UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

MOBILE MEDICAL INTERNATIONAL : CORPORATION, : Plaintiff,

__,

v. : Case No. 2:07-cv-231

ADVANCED MOBILE HOSPITAL SYSTEMS, INC., TRACTUS MEDICAL, INC., and JOHN DOES 1-10,

Defendants.

OPINION AND ORDER

Plaintiff Mobile Medical International Corporation ("MMIC") seeks a declaratory judgment with respect to the validity and non-infringement of U.S. Patent No. 4,915,435 (the "'435 Patent"). Defendants Advanced Mobile Hospital Systems, Inc. ("AMOHS") and Tractus Medical, Inc. ("Tractus") have counterclaimed for patent infringement. Tractus is a subsidiary of AMOHS and owner of the '435 Patent. Now before the Court are motions to disqualify two MMIC expert witnesses (ECF Nos. 138, 144) and a motion to preclude MMIC from relying upon certain evidence (ECF No. 140). For the reasons set forth below, those motions are denied.

Factual Background

The '435 Patent describes a transportable van in which invasive surgical procedures can be performed. It includes a laterally expandable portion that defines the operating room,

with an operating table that need not be removed when the expandable portion is retracted. The unit includes all essential facilities for complete invasive surgical procedures, including pre- and post-op areas.

MMIC is a manufacturer of temporary surgical units, known as "mobile medical units," that can be installed into truck bodies.

MMIC also manufactures temporary surgical units that can be delivered to an emergency location or otherwise built to provide a medical operating room. MMIC was formerly a licensee of the '435 Patent.

MMIC filed this lawsuit on October 30, 2007, and AmoHS and Tractus responded with an answer and counterclaim. On February 25, 2008 and March 29, 2009, MMIC filed requests for reexamination of the '435 patent with the United States Patent and Trademark Office ("USPTO"). The instant litigation was stayed on August 27, 2008 pending the outcome of the reexaminations. During the first reexamination, the USPTO rejected claims 19-25 and 31-35 of the '435 Patent as unpatentable, and the patentee canceled the claims. During the second reexamination, the PTO examiner rejected the remaining claims. The decision was reversed by the Board of Patent Appeals and Interferences, which found claims 1-18 and 30 valid in view of the prior art asserted.

This litigation recommenced in 2012. The parties engaged in

discovery, experts were disclosed, and several motions are now pending before the Court.

Pending Motions

I. Defendants' Motion to Disqualify Anthony Brummel

The Court first addresses the motion of AMoHS and Tractus (collectively "AMoHS") to disqualify MMIC expert Anthony Brummel from presenting his opinions about the validity of the '435 Patent. Under Federal Rule of Evidence 702:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data; the testimony is the product of reliable principles and methods; and
- (c) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

A district court must undertake a "gatekeeping" role with respect to expert opinion testimony. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In Daubert, the Supreme Court set forth a series of factors for determining whether expert testimony rests upon a sufficiently reliable foundation:

(1) whether a theory or technique "can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) a technique's "known or potential rate of error," and the "existence and maintenance of standards controlling the technique's operation"; and (4) whether a particular technique or theory has gained "general acceptance" in the relevant scientific community.

Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir. 2002) (quoting Daubert, 509 U.S. at 593-94). The Supreme Court has made clear that the Daubert guidelines must be applied with flexibility, particularly when the expert is offering opinions based on specialized personal knowledge rather than scientific studies. See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999). "It is well-established that the trial judge has broad discretion in the matter of the admission or exclusion of expert evidence[.]" Boucher v. United States Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996) (citation and quotation marks omitted).

"[T]he proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied[.]" United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007). In patent cases, a witness who is not qualified as a person of ordinary skill in the pertinent art may not testify as an expert on obviousness. Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1364 (Fed. Cir. 2008).

In this case, MMIC has designated Anthony Brummel as one of

its expert witnesses. Mr. Brummel is an engineer and consultant in the field of specialty vehicle engineering, including medical vehicles. He received a B.A. in industrial technology and education in 1983, and a Masters in industrial technology in 1989. Between 1984 and 2011, Mr. Brummel was employed at Calumet Coach Company, now known as Oshkosh Specialty Vehicles, and at the time of his departure from that company was the Director of Engineering.

During his time at Calumet Coach and successor companies,
Mr. Brummel designed and helped build expandable vehicles for a
number of purposes, including expandable surgical and other
medical trailers. According to his report, he proposes to offer
opinions on whether vans described in the '435 Patent, with all
of the features of claims 1-18 and 30, were (1) known and (2)
obvious to those of ordinary skill and art prior to January 1,
1989 and April 5, 1988.

AMoHS moves to disqualify Mr. Brummel on several grounds, arguing first that the expert report is not his own work and was instead drafted by counsel. Federal Rule of Civil Procedure 26(a)(2)(B) requires that the disclosure of a testifying expert "be accompanied by a written report - prepared and signed by the witness." Fed. R. Civ. P. 26(a)(2)(B). With respect to drafting, both sides cite *Trigon Ins. Co. v. United States*, 204 F.R.D. 277, 291-92, 295 (E.D. Va. 2001), which determined that:

[u]nquestionably, Rule 26 requires an expert witness to prepare his own Rule 26 Report. The Advisory Committee Notes accompanying this rule clarify the intended meaning of the phrase "prepared and signed by the witness", explaining that a report can be "prepared" by an expert witness even if counsel has aided the witness in preparing an expert's report. . . [T]he report, which is intended to set forth the substance of the direct examination, should be written in a manner that reflects the testimony to be given by the witness and it must be signed by the witness.

Within the Second Circuit, it has been held that "attorneys are not precluded from assisting expert witnesses in the preparation of their reports so long as the witness remains substantially involved." *Keystone Mfg. Co. v. Jaccard Corp.*, 394 F. Supp. 2d 543, 568 (W.D.N.Y. 2005).

Here, Mr. Brummel testified that he spent nearly 20 hours on his invalidity analysis, including reviewing documents and discussing issues and information with MMIC counsel. He also reportedly spent an entire day dictating his opinions in response to questions from counsel. While counsel prepared the first draft of the report, Mr. Brummel edited for accuracy and made necessary changes.

Given these attested facts, the Court finds that disqualification on the asserted basis is not warranted. Mr. Brummel has confirmed that the opinions set forth in the report are his own, and his testimony reveals substantial involvement in the report's preparation. Furthermore, "[a]s the court noted in Keystone, the appropriate approach, when a party is faced with

participation of counsel in the preparation of an expert report, is to present such facts to the finder of fact . . . Exclusion is not the proper remedy." Lab Crafters, Inc. v. Flow Safe, Inc., 2007 WL 7034303, at *5 (E.D.N.Y. Oct. 26, 2007) (citing Keystone Mfg., 394 F. Supp. 2d at 568).

AMoHS next argues that Mr. Brummel's invalidity analysis should be barred because it does not rest on a reliable foundation. See Daubert, 509 U.S. at 597. Specifically, AMOHS contends that Mr. Brummel failed to include two of the factors required for an invalidity analysis under Graham v. John Deere Co., 381 U.S. 1 (1966). The Supreme Court has held that while "the ultimate question of patent validity is one of law," validity rests on factual inquiries as to (1) the scope and content of prior art; (2) differences between that prior art and the claimed invention; (3) the level of ordinary skill in the pertinent art; and (4) evidence of secondary factors such as obviousness. Graham, 383 U.S. at 17-18; see also KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007). With regard to the fourth factor, it is well established that determinations of obviousness may not be based upon hindsight. See Crown Operations Int'l, Ltd. v. Solutia, Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002).

AMoHS submits that Mr. Brummel failed to properly analyze obviousness and to account for hindsight bias. Mr. Brummel's

report addresses obviousness in the context of what would have been common sense at the time, concluding that the subject matter of the patent was both obvious and predictable. He notes that the inventor of the '435 Patent, Dr. Levine, admitted in a deposition that "he did not invent any new equipment, and that he developed the lists of equipment in the patent by speaking to people in hospitals and asking them to identify commonly used equipment." Id. Mr. Brummel opines that "[p]rior to April 1988, those of ordinary skill in the art did the exact same thing when constructing mobile surgical trailers and other mobile medical trailers." Doc. 142-1 at 7. Accordingly, as he explained in his own deposition, Mr. Brummel concludes that there were no "secondary considerations" relevant to his review. ECF No. 142-2 at 76.

With regard to hindsight bias, Mr. Brummel appears to have analyzed the technology available prior to 1989, the year of the patent filing, and reviewed it in light of what would have been obvious to a person of ordinary skill at that time. For example, in the "Summary of Opinions" section of his report, Mr. Rummel states that "[p]rior to April 1988, those in the specialty vehicle manufacturing industry knew of various types of expandable vehicles," as well as various "well known solutions... that were considered interchangeable depending on customer needs." ECF No. 142-1 at 6. In his deposition, Mr. Brummel

reiterated that when applying his methodology, he took into account the available information and the level of ordinary skill prior to 1989. ECF No. 142-2 at 190-92. The Court therefore declines to disqualify him due to an alleged failure to account for hindsight bias.

AMOHS further submits that as an engineer, Mr. Brummel lacks the necessary experience in the "conception and invention of mobile medical facilities" to qualify as an expert. In assessing the validity of a patent, the scope and content of prior art is reviewed "from the perspective of one of ordinary skill in the art." Sundance, 550 F.3d at 1361 n.3. Mr. Brummel was involved in the engineering of surgical and other mobile medical units in the 1980s. During the course of that work, he became knowledgeable about the types of specialty vehicles being constructed at that time, and he and/or his company consulted with medical professionals to identify their needs. The Court finds this background sufficient for him to offer his opinions.

AMOHS's motion to disqualify Mr. Brummel is denied.

II. Defendants' Motion to Disqualify Dr. Paul K. Carlton

AMOHS also moves to disqualify MMIC's medical expert, Dr.

Paul Carlton. Dr. Carlton was formerly the Surgeon General of
the United States Air Force. He received his undergraduate
degree from the Air Force Academy and his medical degree from the
University of Colorado. He is trained as a general surgeon, and

has been in practice for 40 years. As a result of his years of medical and military experience, he is familiar with "the requirements for conducting invasive surgery in various settings, including hospitals, physician offices, deployed military settings, and the international environment." ECF No. 144-1 at 2. He also formerly sat on the Board of Directors for MMIC.

Dr. Carlton offers opinions with regard to the surgical equipment required in the 1980s, as well as the '435 Patent's obviousness. AMoHS contends that Dr. Carlton's obviousness analysis lacks the required methodology. AMoHS also submits that his testimony with regard to equipment requirements in the 1980s will involve questions of law that are not appropriate for expert testimony, while his testimony about surgeries outside of licensed operating rooms will be irrelevant and confusing since the '435 Patent sought to comply with requirements for surgeries performed in licensed facilities.

Beginning with the question of obviousness, Dr. Carlton compares the '435 Patent to "DEPMED" mobile medical units used by the military since approximately 1980. While DEPMEDs were modular units that could be transported by truck, Dr. Carlton concludes that "[i]t would have been obvious, more than one year prior to Levine's patent, to make one or more DEPMEDS unites integral with a chassis so that it acts as a trailer." ECF No. 144-1 at 4. He similarly concludes that as DEPMEDS were equipped

with the necessary environmental controls, "[i]t would have been obvious prior to April 5, 1989 to provide these environmental controls and others set forth in Medicare and accreditation guidelines existing at the time in a fixed or mobile facility."

Id. at 4.

AMoHS argues that in reaching his conclusions about obviousness, Dr. Carlton was required to explain his methodology so that the Court, as a Daubert gatekeeper, can determine reliability. In Kumho Tire Co., the Supreme Court noted that "there are many different kinds of experts, and many different kinds of expertise." 526 U.S. at 150. In cases of expertise based upon personal experience, courts have commented that the Daubert factors "have little applicability . . . [since] there really is no methodology or technique supporting it." Smith v. Target Corp., 2012 WL 5876599, at *10 (N.D.N.Y. Nov. 20, 2012) (citing Mahoney v. J.J. Weiser and Co., Inc., 2007 WL 3143710, at *4 (S.D.N.Y. 2007)). Nonetheless, the Court must ensure that the expert's opinions are based upon "sufficient facts or data," and that he explains "how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts,' because 'the trial court's gatekeeping function requires more than simply taking the expert's word for it." Bah v. Nordson Corp., 2005 WL 1813023, at *9 (S.D.N.Y. 2005) (quoting

Fed. R. Evid. 702 advisory committee's note).

Dr. Carlton intends to testify about surgical facilities and equipment in use in the 1980s. While AMoHS complains about a lack of methodology, Dr. Carlton's testimony will be based largely upon personal experience. As demonstrated by his report, he intends to explain the basis for his opinions and how his opinions relate to the facts of this case. The persuasiveness of his conclusions and the weight given thereto are questions for the trier of fact. See Figueroa v. Boston Scientific Corp., 254 F. Supp. 2d 361, 368 (S.D.N.Y. 2003) (holding that an expert may base his opinion on experience alone, and even assuming no data to support his opinions, those deficiencies impact the weight of his testimony and not the admissibility). The trier of fact may also choose to find Dr. Carlton not credible. His opinions, however, are admissible to the extent they are based upon his specialized knowledge of the relevant time period, and will he will not be disqualified for lack of reliability.

The Court also rejects AMoHS's contention that Dr. Carlton may not testify about code requirements for operating rooms. The Court acknowledges that expert testimony expressing legal conclusions must be excluded. See Hygh v. Jacobs, 961 F.2d 359, 363 (2d Cir. 1992). Dr. Carlton's testimony, however, will purportedly explain how building codes, Medicare standards, and other legal requirements were being applied in the 1980s.

Accordingly, his testimony will extend beyond the mere content of those requirements, and will likely aid the jury in understanding the significance of the various codes in relationship to the issues presented in this case.

AMOHS's final argument is that Dr. Carlton's testimony about equipment used in facilities outside of fixed hospitals will be irrelevant and confusing. This issue begins with the Court's claim construction opinion, which concluded in part that after "[r]eviewing the entire patent, it is clear that the inventor intended to claim a mobile operating room that included all of the essential requirements for invasive surgery that a permanent and fixed hospital facility has." ECF No. 112 at 6-7. The Court also determined that "[c]onsistent with the description in the specification, the term [essential equipment] is construed as 'equipment required by health, building, and other regulatory codes for invasive surgery at the time and place of the intended use.'" Id. at 8.

MMIC represents that Dr. Carlton will be testifying about the necessary equipment for invasive surgery prior to 1989, and the types of facilities used for invasive surgery at that time. Those areas of testimony are plainly within his expertise, and will assist the jury in understanding the concept of essential equipment consistent with the Court's latter construction of the claim. The motion to disqualify Dr. Carlton as an expert is

therefore denied.

III. Defendants' Motion to Preclude Prior Art

AMOHS further moves to preclude MMIC from relying on prior art references that were not disclosed until after April 3, 2014. According to the discovery schedule in place at the time of the disclosure (ECF No. 136), all discovery was to be completed by March 31, 2014. MMIC opposes the motion, arguing that AMOHS's counsel was in fact notified of those specific art references prior to the close of discovery.

Rule 26(a)(1)(A) of the Federal Rules of Civil Procedure requires a party to provide the opposition with "a copy — or a description by category and location — of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses, unless the use would be solely for impeachment." Fed. R. Civ. P. 26(a)(1)(A)(ii). Under Rule 37(c)(1), if a party fails to provide information required by Rule 26(a) in a timely manner, "the party is not allowed to use that information . . . unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

The Second Circuit has held that preclusion is a discretionary remedy, even if "the trial court finds that there is no substantial justification and the failure to disclose is

not harmless." Design Strategy, Inc. v. Davis, 469 F.3d 284, 297 (2d Cir. 2006) (internal quotation marks omitted). In deciding whether to preclude, a court should consider: "(1) the party's explanation for the failure to comply with the [disclosure requirement]; (2) the importance of the [new evidence]; (3) the prejudice suffered by the opposing party as a result of having to prepare to meet the new [evidence]; and (4) the possibility of a continuance." Patterson v. Balsamico, 440 F.3d 104, 117 (2d Cir. 2006) (quoting Softel, Inc. v. Dragon Med. & Scientific Commc'ns, Inc., 118 F.3d 955, 961 (2d Cir. 1997)).

MMIC submits that AMoHS cannot claim either surprise or prejudice resulting from the April 3, 2014 disclosures, as each piece of evidence had been either disclosed or discussed in correspondence between the parties well prior to the actual disclosure date. Specifically, MMIC represents to the Court that each of the fifteen items in question were "disclosed and discussed in detail in the Expert Report of Anthony Brummel on October 1, 2013, prior to the close of discovery and more than 5 months prior AMoHS's [expert] rebuttal deadline." ECF No. 143 at 3. MMIC also cites detailed email correspondence between counsel in which the art in question is both disclosed and discussed in the context of MMIC's theories of liability.

While AMoHS concedes that the disclosures in question "were produced by MMIC or others at some point in discovery," it

contends that the only explanation of their context came from Mr. Brummel. ECF No. 143 at 8. AMoHS also argues that disclosures by Mr. Brummel, an independent expert, "cannot speak for MMIC or be considered its employee or agent or corporate spokesperson unless and until MMIC adopts his opinions as its own - which did not occur until April 3, 2014." ECF No. 143 at 8.

Given AMoHS's concessions, the Court is hard pressed to identify prejudice as result of MMIC's late disclosure. Also weighing in MMIC's favor is the importance of this evidence. The prior art listed in the motion to preclude includes diagrams of pre-existing medical units that, MMIC contends, counter AMoHS's claim to a valid patent. For example, MMIC disclosed a 1982 European patent showing a trailer that could reportedly be used as a mobile hospital or operating unit. MMIC also offers "Stone and Gasko" articles describing mobile medical and surgical units. While these and the other thirteen items at issue may not be MMIC's only prior art evidence, they appear to be highly relevant to its claims. See Softel, Inc., 118 F.3d at 961.

Finally, the Court may consider the possibility of a continuance. According to the latest discovery schedule (ECF No. 160), Defendants' opposition to MMIC's Motion for Summary Judgment of Invalidity is now due within 30 days of this Opinion and Order, and a final pre-trial schedule is not yet due. If MMIC's disclosure of the prior art in question did not allow

AMOHS ample opportunity to question experts or otherwise prepare its case, the Court will entertain a short continuance provided that AMOHS offers ample support for such a delay. The Court will now, however, preclude MMIC from relying upon that prior art on the basis of a late disclosure, and AMOHS's motion to preclude is denied. Any request for a continuance shall be filed within seven days of this Opinion and Order.

Conclusion

For the reasons set forth above, AMoHS's motions to disqualify Anthony Brummel (ECF No. 138), to disqualify Dr. Paul Carlton (ECF No. 144), and to preclude reliance upon prior art (ECF No. 140) are **denied**.

Dated at Burlington, in the District of Vermont, this $24^{\rm th}$ day of February, 2015.

/s/ William K. Sessions III William K. Sessions III District Court Judge