

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

American Medical Systems, Inc.,
and Laserscope,

Plaintiffs,

v.

Civil No. 08-4798 (JNE/FLN)
ORDER

Laser Peripherals, LLC,

Defendant.

Leland G. Hansen, Esq., Alejandro Menchaca, Esq., and Scott P. McBride, Esq., McAndrews, Held & Malloy, Ltd., and Misti N. Okerlund, Esq., Myers, Boebel & MacLeod L.L.P., appeared for Plaintiffs American Medical Systems, Inc., and Laserscope.

Arne M. Olson, Esq., and Matthew D. Kellam, Esq., Olson & Cepuritis, Ltd., and Steven C. Moore, Esq., Watje & Moore, Ltd., appeared for Defendant Laser Peripherals, LLC.

American Medical Systems, Inc., and its subsidiary, Laserscope, (collectively, AMS) assert claims of patent infringement against Laser Peripherals, LLC (LP). LP counterclaims for declarations of noninfringement, invalidity, and unenforceability. The case is before the Court on cross-motions for summary judgment, motions to exclude expert testimony, and LP's motion to strike certain materials filed by AMS in support of its motion for summary judgment. The Court grants in part and denies in part the summary judgment motions, and resolves the motions to exclude and to strike as set forth below.¹ The Court sets this case for trial beginning Monday, July 12, 2010.

¹ The Court will decide the motions to exclude testimony from damages experts in accordance with the schedule to be set for motions in limine.

I. BACKGROUND

AMS owns U.S. Patent No. 5,428,699 (filed July 2, 1993), which is entitled “Probe Having Optical Fiber for Laterally Directing Laser Beam.” Dr. Russell Pon is the sole named inventor on the ’699 Patent. According to the ’699 Patent, the probe can be used to treat benign prostatic hyperplasia, which causes an enlarged prostate. The probe laterally directs laser energy out of a tip of a waveguide, such as an optical fiber, onto selected portions of the enlarged prostate to cause necrosis of the tissue. The necrotic tissue sloughs off as small particles which are passed away during urination. The claims of the ’699 Patent are directed to apparatuses for communicating and laterally directing electromagnetic energy and probes for treating benign prostatic hyperplasia.

AMS contends that LP infringes independent claims 1 and 25, as well as dependent claims 27-30, of the ’699 Patent. The Court construed the disputed claim terms in an Order dated October 13, 2009. Claim 1 recites:

An apparatus for communicating and laterally directing electromagnetic radiation, comprising:

a waveguide having a tip for communicating electromagnetic radiation in a propagation direction to the tip of the waveguide;

a transmitting surface on the tip of the waveguide;

a reflecting surface on the tip of the waveguide for internally reflecting electromagnetic radiation communicated by the waveguide in a direction lateral to the propagation direction toward a particular area on the transmitting surface; and

wherein the particular area and the reflecting surface are disposed so that greater than about 90% of electromagnetic radiation reflected by the reflecting surface is incident on the particular area at below a critical angle for transmission through the transmitting surface in the lateral direction.

Claim 25 recites:

A surgical probe for treating benign prostatic hyperplasia (BPH), said probe, comprising:

a waveguide having a tip with a glass cladding extending to a distal end of the tip, the waveguide for communicating electromagnetic radiation in a first propagation direction to the tip of the waveguide;

means for positioning the waveguide during surgery;

a transmitting surface on the tip of the waveguide;

a reflecting surface on the tip of the waveguide for internally reflecting electromagnetic radiation communicated in the first propagation direction by the waveguide in a second propagation direction toward the transmitting surface; and

wherein at least 90% of all electromagnetic radiation reflected by the reflecting surface is incident on the transmitting surface at below a critical angle for transmission through the transmitting surface.

According to the '699 Patent, a significant portion of the electromagnetic radiation in prior art probes did not leave the optical fiber in the desired direction due to internal reflection of the laser beam off interfaces between the optical fiber and surrounding environment. Prior art probes used reflective and anti-reflective coating layers to reduce misdirected laser energy, but those layers could melt or carbonize if used at high temperatures, thereby decreasing the efficiency of the probes. The claimed invention improves the efficiency of laterally-directing (side-firing) probes by reducing internal reflection off the surface through which the laser beam is transmitted.

AMS contends that LP's "ScatterFree Lateral Emitting Laser Fibers" infringe the '699 Patent. AMS accuses the following ScatterFree devices: the DBLF-60SF, the HBLF-60SF, the LISA HBLF-60SF, the DBLF-SF-MM, the OBM001239, and the HBLF-60SF-PL. The

for summary judgment for failure to comply with Rules 26(a) and 56(e) of the Federal Rules of Civil Procedure. AMS moves to exclude the expert testimony of Dr. Wayne Knox and George Gerstman under Rule 702.

1. Legal standards

Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

When evaluating the admissibility of expert testimony, a trial court serves as the “gatekeeper” that ensures the reliability and relevance of the expert testimony offered into evidence. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999). The proponent of the proposed expert testimony must demonstrate its admissibility by a preponderance of the evidence. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). Proposed expert testimony must meet three prerequisites to be admitted under Rule 702. *Id.* First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. *Id.* Second, the proposed expert witness must be qualified to assist the finder of fact. *Id.* Third, the proposed testimony must be reliable or trustworthy in an evidentiary sense. *Id.* To satisfy the third requirement, the proposed testimony must be based on sufficient facts or data, the proposed testimony must be the product of reliable principles and methods, and the proposed expert witness must have applied the principles and methods reliably to the facts of the case. *Id.*

Rule 26(a) requires a party to disclose the identity of any expert witness it intends to use at trial and provide with that disclosure a written report prepared and signed by the witness,

including a complete statement of all opinions the witness will express and the basis and reasons for them, “at the times and in the sequence” ordered by a court. Fed. R. Civ. P. 26(a)(2)(A)-(C). A party that fails to disclose information required by Rule 26(a) shall not be permitted to use that information as evidence at a trial, at a hearing, or on a motion unless the failure is harmless or substantially justified. Fed. R. Civ. P. 37(c)(1); *see Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1008 (8th Cir. 1998). When fashioning a remedy for untimely disclosure, a court should consider the reason for noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony. *Wegener v. Johnson*, 527 F.3d 687, 692 (8th Cir. 2008).

Finally, “[t]o be considered on summary judgment, documents must be authenticated by and attached to an affidavit made on personal knowledge setting forth such facts as would be admissible in evidence or a deposition that meets the requirements of Fed. R. Civ. P. 56(e).” *Stuart v. Gen. Motors Corp.*, 217 F.3d 621, 635 n.20 (8th Cir. 2000). Documents that fail to meet those requirements cannot be considered. *Id.*

2. Dr. Thomas Milster

a. Transmission experiments

Milster, a professor of optical sciences, electrical engineering, and computer engineering at the University of Arizona, conducted three experiments intended to measure light transmitted from the accused devices in a desired lateral direction (P1) and in the opposite direction (P2).³ The purpose of those experiments was to determine whether the accused devices met the claim limitations “wherein the particular area and the reflecting surface are disposed so that greater

³ For purposes of this order, the Court uses “light” to refer to “electromagnetic radiation.”

than about 90% of electromagnetic radiation reflected by the reflecting surface is incident on the particular area at below a critical angle for transmission through the transmitting surface in the lateral direction” and “wherein at least 90% of all electromagnetic radiation reflected by the reflecting surface is incident on the transmitting surface at below a critical angle for transmission through the transmitting surface” (collectively, 90% limitations).

LP first contends that Milster’s experiments are irrelevant because they relate to transmission, not incidence, and the claims require the light to be “incident on the [transmitting surface/particular area] at below a critical angle for transmission through the [transmitting surface/particular area].”⁴ LP argues that the incident light does not equal the light transmitted through the particular area/transmitting surface and that Milster should have measured the critical angle, the amount of light reflected off the reflecting surface, and the light incident on the transmitting surface/particular area at below the critical angle.

“A patentee may prove infringement by any method of analysis that is probative of the fact of infringement, and circumstantial evidence may be sufficient.” *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (quotation marks and citation omitted). Here, Milster measured light in the P1 direction and light in the P2 direction using a flat optical power meter and calculated a transmission “ratio” of $P1 / (P1 + P2)$.⁵ This measurement and calculation correspond to a test described in the ’699 Patent. Where, as here, the claims do not specify any particular form of testing, a patentee may use a test “expressly approved by the

⁴ Claims 1 and 25 recite a “transmitting surface on the tip of the waveguide.” Claim 1 also recites “a particular area on the transmitting surface.” The parties treated the “transmitting surface” and “particular area” as one limitation in their motion papers; the Court does the same in this Order.

⁵ The parties express the result of this calculation as a percentage and refer to the result as a “ratio”; the Court does the same.

patent specification” to prove infringement. *See Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil*, 425 F.3d 1366, 1375 (Fed. Cir. 2005). Although LP seeks to limit the transmission test described in the ’699 Patent to embodiments having a certain core-to-core-cladding ratio because the specification described testing such an embodiment, nothing in the language of the ’699 Patent suggests the described transmission test is so limited.

Moreover, while the claims include limitations directed to the ratio of the light reflected by the reflecting surface and light incident on the transmitting surface/particular area at below the critical angle, they do not require any specific critical angle, amount of light reflected by the reflecting surface, or amount of light incident on the transmitting surface/particular area at below the critical angle, nor do they impose any limitation on the size of the transmitting surface/particular area. Consequently, LP’s argument that Milster’s experiments are irrelevant because he did not measure those characteristics is unpersuasive. *Cf. Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998) (explaining that second step in infringement analysis is comparing properly construed claims to accused device). LP also contends that Milster’s experiments are irrelevant because he did not conduct them in water. For the reasons stated below with respect to AMS’s motion to exclude Knox’s testimony, the Court rejects this argument.

Next, LP contends that Milster should have used ray tracing, which is also described in the ’699 Patent, to measure the light activity within the optical fiber. LP cites no authority indicating that a patentee is required to perform every test described in the patent to prove infringement. Moreover, LP did not submit the results of any ray tracing or any other evidence indicating that the results of ray tracing would call into question the relevance of Milster’s experiments. Milster’s failure to perform any ray tracing does not provide a basis for excluding

his opinions about his transmission experiments. The Court denies LP's motion to exclude as irrelevant Milster's testimony about his transmission experiments.

LP also contends that Milster's experiments are unreliable because (1) he did not account for certain losses within the waveguide, (2) he overcaptured light in the P1 direction and undercaptured light in the P2 direction, and (3) he estimated rather than calculated the coupling losses between the laser source's output and the light introduced into the fiber. Because LP provides no evidence of the effect any of those alleged flaws would have on Milster's measurements, LP's concerns go to the weight of Milster's testimony rather than its admissibility. *See Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1221 (Fed. Cir. 2006) (testimony about results of computer models was admissible even though models did not exactly match the accused products). Moreover, Jeffrey Stein, a vice-president of LP, testified that LP measures light emitted from the accused devices using a flat optical power meter as part of its quality testing.⁶ LP's use of a transmission test similar to Milster's indicates that such transmission tests are generally accepted in the field, and therefore are reliable. *See Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 298 (8th Cir. 1996). The Court denies LP's motion to exclude as unreliable Milster's testimony about his transmission experiments.

b. SEM-EDS results

Milster opines, based on his review of the results of tests performed using energy-dispersive x-ray spectroscopy coupled with a scanning electron microscope (SEM-EDS), that fluorine remains in the fused window of the accused devices after the capsule is fused to the fiber. Relying on *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609 (7th Cir.

⁶ LP's calculation differs from Milster's in that LP divides the light transmitted in the desired direction (P1) by the laser source's power output rather than the sum of the light transmitted in the desired direction (P1) and the light transmitted in the opposite direction (P2).

2002), LP argues that Milster's opinions regarding the presence of fluorine should be excluded because the operator of the SEM-EDS designed and conducted the test.

An expert witness may rely on facts or data not based on personal perception if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Fed. R. Evid. 703; *see Monsanto Co. v. David*, 516 F.3d 1009, 1015-16 (Fed. Cir. 2008) (affirming admission of expert testimony where expert relied on "scientific reports prepared by his team"); *Ratliff v. Schiber Truck Co.*, 150 F.3d 949, 955 (8th Cir. 1998) (permitting accident reconstructionist to rely on police officer's report because it was "of the type reasonably relied upon by accident reconstructionists in forming their opinions"). "[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert; and it is apparent from the wording of Rule 703 that there is no *general* requirement that the other expert testify as well." *Dura*, 285 F.3d at 613.

In *Dura*, the excluded expert testimony relied on computer models of groundwater flow created by assistants where the models were "inherently not the most precise of scientific tools" because "one never possesses complete geotechnical information." *Id.* at 614. The court of appeals affirmed the exclusion in part because the creation of such models required the use of professional discretion and "groundwater modeling is not the sort of thing that a lab technician or other subprofessional does." *Id.* Here, Milster prepared the samples and was present while a lab technician performed the tests. According to Milster's deposition testimony, the amount of discretion exercised by the lab technician amounted to adjusting the height and rotation of the sample to look at a specific area of interest and adjusting the focus and astigmatism to obtain a clear image. LP provides no evidence indicating that an SEM-EDS is an imprecise tool, that lab

technicians do not typically perform SEM-EDS testing, or that the lab technician exercised more than a minimal amount of discretion or performed anything other than routine procedures in conducting the tests.⁷ Moreover, LP does not assert that Milster does not know how to interpret SEM-EDS results or that scientists such as Milster do not regularly rely on such testing. In fact, Milster's deposition testimony demonstrates his familiarity with interpreting such test results. *Dura* is distinguishable, and the Court denies LP's motion to exclude Milster's opinions about the SEM-EDS results.

c. Motion to strike

LP also moves to strike additional portions of Milster's reports and a declaration filed by Milster on March 28, 2010. First, LP contends that the results of Milster's transmission experiments should be stricken because their results were not disclosed in AMS's claim chart and "directly contradict" AMS's claim chart. AMS asserted in its claim chart that "testing performed on defendant's ScatterFree Laser Fibers showed that greater than about 90% of the electromagnetic radiation introduced in defendant's fiber product is transmitted in the lateral direction from the device." LP moved to compel production of that testing, and the magistrate judge denied the motion except to the extent LP sought evidence not protected by the work-product doctrine. AMS did not produce the test results, and LP did not appeal the magistrate judge's order.

⁷ According to LP, the lab technician set the color scale for the image indicating how much fluorine is present in the fused window. No evidence supports this contention, and Milster testified "I believe [the color scale is] set by the machine, but I'm not sure." Even if the lab technician did set the color scale, LP submits no evidence in support of its argument that the SEM-EDS results are inaccurate due to the color scale settings. Consequently, LP's concerns about the accuracy of the SEM-EDS test results go to the weight of Milster's testimony, not its admissibility. See *Liquid Dynamics*, 449 F.3d at 1221.

LP now argues that AMS cannot rely on Milster's experiments because AMS did not produce its pre-litigation test results.⁸ LP first asserts that Milster performed the testing referenced in AMS's claim chart. No evidence supports this assertion; rather, Milster testified that all of his experimental results were disclosed with his expert reports and that the only testing he was aware of was his own. LP also asserts that the experimental results disclosed in Milster's expert report should have been disclosed in AMS's claim chart. Given that AMS's claim chart was due in March 2009 and initial expert reports were not due until January 2010, such a requirement would make no sense. LP cites no authority for imposing such a requirement, and the Court declines to do so here.

LP's second argument that Milster's experimental results "directly contradict" the infringement contentions in AMS's claim chart is without merit. Milster stated in his infringement expert report: "[O]f the energy that I attempted to have input into the ScatterFree device, approximately 83-87% was detected in the desired (targeted) lateral direction This corresponds to 96-98% of the reflected electromagnetic radiation being detected in the targeted lateral direction." Milster then explains that, typically, up to 10% of the energy input into a waveguide is lost due to coupling between the laser source and the waveguide and that an additional 4% is lost due to Fresnel reflections. LP may question the accuracy of Milster's conclusions, but Milster's results themselves do not contradict AMS's infringement contentions. Moreover, LP's surprise that Milster calculated the ratio as $P1 / (P1 + P2)$ rather than $P1 / (\text{laser source output})$ is puzzling given that the denominator of the ratio in the test described in the '699 Patent was not the laser source's output. *See* '699 Patent col.12 ll.6-11 (calculating ratio as $80 / (80 + 5)$ and concluding "of the 85% of the input energy which was detected on transmission out

⁸ LP does not dispute that Milster's expert reports and supporting data were disclosed in accordance with the deadlines for expert discovery established by the pretrial schedule.

of the fiber, greater than 90% (about 94%) of the energy was transmitted . . . without undesirable deflection”). The Court denies LP’s motion to strike the results of Milster’s transmission experiments.⁹

LP next argues that Milster’s expert reports contain multiple statements that lack foundation and are hearsay because they relate to medical analysis of prostate glands and benign prostatic hyperplasia, to Laserscope’s sales of various devices, to what LP tells its customers, to how LP’s customers use the accused devices, and to how endoscopes are used during surgery. LP identifies as inadmissible over seventy paragraphs in Milster’s infringement report and over one hundred paragraphs in Milster’s invalidity report, many of which have nothing to do with the asserted grounds for exclusion. In light of LP’s failure to properly identify the paragraphs containing the challenged subject matter, the Court denies LP’s motion to strike without prejudice to LP’s ability to bring a motion in limine on this issue.

Finally, LP argues that Milster’s expert reports must be stricken for failure to comply with Rule 56(e). AMS did not include a declaration or affidavit of Milster swearing to the truth of the matters contained within his expert reports when it filed its motion for summary judgment. *See LP Rainforest Cafe, Inc. v. Amazon, Inc.*, 86 F. Supp. 2d 886, 904 (D. Minn. 1999). On March 28, 2010, AMS filed Milster’s declaration affirming the truth of the matters contained within his reports. Consequently, AMS has “cured” its initial failure to authenticate Milster’s expert reports. *See DG&G, Inc. v. FlexSol Packaging Corp. of Pompano Beach*, 576 F.3d 820, 825-27 (8th Cir. 2009). The Court denies LP’s motion to strike Milster’s expert reports for failure to comply with Rule 56(e).

⁹ LP also moves to strike Milster’s testimony related to the doctrine of equivalents. For the reasons stated with respect to LP’s motion for summary judgment on AMS’s claims under the doctrine of equivalents, the Court denies the motion to strike.

3. Dr. Wayne Knox

a. *Transmission testing*

Knox, a professor of optics and the director of the Institute of Optics at the University of Rochester, opines that whether a device meets the 90% limitations could not be determined using the transmission test described in the '699 Patent because the test does not measure light activity within the waveguide. Knox also stated that he “was not able to think of how to do an experiment that will determine whether any device meets all the limitations of [the claims].” AMS moves to exclude those opinions. For the reasons stated with respect to LP’s motion to exclude Milster’s testimony, the transmission experiments performed by Milster are relevant to the question of whether the accused devices meet the 90% limitations. To permit Knox to testify that whether the 90% limitations are met cannot be determined would not assist the jury in ascertaining whether the accused products meet those limitations. Consequently, the Court excludes Knox’s opinions that no experiment can determine whether the 90% limitations are met and that Milster’s transmission experiments “measure[d] the wrong thing” because they did not measure light activity within the waveguide.

AMS also moves to exclude Knox’s opinion that Milster’s transmission experiments were flawed and the claims are indefinite under 35 U.S.C. § 112, ¶ 2 (2006), because the experimental results will vary depending on whether the test is conducted in air or water. A claim is definite “if a person skilled in the field of the invention would reasonably understand the claim when read in the context of the specification.” *Marley Mouldings Ltd. v. Mikron Indus., Inc.*, 417 F.3d 1356, 1360 (Fed. Cir. 2005). The '699 Patent describes how to determine an appropriate core-to-core-cladding ratio based on the refractive index of the core cladding and the refractive index of air and then explains “[t]his embodiment . . . achieves substantially improved

performance” of the probe, as shown by the subsequently-described “comparative experimental results.” ’699 Patent col.11 l.9-col.12 l.41. Although Knox opines that the described experiment could have been conducted in water if the optical power meter were placed in a plastic bag, he conceded during his deposition that the description of the experiment makes no mention of a plastic bag or any other equipment that would permit it to be conducted in water. Moreover, Pon testified that optical engineers do not conduct tests using optical power meters in water. In short, a person of ordinary skill in the art would understand that the transmission test described in the ’699 Patent was conducted in air and that the appropriate medium for transmission testing is air.¹⁰ The Court excludes Knox’s opinions that Milster’s transmission testing is irrelevant or was otherwise inappropriate because it was conducted in air and that a person of ordinary skill in the art would not know whether to conduct transmission testing in air or water because such testimony would not assist the jury in determining a fact at issue or understand the evidence.¹¹

Knox also opines that Milster’s transmission experiments were flawed and that the claims are indefinite because the results of transmission testing depend on factors including the launch conditions of the laser and the light’s polarization and wavelength. He further opines that

¹⁰ The parties agree on the following definition of a person of ordinary skill in the art: “[H]aving approximately four years experience working as a design engineer or fiber optic technician for a medical device company or similar company, and whose responsibilities include oversight or participation in the design or manufacture of fiber optic devices for delivery of laser radiation in a medical environment. In order to qualify for such a position, a person would normally be required to hold a college degree in a technical field such as optics, physics or electrical engineering.”

¹¹ It is undisputed that the claimed invention and the accused devices may be used in water or saline. LP contends that *Genentech, Inc. v. Wellcome Foundation Ltd.*, 29 F.3d 1555 (Fed. Cir. 1994), supports its argument that the test should be conducted in water. The court in *Genentech* determined that the appropriate test was a bovine fibrin plate assay because the assay was referenced in the prosecution history—i.e., was part of the intrinsic evidence—when distinguishing over the prior art. *Id.* at 1562-63. Here, the intrinsic evidence indicates that the test should be performed in air, not water.

Milster may have overcaptured light in the P1 direction and undercaptured light in the P2 direction. AMS seeks exclusion of those opinions because Knox did not quantify the effect of those factors and their effect is minimal when testing the accused devices. Even if the effect of those factors is minimal when testing the accused devices, whether a claim meets the requirements of § 112 is measured by the scope of the claimed invention, not the scope of the accused devices. *See LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005). AMS's concerns about the significance of those factors go to the weight of Knox's testimony, not its admissibility. *See Liquid Dynamics*, 449 F.3d at 1221. The Court denies AMS's motion to exclude Knox's opinions about the effect of those factors on Milster's transmission experiments or indefiniteness.

b. § 112

AMS also seeks exclusion of Knox's opinions that the terms "transmitting surface," "particular area" and the 90% limitations fail to meet the definiteness, written description, and enablement requirements of § 112 because they are based on the wrong legal standards. LP responds that Knox stated the correct legal standards in his expert report. As previously stated, a claim is definite if a person skilled in the art would reasonably understand the claim when read in light of the specification. *Marley Mouldings*, 417 F.3d at 1360. Claims are enabled if a person of ordinary skill in the art could make and use the full scope of the invention without undue experimentation. *LizardTech*, 424 F.3d at 1345. The written description requirement mandates that the specification describe the invention sufficiently to convey to a person of ordinary skill in the art that the patentee had possession of the claimed invention at the time of the application.

Id.

Despite correctly stating those legal standards in his expert report, Knox failed to properly apply them to the facts of this case. Instead, he concluded that the transmitting surface/particular area and 90% limitations do not meet the requirements of § 112 because the specification “does not clearly define” the location of or where the transmitting surface/particular area begins and ends and because there could be more than one transmitting surface/particular area in a device. The asserted claims do not require the transmitting surface/particular area to have certain dimensions or a precise location, and definiteness does not require specification of the precise location or dimensions of a claim limitation if a person of ordinary skill in the art would understand the claim. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346-47 (Fed. Cir. 2007) (reversing district court’s grant of summary judgment that claim term “near” was indefinite).

Moreover, because the Court construed the claims as permitting, but not requiring, more than one transmitting surface/particular area, it does not matter which transmitting surface/particular area results in infringement as long as at least one does. *See SunTiger, Inc. v. Sci. Research Funding Group*, 189 F.3d 1327, 1336-37 (Fed. Cir. 1999) (“If a claim reads merely on a part of an accused device, that is enough for infringement.”). Consequently, Knox’s opinions are inadmissible because they are based on incorrect legal standards. *See Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996) (“Incorrect statements of law are no more admissible through ‘experts’ than are falsifiable scientific theories.”). The Court excludes Knox’s opinions that the transmitting surface/particular area and the 90% limitations are indefinite because the specification does not include the precise dimensions and location of the transmitting surface/particular area and because a device could have multiple transmitting surfaces/particular areas.

c. Obviousness

AMS moves to exclude Knox's conclusions about obviousness as conclusory and because he provided no reason to combine the claim elements. LP responds that Knox provided "ample analysis" to support his obviousness opinions.

In the obviousness sections of his invalidity report, Knox described the teachings of certain prior art references and then concluded that "[a] person of ordinary skill would have been motivated to combine the [references]" or that "[b]ased on the field of the invention and the subject matter of these prior art references, a person of ordinary skill in the art would have been motivated to combine [these references]." Although the law does not require an explicit teaching, suggestion, or motivation to combine prior art references, it may be important to identify a reason why a person of ordinary skill in the art would have combined the elements in the manner of the claimed invention. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1374 (Fed. Cir. 2010). Because Knox simply describes the prior art, identifies no reason to combine the references in the manner claimed, and fails to "state how or why a person ordinarily skilled in the art would have found the claims . . . obvious in light of some combination of those particular references," his conclusions as to obviousness "would not [be] helpful to a lay jury in avoiding the pitfalls of hindsight that belie a determination of obviousness." *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373 (Fed. Cir. 2008). Knox may not testify as to obviousness under § 103.

d. '312 Patent

AMS moves to exclude Knox's testimony about anticipation and obviousness insofar as it is based on U.S. Patent No. 5,253,312 (filed June 26, 1992) because LP did not include that patent in its prior art chart. LP responds that Knox will not testify about anticipation and

obviousness based on the '312 Patent, but that he may testify about the '312 Patent in the context of § 112 or prosecution history estoppel. Knox did not base any of his conclusions regarding § 112 on the '312 Patent, and he did not opine at all on prosecution history estoppel. LP provides no explanation for his failure to do so, and given that fact and expert discovery have closed, the Court concludes that AMS would be harmed if required to respond to expert opinions not yet disclosed. *See* Fed. R. Civ. P. 26(a)(2)(B), 37(c)(1). Consequently, the Court excludes Knox's opinions regarding the '312 Patent in the context of anticipation, obviousness, § 112, or prosecution history estoppel.

4. Jeff Gang Lei

On March 28, 2010, AMS submitted the declaration of Dr. Jeff Gang Lei in opposition to LP's motions for summary judgment. Lei is a senior optical engineer with experience using ray-tracing software to model side-firing optical fibers used in medical devices. Lei states that he modeled devices having characteristics similar to the accused devices and that his modeling indicates that the modeled devices met the 90% limitations. LP moves to strike Lei's declaration because AMS did not disclose Lei as an expert witness in accordance with the pretrial schedule. AMS responds that Lei's declaration complies with Rule 26(a)(2)(C)(ii) because it "is intended solely to contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B), within 30 days after the other party's disclosure," and with Rule 37 because the late disclosure was substantially justified by Knox's late disclosure of his ray-tracing opinions.

In a declaration filed on March 12, 2010, Knox stated that ray tracing could be used to determine if the 90% limitations are met and criticized Milster for not performing ray tracing. LP asserts that Knox previously disclosed his ray-tracing theory on page 12 of his expert report

on noninfringement. The identified paragraph in Knox's expert report describes taking a series of measurements. It does not suggest that ray tracing could be used to determine if the 90% limitations are met. Moreover, Knox stated at least twice in the same expert report that he could not think of any way to determine if any device meets the claim limitations. The Court concludes that Knox's expert reports did not disclose the opinion that ray tracing could be used to determine if the 90% limitations are met. LP also contends that Knox disclosed his ray-tracing opinions during his deposition on March 2, 2010. Regardless of whether Knox first disclosed his ray-tracing opinions during his March 2 deposition or in his March 12 declaration, Lei's opinions, disclosed on March 28, were still disclosed within the 30-day window of Rule 26(a)(2)(C)(ii). Further, the disclosure of Lei's opinion after the deadline for expert reports is substantially justified given the timing of Knox's declaration and the contradiction between it and his earlier statements about the impossibility of determining whether the 90% limitations are met. The Court denies LP's motion to strike Lei's declaration under Rules 26(a) and 37(c).

LP also contends that Lei's declaration is unreliable because he made assumptions when conducting the analysis. Criticisms of Lei's assumptions go to the weight given his conclusions, not their admissibility. *See Liquid Dynamics*, 449 F.3d at 1221. The Court denies LP's motion to strike Lei's declaration.

5. Deposition testimony from an unrelated case

AMS used testimony from depositions taken in an unrelated case involving the '699 Patent in support of its motion for summary judgment. Relying on *Kirk v. Raymark Industries, Inc.*, 61 F.3d 147 (3d Cir. 1995), LP moves to strike the deposition testimony as hearsay. In *Kirk*, the court of appeals found that the district court abused its discretion by admitting the prior testimony of an out-of-court witness *at trial*. 61 F.3d at 162-64. In the summary judgment

context, a deposition “is at least as good as an affidavit” and may be used whenever an affidavit would be permissible, even if the conditions of the rule on use of a deposition at trial are not satisfied. *Diamonds Plus, Inc. v. Kolber*, 960 F.2d 765, 767-68 (8th Cir. 1992). The Court denies LP’s motion to strike the deposition testimony from the unrelated case.

6. George Gerstman

LP submitted the expert report of George Gerstman, a former patent examiner and practicing patent attorney, in support of its inequitable conduct arguments. AMS moves to exclude Gerstman’s testimony as unhelpful because it is speculative and merely tells the Court what conclusion to reach regarding inequitable conduct. LP responds that Gerstman is qualified and “has been permitted to testify at trial on these types of topics numerous times.”¹²

Inequitable conduct is an equitable defense to patent infringement that is most appropriately reserved for a court. *Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009). In dealing with the U.S. Patent and Trademark Office (USPTO), applicants for a patent have a duty of candor and good faith which includes a duty to disclose all information known by them to be material to patentability. 37 C.F.R. § 1.56 (2008). Whether an applicant has complied with the duty of disclosure is relevant to the issue of inequitable conduct. *See Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

¹² LP does not identify a single case where Gerstman opined on whether a patent applicant committed inequitable conduct or breached the duty of disclosure, opined on what the patent examiner believed or would have done had certain references been before the examiner, or suggested that the USPTO’s limited resources called into question the validity of an issued patent. (The Court does not consider a general citation to Gerstman’s *curriculum vitae* sufficient for this purpose.) In fact, courts excluded such testimony from Gerstman in many of the cases cited by AMS. Consequently, the Court accords no weight whatsoever to LP’s suggestion that Gerstman’s testimony is admissible because other courts have permitted similar testimony from him.

Gerstman opines that Paul Davis, an attorney at Laserscope, breached the duty of disclosure when prosecuting the '699 Patent. Courts routinely exclude such testimony because it simply tells a court what conclusion to reach on the issue of inequitable conduct. *See, e.g., Se-Kure Controls, Inc. v. Diam USA, Inc.*, Civil No. 06-4857, 2009 WL 77463, at *2 (N.D. Ill. Jan. 9, 2009) (“As stated above, Mr. Gerstman’s statements that he expects to testify about Se-Kure’s failure to comply with its duty of disclosure, resulting in equitable conduct, is simply inadmissible. . . . Testimony by a witness . . . may not include legal conclusions.”); *Anagram Int’l, Inc. v. Mayflower Distrib. Co.*, Civil No. 07-1142, 2008 WL 5500764, at *1 (D. Minn. Aug. 21, 2008) (“[A]ny testimony from [the expert] regarding his opinions, legal or otherwise, regarding inequitable conduct, including his opinions regarding materiality or the intent to deceive, are presumptively inadmissible.”); *Pharmacia Corp. v. Par Pharm., Inc.*, Civil No. 01-6011, 2004 WL 5614917, at *2 (D.N.J. Feb. 18, 2004) (“[T]he Court will not permit [the expert] to offer testimony regarding alleged inequitable conduct or materiality.”).

Gerstman also states that the patent examiner “has very limited access to non-patent prior art” and “does not leave the Patent Office to search for prior art nor does he or she visit or telephone the inventor to request prior art from the inventor.” Such statements are inadmissible because they seek to call into question the statutory presumption of validity established in 35 U.S.C. § 282 (2006). *See EZ Dock, Inc. v. Schafer Sys., Inc.*, Civil No. 98-2364, 2003 WL 1610781, at *15, (D. Minn. Mar. 8, 2003) (excluding “testimony disparaging the PTO and its examiners”); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, No. 92-20643, 1995 WL 261407, at *3 (N.D. Cal. Apr. 25, 1995) (“Testimony about overwork, quotas, awards or promotions at the Patent Office, or the number of patents that issue annually or

insinuating that the Patent Office does not do its job properly is excluded. Such evidence would be irrelevant speculation and would constitute an inappropriate attack on the Patent Office.”).

In addition, Gerstman opines that “the ‘at least 90%’ limitation was the critical limitation that the Examiner believed was missing from the prior art of which the Examiner was aware” and that a particular reference “was the missing link which would have helped the Examiner formulate a rejection of the claims which plaintiffs may have been unable to overcome.” These statements are inadmissible because Gerstman cannot know what the examiner believed or would have done. *See, e.g., Se-Kure Controls*, 2009 WL 77463, at *2 (“Mr. Gerstman is also not a mind-reader.”); *Pharmacia*, 2004 WL 5614917, at *2 (prohibiting testimony “as to how a ‘reasonable patent examiner’ would have acted in light of the facts of this case”); *Applied Materials*, 1995 WL 261407, at *2-3 (excluding testimony “about what the examiner would have done if [the expert] had been the examiner, or if the examiner had different information”). Finally, Gerstman, who LP admits is not a person of skill in the relevant art, is not qualified to testify about the materiality of any references. *See Applied Materials*, 1995 WL 261407, at *2-3. The Court grants AMS’s motion to exclude Gerstman’s testimony.¹³

B. Infringement

The parties brought cross-motions on the issues of literal infringement and infringement under the doctrine of equivalents. The terms at issue with respect to infringement are the 90% limitations, transmitting surface/particular area, “glass cladding extending to a distal end of the tip” (glass cladding limitation), and “means for positioning.”

¹³ LP argues that Gerstman should be permitted to testify at trial about general USPTO procedures. Because the Court grants summary judgment in favor of AMS on LP’s inequitable conduct defense, such testimony would be irrelevant.

1. Legal standard

Determining infringement is a two-step process. *Bai*, 160 F.3d at 1353. First, the claim is properly construed, and second, the claim as properly construed is compared to the accused device. *Id.* Whether a claim is literally infringed or infringed under the doctrine of equivalents is a question of fact. *Id.*

Literal infringement requires the accused device to literally embody every limitation of the claim. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1370 (Fed. Cir. 2000). “[A] literal infringement issue is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device.” *Bai*, 160 F.3d at 1353.

“An accused device that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused device either literally or equivalently.” *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1459 (Fed. Cir. 1998) (en banc). An element in the accused product is equivalent to a claim limitation if the differences between the two are insubstantial to one of ordinary skill in the art. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). Insubstantiality may be determined by whether the accused device performs substantially the same function in substantially the same way to obtain the same result as the claim limitation. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). When deciding whether summary judgment of infringement under the doctrine of equivalents is proper, a court first determines if prosecution history estoppel applies and then determines whether a reasonable jury could find that the accused device contains

elements that are equivalent to each of the properly construed claim limitations. *Bai*, 160 F.3d at 1354. Whether prosecution history estoppel applies is a question of law. *Id.*

2. Literal infringement

a. 90% limitations

Repeating the arguments it made in support of its motion to exclude Milster's testimony, LP contends that no reasonable jury could find the accused devices meet the 90% limitations because Milster's experiments do not measure what is claimed, Milster failed to account for certain losses within the waveguide, and Milster overcaptured and undercaptured light. In the absence of any evidence quantifying the effect of the alleged flaws in Milster's experiments, the Court concludes that a reasonable jury could find the 90% limitations were met. LP also contends that Milster's experiments show that only between 83% and 87% of the "input energy" was detected in the desired lateral direction. As stated with respect to LP's motion to strike Milster's testimony, this "input energy" argument ignores the coupling losses and Fresnel losses identified by Milster in his expert report. The jury should decide whether Milster's explanation of those losses is credible.

AMS maintains that there is no issue of fact as to whether the 90% limitations are present in the accused device. AMS submits Milster's transmission experiments, Lei's declaration, and LP's quality testing in support of its motion. The Court concludes that Knox's opinions regarding possible flaws in Milster's transmission experiments create an issue of fact as to whether the 90% limitations are met. Moreover, the jury should decide whether Lei made appropriate assumptions when modeling the accused devices for his ray tracing. AMS also relies on LP's representations to the Food and Drug Administration (FDA) that the accused products are "equivalent" to AMS's AddStat products, which embody the claimed invention. With

respect to FDA submissions, “[c]ourts have repeatedly refused to allow FDA 510(k) notification of substantial equivalence as admission of infringement in patent cases” because “equivalence” has a different meaning in the FDA context than in the patent infringement context.

CardioVention, Inc. v. Medtronic, Inc., 483 F. Supp. 2d 830, 840 (D. Minn. 2007).

Consequently, a reasonable jury could find that the accused devices do not meet the 90% limitations regardless of LP’s representations to the FDA. Finally, AMS submits Stein’s deposition testimony that the accused devices have “nearly zero scattering” and LP’s representations in its advertising materials that the accused products are “scatter free” in support of its motion. A reasonable jury could find that the 90% limitations are not met despite those statements because neither necessitates the conclusion that the accused devices meet the structural requirements of the 90% limitations. Issues of fact remain as to whether the 90% limitations are present in the accused devices.

b. Transmitting surface/particular area

AMS identifies the outer surface of the fused window in the accused devices as the transmitting surface/particular area on the tip of the waveguide. LP contends that neither limitation is found in the accused devices because the transmitting surface/particular area identified by AMS is not, as required by the claims, “on the tip of the waveguide.”

The Court construed “tip of the waveguide” as:

the distal end portion of the waveguide, including a separate component coupled thereto in a manner that prevents internal reflection at any interface between the components (for example, by fusing or a transparent, index-matched adhesive), but not including a cap or tube enclosing a transmitting surface on the distal end portion of the waveguide or a reflecting surface on the distal end portion of the waveguide.

Accordingly, the capsule of the accused devices is not the “tip of the waveguide.” AMS, however, contends that the portion of the capsule that is fused to the optical fiber becomes a part

of the “tip of the waveguide” because the fused window does not “enclose” the reflecting or transmitting surface. LP responds that this argument is precluded by the Court’s construction of “tip of the waveguide.”¹⁴

When taking the evidence in the light most favorable to AMS, a reasonable jury could find that the fused window is part of the tip of the waveguide based on its attachment to the tip. However, when considering the evidence in the light most favorable to LP, a reasonable jury could find that the fused window is part of the capsule regardless of its attachment to the optical fiber. An issue of fact remains as to whether the fused window is part of the tip of the waveguide, and therefore, whether the accused devices include a transmitting surface/particular area on the tip of the waveguide.

AMS also contends that, even if the fused window is not part of the tip of the waveguide, the outer surface of the fused window is “on” the tip of the waveguide in the same manner that a second book in a stack of books resting on a table is “on” the table. LP responds that this interpretation would permit any object, including the patient’s internal organs, to be “on” the tip of the waveguide. The Court concludes that an issue of fact remains regarding whether a surface is “on” the tip of the waveguide even if it does not directly contact the tip.¹⁵

Finally, LP contends that no reasonable jury could find that the transmitting surface/particular area is present in the accused devices because AMS did not identify the precise location or dimensions of the transmitting surface/particular area. This argument does not

¹⁴ Relying on Knox’s declaration, LP also contends that the tip of the waveguide ends before the fused window because light is no longer confined to the core of the optical fiber in that region. The Court addresses this contention in the context of the glass cladding limitation.

¹⁵ In the *Markman* Order, the Court declined to construe “on” in light of its construction of “transmitting surface” and “tip of the waveguide.” The parties accepted that determination for purposes of summary judgment.

establish the absence of fact issues regarding infringement because the claims do not require a precise location or specific dimensions. *See Bai*, 160 F.3d at 1353. The Court concludes that issues of fact remain as to whether the accused devices meet the transmitting surface/particular area limitation.

c. Glass cladding limitation

The parties dispute whether a reasonable jury could find the glass cladding limitation present in the accused devices. The Court construed “glass cladding” as a “glass material that surrounds and protects a fiber core and confines electromagnetic radiation to the waveguide during its communication to the tip of the waveguide where the glass material need not contact the fiber core.”

It is undisputed that the accused devices include an optical fiber having a core and a core cladding of fluorine-doped silica. When the accused devices are manufactured, the inside wall of the capsule is fused to the distal end of the optical fiber. AMS maintains, based on Milster’s interpretation of the SEM-EDS results, that fluorine remains in the fused window. LP, relying on Knox’s declaration, contends that the presence of fluorine does not mean that light is confined in the fused window. Relying on Milster’s deposition testimony and statements in his expert report that the fusing “prevents internal reflection” at the interfaces between the capsule and the fiber and “erases all optical interfaces that would strongly reflect the light,” LP attributes this non-confinement to the absence of optical interfaces in the fused window. AMS objects to LP’s characterization of Milster’s deposition testimony and expert reports, and responds that Milster testified during his deposition that the fused window “still maintains [the relationship between the core and fluorine-doped silica cladding] to communicate the light traveling down the fiber to

the reflecting surface.” The Court concludes that issues of fact remain as to whether the fused window confines light.

AMS alternatively contends that, even if the fluorine in the fused window does not confine light at the tip, the fluorine-doped silica in the fused window is still “glass cladding” because the construction of “glass cladding” only requires confinement of light “during its communication to the tip of the waveguide.” In support of this argument, AMS identifies embodiments disclosed in the ’699 Patent where light is transmitted through the cladding. AMS also contends that the glass cladding limitation is met regardless of whether the fused window meets the “confinement” requirement because the glass cladding extends to the reflecting surface on the tip and sides of the optical fiber. The Court concludes that issues of fact remain regarding those arguments.

d. Means for positioning

Finally, LP seeks summary judgment that the accused devices do not directly infringe claims 25 and 27-30, which require a means for positioning the waveguide during surgery, because it does not sell any such means. AMS responds that it does not allege direct infringement of those claims. Consequently, LP’s motion for summary judgment on the issue of direct infringement of claims 25 and 27-30 is denied as moot.

LP moves for summary judgment of noninfringement of claims 25 and 27-30 under theories of indirect infringement because AMS has produced no evidence of third-party use of the accused devices with a means for positioning. *See Novartis Pharm. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1308 (Fed. Cir. 2004). The directions for use for the accused devices indicate that they are intended for use with an endoscope, which is identified as a means for

positioning in the '699 Patent. This is sufficient evidence of third-party infringing use to withstand LP's motion for summary judgment of noninfringement.

AMS moves for summary judgment that claims 25 and 27-30 are indirectly infringed under a theory of contributory infringement or inducement. Because fact issues remain regarding the 90% limitations, the transmitting surface/particular area, the glass cladding limitation, and the means for positioning, the Court denies AMS's motion.

3. Infringement under the doctrine of equivalents

LP contends that AMS is precluded from relying on the doctrine of equivalents for any limitations other than the glass cladding limitation. AMS responds that it may rely on the doctrine of equivalents for all of the claim limitations.

The pretrial schedule required AMS to identify on its claim chart "which claim(s) of its patent(s) it alleges are being infringed" and "where each element of each claim . . . is found in each product or method." The pretrial schedule also required AMS to "separately indicate [contentions of infringement under the doctrine of equivalents] on its Claim Chart and, in addition to the information required for literal infringement . . . also explain each function, way, and result that it contends are equivalent." In its claim chart, AMS generally asserted that LP infringes "literally and/or under the doctrine of equivalents," but made specific allegations of infringement under the doctrine of equivalents only with respect to the glass cladding limitation. AMS first indicated that it intended to assert infringement under the doctrine of equivalents for the other limitations in Milster's expert report on infringement on January 25, 2010. To the extent AMS asserts infringement under the doctrine of equivalents for limitations other than the glass cladding limitation, AMS has not complied with the pretrial schedule. The Court therefore

considers whether AMS's untimely disclosure of its allegations of infringement under the doctrine of equivalents was substantially justified or harmless. *See Trost*, 162 F.3d at 1008.

AMS asserts no justification for its untimely disclosure. It appears, however, that AMS's untimely disclosure was harmless. LP identifies no harm arising from the untimely disclosure, and Knox responded in his noninfringement report to Milster's opinions regarding the doctrine of equivalents for each element. The Court therefore permits AMS to assert infringement under the doctrine of equivalents with respect to the transmitting surface/particular area, the glass cladding limitation, and the 90% limitations.

AMS moves for summary judgment that the accused devices infringe under the doctrine of equivalents, while LP moves for summary judgment of noninfringement under the doctrine of equivalents for the glass cladding limitation. LP also maintains that prosecution history estoppel bars application of the doctrine of equivalents for the glass cladding limitation. A court generally determines if prosecution history estoppel applies before deciding a motion for summary judgment of infringement under the doctrine of equivalents. *Bai*, 160 F.3d at 1354. LP, however, only made prosecution history estoppel arguments with respect to the glass cladding limitation. Having decided that AMS may assert infringement under the doctrine of equivalents for the other limitations, the Court permits LP to bring a motion in limine regarding the application of prosecution history estoppel to those limitations. The Court will consider all of LP's prosecution history estoppel arguments at that time. Should LP make no additional arguments regarding prosecution history estoppel, the Court will rely on the parties' summary judgment briefs with respect to the glass cladding limitation. In light of the contradictory opinions of Milster and Knox and the incomplete briefing on the issue of prosecution history

estoppel, the Court denies the motions for summary judgment on the issue of infringement under the doctrine of equivalents.

4. Willful infringement

LP seeks summary judgment on the issue of willful infringement on the ground that AMS failed to plead it. AMS responds that it pleaded willful infringement in its Complaint because it pleaded continuing infringement and infringement by inducement or contributory infringement, which require knowledge of the '699 Patent.

AMS relies on two cases to support its contention that it sufficiently pleaded willful infringement. In both cases, however, the patentee actually pleaded “willful” infringement. *See Sentry Protection Prods., Inc. v. Eagle Mfg. Co.*, 400 F.3d 910, 918 (Fed. Cir. 2005) (finding patentee did not waive marking argument by failing to plead notice where patentee alleged “that the infringements have been willful and with full knowledge of the [patents at issue]”); *Jardin v. Datallegro, Inc.*, No. 08-1462, 2009 WL 186194, at *1, 7 (S.D. Cal. Jan. 18, 2009) (finding complaint stated a claim for willful infringement where “Plaintiff allege[d] Defendants have committed patent infringement and willful infringement of the patent”). AMS did not allege “willful” infringement in its Complaint, nor did it seek enhanced damages under 35 U.S.C. § 284 (2006). *Cf. SRI Int’l, Inc. v. Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1464 (Fed. Cir. 1997) (explaining that “willful infringement” is the phrase “designating behavior for which enhanced damages [under § 284] may be assessed”). Nothing in AMS’s Complaint gave LP “fair notice” of a claim for willful infringement. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Consequently, the Court grants LP’s motion for summary judgment of no willful infringement.¹⁶

¹⁶ LP also seeks summary judgment that its HBLF-60S product does not infringe the '699 Patent. AMS responds that LP seeks an improper advisory opinion because AMS has not accused the HBLF-60S of infringement and no discovery has taken place regarding this product.

C. Invalidation

The parties cross-moved for summary judgment on the issues of invalidity under §§ 112, 102, and 103 (2006).¹⁷ The Court sets forth the legal standards here only to the extent they have not been previously stated.

1. Legal standard

An issued patent is presumed valid. 35 U.S.C. § 282. An accused infringer has the burden of proving invalidity by clear and convincing evidence. *Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). “When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits.” *Id.* A moving party seeking to invalidate a patent on a motion for summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. *Id.* A moving party seeking to have a patent found not invalid at summary judgment must show that the nonmoving party failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. *Id.*

The Court declines to grant summary judgment of noninfringement for a product not at issue in this lawsuit.

¹⁷ To the extent LP relies on the ongoing reexamination of the '699 Patent in support of its invalidity arguments, the Court “agrees . . . that evidence of incomplete patent reexamination proceedings is not admissible to prove invalidity of a patent, because it has no probative value on that issue . . . and even if the evidence has some marginal probative value, that probative value is outweighed by its potential for undue prejudice or confusion of the jury about the presumption of validity of the patent.” *Transam. Life Ins. Co. v. Lincoln Nat’l Life Ins. Co.*, 597 F. Supp. 2d 897, 908 (N.D. Iowa 2009).

2. Section 112

a. *Functionality*

Citing *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), LP contends the asserted claims are invalid because the 90% limitations, which LP characterizes as the “exact point of novelty,” are “purely functional.” “[T]here is no support, either in the actual holdings of prior cases or in the [Patent Act], for the proposition, put forward here, that ‘functional’ language, in and of itself, renders a claim improper,” and no “other ground for objecting to a claim on the basis of any language, ‘functional’ or otherwise, beyond what is already sanctioned by the provisions of 35 U.S.C. § 112.” *In re Swinehart*, 439 F.2d 210, 213 (C.C.P.A. 1971); *see also Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255-56 (Fed. Cir. 2008) (citing *Swinehart* with approval and explaining that functional claim language may render the claim indefinite under § 112, ¶ 2); 3 Donald S. Chisum, *Chisum on Patents* § 8.04[3] (2010) (“Under *Swinehart*’s analysis, functional language is not per se objectionable in claims. Functionality in claim language may raise problems under the established patent law standards requiring claim definiteness, full enabling disclosure, and patentable distinctness over the prior art.”). *Swinehart* is consistent with *Walker*, as the U.S. Supreme Court invalidated the claims at issue in *Walker* as indefinite. *See Walker*, 329 U.S. at 8-14.

LP, however, contends that “pure functionality” provides an independent basis for invalidating claims unless the claim language is limited to the structures disclosed in the specification pursuant to § 112, ¶ 6. In support of this proposition, LP cites *Ex parte Miyazaki*, in which the Board of Patent Appeals and Interferences (Board) found certain claims invalid as “purely functional.” 89 U.S.P.Q.2d 1207, 2008 Pat. App. LEXIS 26, at *27-36 (B.P.A.I. Nov. 19, 2008). LP’s reliance on *Miyazaki* is misplaced for three reasons. First, the Board explicitly

limited its holding to “claim construction before the USPTO.” *Id.* at *36. Second, the Board linked the concerns of purely functional language to the requirements of § 112. *Id.* at *34-35 (identifying indefiniteness and failure to meet the written description requirement as concerns arising from a “purely functional claim element”). Third, Board opinions, while potentially persuasive, are not binding on federal courts. *See Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004). The Court therefore considers LP’s “functionality” arguments in the context of the requirements of § 112.

b. Indefiniteness

Both parties moved for summary judgment on the issue of indefiniteness. The definiteness requirement is set forth in § 112, ¶ 2, which provides: “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” Claims are considered indefinite when they are “not amenable to construction or are insolubly ambiguous.” *Young*, 492 F.3d at 1346. A claim is not indefinite if it can be given “any reasonable meaning.” *Id.* Indefiniteness is a question of law, and any factual determinations underlying the indefiniteness conclusion must be proven by clear and convincing evidence. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008). Summary judgment on the issue of indefiniteness is inappropriate where there are issues of fact underlying the indefiniteness determination. *See BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) (“Like enablement, definiteness, too, is amenable to resolution by the jury where the issues are factual in nature.”); *Dow Chem. Co. v. NOVA Chems. Corp. (Canada)*, 629 F. Supp. 2d 397, 403-04 (D. Del. 2009) (“Although it may generally behoove the Court to address indefiniteness as a legal matter in the context of claim construction, there may arise cases where genuine issues of fact simply preclude

such a treatment. In these circumstances, the question of indefiniteness must be addressed by the trier of fact.”).

LP first contends that the 90% limitations are indefinite because they are “purely functional.” “[T]he ambiguities of a functional limitation” can be resolved “by using a quantitative metric (e.g., numeric limitation as to a physical property) rather than a qualitative functional feature” or if “the specification provide[s] a formula for calculating a property along with examples that meet the claim limitation and examples that do not.” *M-I*, 514 F.3d at 1255-56. Here, the 90% limitations are constrained by the use of a quantitative metric, and the ’699 Patent describes a test for determining whether the 90% limitations are met. Moreover, the 90% limitations are not purely functional because the claims do contain language directed toward the location and orientation of the transmitting surface and reflecting surface used to achieve the claimed result of 90% incidence at below the critical angle. The Court therefore denies LP’s motion for invalidity as indefinite insofar as it is based on the argument that the 90% limitations are “purely functional.”

LP next contends that the 90% limitations and the transmitting surface/particular area are indefinite because a person of ordinary skill in the art cannot determine the location and size of the transmitting surface/particular area and because an accused device could have multiple transmitting surfaces/particular areas. For the reasons stated with respect to AMS’s motion to exclude Knox’s testimony, LP’s reliance on the possibility of multiple transmitting surfaces/particular areas and the failure to specify their dimensions and locations does not establish that there is no issue of fact regarding indefiniteness. LP’s reliance on Pon’s testimony as “confirm[ing] that based upon the teachings of the Pon Patent ‘it would be difficult for [Pon] to determine’ where the transmitting surface beings and ends” is misplaced because his

testimony was limited to making such a determination based only on Figure 11 of the '699 Patent. LP also quotes Pon's statement that "you might not be able to determine where the transmitting surface begins and ends." Pon's testimony is clear that "you" refers to a layperson and that a person of ordinary skill in the art could make the determination based on the waveguide's configuration. In short, the statements quoted by LP are not evidence that a person of ordinary skill in the art could not determine where the transmitting surface begins and ends.

LP also contends that the 90% limitations and the transmitting surface/particular area are indefinite despite the description of the transmission test in the '699 Patent. Generally, a claim limitation is not indefinite if the specification provides a method for determining whether the limitation is met. *See, e.g., Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1022 (Fed. Cir. 2009) (rejecting argument that "reduction in bacterial density in the wound by at least 50%" was indefinite where example in patent described a particular method); *Marley Mouldings*, 417 F.3d at 1360-61 (stating "§ 112 ¶ 2 is satisfied when the relevant values can be 'calculated or measured'" (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558 (Fed. Cir. 1983))). Here, however, Knox opines that polarization, wavelength, and other variables would affect the transmission test results and that a person of ordinary skill in the art would not know which variables to select before conducting the test described in the '699 Patent. *See Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1340 (Fed. Cir. 2003) (concluding that claim including a specified melting parameter of a polymeric yarn was indefinite where the intrinsic evidence did not indicate which of four known methods of preparing and testing the yarn to use and only one of the four methods produced a measurement within the claimed range). AMS responds that whether § 112 is satisfied is determined from the perspective of a person of ordinary skill in the relevant art of optical fibers for surgical

applications. AMS maintains that the claims are not indefinite based on Milster's testimony that a person of ordinary skill in the art would know which launch conditions, optical fibers, wavelength, and polarization to select and on the testimony of Milster, Stein, and Griffin that the results of the transmission testing of the accused devices and other side-firing devices do not vary significantly across wavelength, polarization, or launch conditions.

“The definiteness inquiry focuses on whether those skilled in the art would understand *the scope of the claim* when the claim is read in light of the rest of the specification.” *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) (emphasis added). As construed by the Court, the scope of the claims is not limited to optical fibers for surgical applications. Consequently, the claims must be definite across their entire scope, not simply within the field of optical fibers for surgical applications or with respect to the accused devices. The testimony and opinions of Milster, Stein, and Griffin, however, relate only to whether the claims are definite in the field of optical fibers for surgical applications. Moreover, to the extent AMS relies on the transmission test described in the '699 Patent, the results of that test depend not only on the characteristics of the product being tested, but also on test conditions not stated in the '699 Patent. No evidence indicates that a person of ordinary skill in the art would know which test conditions to select across the scope of the claims. In view of Knox's testimony to the contrary, and when taking the evidence in the light most favorable to LP, issues of fact remain as to whether a person of ordinary skill in the art would understand the scope of the claims. *Compare Marley Mouldings*, 417 F.3d at 1359-61 (reversing summary judgment of indefiniteness where variable alleged to affect the test results was the “volume of a given weight of wood flour”), *with Honeywell*, 341 F.3d at 1335-42 (affirming determination of indefiniteness where test results varied greatly depending on which sample preparation method was used and

intrinsic evidence did not “lead one of ordinary skill in the art to a particular sample preparation method”). When taking the evidence in the light most favorable to AMS, however, issues of fact remain as to whether a person of ordinary skill in the art would not understand the scope of the claims. Those issues of fact preclude the entry of summary judgment on the issue of indefiniteness.

c. Written description and enablement

The parties move for summary judgment on the issues of written description and enablement. The specification of a patent must include a written description of the invention and the manner and process of making and using it. 35 U.S.C. § 112, ¶ 1. “Those two requirements usually rise and fall together. That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa.” *LizardTech*, 424 F.3d at 1345. Whether the written description requirement is met is a question of fact, while enablement is a question of law involving underlying factual inquiries. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006).

LP first contends that the functional language of the 90% limitations renders the claims invalid for failure to meet the written description requirement. “[F]unctional claim language can meet the written description requirement when the art has established a correlation between structure and function.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010). Milster’s explanation in his expert report of how a person of ordinary skill in the art would determine the location and relative size of the transmitting surface/particular area and Milster’s and Knox’s descriptions of how light behaves in prior art waveguides based on figures illustrating the waveguides are evidence of a correlation between structure and function. The

Court denies LP's motion for summary judgment that the claims are invalid for failure to meet the written description requirement on functionality grounds.

LP next contends that the written description requirement is not met because the claims are broadly drafted, yet the specification discloses only five embodiments of the invention. With respect to the written description requirement,

[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention.

LizardTech, 424 F.3d at 1345.

Accordingly, “disclosure of a species may be sufficient written description support for a later claimed genus including that species.”¹⁸ *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004). “If the difference between members of the group is such that the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus.” *Id.*

Relying on Knox's declaration, LP contends that a person of ordinary skill in the art would not understand that Pon was in possession of waveguides that do not employ optical fibers or certain microlens and microball structures that Knox contends meet the 90% limitations.

¹⁸ In the context of patent law, “genus” is used to refer to a “class of individual embodiments, each of which shares one or more characteristics in common,” while a “species” is one embodiment in the class. 4 R. Carl Moy, *Moy's Walker on Patents* § 4:65 (2010). “Two inventions can be related as genus and specie even though the subject matter to which they pertain is not organized taxonomically with strict precision. Rather, generic and specific forms of an invention are possible whenever a part of the invention can be described in different degrees of generality.” *Id.*

Milster opines, referring to embodiments described in the specification, that a person of ordinary skill in the art would understand Pon to have had possession of the claimed subject matter.

Milster's expert report does not explain how a person of ordinary skill in the art would understand Pon to have had possession of waveguides meeting the claim limitations that do not fall into the category of optical fibers used in medical devices, and the summary judgment record includes no evidence of the predictability of the art. Given the breadth of the claims, the Court concludes that, when taking Knox's declaration in the light most favorable to LP, a reasonable jury could find that LP had demonstrated by clear and convincing evidence that Pon was not in possession of the microlens and microball structures or waveguides that do not employ optical fibers. However, a reasonable jury also could find that LP had not made that showing. The Court therefore denies the parties' motions for summary judgment on the issue of invalidity for failure to meet the written description requirement.

LP also contends that the claims are not enabled because the '699 Patent only discloses five embodiments. "If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment, and is not invalid for lack of enablement simply because it reads on another embodiment of the invention which is inadequately disclosed." *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987) (citations omitted); *see also Invitrogen Corp. v. Clontec Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) ("Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise."). Milster opines that a person of ordinary skill in the art would know how to make and use the claimed invention, and describes the process a person of ordinary skill in the art would use to do so. Nevertheless, it is unclear from his expert report whether the claims are

enabled beyond the field of optical fibers for surgical applications, and Knox opined that the claims are not enabled across the scope of the claims. The Court concludes that issues of fact preclude the entry of summary judgment on the issue of invalidity due to lack of enablement.¹⁹

3. Section 102

Both parties moved for summary judgment on the issue of anticipation under 35 U.S.C. § 102. To anticipate a prior art reference under § 102, the reference must disclose all elements of the claim, either expressly or inherently, within the four corners of the document and arranged as in the claim. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010). Anticipation is a question of fact. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1322 (Fed. Cir. 2008).

a. Hashimoto

LP argues that a 1986 publication by D. Hashimoto et al. (Hashimoto) anticipates claim 1.²⁰ AMS contends that none of the asserted claims are anticipated by Hashimoto.

¹⁹ In response to AMS's motion for summary judgment of enablement, LP maintains that the "means for positioning" limitation of claim 25 and dependent claims 27-30 is not enabled. The Court construed "means for positioning the waveguide during surgery" as "(a) an endoscope, (b) a cytoscope, (c) an in-line scope, (d) a tube having a hollow passage, (e) a rigid cannula, (f) a flexible catheter, or (g) equivalents thereof." Claim 25 recites "a surgical probe . . . comprising . . . a means for positioning" while the dependent claims recite "wherein the means for positioning" either "includes" or "comprises" a tube, cannula, or catheter. LP maintains that claims 25 and 27-30 are not enabled because a tube, cannula, or catheter cannot independently perform the positioning function. AMS, presumably relying on the "comprising" or "including" language, argues that LP's argument is self-defeating because LP conceded that a tube, cannula, or catheter in conjunction with an endoscope can perform the positioning function. The Court notes, however, that the construction of "means for positioning" suggests that the "means for positioning" can *be*, not *include*, a tube, cannula, or catheter. The parties did not cite any applicable case law. Because LP did not move for summary judgment of invalidity on this ground, the Court need not decide this issue.

²⁰ LP does not dispute that Hashimoto does not teach the glass cladding limitation or a means for positioning.

Hashimoto is directed to a “micro-prism incorporated on [a] fiber tip” that reflects a laser beam at 90 degrees to the axis of the waveguide. The parties dispute whether Hashimoto teaches a “reflecting surface on the tip of the waveguide.” The Court construed “tip of the waveguide” as “including a separate component coupled thereto in a manner that prevents internal reflection at any interface between the components (for example, by fusing or a transparent, index-matched adhesive)” and “reflecting surface” as a “surface that internally reflects essentially all of the incident electromagnetic radiation that is communicated by the waveguide toward the tip, where ‘internally reflects’ means the electromagnetic radiation is reflected because it is incident on the reflecting surface at an angle greater than the critical angle.”

Milster opines that Hashimoto does not teach that the prism “is coupled to the fiber at all, much less in a manner that prevents internal reflection at any interface between the components.” Consequently, according to Milster, Hashimoto discloses neither a reflecting surface nor a particular area/transmitting surface “on the tip of the waveguide” because the bevelled surface that reflects the laser beam and the surface through which the laser beam is transmitted are on the prism, which is not the tip. In addition, Milster opines that the bevelled surface is not a “reflecting surface” because it is angled at 45 degrees, and therefore would not internally reflect the laser beam. Finally, Milster opines that Hashimoto does not expressly nor inherently disclose the 90% limitations.

Knox opines that a person of ordinary skill in the art would know to attach the prism to the fiber using an index-matching adhesive and to select a prism material having an index of refraction that would cause the bevelled surface of the prism to internally reflect light. He further opines that, under those conditions, the 90% limitation would be met. “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain

thing may result from a given set of circumstances is not sufficient.” *Therasense*, 593 F.3d at 1332. Rather, “anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation.” *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002).

LP, relying on Stein’s declaration, contends that the prism must be connected to the optical fiber in an index-matched manner because the light rays passing from the optical fiber to the prism are shown as straight lines in Figure 2 in Hashimoto. Stein stated that “representative light rays are sometimes used to indicate how rays will generally react at different interfaces and surfaces” and that the rays in Hashimoto “would indicate to a person of ordinary skill that there is no change in the optical properties (such as the index of refraction) between the fiber and the microprism” because they are shown as straight. Even if this assertion is true, a disclosure is not “necessarily present” if it is only “sometimes” true. Moreover, given that Hashimoto shows other light rays as straight lines when travelling through materials having different refractive indices, Hashimoto is “devoid of any indication” that the rays are intended to indicate whether there is a change in refractive index. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005). No reasonable finder of fact could conclude that Hashimoto necessarily discloses the micro-prism attached to the optical fiber using an index-matched adhesive based on the straight lines of Figure 2.

LP also contends that Griffin testified that “nearly 100% of reflected light would be incident on the particular area at below a critical angle for transmission through the surface.” Griffin qualified his testimony, however, by stating that it was based on the dimensions shown in Hashimoto, which he noted was not a scale drawing. *See id.* (explaining that “arguments based on drawings not explicitly made to scale in issued patents are unavailing”). In short, no evidence

indicates that Hashimoto necessarily includes a prism coupled to the fiber in a manner that prevents internal reflection or a prism having an index of refraction that would result in the 90% limitations being met. Because no reasonable jury could find that Hashimoto discloses the 90% limitations, a reflecting surface on the tip of the waveguide, or a transmitting surface/particular area on the tip of the waveguide, the Court finds as a matter of law that Hashimoto does not anticipate the asserted claims.

b. Hussein

LP contends that U.S. Patent No. 4,445,892 (filed May 6, 1982) to Hany M.G. Hussein et al. (Hussein) anticipates claim 1. AMS maintains that Hussein anticipates none of the asserted claims.

Hussein is directed to a laser transmitting fiber located within a stem where laser radiation is laterally directed from the fiber using a prism. The prism bevel has an angle of 45 degrees. Milster opines that Hussein does not teach that the prism is connected to the fiber in a manner that eliminates internal reflection, the 90% limitations, or a reflecting surface. Again, Knox opines that a person of ordinary skill in the art would know to attach the prism to the fiber using an index-matching adhesive and to select a prism material having an index of refraction that would cause the bevelled surface of the prism to internally reflect light. For the reasons stated with respect to Hashimoto, Knox's opinions are insufficient to create a genuine issue of material fact as to whether claim 1 is anticipated by Hussein. The Court finds as a matter of law that Hussein does not anticipate the asserted claims.

c. Fletcher

LP argues that U.S. Patent No. 5,257,991 (filed Aug. 11, 1992) to Henry H. Fletcher et al. (Fletcher) anticipates all of the asserted claims. AMS contends that Fletcher anticipates none of the asserted claims.

LP first relies on Figure 22a and the related description in Fletcher. Figure 22a discloses an optical fiber having a bevelled end. Fletcher col.11 ll.1-3. A reflective coating is deposited on the bevelled end and adjacent sides of the optical fiber, except for an area adjacent to the end of the optical fiber. Fletcher col.11 ll.3-6. Light directed by the optical fiber is reflected through the uncoated area by the bevelled angle and reflective coating. Fletcher col.11 ll.8-11. Knox opines that Figure 22a teaches the 90% limitation because “the reflective coating would prevent light from being transmitted out of the fiber except through [the] uncoated window.” Milster opines that Fletcher does not teach a “reflecting surface” because the light is reflected by the reflective coating rather than internally reflected and the Court construed “reflective coating” as a separate component from the “reflecting surface.” Because it is undisputed that the reflective coating on the bevelled end and adjacent sides reflects the light, there is no issue of fact as to whether Figure 22a discloses a reflecting surface or the 90% limitations. Although LP maintains that Figure 1 of Fletcher teaches an optical fiber having a bevelled end for internally reflecting light, this does not create an issue of fact as to anticipation because anticipation requires the reference to disclose all elements of the claim “arranged as in the claim.” *Therasense*, 593 F.3d at 1332.

LP also contends that Figure 23 anticipates the claims. Knox opines that the device shown in Figure 23 would meet the 90% limitations if tested in water. Milster opines that Figure 23 does not inherently or expressly disclose the 90% limitations if tested in air or water. Having

concluded that the transmission test must be conducted in air, not water, Knox's opinion does not create an issue of fact as to whether Figure 23 anticipates the asserted claims. The Court finds as a matter of law that the asserted claims are not anticipated by Fletcher.

d. JP 377

LP argues that Japanese Patent No. 3-63377 (JP 377) to Hashimoto et al. anticipates all asserted claims. AMS maintains that JP 377 does not anticipate any of the asserted claims.

JP 377 is directed to a "laser beam side irradiating fiber used for irradiating the laser beam from the side on the lesion portion in lumina of viscera via an endoscope."²¹ The fiber, which terminates at an angle of 45 degrees, is "characterized by the fact that it has a highly reflective output and without the formation of a reflective coating surface on the laser beam reflective surface." JP 377 describes the inventive fiber as follows:

Fiber base conductor (11) is a conventional optical fiber base conductor made of glass or plastic, with a configuration made of a core and a cladding having different refractive indexes. . . . [T]he fiber base conductor is a fused silica fiber with a core size of 400 μm and with an outer diameter of the cladding layer of 650 μm . Over the entire length of fiber base conductor (11), a primary coating layer (12) is formed. Fiber base conductor (11) with said primary coating layer (12) formed on it is further protected by a protective coating tube (13) which can prevent cracks on fiber base conductor (11) or damage by folding of fiber base conductor (11). Said protective coating tube (13) is preferably made of a vinyl resin material, nylon, Teflon, or another synthetic resin material. . . . After peeling of the primary coating layer and protective coating tube (13) from a portion of the fiber, the output face of fiber base conductor (11) is equipped with a transparent cylinder (15) . . . with air-tight bonding between them by means of epoxy type adhesive (16).

LP contends that the 90% limitation is met by the fiber disclosed in JP 377 because the core-to-core-cladding ratio is over 1.4, which the '699 Patent teaches will achieve the 90% limitations. LP's contention that the core-to-core-cladding ratio is greater than 1.4 rests on its

²¹ The parties relied on the same English translation of JP 377 for purposes of summary judgment.

argument that the 650 μm dimension includes the core cladding but excludes the primary coating layer (12) and protective coating tube (13). LP relies on Knox's opinion that JP 377 teaches a core-to-core-cladding ratio of 1.625 based on those dimensions and that a person of ordinary skill in the art would know to select an index of refraction to cause internal reflection at an angle of 45 degrees.²²

AMS contends that the 650 μm dimension includes the primary coating layer (12) and protective coating tube (13), and consequently, that the core-to-core-cladding ratio is not greater than 1.4. In support of this argument, AMS relies on Milster's opinion that the 650 μm dimension includes the primary coating layer (12) and protective coating tube (13) and that a person of ordinary skill in the art would understand the term "cladding" to refer to those layers as well as the core cladding. Milster contends that the language in JP 377 describing a gap (21) that "cover[s] the entire outer circumference of fiber base conductor (11)" indicates that primary coating layer (12) and protective coating tube (13) are part of the fiber base conductor (11) because Figure 1 of JP 377 shows the gap (21) covering the outer circumference of protective coating tube (13). AMS also relies on the testimony of Griffin that no conventional optical fiber at the time the application for JP 377 was filed had core cladding with an outer diameter of 650 μm and that nomenclature problems are common in the industry.

In addition, AMS contends that JP 377 does not expressly or inherently disclose the 90% limitations because there is an air gap between the fiber (11) and the cylinder (15). JP 377 refers to bonding the cylinder (15) to the fiber (11) "by means of epoxy type adhesive (16)" while Figure 1 shows an object (16) surrounding the fiber (11). Milster opines, however, that a person

²² LP suggests that Griffin testified that the 90% limitation was met by JP 377. It is evident from the cited deposition testimony that Griffin did not believe the core-to-core-cladding ratio was greater than 1.4 or that the 650 μm excluded the primary coating layer (12) and protective coating tube (13).

of ordinary skill in the art would understand (16) to be the core cladding, not the adhesive, because Figure 1 shows (16) continuing proximally under the primary coating layer (12), but epoxy would not extend so far. Instead, according to Milster, a person of ordinary skill would understand the epoxy to be used at the proximal end of the cylinder. In support of these arguments, AMS relies on U.S. Patent No. 4,740,047 (filed Mar. 19, 1986), which shares inventors with JP 377. The '047 Patent, when describing Figure 1 in JP 377, states that that a “thin air layer” forms between the glass cylinder surrounding the tip and the stripped base fiber, which causes optical leaks and thereby reduces the transmission. According to AMS, this air gap means the 90% limitations are not taught by JP 377.

Milster also opines that, even if the epoxy were located between the outer surface of the cladding and the cylinder (15) and had the refractive index suggested by Knox, there would be no transmitting surface on the core cladding because there would no critical angle at that interface. Milster further opines that, because there would be no transmitting surface, JP 377 would not disclose the 90% limitations. Finally, although JP 377 states that “the laser beam transmitted through fiber base conductor (11) is totally reflected from the inclined surface,” Milster also opines that the inclined surface is not a reflecting surface because it is at 45 degrees. AMS additionally relies on the statement in the '047 Patent that, in the device shown in JP 377, a “significant component” of laser energy incident on the bevelled surface would be transmitted through the bevelled surface.

The parties' arguments regarding how a person of ordinary skill in the art would understand the disclosures of JP 377 and whether certain limitations are present under specific conditions demonstrate that issues of fact remain as to anticipation by JP 377. Those issues of fact preclude the entry of summary judgment on the issue of invalidity by anticipation.

4. Section 103

AMS and LP move for summary judgment on the issue of invalidity due to obviousness. A patent is invalid when “the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. § 103(a). Obviousness is a question of law based on underlying factual findings. *Honeywell Int’l, Inc. v. United States*, 596 F.3d 800, 806 (Fed. Cir. 2010).

The following factors control the obviousness inquiry: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the pertinent art; and (4) objective evidence of nonobviousness. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). “While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (‘TSM’) test in an obviousness inquiry, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination.” *Takeda Chem. Indus., Ltd. v. Alphapharm Pty.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007).

AMS first asserts that summary judgment of nonobviousness should be granted because none of the cited references teach the 90% limitations.²³ Having concluded that genuine issues of material fact remain as to whether JP 377 discloses the 90% limitations, the Court denies AMS’s motion for summary judgment insofar as it is based on that ground.

AMS also maintains that there is no evidence of any reason to combine the cited references. Although the Court has excluded Knox’s testimony on the issue of obviousness, “an expert is not the only source for evidence that it would be obvious for one skilled in the art to

²³ AMS does not dispute that at least JP 377 teaches the “glass cladding extending to a distal end of the tip” and “means for positioning” limitations.

combine references.” *Innogenetics*, 512 F.3d at 1374. In light of the teachings of the cited prior art, for example, the use of an endoscope in JP 377 to transport optical fibers within the body, a fact finder could understand that an endoscope was a known solution to a known problem of transport and therefore why a person of ordinary skill in the art would combine the references in the manner claimed. *See KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”). Issues of fact remain as to whether there is a reason to combine the cited references.

LP maintains that the asserted claims are invalid as obvious. Issues of fact regarding whether all of the claim limitations are found in the cited references and whether there is a reason that would have prompted a person of ordinary skill to combine the elements in the manner claimed preclude the entry of summary judgment of invalidity due to obviousness.

For the reasons stated above, the Court denies LP’s motion for summary judgment of invalidity and denies AMS’s motion for summary judgment of non-invalidity. However, the Court finds as a matter of law that Hashimoto, Hussein, and Fletcher do not anticipate the asserted claims of the ’699 Patent.

D. Enforceability

1. Inequitable conduct

AMS moves for summary judgment on LP’s affirmative defense of inequitable conduct. To prove that a patent is unenforceable due to inequitable conduct, the alleged infringer must provide clear and convincing evidence of (1) affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information and (2) an

intent to deceive. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1373 (Fed. Cir. 2004). Once threshold findings of materiality and intent are established, the trial court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred, which requires a careful balancing. *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1128-29 (Fed. Cir. 2006). When the misrepresentation or withheld information is highly material, a lesser quantum of proof is needed to establish the requisite intent, while the less material the information, the greater the quantum of proof required. *Id.* at 1129. “Intent to deceive cannot be inferred from a high degree of materiality alone, but must be separately proved to establish unenforceability due to inequitable conduct.” *Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009). Summary judgment on the issue of inequitable conduct is appropriate when, “drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail.” *Id.*

The Court first addresses what bases LP may assert for its inequitable conduct claim. In its Amended Answer and Counterclaim, LP alleged that Davis, who was involved with the prosecution of the '699 Patent, failed to disclose to the USPTO Hashimoto and Figure 22a in Fletcher. LP also alleged that Davis was aware of both because he drafted the application to which Fletcher claimed priority (Fletcher application) and cited Hashimoto to the USPTO when prosecuting the Fletcher application.²⁴ In its motion for summary judgment, however, LP asserts the failure to disclose Figure 23 in Fletcher and AMS's conduct during the reexamination of the '699 Patent as additional bases. AMS contends that LP may not base its inequitable conduct claim on Figure 23 and AMS's reexamination conduct because LP did not allege them as bases for inequitable conduct in its Amended Answer and Counterclaim.

²⁴ Fletcher is a continuation-in-part of the Fletcher application. The Fletcher application did not include Figure 23 of Fletcher.

Inequitable conduct must be pleaded with particularity under Rule 9(b) of the Federal Rules of Civil Procedure. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009). The pleading must “identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the ‘what’ and ‘where’ of the material omissions.” *Id.* at 1329. LP maintains that it met the particularity requirement because its Amended Answer and Counterclaim identified “at least Figure 22a” in Fletcher as the basis for its inequitable conduct defense. “At least” does not meet the particularity requirement of Rule 9(b). *See id.* at 1329 (finding that pleading did not satisfy Rule 9(b) because it failed to identify “*where in those references* the material information is found” (emphasis added)). LP also maintains that it pleaded inequitable conduct based on the identification of Figure 23 as allegedly teaching the 90% limitations in water in its May 4, 2009, Prior Art Statement. This argument is unpersuasive because a prior art statement is not a pleading, nor does it relate to LP’s allegations of inequitable conduct.

Moreover, LP fails to explain why, if it was aware of Figure 23’s significance when serving its Prior Art Statement in May 2009, it did not move to amend its Amended Answer and Counterclaim to include Figure 23 in its inequitable conduct allegations. LP also did not move to amend its Amended Answer and Counterclaim to include allegations based on AMS’s reexamination conduct, although the complained-of conduct began in July 2009. Because LP failed to plead with particularity inequitable conduct based on Figure 23 of Fletcher or AMS’s reexamination conduct, the Court will not permit LP to assert either as a basis for its defense.

The Court next considers whether Figure 22a and Hashimoto are material in the context of inequitable conduct. There are several standards for establishing materiality, but the most frequently used standard is “whether a reasonable examiner would have considered the

information important in deciding whether to grant the patent, even when the omitted information does not negate patentability.” *Astrazeneca*, 583 F.3d at 773. A reference need not be provided to the examiner if it is merely cumulative to or less material than other references before the examiner. *Id.* Pon testified that he believed Fletcher should have been disclosed to the USPTO. While a reasonable finder of fact could conclude that a reasonable examiner would have considered Figure 22a important based on Pon’s testimony, a reasonable finder of fact could not conclude that Figure 22a was highly material because it does not disclose the 90% limitations or a reflecting surface. As for Hashimoto, a reasonable finder of fact could not conclude that Hashimoto was as material as or more material than Figure 22a because Hashimoto does not disclose the 90% limitations or a reflecting surface, particular area, or transmitting surface on the tip of the waveguide.

Because the materiality of Hashimoto and Figure 22a is low, a greater quantum of proof of intent to deceive is required. *See Purdue Pharm.*, 438 F.3d at 1128-29. The ’699 Patent incorporated by reference the Fletcher application, which discloses Figure 22a and the related description. Such incorporation is inconsistent with any intent to deceive.²⁵ *See Grantley Patent Holdings, Ltd. v. Clear Channel Commc’ns, Inc.*, 540 F. Supp. 2d 724, 732 (E.D. Tex. 2008). LP contends that Davis’s failure to comply with the USPTO requirement of providing a copy of the Fletcher application (rather than simply incorporating it by reference) is evidence of intent to deceive. “Intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO.” *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1343 (Fed. Cir. 2006) (quotation

²⁵ Gerstman opined that the USPTO did not consider the Fletcher application, but it is whether a reference was disclosed, not whether it was considered, that is relevant to inequitable conduct.

marks omitted). Because Davis incorporated the Fletcher application by reference, no reasonable finder of fact could conclude that Davis intended to deceive the USPTO regarding Figure 22a based on his failure to provide a copy of the Fletcher application to the USPTO. In addition, the mention of Hashimoto in the Fletcher application weighs against an intent to deceive with respect to Hashimoto.

Moreover, “[i]n an inequitable conduct determination based upon a nondisclosure, the applicant must know, or should have known, of the materiality of the reference for an inference of intent.” *M. Eagles Tool Warehouse*, 439 F.3d at 1341. LP has identified no evidence indicating that Davis knew or should have known that Hashimoto was material to the application for the ’699 Patent. The prosecution history of the application that issued as Fletcher indicates that Davis cited Hashimoto to the USPTO on August 7, 1992. Davis filed his first substantive paper in the prosecution of the application for the ’699 Patent on May 20, 1994, twenty-one months later.²⁶ Even assuming Hashimoto were material to the ’699 Patent, in light of this 21-month gap, and in the absence of any evidence indicating Davis knew or should have known Hashimoto was material, no reasonable finder of fact could conclude that LP had shown by clear and convincing evidence that Davis knew or should have known Hashimoto was material.

“[W]hile ‘smoking gun’ evidence is not required in order to find intent to deceive, ‘the involved conduct, viewed in light of all the evidence, *including evidence indicative of good faith*, must indicate sufficient culpability to require a finding of intent to deceive.’” *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1345 (Fed. Cir. 2005) (quoting *Kingsdown Med. Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc)). An inference of deceptive intent must be “the single most reasonable inference able to be drawn from the

²⁶ On October 22, 1993, another attorney filed an information disclosure statement in connection with the application for the ’699 Patent.

evidence to meet the clear and convincing standard.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008). No reasonable finder of fact could find that an inference of deceptive intent was the single most reasonable inference to be drawn from Davis’s incorporation of the Fletcher application, the mention of Hashimoto in the Fletcher application, and the 21-month gap between Davis’s citation of Hashimoto to the USPTO in connection with Fletcher and his first substantive action in the prosecution of the ’699 Patent. The Court therefore grants AMS’s motion for summary judgment on the affirmative defense of inequitable conduct.²⁷

2. Patent misuse

AMS seeks summary judgment on LP’s affirmative defense of patent misuse. The purpose of the patent misuse defense is to prevent a patentee from using the patent to obtain market benefit beyond that inherent to the statutory patent right. *U.S. Philips Corp. v. Int’l Trade Comm’n*, 424 F.3d 1179, 1184 (Fed. Cir. 2005). “The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.” *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). “The bringing of a lawsuit to enforce legal rights does not of itself constitute violation of the antitrust laws or patent misuse; there must be bad faith and improper purpose in bringing the suit, in implementation of an illegal restraint of

²⁷ Even if the Court permitted LP to assert Figure 23 of Fletcher as a basis for inequitable conduct, having found that there is no genuine issue of material fact as to whether Figure 23 discloses the 90% limitations, the Court concludes that no reasonable finder of fact could find that LP had shown by clear and convincing evidence that its materiality was high. Moreover, in light of Davis’s incorporation of the Fletcher application, and in the absence of any evidence that Davis believed Figure 23 was material, no reasonable finder of fact could find that deceptive intent was the “single most reasonable inference” that could be drawn from the nondisclosure of Figure 23.

trade.” *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995).

LP first asserts that summary judgment is inappropriate because there is a genuine issue of material fact as to whether AMS sought to impermissibly broaden the scope of the '699 Patent. LP contends that AMS filed suit to force LP and other competitors out of the side-firing market. In support of this argument, LP submits evidence indicating that AMS wanted to pursue its own fused-window technology and therefore suggested the parties settle this lawsuit through a cross-license agreement involving the '699 and '499 Patents. LP relies on Stein's statement that an AMS representative indicated AMS's "interest in obtaining LP's intellectual property related to side-fire technology" and AMS's desire for an exclusive license to the '499 Patent.

There is nothing improper in seeking a cross-licensing agreement. *Boston Scientific Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 269 (D. Mass. 1997) ("It is well-established that settlement of patent litigation through a cross-licensing agreement does not in and of itself violate the antitrust laws."). Further, the evidence indicates that it was LP, not AMS, who proposed the cross-licensing agreement, and AMS explicitly stated in one of its counteroffers that the proposed exclusive license would not preclude LP from practicing the invention claimed in the '499 Patent. No evidence supports LP's contention that AMS sought to force LP out of the side-firing market. LP's argument that AMS sought to impermissibly broaden the scope of its patent grant by enforcing the '499 Patent against other competitors is similarly without merit because the acquisition of patent rights for the purpose of enforcing them, without more, does not constitute patent misuse. *See C.R. Bard*, 157 F.3d at 1372-73 ("Although the law should not condone wrongful commercial activity, the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce."). No reasonable finder of

fact could conclude that LP has shown by clear and convincing evidence that AMS filed suit for the purpose of putting LP and other competitors out of the side-firing market.

LP's other assertions of improper purpose are equally unpersuasive. First, LP criticizes AMS's characterization of Milster's expert reports as "Attorney's Eyes Only." LP fails to explain how this characterization has any relevance to whether AMS brought the suit for an improper purpose. Next, LP discerns a sinister motive in AMS's amendment of claims during the reexamination to cover the accused devices. There is nothing improper in AMS's amendment of its claims. *See Kingsdown Med.*, 863 F.2d at 874 (explaining that it is not "in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application"). Finally, LP argues that AMS's assertion of the '699 Patent against LP's predecessor that manufactured the accused devices in 1997 and subsequent dismissal of that lawsuit is evidence of improper purpose. AMS's decision to reassert its patent rights, without more, is not evidence of improper purpose.

LP also contends that AMS had no good faith basis for filing suit against LP. To establish bad faith, the defendant must prove by clear and convincing evidence that the claims asserted were objectively baseless. *See Dominant Semiconductors SDN. BHD. v. Osram GMBH*, 524 F.3d 1254, 1260, 1263-64 (Fed. Cir. 2008). Infringement allegations are objectively baseless when "no reasonable litigant could reasonably expect success on the merits." *Id.*

LP argues this lawsuit is objectively baseless because the tests show that only between 83% and 87% of the light input into the accused devices is output in the desired lateral direction. As stated with respect to LP's motion to strike Milster's expert reports and noninfringement arguments, LP's "input energy" argument ignores Milster's estimation of coupling and Fresnel

losses. There is no issue of fact as to whether a reasonable litigant could reasonably expect success on the argument that the accused devices meet the 90% limitations based on Milster's transmission testing. LP next contends that the suit is objectively baseless because AMS did not identify the critical angle or the location of the transmitting surface and was unaware that the accused devices had a fused window when it filed suit and because the '699 patent is invalid over the prior art. Based on the Court's review of the evidence, and for the reasons stated with respect to the motions for summary judgment on the issues of infringement and invalidity, there is no issue of fact as to whether a reasonable litigant could reasonably expect success on AMS's infringement and non-invalidity arguments. The Court therefore grants AMS's motion for summary judgment on LP's patent misuse defense.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. LP's motion to exclude Milster's testimony [Docket No. 245] is DENIED.
2. AMS's motion to exclude Knox's testimony [Docket No. 270] is GRANTED IN PART and DENIED IN PART.
3. LP's motion to strike Lei's declaration, portions of Milster's expert reports, Milster's March 28, 2010, declaration, and the deposition testimony of Pon and Novak [Docket No. 324] is DENIED.
4. AMS's motion to strike Gerstman's testimony [Docket No. 258] is GRANTED.
5. LP's motion for summary judgment of noninfringement [Docket No. 240] is GRANTED IN PART and DENIED IN PART.
6. LP's motion for summary judgment of invalidity [Docket No. 235] is DENIED.
7. AMS's motion for summary judgment of infringement [Docket No. 276] is DENIED.

8. AMS's motion for summary judgment of non-invalidity [Docket No. 276] is DENIED.
9. AMS's motion for summary judgment of enforceability [Docket No. 276] is GRANTED.
10. This case is set for trial beginning on Monday, July 12, 2010. A pretrial order establishing the schedule for motions in limine will issue in due course.

Dated: May 13, 2010

s/ Joan N. Ericksen

JOAN N. ERICKSEN
United States District Judge