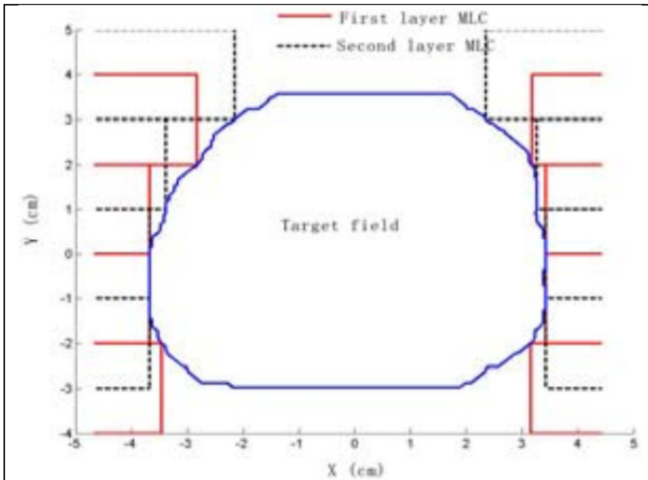
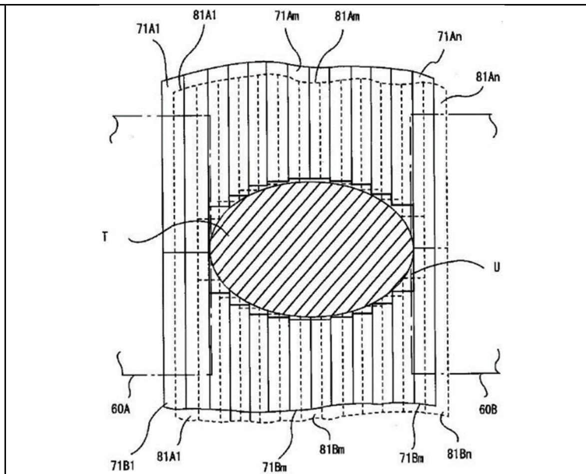


B. Multi-layer MLCs

A prior art method for reducing the inter-leaf leakage of MLCs uses multiple layers of MLCs in an offset, stacked design. In the illustration below, the lower layer MLC 200 is offset from the upper layer MLC 100 so that the spaces "s" between the leaves of the top layer are lined up with the middle of the leaves in the lower layer. As a result, leaves 202 in the lower MLC 200 block radiation leaking between leaves 102 of the upper MLC 100. Papanikolaou ¶35.



This strategy of using an offset double-stack MLC was known in the prior art and is disclosed in the Dai and Noguchi references, as shown in the figures reproduced below. Papanikolaou ¶36.

	
Ex. 1009 (Dai) at 696 (Figure 1) – looking down, from above the dual-layer MLC, it can be seen that the leaves of the bottom MLC (*i.e.*, the "second layer" shown with dotted black lines) are offset one-half a leaf width from the leaves of the top MLC (*i.e.*, the "first layer" shown with red lines).	Ex. 1014(Noguchi) at Figure 6 – looking down, from above the dual-layer MLC, it can be seen that the leaves of the bottom MLC (shown with dotted black lines) are offset one-half a leaf width from the leaves of the top MLC (shown with solid black lines).

C. Focusing for improved penumbra

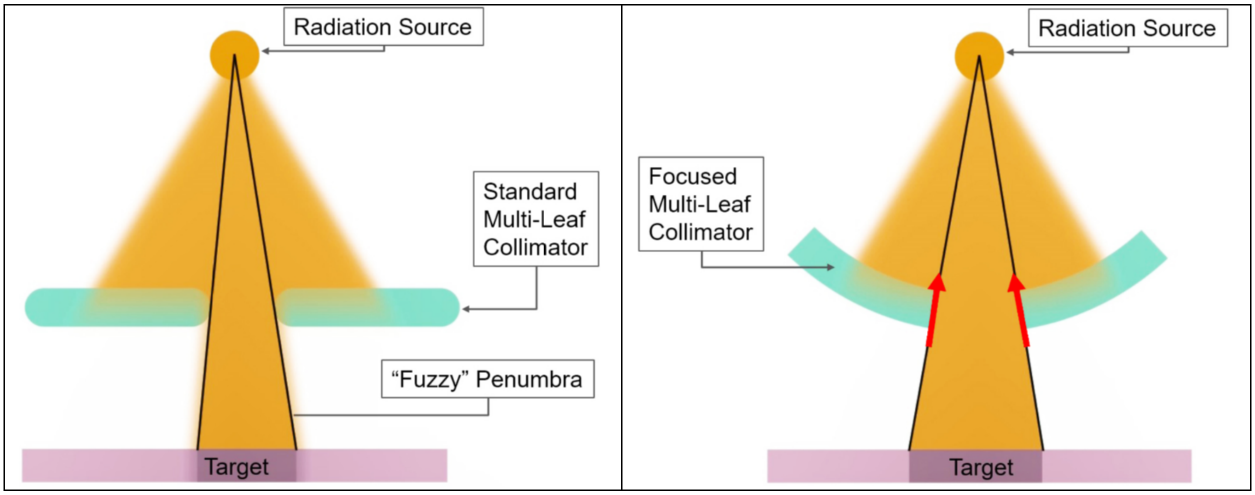
Beyond interleaf leakage, another concept relevant to the issues in this petition is leaf "focusing." "Focused" MLC leaves ensure that the radiation beam aimed at a patient's tumor has sharp (*i.e.*, focused) edges. Sharp beam edges are needed to prevent radiation in the "penumbra" of the beam from striking healthy tissues adjacent to the target tumor. Papanikolaou ¶37.

While understanding focused leaf designs requires a somewhat challenging visualization of leaves in three-dimensional space, the focusing concept is actually quite simple – for leaves to be focused, they must be designed so their edges (sides and ends) <u>point back toward the radiation source</u>. When this is done, radiation will either pass through the entire attenuating thickness of the leaf or not hit the leaf at all – thus reducing any "penumbra" that occurs when the beam passes through only a portion of the leaf's thickness. Papanikolaou ¶38.

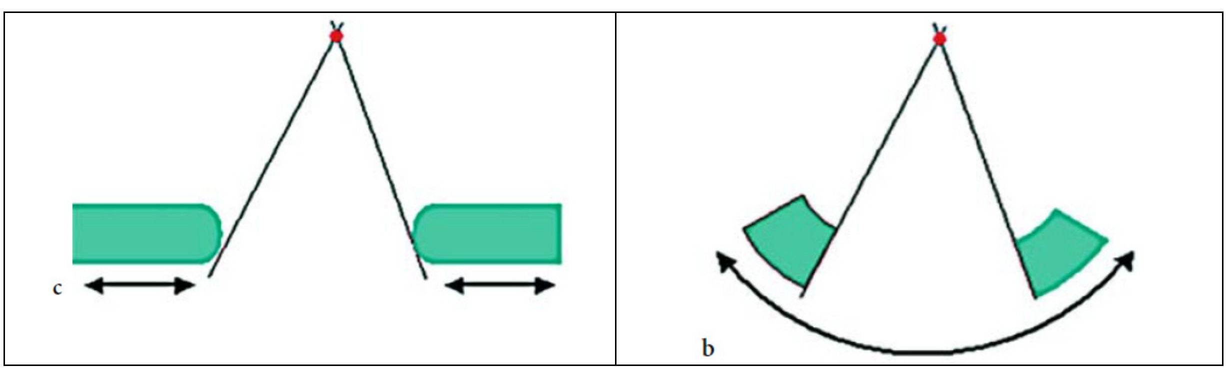
When leaf <u>sides</u> are focused back to the source, is common in the art to refer to such an MLC as focused or single-focused. When both the leaf sides and the leaf <u>ends</u> are focused back to the source, it is common in the art to refer to such an MLC as "double focused." Papanikolaou ¶39.

1. Focusing leaf ends – arc leaf movement

One prior art method of focusing to reduce penumbra is demonstrated in the figures below. The focused design on the right ensures that the leaf ends are always directed toward the radiation source. In this way, radiation is either completely blocked by the full thickness of the leaf or not blocked at all. The beam's edges are sharp and exhibit minimal penumbra. The design on the left has leaf ends that are rounded and thus only partially block the beam, which results in a beam that is not as sharp at the target and has greater penumbra. Papanikolaou ¶40.



It was well known before the '520 Patent priority date that beam penumbra should be minimized. For example, the Schlegel textbook (Ex. 1011) discusses the focusing properties of MLCs and includes the figures below on page 262, in Figure 20.7, which notes that "focusing in the direction of leaf motion can…be realized by the leaves traveling on a circular path (b)." Papanikolaou ¶41.



Indeed, Schlegel notes in Table 20.2 on page 259 that <u>all</u> of the commercially available MLCs at the time (2006) employed focusing, as shown below. Papanikolaou ¶42.

Table 20.2 Commercial integrated MLCs

Manufacturer	Product name	Leaf width at isocenter (mm)	Midline over-travel (cm)	No. of leaves	Maximum field size (cm^2)	Focusing properties	Remarks
Elekta-1	Integrated MLC	10	12.5	40×2	40×40	Single focusing	
Elekta-2	Beam modulator	4	11	40×2	16×22	Single focusing	
Siemens-1	3D MLC	10	10	29×2	40×40[b]	Double focusing	
Siemens-2	Optifocus	10	10	41×2	40×40	Double focusing	
Siemens-3	160 MLC	5	20[a]	80×2	40×40	Single focusing	Announced for 2006
Varian-1	Millennium MLC-52	10	20[a]	26×2	26×40	Single focusing	
Varian-2	Millennium MLC-80	10	20[a]	40×2	40×40	Single focusing	
Varian-3	Millennium MLC-120	Central 20 cm of field: 5 mm; outer 20 cm of field: 10 mm	20[a]	60×2	40×40	Single focusing	

2. Focusing leaf sides – trapezoidal cross-sections

The ubiquitous "single focusing" used in all the of commercial MLCs listed in Schlegel's Table 20.2 refers to the focusing of leaf sides. This manner of focusing is based on the same concept of having leaf edges directed back toward the radiation source, so when radiation passes the leaves, it will either pass through the entire thickness of the leaf, or no leaf at all. For this case, we must examine the leaves' design by looking at their cross-sections. Figure 5 from the '520 Patent, excerpted below, helps illustrate this viewpoint by showing a perspective view, and Figure 2 of the patent (also below) illustrates a cross-sectional view of an MLC's leaves. Papanikolaou ¶43.

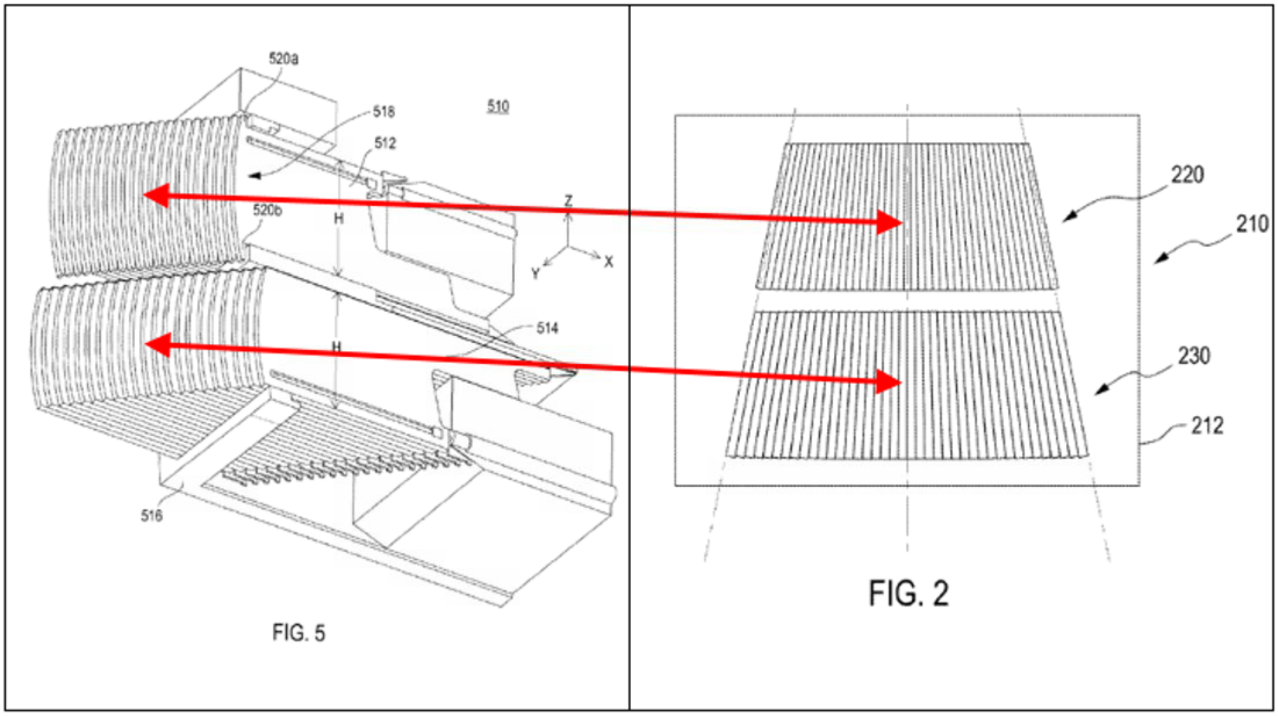
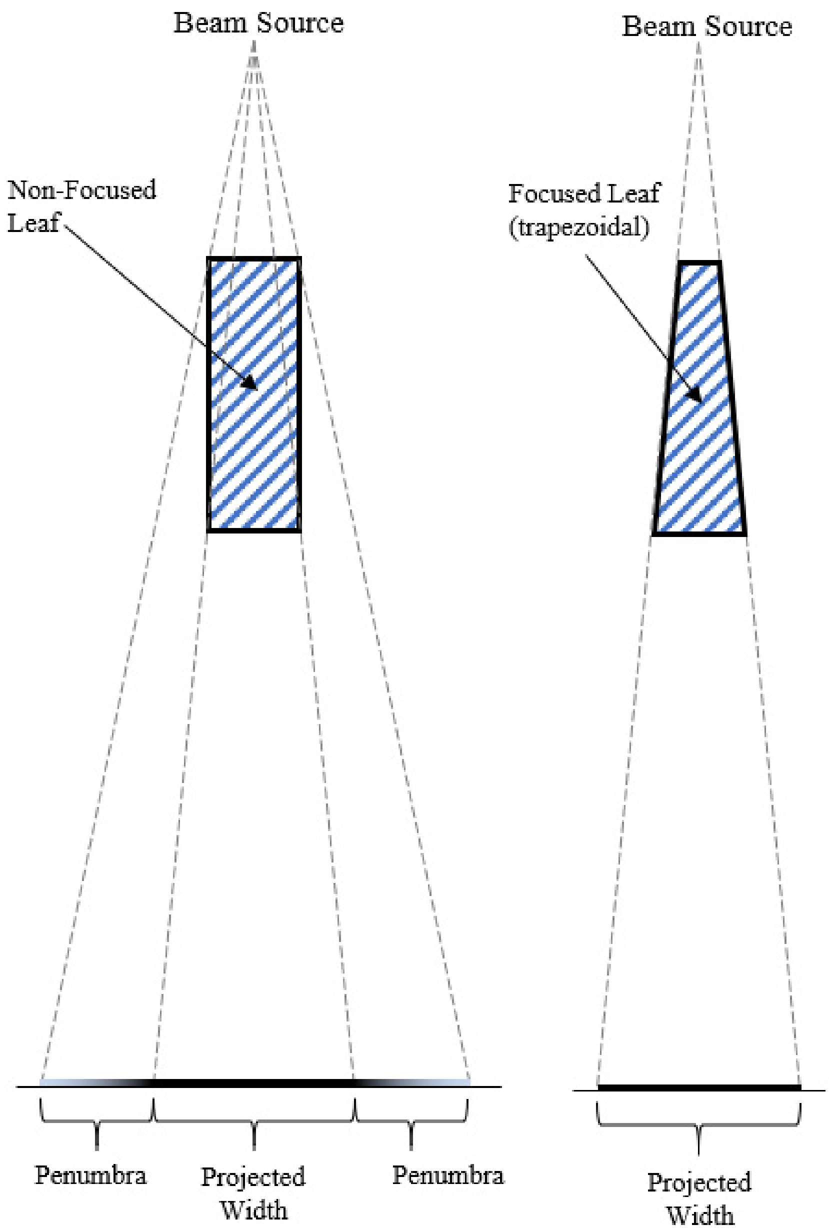


FIG. 5

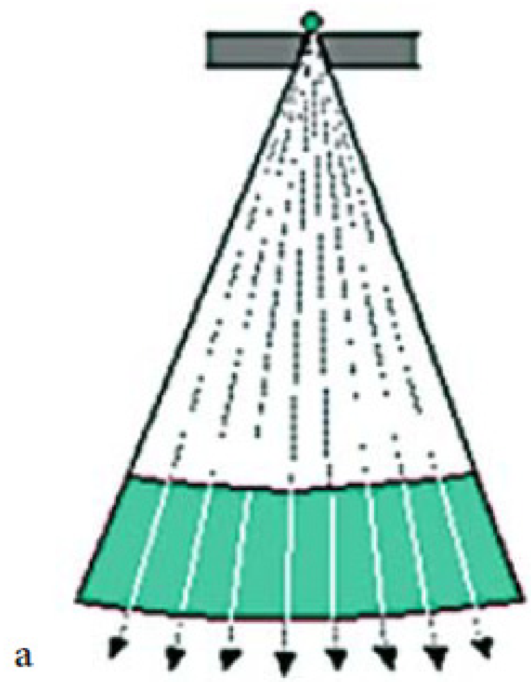
FIG. 2

Referring now to the figure below, the leaf design on the right illustrates how leaves with trapezoidal leaf cross-sections have their sides focused back to the beam source – thus resulting in sharper beam edges. Papanikolaou ¶44.



When a (non-focused) *rectangular* leaf cross-section is used, the beam will hit the corners of the rectangle and create a fuzzy penumbra effect at the target site. This occurs because the radiation beam is only partially blocked by the corners of the rectangular cross-section leaf. Papanikolaou ¶45.

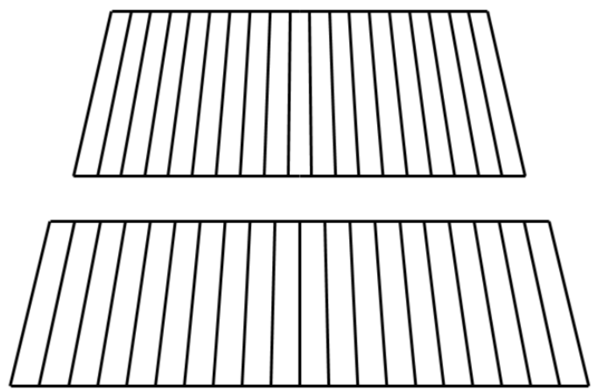
It was well known in the prior art to use trapezoidal leaves having sides focused toward the source. The Schlegel textbook also taught this concept on page 262, in Figure 20.7 (excerpted below), noting that "…leaves have trapezoid cross-sections to perform focusing perpendicular to the direction of leaf motion…." Papanikolaou ¶46.



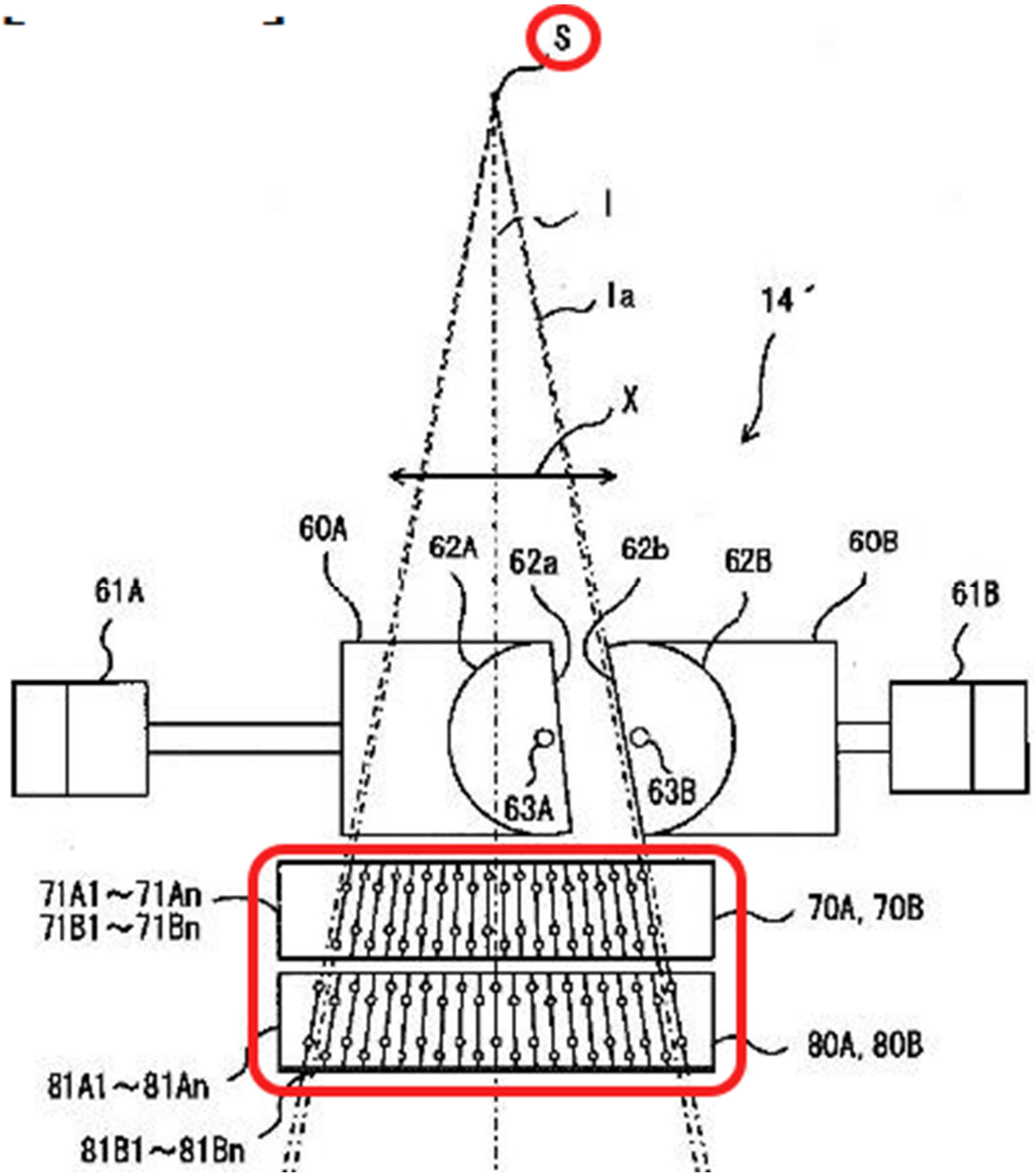
In the discussion of the grounds below, it will be seen that many of the limitations of the '520 Patent claims are simply design aspects inherent in focused leaf designs that were well known in the art–years before the '520 Patent priority date. *See, e.g.*, claims 5 and 7 ("the leaves…substantially focus on a converging virtual point located substantially at a radiation source"), claim 13 ("the leaves…have a substantially trapezoidal cross-section"), etc. Papanikolaou ¶47.

3. Focusing in a multi-level MLC – projected widths

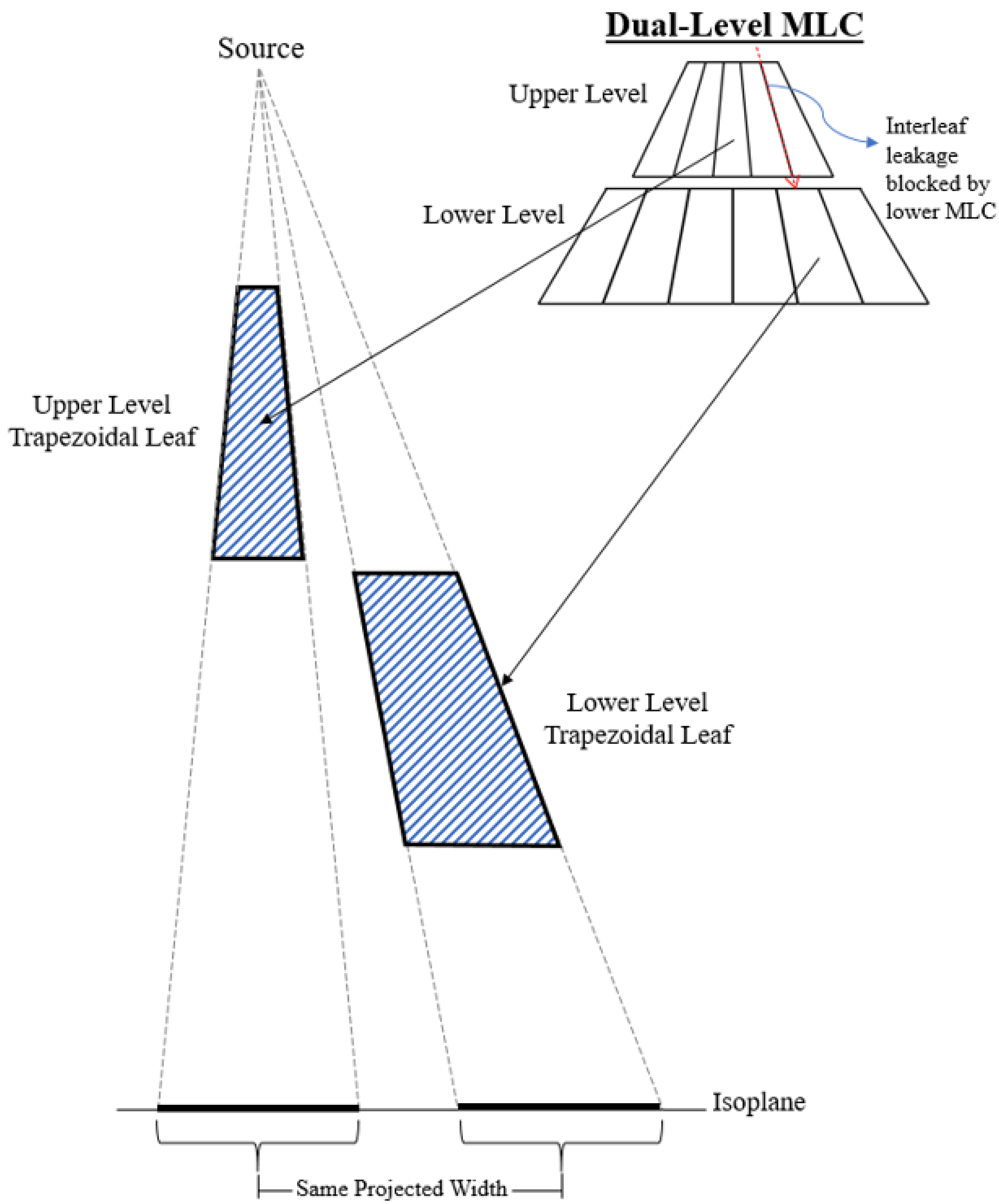
When focusing is employed in a double-stack MLC, the leaves in the top MLC and the bottom MLC both have trapezoidal cross-sections. The figure below depicts such a double-stack, focused design. Papanikolaou ¶48.



Such double stack, focused MLC designs were known in the prior art. For example, Figure 1 of Noguchi (excerpted below) shows top MLC 70 and bottom MLC 80, with trapezoidal leaves focused back to source S. Papanikolaou ¶49.



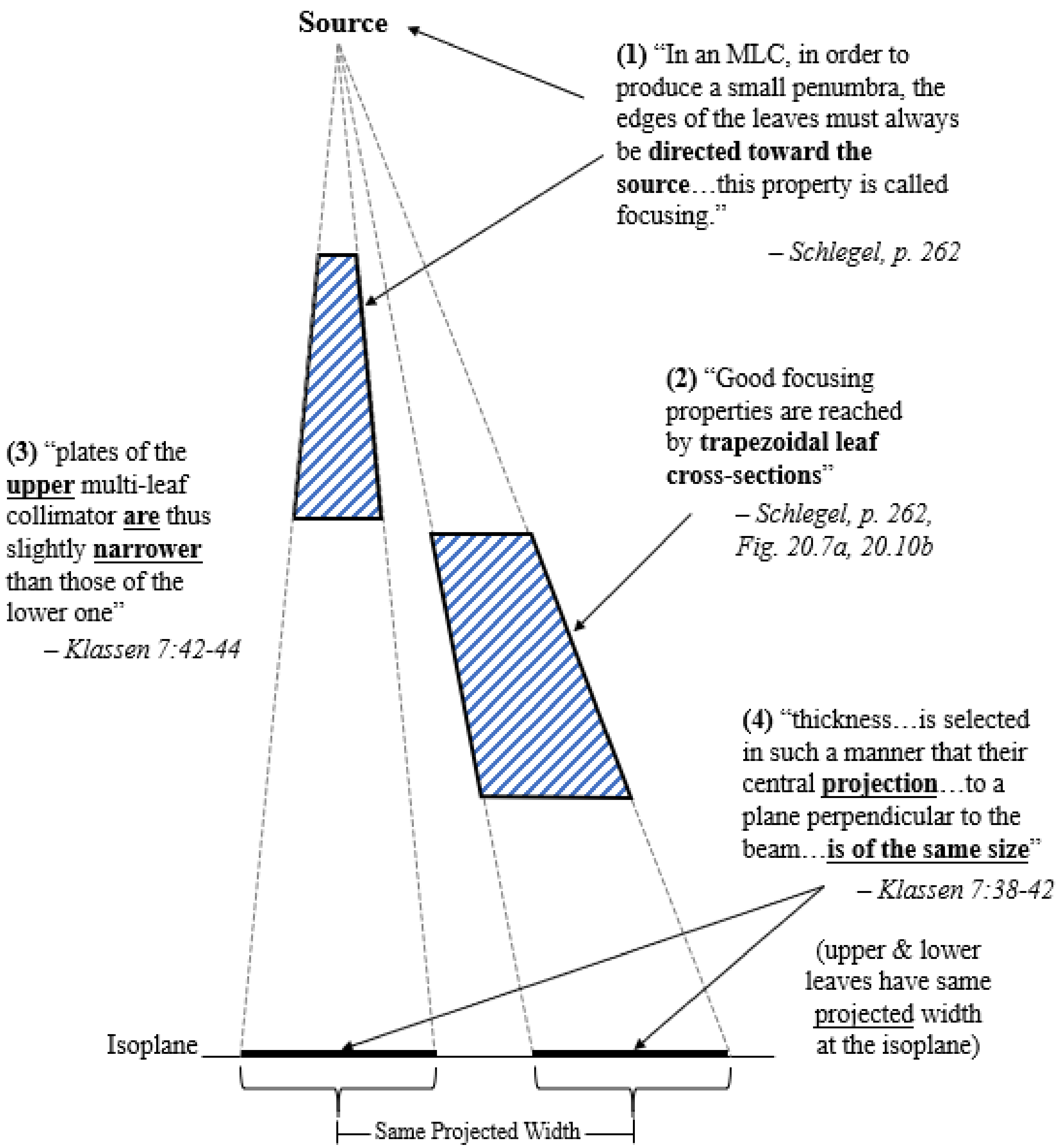
Because a radiation beam broadens as it gets farther from the source, leaves of a focused MLC naturally get wider farther from the radiation source. The illustration below demonstrates this. Papanikolaou ¶50.



The illustration above also shows that another inherent characteristic of a double stack, focused design is that the "projected width" of the leaves (*i.e.*, the "shadow" that a leaf casts at isocenter) will be the same for the leaves in the top MLC and the bottom MLC. This again is a naturally existing, inherent characteristic of double-stack focused MLCs in the prior art, which was not addressed during prosecution of the '520 Patent. Papanikolaou ¶51.

Another aspect of a double-stack, focused MLC design (demonstrated in the illustration above) is that, to achieve focusing, the lower level leaf must have a wider *physical* cross section. This is true because the radiation beam continues to diverge as it propagates farther from the source. As such, the upper leaves will inherently have thinner or narrower physical cross sections compared to the lower leaves, but all of the leaves will have the same *projected* widths at isocenter. Papanikolaou ¶52.

As noted in the figure below, Klassen further demonstrates that it was known in the art to have the projected widths of the leaves of an upper MLC and the leaves of a lower MLC be the same at isocenter. Ex. 1008 (Klassen) at 7:38-44; Papanikolaou ¶53.


Source
(1) "In an MLC, in order to produce a small penumbra, the edges of the leaves must always be directed toward the source…this property is called focusing."
– Schlegel, p. 262
(2) "Good focusing properties are reached by trapezoidal leaf cross-sections"
– Schlegel, p. 262, Fig. 20.7a, 20.10b
(3) "plates of the upper multi-leaf collimator are thus slightly narrower than those of the lower one"
– Klassen 7:42-44
(4) "thickness…is selected in such a manner that their central projection…to a plane perpendicular to the beam…is of the same size"
– Klassen 7:38-42
(upper & lower leaves have same projected width at the isoplane)
Isoplane
Same Projected Width

V. OVERVIEW OF THE '520 PATENT

A. Summary of the patent

The purported invention of the '520 Patent relates to particular arrangements of pairs of beam blocking leaves in a multilevel multileaf collimator. *See, e.g.*, Exhibit 1002 ('520 Patent) at Abstract. In its simplest form, an MLC consists of two opposed banks of leaves, with each leaf capable of individually moving in and out of the radiation field to shape the beam to match a tumor. *See, id.* at Fig. 1.

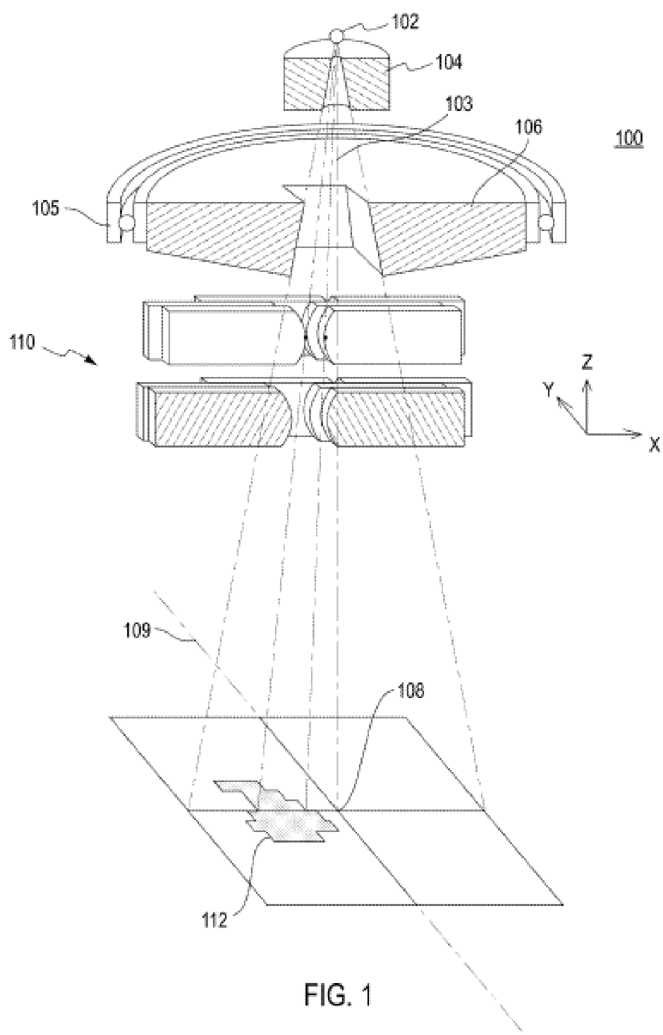


FIG. 1

The '520 Patent recognizes that interleaf leakage in single level MLCs was a known problem and various prior art techniques were directed at its solution. *Id.* at 1:32-45. It also recognizes the desire to improve beam shaping resolution, and notes that reducing leaf width could be useful for that purpose, but recognizes mechanical problems associated with such an approach. *Id.* at 1:46-56. The purported solutions proposed are a dual level MLC with leaves at different levels offset to block interleaf leakage. *Id.* at 4:1-9. However, as described herein, these problems and these exact solutions were known in the prior art before the priority date of the '520 Patent. Papanikolaou ¶55.

B. Prosecution history of the patent and related patents

The '520 Patent was filed as US Patent Application No. 14/144,509 on December 30, 2013. It was denoted a continuation of US patent application 12/861,368, which was filed on August 23, 2010, and later issued as US patent 8,637,841. Ex. 1006 ('520 Prosecution History) at 1/15/14, Filing Receipt.

A preliminary amendment was filed on April 23, 2014 adding new claims 3-14. A first office action was issued on October 23, 2014 rejecting claims 1-2 for obviousness-type double patenting based on the parent application and anticipation based on the Hughes reference (Ex. 1012). For unknown reasons, the Examiner did not address newly added claims 3-14.

Applicant filed a response on January 2, 2015 traversing the rejections and noting that the Examiner had failed to address claims 3-14. In response, the Examiner issued a new office action on January 28, 2015 maintaining the rejections (and adding claims 3-14 to the double patenting rejection and claims 3-4 to the prior art rejection). The Examiner did not issue a prior art rejection concerning claims 5-14.

On April 2, 2015, the Applicant and Examiner conducted a telephone interview during which the Hughes reference was discussed. Applicant then filed a response to the office action on April 6, 2015, with a terminal disclaimer to overcome the double patenting rejection, and arguing for patentability over the Hughes reference.

The crux of the dispute over the Hughes reference turned on whether or not it taught having a different number of leaf pairs between the two layers of MLC leaves. Applicant argued that Hughes failed to teach or suggest such subject matter. The Examiner's April 15, 2015 Reasons for Allowance focused on this limitation as rendering the claims allowable over the prior art. Yet, as demonstrated below, this feature is clearly taught in the prior art relied upon in this Petition and not considered by the Examiner.

C. Priority date

The '520 Patent's earliest priority claim is to August 23, 2010, which is the filing date of its parent application. Because all the relied upon prior art in this

Petition is prior to that date, there is presently no reason to address the issue further.

D. Level of ordinary skill in the art

As Dr. Papanikolaou explains, a person having ordinary skill in the art (PHOSITA) would hold a PhD in physics, medical physics, or a related discipline, and have at least three years' experience working in medical physics, specifically in the field of external beam radiotherapy (extensive experience and technical training may substitute for the education requirement). (Ex. 1003) Papanikolaou ¶¶58-61.

In the District Court, the Patent Owner has taken the position that the appropriate PHOSITA would only have an undergraduate degree in physics, biomedical engineering, or a similar degree and at least two years of work experience with multileaf collimators (a person with less education but more relevant practical experience may also meet this standard according to the Patent Owner). While Petitioner disagrees with that position, the analysis provided herein, and in Dr. Papanikolaou's declaration is equally applicable under Patent Owner's proposed level of skill in the art. That is, even under Patent Owner's proposed level of skill in the art, the subject claims are invalid for obviousness. Dr. Papanikolaou has considered this alternative level of skill in the art and confirms that his opinions hold true under that level as well. Papanikolaou ¶60.

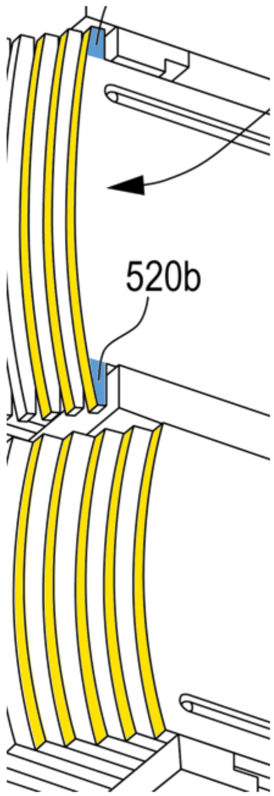
E. Claim construction

Claims are interpreted under the same standard applied in a civil actions under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b). The parties have completed their claim construction briefing concerning the '520 Patent in the district court and a claim construction hearing is currently set for July 7, 2020. Copies of the parties' briefing is submitted as Exhibits 1017-1019. The only term relevant to this proceeding and disputed by the parties in the district court is "an end portion having an upward and/or downward extended portion" (in claim 14).

1. "end portion having an upward and/or downward extended portion" (appears in claim 14)

In the District Court, Patent Owner has asserted that this term should take its plain and ordinary meaning. Petitioner believes the appropriate construction of the term is: the end portion (*i.e.,* the leading edge of a leaf that is inserted into a radiation field to abut an opposing leaf) has an upward and/or downward extended portion that extends beyond the height of the main portion (*i.e.,* beyond the height of the side surface throughout the remainder of the length of the leaf).

The '520 patent specification defines the "end" of a leaf a**s "*the surface of the leaf inserted into the field* along** the length," (*id.* at 6:3-5; emphasis added). Further, the specification identifies that the end portion has projections that extend upward and/or downward beyond the height of the main portion. Figure 5 shows the main portion/side surface has a height "H". The end portion of the upper layer leaf has two projections 520a, 520b (shown in blue below) that extend upwards and downwards beyond the height of the main portion/side surface.



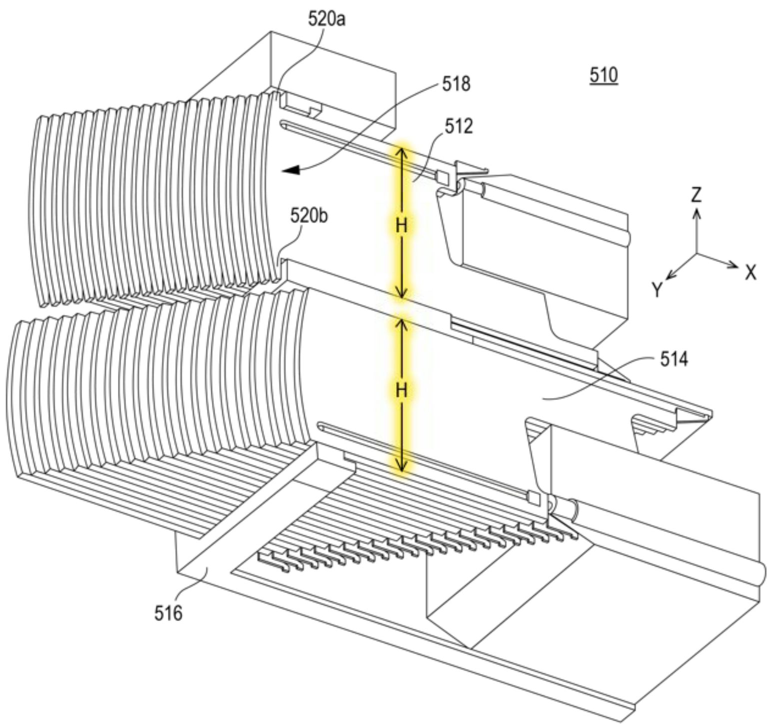


FIG. 5

The construction thus describes the main portion of the leaf relationally to the end portion, consistent with the specification. *See, e.g.* '520 Patent at 7:44-48 ("The upper leaves 512 and lower level leaves 514 may have a main portion of substantially same height ("H" as shown)").

Patent Owner's interpretation of the "plain and ordinary meaning" of this term includes "projections" that are part of the main portion height, or that extend throughout the leaf and not just at the end portion. Specifically, Patent Owner's infringement analysis in the district court would allow the "end portion" to refer to the leading edge (*e.g.*, the yellow portion in the top left figure) ***or*** the top edge, or bottom edge of the leaf a distance back from the leading edge. *See*, Ex. 1020 (Varian Infringement Contentions) (attempting to read claim 14 term on portion of the leaf that extends the entire length of leaf and includes part of the main portion).

VI. REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM IS UNPATENTABLE

A. The cited references are prior art

Dai and Schlegel were publicly available prior to the earliest possible effective filing date of the '520 Patent and indeed more than one year prior to such date. Hall-Ellis Decl. ¶¶39-44, 52-57. The remaining references relied upon are U.S. and Japanese patent documents published more than one year prior to the earliest possible effective filing date of the '520 Patent. Thus, all cited references herein qualify as prior art under pre-AIA 35 U.S.C. §§ 102(a and b) and 103.

B. The primary asserted references were not considered during the original prosecution

The grounds for this Petition rely on Dai and Noguchi as primary references. Neither reference was cited to, by, or considered by the Examiner during prosecution of the '520 Patent or its parent. None of the secondary references, except for Klassen, was cited during the prosecution either. Klassen was submitted in an IDS in the '520 Patent prosecution but was not relied upon by the Examiner or discussed during the prosecution. It also was not considered in the proposed combinations or in the light of the grounds herein.

Therefore, this Petition presents new grounds of unpatentability not previously considered. 35 U.S.C. § 325(d).

C. Ground 1: Claims 1-3 are unpatentable under 35 U.S.C. § 103 as obvious over Dai (Ex. 1009)

Dai:

Dai is a journal article concerning design options for leaf ends in a dual layer MLC. Dai describes two types of MLCs known in the art. "One type of MLCs ha[s] focused leaf end[s], and [a] leaf end follows [the] beam divergence as [the] leaves move along focused trajectories. Another type of MLCs ha[s] a rounded leaf end, and [the] leaf end approximately follows [the] beam divergence as [the] leaves horizontally move in and out." Dai at cover page, left column. The first type is a double focused MLC arrangement, and the second is a longitudinally movable single focused MLC arrangement. Papanikolaou ¶70.

Dai discloses that two layers (or stacks) of conventional MLCs may be arranged one above the other. Dai at cover page, left column. The layers of conventional MLCs are then offset a half leaf width in the direction perpendicular to leaf movement so that interleaf transmission is minimized. *Id.* This dual-layering and offset of a half leaf width is also shown in Dai Figure 1 and 2 reproduced below:

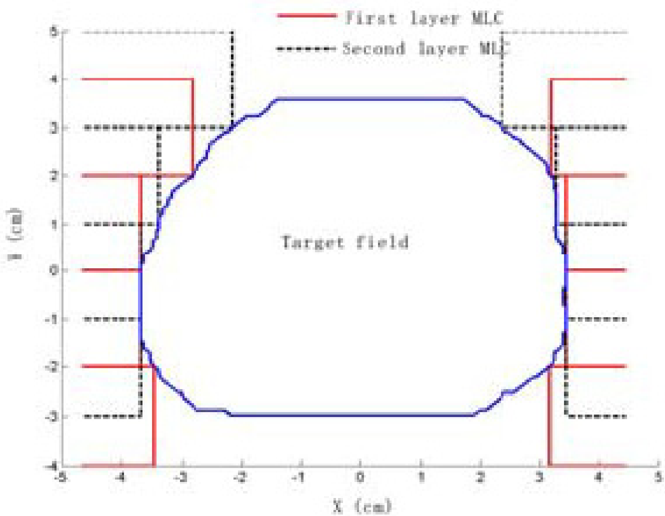


Fig. 1 Shaping a target field with a conventional MLC

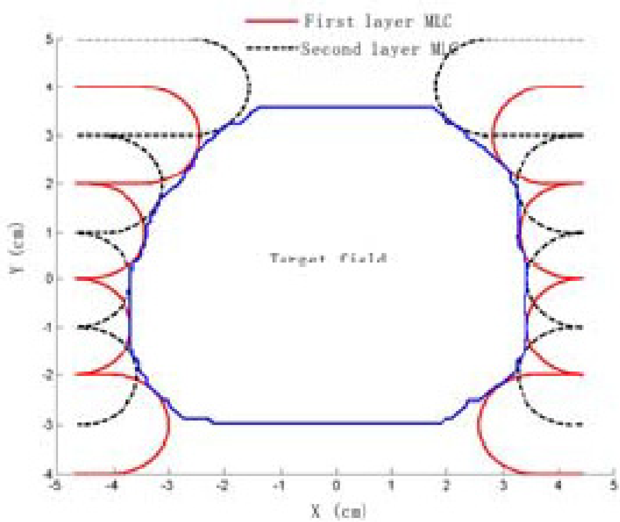


Fig. 2 Shaping a target field with a finger leaf MLC

The different layers of MLCs may have different numbers of leaf pairs. For example, Dai discloses having one layer with 20 leaf pairs and a different layer with 21 leaf pairs. Dai at 697, right column to 698, left column.

Claim 1 of the '520 Patent reads as follows:

[1pre] A multileaf collimator comprising:

[1a] a first set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the first set being disposed in an opposed relationship and longitudinally movable relative to each other in a first direction; and

[1b] a second set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the second set being disposed in an opposed relationship and longitudinally movable relative to each other in a second direction generally parallel to the first direction;

[1c] wherein the first and second sets of pairs of leaves are disposed in different planes and the first set of pairs of leaves comprises a first quantity of pairs of leaves and the second set of pairs of leaves comprises a second quantity of pairs of leaves wherein the first quantity and the second quantity are different.

As demonstrated below, Dai teaches or suggests each and every limitation of claim 1.

1. Claim 1: A multileaf collimator comprising:

To the extent the preamble may be considered a limitation, Dai teaches it. Dai is directed to a dual layer MLC, which it defines as a multileaf collimator. Dai at cover page. *See also,* the remainder of the document. Papanikolaou ¶74.

a. [1a] a first set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each

pair in the first set being disposed in an opposed relationship and longitudinally movable relative to each other in a first direction

Dai expressly teaches or suggests this limitation. The Dai system includes two "conventional MLCs arranged one above another." Dai at cover page, left column. In a conventional MLC, a plurality of pairs of beam blocking leaves are arranged adjacent one another, leaves of each pair are disposed in an opposed relationship and longitudinally movable relative to each other in a first direction. Papanikolaou ¶75. In Dai, a plurality of pairs of beam blocking leaves are arranged adjacent one another as shown in Figures 1 & 2:

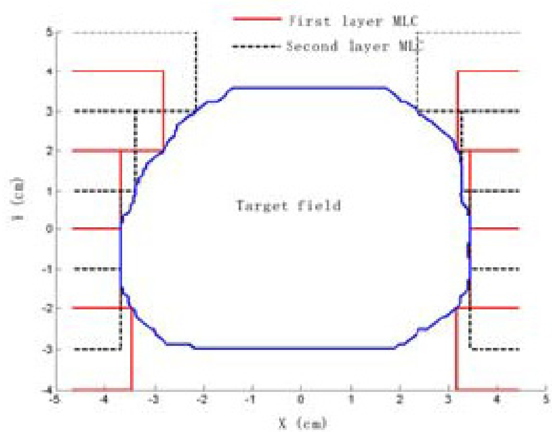


Fig. 1 Shaping a target field with a conventional MLC

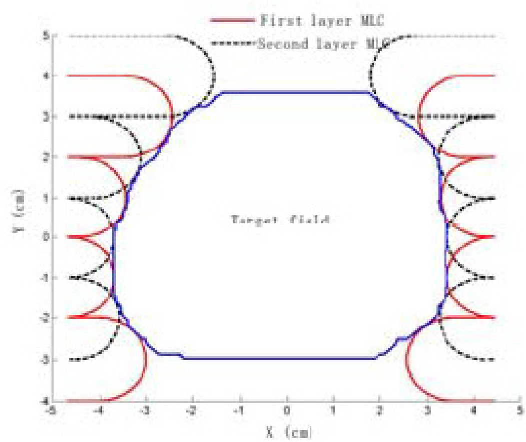


Fig. 2 Shaping a target field with a finger leaf MLC

In the Figures, the red leaves are at one level and the black leaves are at another level. Papanikolaou ¶76. The leaves of each pair in a level are opposed to each other as shown in the figures. They are longitudinally movable relative to each other in a first direction. Dai at cover page ("Another type of MLCs have rounded leaf end[s, *see* Fig. 2] and [the] leaf end[s] approximately follow [the] beam divergence as leaves horizontally [*i.e.*, longitudinally] move in and out.”). Papanikolaou ¶76. Either one of the sets of the red and black leaves meets this limitation.

b. [1b] a second set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the second set being disposed in an opposed relationship and longitudinally movable relative to each other in a second direction generally parallel to the first direction;

Dai expressly teaches or suggests this limitation. This limitation is met by the second MLC in Dai – which is the second of the red or black leaves in Figures 1 and 2 reproduced above. Papanikolaou ¶77.

c. [1c] the first and second sets of pairs of leaves are disposed in different planes and the first set of pairs of leaves comprises a first quantity of pairs of leaves and the second set of pairs of leaves comprises a second quantity of pairs of leaves wherein the first quantity and the second quantity are different.

Dai expressly teaches or suggests this limitation. First, as explained above, the two sets of leaves are stacked “one above another” and are thus in different planes. Papanikolaou ¶78.

Second, Dai teaches an arrangement where “the first layer MLC contains 20 leaf pairs and . . . the second layer MLC contains 21 leaf pairs . . . .” Dai at 697. Thus, the first quantity is different from the second quantity. Papanikolaou ¶79.

Accordingly, Dai renders obvious claim 1.

2. Claim 2: The multileaf collimator of claim 1 wherein the first quantity is greater than the second quantity by one pair.

Dai teaches or suggests this limitation. As explained above, Dai teaches a first quantity of 21 pairs of leaves and a second quantity of 20 pairs of leaves, for a difference of one pair. *Id.* at 697. Thus, Dai renders obvious claim 2. Papanikolaou ¶81.

3. Claim 3: The multileaf collimator of claim 1 wherein each leaf in the first set is offset from a leaf in the second set by about half a leaf width in a direction generally traverse to the first and second directions.

Dai expressly teaches or suggests this limitation. Dai states that the "two layers of conventional MLCs [are] offset half [a] leaf width in the direction perpendicular to leaf movement so that interleaf transmission is minimized." *Id.* at cover page; *id.* at 697-98 (the "two layers are arranged one above another in the beam direction and [are] offset a half leaf width in a lateral direction"). This is further illustrated in Figures 1 and 2. The first and second sets of leaves move in and out in first and second directions generally parallel to each other (e.g., horizontally in the figures) and the leaves are offset in a generally traverse direction (*i.e.*, vertically in Figures 1 and 2). Papanikolaou ¶82.

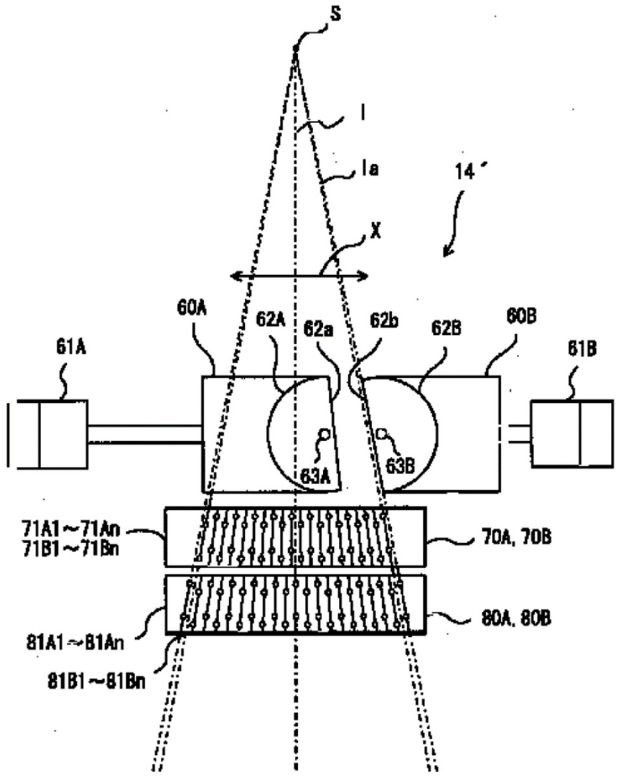
Thus, Dai renders obvious claim 3.

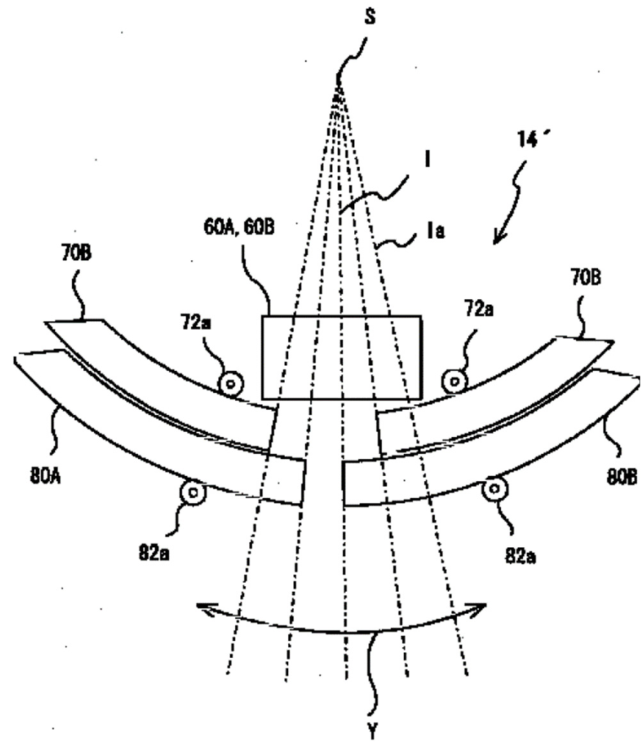
D. Ground 2: Claims 1-3 are unpatentable under 35 U.S.C. § 103 as obvious over Noguchi (Ex. 1014) alone or in view of Dai (Ex. 1009)

As explained below, Petitioner believes that Noguchi alone renders obvious claims 1-3. However, to the extent it could be argued that Noguchi does not expressly teach or suggest claim element 1[c] or claim 2, Dai expressly teaches this subject matter and it would have been obvious to PHOSITA to combine the teachings of the two references as described further below. Papanikolaou ¶84.

Noguchi:

Noguchi is a Japanese patent document entitled "Radiotherapy Apparatus and Diaphragm Apparatus for Setting Radiation Field." Exhibit 1014 (Noguchi). Noguchi Figures 1 and 2, reproduced below, illustrate a radiation source S, which radiates a beam about a radiation axis I towards a "diaphragm apparatus 14' [that] is configured from three layers of diaphragms 60, 70, 80 . . . [these diaphragms] are divided into pairs that move toward and away from each other relative to the radiation axis I." Noguchi, [0011].





The second "diaphragm" 70 includes two parts 70A and 70B. A third "diaphragm" 80 is arranged below the second diaphragm 70 and includes two parts 80A and 80B. *Id.* at [0017]. Noguchi describes these items as "multisegmented diaphragm apparatuses" that include "leaves" 71A1 to 71An, 71B1 to 71Bn, 81A1 to 81An, and 81B1 to 81Bn. *Id.* at [0017-18]. Diaphragms 70 and 80 thus constitute a double-stacked multileaf collimator. Papanikolaou ¶86.

Noguchi distinguishes its arrangement from the prior art, in part, by reducing or minimizing penumbra. *Id.* at [0006-10].

1. Claim 1: A multileaf collimator comprising:

To the extent the preamble may be considered a limitation, Noguchi teaches it. Noguchi includes a double-stacked multileaf collimator, as shown in Figures 1 and 2 including leaf banks 70 and 80. Papanikolaou ¶88.

a. [1a] a first set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the first set being disposed in an opposed relationship and longitudinally movable relative to each other in a first direction

Noguchi expressly teaches or suggests this limitation. Noguchi's set of leaves 70A and 70B include a plurality of leaves 71A1 to 71An that are opposed to corresponding leaves 71B1 to 71Bn. These pairs "move toward and away from each other relative to the radiation axis I." Noguchi, [0011, 17-19]; Figures 1, 2, 5-7. Thus, they are longitudinally movable relative to each other in a first direction. Papanikolaou ¶89.

Similarly, Noguchi's set of leaves 80A and 80B include a plurality of leaves 81A1 to 81An that are opposed to corresponding leaves 81B1 to 81Bn. These pairs "move toward and away from each other relative to the radiation axis I." Noguchi, [0011, 17-19]; Figures 1, 2, 5-7. Thus, they are longitudinally movable relative to each other in a first direction. Noguchi's set of leaves 80(A and B) meets this limitation. Papanikolaou ¶90.

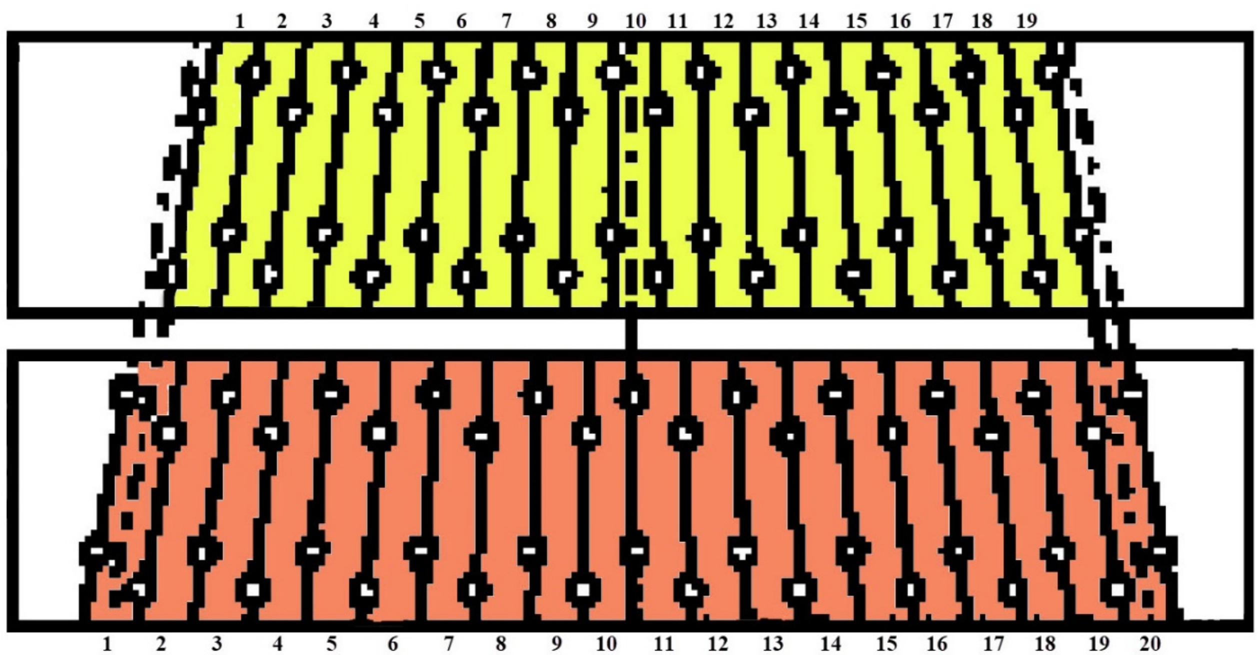
b. [1b] a second set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the second set being disposed in an opposed relationship and longitudinally movable relative to each other in a second direction generally parallel to the first direction;

Noguchi expressly teaches or suggests this limitation. The second set of leaves 70(A and B), as described above, meets this limitation. As can be seen in Figures 2 and 6, the sets 70 and 80 are stacked one above the other, and both have longitudinally movable leaves that move generally parallel to each other. *See also* Noguchi at [0017]; Papanikolaou ¶91. Because the leaves in each set move parallel to the leaves in the other set, the first and second direction requirements are met. Papanikolaou ¶91.

c. [1c] the first and second sets of pairs of leaves are disposed in different planes and the first set of pairs of leaves comprises a first quantity of pairs of leaves and the second set of pairs of leaves comprises a second quantity of pairs of leaves wherein the first quantity and the second quantity are different.

Noguchi expressly teaches or suggests this limitation. The diaphragm apparatus "is configured from three ***layers*** of diaphragms 60, 70, 80." *Id.* at [0011]. The two sets 70(A and B) and 80(A and B) of leaves are stacked "above and below" and are thus in different planes. *Id.* at [0023]. *See also,* Figures 1, 2 and 6.

While not expressly stated in Noguchi, the figures illustrate a different number of leaves in one set versus the other. In the enlarged and annotated excerpt from Figure 1, reproduced below, the 80(A and B) leaf set has a first quantity of 20 leaf pairs versus the 70(A and B) set which has a second quantity of 19 leaf pairs:



Papanikolaou ¶93.

Alternatively, if not considered disclosed or inherent in Noguchi, it would have been obvious to PHOSITA to have a different number of leaf pairs in one set versus a different set in a Noguchi-type double stack MLC. Papanikolaou ¶94. As described, the first set of leaves (80) is laterally offset from the second set of leaves (70). Noguchi, [0018, 0022]. This offset is provided so that "radiation leakage from gaps between adjacent leaves can be prevented . . .." *Id.* at [0023]. As was known in the art, gap leakage can be reduced by lining up leaves of the lower MLC to block gap leakage through leaves in the top MLC. Papanikolaou ¶94.

A natural result of having such an offset arrangement is that one layer will have a first quantity of pairs of leaves, and the other layer will have one less pair of leaves, so that each leaf in that layer lines up with the gap between two leaves in the other layer. Papanikolaou ¶95. This would provide a rationale for a PHOSITA to select a one leaf pair difference between the 70 set of leaves and the 80 set of leaves. *Id.*

Indeed, there are only two practical choices – have a one pair or no pair difference between the sets. If there is more than one pair difference, then there will be at least one gap between adjacent leaves in one set that is not blocked by a leaf pair in the other set; thus ***allowing for, as opposed to preventing,*** "radiation leakage from gaps between adjacent leaves." Papanikolaou ¶96. As such, since there is a finite number of identified, predictable solutions (two), it would have at least been obvious to try an arrangement with a one pair difference between the two layers of leaves in Noguchi. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 414-18 (2007) ("obvious to try"); Papanikolaou ¶96. A PHOSITA would also be motivated to reduce cost and complexity by eliminating one leaf pair in the system (including its associated drive motors, guides, etc.). Papanikolaou ¶96.

Alternative Theory: Noguchi in view of Dai:

To the extent one could argue that Noguchi alone does not teach or suggest claim limitation 1[c] it would have been obvious in view of Dai.

Specifically, it would have been obvious to PHOSITA to use a different number of leaves in each set of Noguchi. Papanikolaou ¶98. It was known to use one less pair of leaves in one set versus the other set in a double stack MLC arrangement. For example, Dai specifically teaches having a double stack arrangement, with half-leaf offset, having a one pair difference between levels (20 pairs vs. 21 pairs). Exhibit 1009 (Dai), Figures 1 & 2, pp. 696-698. It would have been obvious to a PHOSITA to use the one less leaf pair arrangement, as taught by Dai, in the MLC of the Noguchi system for, *e.g.,* reduced expense and industry standardization. Papanikolaou ¶98. Alternatively, such a combination would have been obvious under *KSR* as combining prior art elements according to known methods to yield predictable results; the mere simple substitution of one known element for another to obtain predictable results; and/or the use of a known technique to improve similar devices in the same way. *KSR*, 550 U.S. at 414-18.

Accordingly, claim 1 should be canceled for obviousness.

2. Claim 2: The multileaf collimator of claim 1 wherein the first quantity is greater than the second quantity by one pair.

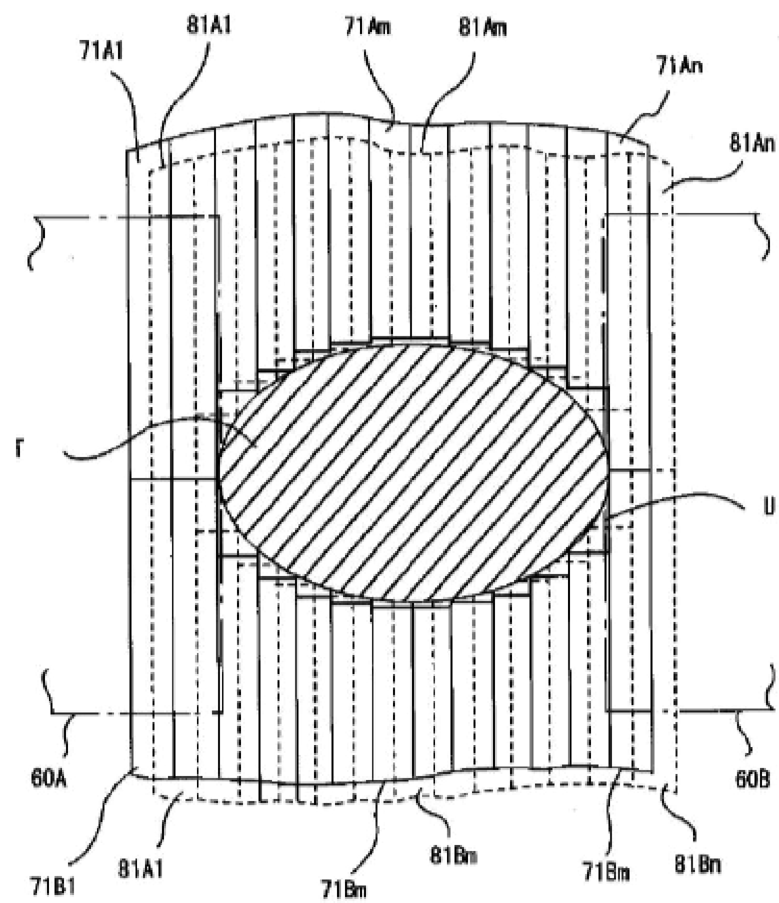
Noguchi alone or in view of Dai teaches or suggests this limitation. This limitation is met for the same reasons as discussed with respect to limitation 1[c] above, under both theories.

Thus, claim 2 should be canceled for obviousness.

3. Claim 3: The multileaf collimator of claim 1 wherein each leaf in the first set is offset from a leaf in the second set by about half a leaf width in a direction generally traverse to the first and second directions.

Noguchi expressly teaches or suggests this limitation. For example, as shown in Noguchi Fig. 6, reproduced below, one set of leaves (70) is laterally offset by about a half leaf width from the other set of leaves (80). *Id.* at [0018, 22-23]. Papanikolaou ¶102.

[FIG. 6]



While Noguchi may not expressly state that the offset is "about half a leaf width," it can be seen in Fig. 6. Moreover, Noguchi teaches that because "the second and third diaphragms 70 and 80 are disposed above and below with the leaf positions shifted in this matter, a thickness of the leaves can be formed to be twice the conventional thickness, enabling precise manufacturing of the leaves without problems of warping or the like." *Id.* at [0023]. This is obtained by using an "about a half a leaf width" offset. Papanikolaou ¶103.

Alternative Theory: Noguchi in view of Dai:

To the extent that one could argue that Noguchi alone does not teach or suggest claim 3 it would have been obvious in view of Dai.

To the extent a PHOSITA would not know or appreciate that Noguchi is using "about half a leaf width" offset, they would have been motivated to consider the appropriate amount of offset to achieve Noguchi's purpose of minimizing or preventing interleaf transmission. Dai teaches that in conventional MLC systems, the "two layers of conventional MLCs offset a half leaf width in the direction perpendicular to leaf movement so that interleaf transmission [*i.e.,* "radiation leakage from gaps between adjacent leaves" as mentioned in Noguchi] is minimized. Dai, p. 696. Papanikolaou ¶105.

Thus, a PHOSITA would thus have considered Dai and used its teaching of a half leaf width offset to achieve this objective. Papanikolaou ¶106.

Alternatively, such a combination would have been obvious under *KSR* as combining prior art elements according to known methods to yield predictable results; the mere simple substitution of one known element for another to obtain predictable results; and/or the use of a known technique to improve similar devices in the same way. *KSR*, 550 U.S. at 414-18.

Thus, claim 3 should be canceled for obviousness in view of Noguchi alone or Noguchi in view of Dai.

E. Ground 3: Claims 5-8, 10, 13, 14 are unpatentable under 35 U.S.C. § 103 as obvious over Noguchi (Ex. 1014) alone or in view of Dai (Ex 1009), Schlegel (Ex. 1011) and Klassen (Ex. 1008)

1. Claim 5: The multileaf collimator of claim 1 wherein the leaves in the first and second sets substantially focus on a converging virtual point located substantially at a radiation source.

Noguchi alone expressly teaches or suggests this limitation. Noguchi states that "each leaf . . . has a flat face formed in a fan shape that ***converges toward the radiation source S.***" *Id.* at [0018]. This description means the leaves substantially focus on a virtual point substantially at the radiation source. *See* Papanikolaou ¶108 and explanation of focusing in Background (Section IV.C, *supra*). As such, the claim limitation is met by Noguchi.

Alternative Theory: Noguchi in view of Dai, Schlegel, and Klassen:

To the extent it could be argued that a PHOSITA would not appreciate that

Noguchi teaches this subject matter, a PHOSITA would have understood from Schlegel and Klassen that Noguchi's description of leaf faces converging towards the source means focusing in the claimed manner. *See,* Background (Section IV.C, *supra*); Schlegel, p. 262 ("In an MLC, in order to produce a small penumbra, the edges of the leaves must always be directed toward the source . . . ***this property is called focusing***."). These secondary references are used to demonstrate what is inherent or described in Noguchi. *See, e.g., Realtime Data, LLC v. Iancu,* 912 F.3d 1368, 1372-74 (Fed. Cir. 2019) (affirming PTAB finding of obviousness where secondary reference was used to explain what was inherent or described in primary reference). In any event, a PHOSITA would have been motivated to consider Schlegel and to appreciate the reasons and benefits of convergence as taught by Noguchi. Papanikolaou ¶109. Thus, claim 5 should be canceled for obviousness.

2. Claim 6

Claim 6 of the '520 Patent reads as follows:

[6pre] A multileaf collimator comprising:

[6a] a first set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the first set being disposed in an opposed relationship and longitudinally movable relative to each other in a first direction; and

[6b] a second set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the second set being disposed in an opposed relationship and longitudinally movable

relative to each other in a second direction generally parallel to the first direction; wherein

[6c] the leaves of the first set are disposed in a first level providing first projected widths at an isocenter plane, and the leaves of the second set are disposed in a second level providing, at the isocenter plane, second projected widths that are substantially same as the corresponding first projected widths; and

[6d] the leaves in the first level are arranged offset from the leaves in the second level in a direction generally traverse to the first and second directions such that one of the first projected widths offsets about half of corresponding one of the second projected widths at the isocenter.

a. 6 [pre]: A multileaf collimator comprising:

To the extent the preamble may be considered a limitation, Noguchi teaches it. Noguchi includes a double stacked multileaf collimator, as shown in Figures 1 and 2, including leaf banks 70 and 80. Papanikolaou ¶110.

b. [6a] a first set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the first set being disposed in an opposed relationship and longitudinally movable relative to each other in a first direction;

This limitation is identical to 1[a] and is thus expressly taught or suggested by Noguchi for the same reasons as described above in connection with 1[a]. Papanikolaou ¶111.

c. [6b] a second set of a plurality of pairs of beam blocking leaves arranged adjacent one another, leaves of each pair in the second set being disposed in an opposed relationship and longitudinally movable relative to each other in a second direction generally parallel to the first direction;

This limitation is identical to 1[b] and is thus expressly taught or suggested by Noguchi for the same reasons as described above in connection with 1[b]. Papanikolaou ¶112.

d. [6c] the leaves of the first set are disposed in a first level providing first projected widths at an isocenter plane, and the leaves of the second set are disposed in a second level providing, at the isocenter plane, second projected widths that are substantially same as the corresponding first projected widths;

Noguchi teaches or suggests this limitation.

First, the leaves of the first set are disposed in a first level and the leaves of the second set are disposed in a second level. In Noguchi, the diaphragm apparatus "is configured from three ***layers*** of diaphragms 60, 70, 80." *Id.* at [0011]. The two sets 70(A and B) and 80(A and B) of leaves are stacked "above and below" and are thus in different planes or levels. *Id.* at [0023]. *See also,* Figures 1, 2 and 6. Papanikolaou ¶114.

Second, the Noguchi system's two sets of leaves 70(A and B) and 80(A and B) are ***focused.*** Papanikolaou ¶115. Noguchi states that "each leaf . . . has a flat face formed in a fan shape that ***converges toward the radiation source S.***"

Noguchi at [0018]. As explained in the Background Section IV.C.2 above, leaves with faces that converge toward the radiation source are referred to as focused. *See also,* Schlegel, p. 262 ("In an MLC, in order to produce a small penumbra, the edges of the leaves must always be directed toward the source . . . this property is called focusing"); Papanikolaou ¶115. As discussed above in the Background, a double stack, focused MLC like Noguchi's will <u>inherently</u> have leaves in the upper layer and the lower layer exhibiting the same projected width. The inherent nature of this feature is fully described above in Background Section IV.C.3. and is further supported by Ex. 1008 (Klassen) at 7:38-44, which notes that the "thickness [of the leaves]…is selected in such a manner that their central projection…to a plane perpendicular to the beam [i.e., their projected width at the isocenter]…is of the same size." Papanikolaou ¶115.

As further explained in the Background section, a PHOSITA understands that a leaf will have a "physical" width and a "projected width." Background (Section IV.C, *supra*); Papanikolaou ¶116. That is, depending how far the leaf is from the radiation source and from the isocenter, the projected width will vary from the physical width of the leaf. As an analogy, one can consider holding a wood plank of a given physical width below an overhead lamp, which will form a shadow of the plank on the floor. Depending on how far the plank is the from the lamp and from the floor, the shadow's width will vary from the physical width of the plank. Papanikolaou ¶116.

Generally, in the literature and in the art, when MLC leaf width is discussed, and no mention is made of whether it is the physical or projected width, the reference is typically presumed to be the projected width. Papanikolaou ¶117. There are various reasons for this, one of which is that a PHOSITA cares primarily about the projected width at isocenter because the patient is at isocenter – and the dimensions/resolution of the beam at the location of the patient's tumor is what matters. The beam resolution at the patient, determined by the projected width of the MLC leaves, is what is utilized to program the dose that will be delivered. Papanikolaou ¶117.

Noguchi states, in two different embodiments, that the width of the leaves in both sets 70 and 80 are identical by referring to them, in the singular, as having "***a*** ***or "the"*** thickness:

(a) "***a thickness*** of the leaves can be formed to be ***twice the conventional thickness***, enabling precise manufacturing of the leaves without problems of warping or the like. Moreover, although the number of leaves per diaphragm 70, 80 is halved by doubling the leaf thickness to twice the conventional thickness . . . a total leaf count is unchanged from the conventional leaf count." *Id.* at [0023]

(b) "Moreover, if ***the thickness*** of each leaf of the second and third diaphragms 70 and 80 is kept ***identical to the conventional thickness***, the total leaf count becomes double the conventional leaf count…" *Id.*

In each embodiment, a single width is mentioned ("a thickness," "the conventional thickness," and "the thickness") for both levels of the MLC. A PHOSITA reading these passages would understand that Noguchi is referring to the projected width, not the physical width. Papanikolaou ¶119.

Thus, Noguchi teaches that the projected widths (from the first and second of leaf sets) are substantially the same. This would require all leaves at the same level to have the same physical width. Papanikolaou ¶120. This is consistent with the expectation in the art. For example, 6 of the 8 Commercial Integrated MLCs listed in Schlegel had identical projected widths for each leaf. Schlegel, p. 259, Tbl. 20.2

Alternative Theory: Noguchi in view of Dai, Schlegel, and Klassen:

To the extent, that it could be argued that Noguchi alone does not meet all the requirements of 6[c], it would have been obvious in view of Schlegel and Klassen.

For example, because Noguchi is concerned with reducing penumbra, a PHOSITA would have been motivated to consider Schlegel and/or Klassen's teachings of improving focusing (and thus reducing penumbra), as such teachings are directed to the same field of endeavor and problem to be solved.

In particular, Schlegel teaches that in "an MLC, in order to produce small penumbra, the edge of the leaves must always be directed to the source . . . this property is called focusing." Exhibit 1011 (Schlegel), p.262. This is consistent with Noguchi's own teachings as explained above. Schlegel further teaches that good "focusing properties are reached by trapezoidal leaf cross-sections." *Id.* Moreover, Klassen specifically teaches that in such a system, the upper and lower leaves must have different physical widths, but should be selected so that the projected widths are identical. Exhibit 1008 (Klassen), 7:38-44. Thus, PHOSITA would understand that in a focused double stack system, such as Noguchi, it would be beneficial to have thinner trapezoidal leaves in one stack versus thicker trapezoidal leaves in the other stack so as to provide good focusing and identical projected widths at isocenter. Papanikolaou ¶123.

e. [6d] the leaves in the first level are arranged offset from the leaves in the second level in a direction generally traverse to the first and second directions such that one of the first projected widths offsets about half of corresponding one of the second projected widths at the isocenter.

Noguchi expressly teaches or suggests this limitation.

For example, as shown in Noguchi Fig. 6, the first set of leaves (80) is laterally offset by about a half leaf width from the second set of leaves (70). *Id.* at [0018, 22-23]. Papanikolaou ¶125. This is in a direction generally traverse to the first and second directions, as can be seen from the figures and description.

Papanikolaou ¶125.

While Noguchi does not expressly state that the offset is "about half a leaf width," it can be seen in Fig. 6. Papanikolaou ¶126. Moreover, Noguchi teaches that because "the second and third diaphragms 70 and 80 are disposed above and below with the leaf positions shifted in this matter, a thickness of the leaves can be formed to be twice the conventional thickness, enabling precise manufacturing of the leaves without problems of warping or the like." Noguchi at [0023]. This is obtained by using an "about a half a leaf width" offset. Papanikolaou ¶126.

As a result of the offset described above, and because the Noguchi system is focused, one of the first projected widths offsets about half of a corresponding one of the second projected widths at the isocenter. When the leaves are physically offset half a leaf width, the projections will similarly be offset half a projected width at isocenter. Papanikolaou ¶127.

Alternative Theory: Noguchi in view of Dai, Schlegel, and Klassen:

To the extent it could be argued that Noguchi alone does not meet 6[d], it would have been obvious in view of Dai. In particular, to the extent it could be argued that a PHOSITA would not know or appreciate that Noguchi is using "about half a leaf width" offset, they would have been motivated to consider the appropriate amount of offset to achieve Noguchi's purpose of minimizing or preventing interleaf transmission. A PHOSITA would thus have considered Dai and used its teaching of a half width offset to achieve this objective. Papanikolaou ¶128. Alternatively, such a combination would have been obvious under *KSR* as combining prior art elements according to known methods to yield predictable results; the mere simple substitution of one known element for another to obtain predictable results; and/or the use of a known technique to improve similar devices in the same way. *KSR*, 550 U.S. at 414-18.

Thus, claim 6 should be canceled for obviousness.

3. Claim 7: The multileaf collimator of claim 6 wherein the leaves in the first and second sets substantially focus on a converging virtual point located substantially at a radiation source.

Noguchi alone or in view of Dai, Schlegel and Klassen expressly teaches or suggests this limitation for the same reasons explained in connection with claim 5 above, under both theories. Papanikolaou ¶130.

Thus, claim 7 should be canceled for obviousness.

4. Claim 8: The multileaf collimator of claim 6 wherein the first projected widths at the isocenter plane are substantially identical and the second projected widths at the isocenter plane are substantially identical.

Noguchi alone or in view of Dai, Schlegel and Klassen expressly teaches or suggests this limitation for the same reasons explained in connection with claim 6[c] above, under both theories. Papanikolaou ¶132.

Thus, claim 8 should be canceled for obviousness.

5. Claim 10: The multileaf collimator of claim 6 wherein a quantity of the leaves in the first set is different from a quantity of the leaves in the second set.

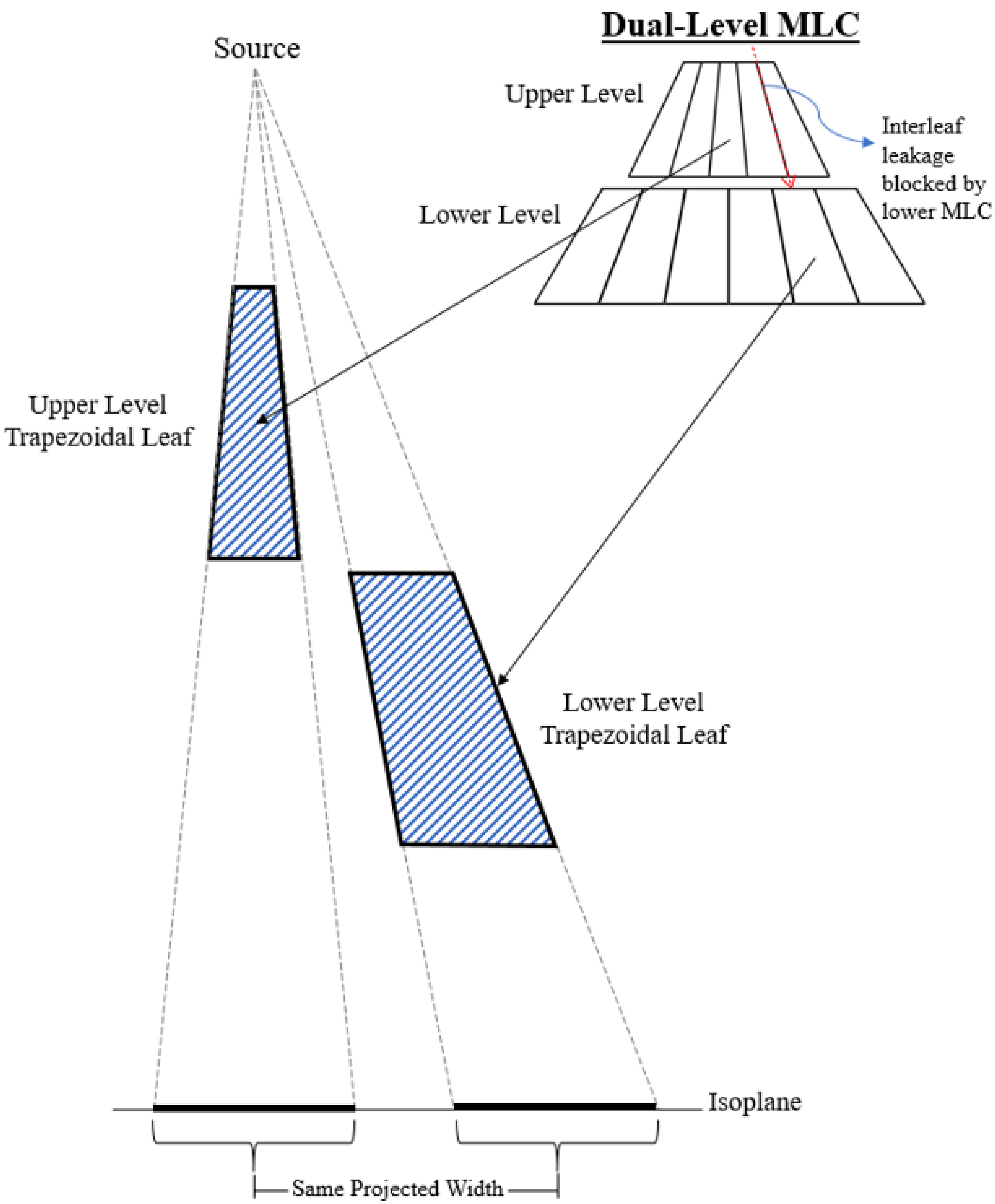
Noguchi alone or in view of Dai expressly teaches or suggests this limitation for the same reasons explained in connection with claim 1[c] above, under both theories. Papanikolaou ¶134.

Thus, claim 10 should be canceled for obviousness

6. Claim 13: The multileaf collimator of claim 6 wherein the leaves in the first and second sets have a substantially trapezoidal cross section where the parallel sides of the trapezoidal cross-section have different dimensions.

Noguchi alone or in view of Dai, Schlegel and Klassen expressly teaches or suggests this limitation.

This limitation is met for the reasons and disclosure described above with respect to 6[c]. Papanikolaou ¶137. In particular, based on the focusing arrangement of Noguchi, alone or in view of the other teachings, the leaves will have trapezoidal cross sections with different top and bottom dimensions (the tops and bottoms are the parallel sides). Papanikolaou ¶137. As described above, the Noguchi MLC is focused and the leaves in Figure 1 of Noguchi are trapezoidal. The parallel sides of the trapezoids inherently have different dimensions because the leaves become wider further from the radiation source in the double stack focused design. Papanikolaou ¶137; *see* Background Section IV.C.3 and the figure reproduced below:



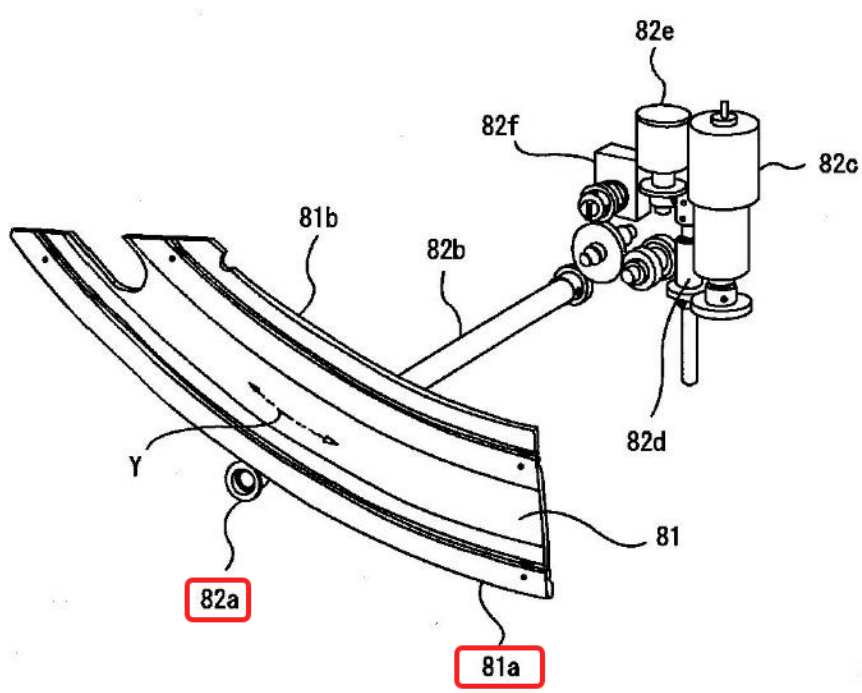
Thus, claim 13 should be canceled for obviousness.

7. Claim 14: The multileaf collimator of claim 6 wherein at least some of the leaves of the first set have an end portion having an upward and/or downward extended portion.

Noguchi alone or in view of Dai, Schlegel and Klassen expressly teaches or suggests this limitation under the construction taken by the Patent Owner. Specifically, as described above, under Patent Owner's construction the end portion may be the leading-edge portion, the top edge portion, or the bottom edge portion of the leaf. Ex. 1020 (Excerpts from Varian's Amended '520 Patent Infringement Contentions). In its infringement contentions, Patent Owner has taken the position that a guiding edge on the top of the leaf meets this claim. *Id.* at 169-176.

Under that construction, Noguchi teaches or suggests this subject matter as Noguchi describes (in connection with Fig. 5, reproduced below) that, "<u>teeth</u> are cut in a curved outer end portion 81a [of leaf 81]. A drive gear 82a meshes with these teeth on the leaf. *Id.* at [0019]. Papanikolaou ¶140.

[FIG. 5]



Under the Patent Owner's construction, the curved outer end portion with these teeth would meet the claim requirement of an end portion having an upward and/or downward extended portion. Papanikolaou ¶141. Note also that the '520 Patent at 7:47 refers to this claim limitation as "<u>tooth</u> portions or projections."

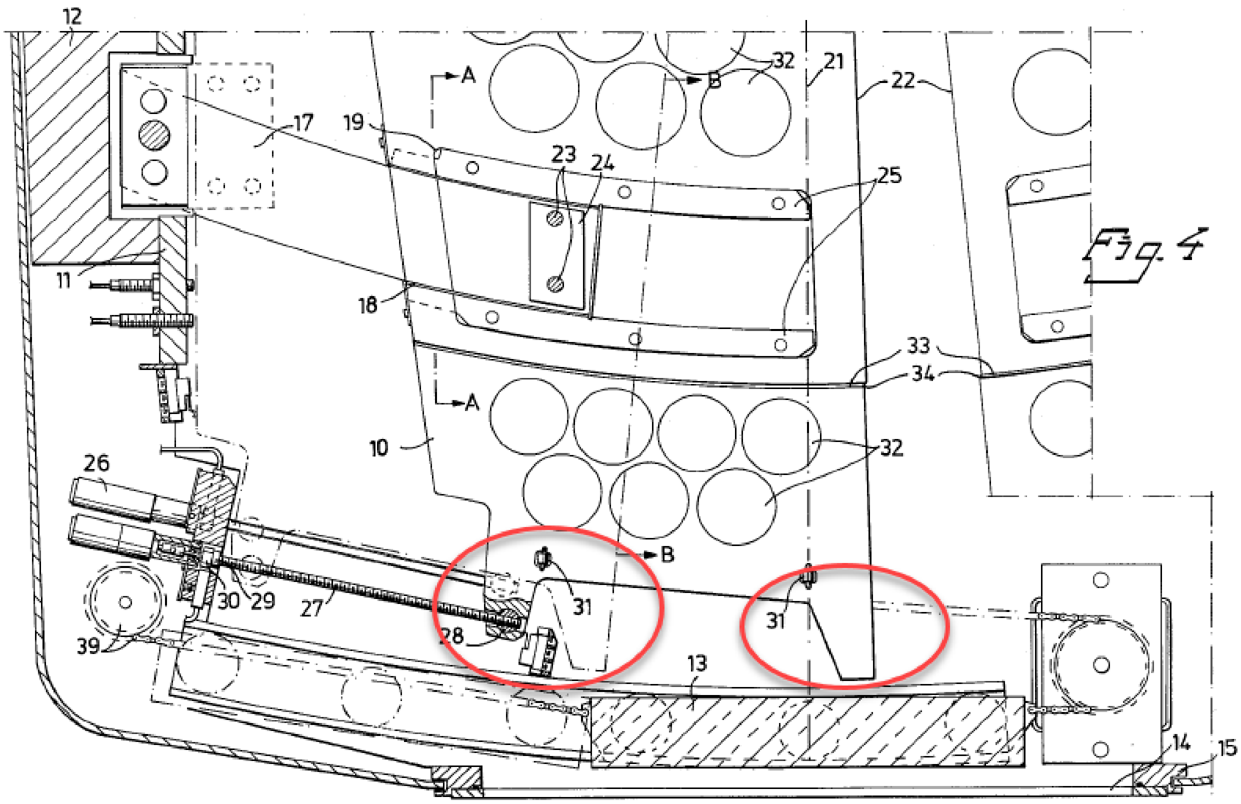
Thus, claim 14 should be canceled for obviousness.

F. Ground 4: Claim 14 is unpatentable under 35 U.S.C. § 103 as obvious over Noguchi (Ex. 1014) in view of Noguchi '492 (Ex. 1021) and Brahme (Ex. 1007), or in the alternative, in further view of Dai (Ex. 1009), Schlegel (Ex. 1011), and Klassen (Ex. 1008)

1. Claim 14: The multileaf collimator of claim 6 wherein at least some of the leaves of the first set have an end portion having an upward and/or downward extended portion.

Noguchi in view of Noguchi '492 and Brahme, or in the alternative, in further view of Dai, Schlegel and Klassen expressly teaches or suggests this limitation under either Patent Owners' or Petitioner's claim construction.

It would have been obvious to modify Noguchi in view of Noguchi '492 and Brahme to include a mechanical stop system as shown in Brahme Fig. 4:

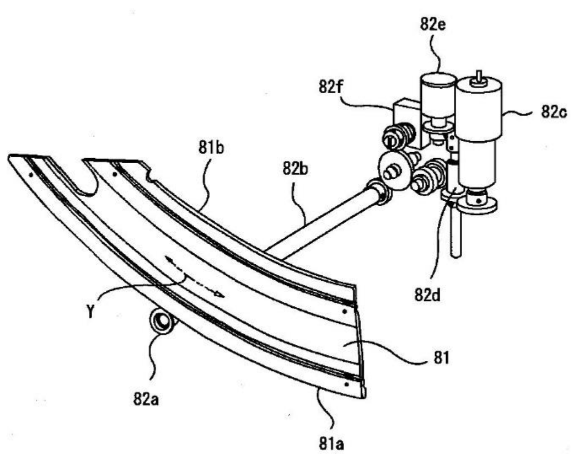


Noguchi recognizes the need to have a means to control the forward and backward motion of each leaf, and proposes a system including a potentiometer and encoder and using rotation detection to control the operation. Noguchi, [0019]. However, it fails to teach the use of a mechanical limit element to limit the longitudinal movement to open and close the leaf. Yet, as explained by Noguchi '492, a Noguchi-type system requires such a mechanical limit. Papanikolaou ¶145.

Noguchi '492 is a later patent application publication by the same inventor as Noguchi. Noguchi '492 describes improvements over the earlier Noguchi-type system. Because Noguchi '492 is closely related to the same field and technology as Noguchi and it provides additional details regarding the operation of a Noguchi-type system a PHOSITA would have been motivated to consider its teachings. Papanikolaou ¶146; *see also, Realtime,* 912 F.3d at 1372-74 (affirming PTAB finding of obviousness where secondary reference was used to explain what was inherent or described in primary reference).

Noguchi '492 describes the inclusion of a slot L in the leaf to allow for a support member 144 to be placed therein. *See*, Fig. 6 of Noguchi '492, reproduced below. This figure illustrates an MLC leaf and associated drive arrangement that is nearly identical to the arrangement shown in Fig. 5 of Noguchi (reproduced below). Papanikolaou ¶147. The key difference is the inclusion of the slot L and support member 144. Noguchi '492 states that under this arrangement "both the ends in the direction of length of the elongated hole L serve as mechanical limits in the directions to open or close the diaphragm [leaf]. As the result, the diaphragm element 141Ak (141 Bk) is not required to have any additional form adapted for mechanical limits, allowing the form of the diaphragm element to be simplified and the count of parts to be reduced." Noguchi '492 at [0053]. Papanikolaou ¶147

[FIG. 5]



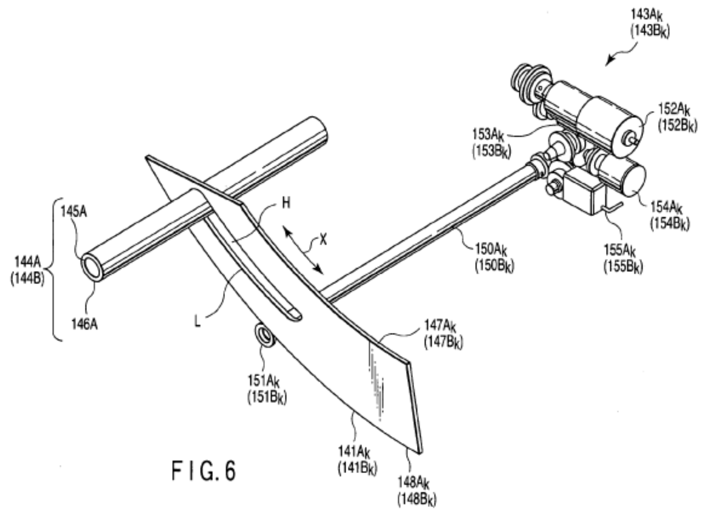


Figure 5 of Noguchi

Figure 6 of Noguchi '492

Based on the foregoing, a PHOSITA would understand that a Noguchi-type system must have a mechanical limit (if the new slot and support member of Noguchi '492 are not adopted). However, Noguchi does not describe such an arrangement. Papanikolaou ¶148. Accordingly, a PHOSITA would have been motivated to find a suitable mechanical limit to use in Noguchi and would have found it obvious to use the mechanical limit shown in Fig. 4 of Brahme. This includes an extended portion (shown in red in Brahme Fig. 4 reproduced above) at the end portion of the leaf. This would easily work with the teeth and gear system of Noguchi as it would block undue retraction. Papanikolaou ¶148. The suggested combination would thus include at least some of the leaves of the first set having an end portion having an upward and/or downward extended portion, as claimed.

Thus, claim 14 should be canceled for obviousness.

VII. CONCLUSION

Claims 1-3, 5-8, 10, 13, 14 are unpatentable and should be cancelled.

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Dated: July 7, 2020

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. 42.24, I hereby certify that the "**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,082,520 B2**" contains 10,025 words, not including a table of contents, table of authorities, mandatory notices under § 42.8, certificate of service or word count, or appendix of exhibits or claim listing, as counted by the word-processing system used to prepare the paper.

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CERTIFICATE OF SERVICE

I, hereby certify that a true copy of the "**PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,082,520 B2**" and supporting materials (Exhibits 1001-1012, 1014-1021 and Power of Attorney) have been served in their entirety this 7th day of July, 2020 by PRIORITY MAIL EXPRESS™ on Patent Owner at the correspondence address for the attorney [or agent] of record for the '520 Patent shown in USPTO PAIR:

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