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TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVELAND, OH 44114

EXAMINER	
IP, JASON M	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL A. PICOT, MICHAEL M. THORNTON, and DAVID A. STEINBERG

Appeal 2019-007019
Application 13/321,836
Technology Center 3700

Before DANIEL S. SONG, BRETT C. MARTIN, and MICHELLE R. OSINSKI, *Administrative Patent Judges*.

OSINSKI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1, 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, 70, and 71, which are all of the pending claims. We have jurisdiction over the appeal under 35 U.S.C. § 6(b). A telephonic oral hearing was held September 15, 2020.[2]

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[1] We use the term "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies ENDRA LIFE SCIENCES INC., as the real party in interests. Appeal Br. 2.

[2] The record includes a transcript of the oral hearing (hereinafter "Tr.").

We AFFIRM.

THE CLAIMED SUBJECT MATTER

Claims 1 and 37 are independent. Claim 1 is reproduced below.

1. A method for analyzing soft tissue or vasculature of a subject, comprising:

(a) coupling an ultrasound transducer to the subject;

(b) delivering to the subject a contrast agent having one of (i) an increased dielectric absorption that is 1.5-fold to 100-fold greater than the dielectric absorption of the soft tissue or vasculature, (ii) a decreased dielectric absorption that is 1.5-fold to 100-fold less than the dielectric absorption of the soft tissue or vasculature, (iii) an increased ionic conductivity that is 1.5-fold to 100-fold greater than the ionic conductivity of the soft tissue or vasculature, and (iv) a decreased ionic conductivity that is 1.5-fold to 100-fold less than the ionic conductivity of the soft tissue or vasculature, the delivered contrast agent changing the conductivity or permittivity of the soft tissue or vasculature and as a result changing the radiofrequency or microwave energy absorption rate of the soft tissue or vasculature, and the delivered contrast agent being selected from the group consisting of: a hyperionic solution; a hypo-ionic solution; an isotonic solution; a hypertonic solution; a non-ionic solution; an isotonic solution; de-ionized osmolarity-balanced water; a solution containing safflower oil; an aqueous solution containing mannitol, dextrose, or glycerol; isotonic saline; hypertonic saline; hypotonic saline; physiologic saline; a suspension or colloids that comprise enzyme-modified fats, maltoextran, malt extract, com sugar, corn syrup, safflower oil, glycerol, lipids, oils and/or blood substitutes;

(c) irradiating the soft tissue or vasculature with modulated radiofrequency or microwave electromagnetic energy pulses to cause the soft tissue or vasculature to generate a thermoacoustic signal, the pulses having a pulse width in the range of 1 nanosecond to 10 microseconds;

(d) detecting the thermoacoustic signal using the ultrasound transducer; and

(e) processing the detected thermoacoustic signal to generate a series of images based on the concentration of the contrast agent in the soft tissue or vasculature over time.

EVIDENCE

The Examiner relied on the following evidence in rejecting the claims on appeal:

MacKenzie	US 6,403,944 B1	June 11, 2002
Cerofolini	US 6,572,548 B2	June 3, 2003
Van Zijl et al.	US 2004/0030239 A1	Feb. 12, 2004
Beard	US 2005/0150309 A1	July 14, 2005
Filkins	US 2007/0015992 A1	Jan. 18, 2007
Kalafut	US 2007/0276327 A1	Nov. 29, 2007

Kruger, Robert A. et al., *Breast Cancer in Vivo: Contrast Enhancement with Thermoacoustic CT at 434 MHz—Feasibility Study*, Radiology Vol. 216, No. 1, 279–83 (2000) (hereinafter "Kruger")

Jin, Xing et al., *Iron-oxide nanoparticles as a contrast agent in thermoacoustic tomography*, Proceedings of SPIE, Vol. 6437, Photons Plus Ultrasound: Imaging and Sensing 2007, (2007) (hereinafter "Jin")

REJECTIONS[3]

I. Claims 1, 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, and 70 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Filkins, Kalafut, and Jin. Final Act. 10–14.

[3] A rejection of claims 1, 4–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, 70, and 71 under 35 U.S.C. § 112 (pre-AIA), first paragraph as failing to comply with the written description requirement (Final Act. 10) is withdrawn and is not before us on appeal (Ans. 10–11).

II. Claims 11, 12, 16, 17, and 46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Filkins, Kalafut, Jin, and Beard. *Id.* at 14–15.

III. Claim 45 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Filkins, Kalafut, Jin, and Cerofolini. *Id.* at 15–16.

IV. Claim 47 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Filkins, Kalafut, Jin, and Kruger. *Id.* at 16.

V. Claims 48 and 49 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Filkins, Kalafut, Jin, and MacKenzie. *Id.* at 16–17.

VI. Claim 71 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Filkins, Kalafut, Jin, and Van Zijl. *Id.* at 17.

OPINION

Rejection I

Appellant argues claims 1, 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, and 70 as a group. Appeal Br. 11–22. We select claim 1 as the representative claim, and claims 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, and 70 stand or fall therewith. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Filkins teaches most of the limitations of independent claim 1, including, among other things, the steps of: (1) delivering to the subject a contrast agent; (2) irradiating the soft tissue or vasculature of a subject with energy to cause the soft tissue or vasculature to generate a thermoacoustic signal; (3) detecting the thermoacoustic signal using an ultrasound transducer coupled to the subject; and (4) processing the

detected thermoacoustic signal to generate a series of images based on a concentration of the contrast agent in the soft tissue or vasculature over time. Final Act. 11 (citing Filkins ¶¶ 28, 48, and Abstract).

More specifically, the Examiner points to the disclosure in Filkins that "metal nano-particles may . . . be used as contrast agents." Ans. 15 (citing Filkins ¶ 49). The Examiner also points to the disclosure in Filkins that "the source of stimulation may be radiofrequency or microwaves." *Id.* (citing Filkins ¶ 28). Although the Examiner acknowledges that the disclosure relating to RF and microwave radiation in Filkins is brief, the Examiner takes the position that "Filkins is explicitly teaching that the imaging may also be thermoacoustic, not just optoacoustic." *Id.* at 15–16; *see also* Tr. 4:9–13 ("As understood by persons having ordinary skill in the art, when the application source uses RF or microwave excitation, this is referred to as 'thermoacoustic imaging.' When the excitation source uses light, such as infrared, near-infrared, visible, and ultraviolet, this is referred to as 'photoacoustic imaging' or 'optoacoustic imaging.'"). The Examiner further finds that "[t]he metal nano-particles mentioned by Filkins would clearly draw contrast to a microwave-based stimulation of the tissue." Ans. 16; *see also* Tr. 7:20–8:25 (Appellant explaining that metal nano-particles would "absolutely" change the electromagnetic energy absorption of tissue, albeit via changes in permeability, not necessarily via changes in permittivity or conductivity) and Filkins ¶ 50 ("[C]ontrast agents may be used to create or enhance selective absorption of radiation in biological specimens such as healthy or diseased organs and facilitate acoustic wave generation.").

The Examiner acknowledges that "Filkins does not explicitly disclose that the contrast agent *changes the permittivity of the soft tissue and as a*

result changes the radiofrequency or microwave energy absorption rate of the soft tissue." Final Act. 11 (emphasis added). The Examiner instead finds that "Kalafut teaches that contrast agents can have an appreciable complex permittivity difference from tissue and that permittivity can govern how an electromagnetic wave will propagate through a substance such as subcutaneous tissue." *Id.* (citing Kalafut ¶ 36). The Examiner concludes that it would have been obvious "to apply the radiation as taught by Filkins, as to provide a wide range of electromagnetic frequencies, and the contrast agent of Kalafut to the system of Filkins, [so] as to provide agents which alter tissue in known ways." *Id.*

The Examiner further explains that "Kalafut provides information on how contrast agents work when used in tissue, and specifically, how the property of permittivity of a contrast agent compares to the tissue in which it resides and how propagation of an electromagnetic wave would be affected." Final Act. 9. The Examiner additionally explains that "[t]he claim limitation in question recites a relationship between permittivity and energy absorption," and "[a] contrast agent which bears an 'appreciable complex permittivity difference from tissue' as taught by Kalafut, is a contrast agent which may be used in the system of Filkins." *Id.*

The Examiner acknowledges that neither Filkins nor Kalafut explicitly discloses a contrast agent specifically having one of: (i) an increased dielectric absorption that is 1.5-fold to 100-fold greater than the dielectric absorption of the soft tissue or vasculature; (ii) a decreased dielectric absorption that is 1.5-fold to 100-fold less than the dielectric absorption of the soft tissue or vasculature; (iii) an increased ionic conductivity that is 1.5-fold to 100-fold greater than the ionic conductivity of the soft tissue or

vasculature; and (iv) a decreased ionic conductivity that is 1.5-fold to 100-fold less than the ionic conductivity of the soft tissue or vasculature, and being selected from the group consisting of: a hyperionic solution; a hypo-ionic solution; an isotonic solution; a hypertonic solution; a non-ionic solution; an isotonic solution; de-ionized osmolarity-balanced water; a solution containing safflower oil; an aqueous solution containing mannitol, dextrose, or glycerol; isotonic saline; hypertonic saline; hypotonic saline; physiologic saline; a suspension or colloids that comprise enzyme-modified fats, maltoextran, malt extract, com sugar, corn syrup, safflower oil, glycerol, lipids, oils and/or blood substitutes. Final Act. 11–12. The Examiner instead finds that "Jin teaches a contrast agent with dielectric properties which would produce contrast in a thermoacoustic image . . . and that a contrast agent is diluted with water." *Id.* at 12 (citing Jin, 4–6, Fig. 3). The Examiner concludes that it would have been obvious "to apply the contrast agent of Jin to the systems of Filkins and Kalafut, as to provide exogenous contrast to a thermoacoustic image." *Id.*

Appellant argues that "Filkins does NOT relate to thermoacoustic imaging." Appeal Br. 15 (emphasis omitted). Appellant argues that "Filkins actually describes photoacoustic imaging." *Id.* at 16; *see also id.* at 17 ("Filkins simply does not enable thermoacoustic imaging and this is highlighted by the fact that Filkins does not mention or hint at conductivity or permittivity as parameters for gauging image effectiveness or contrast. The imaging modalities of photoacoustics/optoacoustics as taught by Filkins and thermoacoustics as described and claimed in the subject patent application are substantially different."). Appellant argues that the "reliance upon Filkins to reject independent claim 1 (and similarly independent claim

37) is improper as Filkins in no way relates to thermoacoustic imaging." *Id.* at 18.

Appellant's Specification describes that "[t]hermoacoustic imaging uses short pulses of electromagnetic energy to heat absorbing features within an object rapidly, which in turn induces an acoustic pressure wave that can be detected using acoustic receivers. These acoustic waves are analyzed through signal processing, and further processed for presentation and interpretation by an operator." Spec. 1:19–23. Appellant's Specification further states that "[t]hermoacoustic imaging, a general term encompassing photoacoustic, optoacoustic, and photothermoacoustic imaging, is a field of technology used in characterizing and imaging materials based on their electromagnetic absorption and thermal properties." Spec. 9:1–4.

Filkins similarly describes that "[o]ptoacoustic imaging techniques typically use electromagnetic signals to generate acoustic waves from an object of interest, which is then measured and processed to retrieve information about the object imaged." Filkins ¶ 2; *see also id.* ¶ 23 ("Optoacoustic imaging techniques typically uses an electromagnetic excitation signal, which is directed at an object. Absorption of radiation by the object results in heat output, leading to a rise in temperature locally, causing thermal expansion. The thermal expansion leads to the generation of pressure waves or acoustic waves, which propagate outward from the source of the heating. The acoustic wave generated is both a function of the material properties of the object, as well as the wavelength optical signal used to generate the acoustic wave. A receiver detects the time, magnitude and shape of the received acoustic waves, which are then measured and processed to retrieve information on the structural and compositional

features of the object."). Filkins explicitly references "electromagnetic radiation wavelengths [that] may fall in the radio frequency region, microwave region . . . of the electromagnetic spectrum." *Id.* ¶ 28. The Examiner states that "both thermoacoustic and photoacoustic measurements stem from the same principle of detecting acoustic pressure waves that are generated by stimulating an object with an electromagnetic wave" and "[t]he electromagnetic wave may be in the microwave region or other visible/non-visible portion of the electromagnetic spectrum and this is known in the art." Final Act. 5. In light of the foregoing Appellant has not persuaded us that "Filkins in no way relates to thermoacoustic imaging." Appeal Br. 18.

Appellant argues that "Filkins relies on a contrast mechanism that does NOT involve changing the conductivity or permittivity of the soft tissue or vasculature, and as a result, changes the radiofrequency or microwave energy absorption rate of the soft tissue or vasculature." Appeal Br. 16 (emphasis omitted). In particular, Appellant argues that all of the specific contrast agents of Filkins are "optical absorbing dyes [that] are active in the infrared, near infrared and visible wavelengths" and "are not active in the radiofrequency and microwave wavelengths." *Id.* Appellant argues that these "optical absorbing dyes . . . would NOT yield the desired image contrast in the radiofrequency/microwave wavelengths referenced by Filkins in paragraph [0028]." *Id.* (emphasis omitted).

Although Appellant may be correct that Filkins does not disclose specifically a contrast agent that changes conductivity or permittivity of the soft tissue or vasculature, the Examiner does not rely on Filkins for such a teaching. Appeal Br. 16. Rather, the Examiner acknowledges that Filkins "does not explicitly disclose that the contrast agent changes the permittivity

of the soft tissue and as a result changes the radiofrequency or microwave energy absorption rate of the soft tissue," and instead the Examiner's rejection is based on modifying the contrast agents of Filkins to that disclosed by Kalafut. Final Act. 11. Appellant acknowledges that "Kalafut describes injecting a less toxic fluid such as saline into the body having a permittivity different from tissue" (albeit "during a pre-non-imaging procedure ***solely*** to determine if extravasation of the fluid occurs") and "two antennas are employed to transmit and receive RF and a bulk measurement is made based on RF transmission through the subject only." Appeal Br. 19; *see also* Kalafut ¶¶ 20–21, 35 (describing a first sensor including a transmitting antenna to transmit electromagnetic energy (e.g., microwave energy) and a receiving antenna to receive a resultant signal that is proportional to permittivity changes in tissue in order to detect permittivity changes in tissue). Appellant has not persuaded us that the Examiner's findings regarding the teachings of Filkins that are relied on in the articulated rejection are erroneous.

Appellant also argues that "Kalafut is not analogous prior art and cannot be properly combined with Filkins to form an obviousness rejection." Appeal Br. 18. More specifically, Appellant argues that Kalafut describes injecting a less toxic fluid such as saline into the body during a pre-non-imaging procedure (e.g., an injection) in order to determine if extravasation of the fluid occurs before injecting a more toxic substance such as contrast agent during CT and other imaging procedures. *Id.* at 19 (citing Kalafut ¶ 64). Appellant argues that "[a]n inventor, faced with the problem solved by the claimed subject matter, would not look to Kalafut" for this reason. *Id.* at 18.

The established precedent of our reviewing Court sets up a two-fold test for determining whether art is analogous: "[']](1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved."' *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011) (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)). The Examiner responds to Appellant's argument by stating that "[b]oth Filkins and Kalafut are directed to contrast enhanced imaging and thus belong within a similar field of endeavor." Ans. 17. Appellant has not persuasively presented arguments and evidence to refute the Examiner's position that Kalafut is in Appellant's field of endeavor.

Appellant further argues that "there is no teaching, suggestion, or motivation in the prior art to combine Filkins with another reference to reject independent claim 1 (and similarly independent claim 37)." Appeal Br. 18. Appellant states that "[t]he Examiner is picking from Kalafut to support the obviousness rejection while disregarding the teachings of Kalafut as a whole." *Id.* at 19. More specifically, Appellant argues that "Kalafut's discussion surrounding permittivity relates to determining if permittivity/fluid level in the tissue has changed indicating extravasation," rather than suggesting "using a contrast agent during imaging that changes the conductivity or permittivity of soft tissue or vasculature to change the radiofrequency or microwave energy absorption rate of the soft tissue or vasculature, for the purpose of thermoacoustic imaging." *Id.* at 19, 20 Appellant suggests that "the Examiner's combination of Filkins and Kalafut is based on impermissible hindsight." *Id.* at 19.

To the extent that Appellant is insisting on an explicit teaching, suggestion, or motivation in Filkins or another reference for the Examiner's proposed modification, such an argument has been foreclosed by the Supreme Court. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 419 (2007) (stating that a rigid insistence on teaching, suggestion, or motivation is incompatible with its precedent concerning obviousness). Rather, the Court requires that we look to whether the Examiner has provided "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR*, 550 U.S. at 418).

As to the argument that the Examiner is improperly disregarding the teachings of Kalafut as a whole and impermissibly relying on hindsight in formulating the rejection, we are not persuaded of error by the Examiner. Filkins discloses that absorption of radiation by an object leads to a rise in temperature, and ultimately leads to the generation of acoustic waves that can be processed to determine the structural and compositional features of an object and that "[c]ontrast agents . . . may be preferentially absorbed by certain parts of the biological object and can be preferentially excited" or that "contrast agents can be used to create or enhance selective absorption of radiation." Filkins ¶¶ 23, 50. Kalafut discloses that "permittivity . . . govern[s] how an electromagnetic wave will propagate through a substance" and "[s]ome fluids . . . such as . . . contrast agents can have an appreciable complex permittivity difference from tissue." Kalafut ¶ 36. When considering these disclosures, the Examiner has explained adequately that it would have been obvious to one of ordinary skill in the art to modify a contrast agent like the metal nano-particles of Filkins that change absorption

of radiation of tissue for thermoacoustic imaging (in light of the disclosure of Filkins of the emission of electromagnetic radiation in the radio frequency and microwave regions) to the contrast agent of Kalafut because Kalafut's contrast agent would also have a known and detectable effect on tissue (i.e., a change in how the electromagnetic wave will propagate through the tissue) including when subjected to microwave radiation. The fact that Kalafut does not use contrast agents to generate thermoacoustic signals that may be detected with an ultrasound transducer in order to generate images based on the concentration of contrast agent in tissue (Appeal Br. 19) does not necessarily identify a flaw in the Examiner's articulated reasoning for modifying the contrast agent of Filkins to that disclosed by Kalafut. Moreover, Appellant does not point to any knowledge relied on by the Examiner that was gleaned only from Appellant's disclosure and that was not otherwise within the level of ordinary skill in the art at the time of the invention. *See In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) ("Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.").

We have also considered Appellant's argument that there is "no motivation for one having ordinary skill in the art to replace the optical absorbing dyes of Filkins with the saline injection of Kalafut," and that "[t]o replace the optical absorbing dyes of Filkins, or to abandon the optics-based approach of Filkins completely, would be a complete change in the principle of operation of Filkins and/or would render it inoperable for its intended

purpose." Appeal Br. 20. We do not find such argument persuasive because, as explained above, the disclosure of Filkins is not limited only to optical absorbing dyes, but contemplates, albeit briefly, the use of a contrast agent including metal nano-particles and the utilization of electromagnetic energy in the radiofrequency region and microwave region. In this way, replacement of the contrast agent of Filkins with one that is not an optical absorbing dye cannot be said to be a change in the principle of operation of Filkins because Filkins already explicitly contemplates a contrast agent other than optical absorbing dyes.

Appellant asserts that "[t]he addition of Jin to the combination of Filkins, and Kalafut does not remedy the aforementioned deficiencies of Filkins and Kalafut" and "[a]s a result, the combination of Filkins, Kalafut, and Jin does not disclose, teach or suggest the Appellant's claimed invention and . . . the combination remains improper." Appeal Br. 21. This argument solely relates to the perceived deficiencies in the combination of Filkins and Kalafut. Because we have not been persuaded of such deficiency in the combination of Filkins and Kalafut for the reasons discussed above, we are not persuaded by this argument.

For the foregoing reasons, Appellant does not apprise us of error in the Examiner's determination that Filkins, Kalafut, and Jin render obvious the subject matter of independent claim 1. Accordingly, we sustain the rejection of claim 1, and claims 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, and 70 falling therewith, under 35 U.S.C. § 103(a) as unpatentable over Filkins, Kalafut, and Jin.

Rejections II–VI

In contesting the rejections of dependent claims 11, 12, 16, 17, 45–49, and 71, Appellant relies on the same arguments and reasoning we found unpersuasive in connection with independent claim 1 as the basis for seeking reversal of these rejections. Appeal Br. 22–30. Accordingly, for the same reasons discussed above in connection with the rejection of claim 1, we also sustain the rejections, under 35 U.S.C. § 103(a), of (i) claims 11, 12, 16, 17, and 46 as unpatentable over Filkins, Kalafut, Jin, and Beard; (ii) claim 45 as unpatentable over Filkins, Kalafut, Jin, and Cerofolini; (iii) claim 47 as unpatentable over Filkins, Kalafut, Jin, and Kruger; (iv) claims 48 and 49 as unpatentable over Filkins, Kalafut, Jin, and MacKenzie; and (v) claim 71 as unpatentable over Filkins, Kalafut, Jin, and Van Zijl.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, 70	103(a)	Filkins, Kalafut, Jin	1, 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, 70	
11, 12, 16, 17, 46	103(a)	Filkins, Kalafut, Jin, Beard	11, 12, 16, 17, 46	
45	103(a)	Filkins, Kalafut, Jin, Cerofolini	45	
47	103(a)	Filkins, Kalafut, Jin, Kruger	47	
48, 49	103(a)	Filkins, Kalafut, Jin, MacKenzie	48, 49	

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
71	103(a)	Filkins, Kalafut, Jin, Van Zijl	71	
Overall Outcome			1, 5–7, 9–12, 14, 16–19, 25, 37, 41, 43–51, 53, 54, 59–63, 65, 67, 68, 70, 71	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED