

United States District Court,  
W.D. Wisconsin.

**GENERAL ELECTRIC COMPANY,**  
Plaintiff.

v.  
**SONOSITE, INC,**  
Defendant.

No. 08-cv-298-bbc

**May 26, 2009.**

**Background:** Competitor filed action seeking declaration that patent for compact, handheld ultrasound machines was invalid. Assignee of patent counterclaimed for infringement. Cross-motions for summary judgment were filed, and patent assignee filed motion seeking to bar competitor's expert opinions and reports.

**Holdings:** The District Court, Barbara B. Crabb, J., held that:

- (1) accused ultrasound device did not infringe patent;
- (2) accused lightweight ultrasound device infringed patent;
- (3) patent was not invalid based on obviousness;
- (4) patent was not invalid for lack of enablement; and
- (5) patent was not invalid for failure to comply with best mode requirement.

Plaintiff's motion granted in part and denied in part; defendant's motion granted in part and denied in part.

Court-Filed Expert Resumes

5,722,412. Construed and Ruled Infringed by.

Allen Arntsen, Jeffrey A. Simmons, Justin Edwin Gray, Foley & Lardner LLP, Madison, WI, Jennifer Sklenar, Howrey LLP, Los Angeles, CA, Matthew Wolf, Sara P. Zogg Howrey LLP, Washington, DC, Robert E. McAlhany, Howrey LLP, East Palo Alto, CA, Terri Gillis, Howrey LLP, New York, NY, for Plaintiff.

Alan Chen, Orrick Herrington & Sutcliffe, Menlo Park, CA, Christopher G. Hanewicz, John S. Skilton, Sarah C. Walkenhorst, Perkins Coie LLP, Allen Arntsen, Foley & Lardner LLP, Madison, WI, Jeffrey Cox, Mark Parris, Orrick, Herrington & Sutcliffe, LLP, Seattle, WA, Patricia Thayer, Heller Ehrman LLP, San Francisco, CA, Lissa Koop, Perkins Coie LLP, Chicago, IL, for Defendant.

## OPINION and ORDER

BARBARA B. CRABB, **District Judge.**

This is a civil action for infringement of a patent for compact, handheld ultrasound machines. Defendant SonoSite, Inc., is the owner of U.S. Patent No. 5,722,412 (the '412 patent) that claims an ultrasound system weighing less than ten pounds. Plaintiff is in the business of creating predominantly large scale ultrasound systems. Planning to launch two new portable systems, the Venue 40 and a lightweight version of the Venue 40, and believing reasonably that defendant might file a patent infringement suit regarding these products, plaintiff filed a complaint on May 5, 2008, seeking a declaration that defendant's patent was invalid. On August 25, 2008, defendant filed an amended answer, in which it included a counterclaim that plaintiff's new products infringed claims 11-14 and 16-18 of the '412 patent. This court has jurisdiction to hear this dispute under 28 U.S.C. s.s. 1331 and 1338.

Now before the court are the parties' cross motions for summary judgment on the issues of infringement and invalidity and defendant's motion to bar plaintiff from relying on untimely expert opinions and reports. Plaintiff's motion for summary judgment will be granted on plaintiff's claim that the Venue 40 system does not infringe claims 11-14 and 16-18 of the '412 patent and that neither product infringes under the doctrine of equivalents. Its motion will be denied on plaintiff's claims of invalidity based on anticipation, obviousness, enablement and indefiniteness and its claim that the lightweight Venue 40 system does not infringe defendant's '412 patent. Because defendant did not move for summary judgment on plaintiff's claims of invalidity based on anticipation or obviousness, these claims remain for trial.

Defendant's motion for summary judgment will be granted in the following respects: (1) plaintiff's lightweight Venue 40 system infringes claims 11-14 and 16-18 of the '412 patent as a matter of law; (2) plaintiff has failed to adduce evidence to prove its claim that the '412 patent is invalid because it fails to meet the enablement, written description or best mode requirements of 35 U.S.C. s. 112; and (3) plaintiff has failed to prove its claim that plaintiff's 1986 ultrasound project is prior art under 35 U.S.C. s. 102 and anticipates the '412. Defendant's motion will be denied in all other respects.

[1] Before turning to the undisputed facts, I address defendant's motion to preclude plaintiff from relying on a supplemental expert opinion and report by plaintiff's expert Dr. Schafer for the purpose of summary judgment or trial. Defendant contends that the report violates this court's preliminary pretrial conference order and Rule 26. Defendant's motion will be granted. Plaintiff's supplemental reports add new expert opinion as opposed to merely supplementing the subjects addressed in plaintiff's initial expert report.

In this court's preliminary pretrial conference order, dkt. # 14, issued on June 12, 2008, the magistrate judge explained to the parties that:

[a]ll disclosures mandated by this paragraph must comply with the requirements of Rule 26(a)(2)(A), (B) and (C). There shall be no third round of rebuttal expert reports. *Supplementation pursuant to Rule 26(e)(1) is limited to matters raised in an expert's first report*, must be in writing and must be served not later than five calendar days before the expert's deposition, or before the general discovery cutoff if no one deposes the expert.... Failure to comply with these deadlines and procedures could result in the court striking the testimony of a party's experts pursuant to Rule 37. The parties may modify these deadlines and procedures only by unanimous agreement or by court order.

Dkt. # 14, at 2-3 (emphasis added). By court order, initial expert reports were due December 19, 2008 and responsive reports were due January 23, 2009.

Although plaintiff filed its initial expert reports in accordance with this court's order, it failed to follow this court's order when it filed a supplemental report by Dr. Scafer, dkt. # 108-3, on February 5, 2009. The supplemental report contains new opinions regarding (1) whether the prior art reference known as the Karaman Reference enables the '412 patent; (2) the "conception date of the '412 patent"; and (3) plaintiff's RT-50 ultrasound system, a portable non-digital ultrasound machine conceived in the 1980s. It also contains a passage rebutting defendant's rebuttal report.

Plaintiff argues that its supplement is proper because defendant failed to disclose its argument regarding enablement and the "conception date of the '412 patent"; plaintiff's expert learned about the RT-50 model after its initial expert report; and defendant offered a new opinion regarding a person of ordinary skill in the art. In addition, plaintiff argues that even if these issues were not raised in the initial report, defendant has not been prejudiced because it received the report five days prior to deposing Dr. Shafer.

Under Fed.R.Civ.P. 26(e)(1), a party may supplement or correct its Rule 26(a) disclosures "if the party learns that in some material respect disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed.R.Civ.P. 26(e)(1). That is not the case here. The supplemental expert report raises entirely new matters regarding invalidity not raised in Dr. Schafer's initial report.

First, plaintiff cannot contend that it was prejudiced by not receiving discovery regarding the conception date of the '412 patent or that it did not know about the RT-50 until after his initial report. Defendant submitted a response to plaintiff's interrogatories on December 15, 2008 with the information on which defendant would rely in making its argument regarding the original conception date of the '412 patent. In addition, because plaintiff designed the RT-50, plaintiff would have had the relevant information in its possession prior to the filing of the expert report. The fact that plaintiff's expert did not discuss these matters is plaintiff's fault. It has failed to show good cause for its failure to disclose the information initially.

Second, a supplemental report is not an opportunity to rebut issues raised in defendant's rebuttal expert report. Plaintiff's expert discussed the "person of ordinary skill in the art" with respect to the '412 patent. It is not entitled to rebut these arguments through a supplement. Also, in the initial expert report, plaintiff's expert did not address the issue whether the Karaman reference was enabling but discussed whether it anticipated the '412 patent. Although plaintiff alleges that it did not address the issue because defendant failed to disclose documents regarding its enablement theory until after the initial experts reports were due, this does not allow plaintiff to supplement its report to rebut matters raised in defendant's rebuttal report. The pretrial conference order states explicitly that the court will not allow a third round of rebuttal expert reports, which is what plaintiff seeks to do.

If at any time plaintiff believed that it lacked discovery it needed in order for its expert to offer a proper opinion on invalidity, it was plaintiff's responsibility to file a motion to compel discovery on this issue with the court. It did not. In addition, if plaintiff believed it was being prejudiced by not being able to offer expert opinion on issues of enablement, it should have sought leave of court to file its supplemental expert report and argued its case then. By submitting a supplemental expert report after the deadlines, plaintiff undercut defendant's opportunity to address the issues raised by plaintiff's expert. Defendant's motion to bar plaintiff's supplemental expert report will be granted.

From the parties' proposed findings of fact, I find the following facts to be material and undisputed.

## **UNDISPUTED FACTS**

### ***A. Parties***

Plaintiff General Electric is a corporation organized and existing under the laws of the state of New York, having its principal place of business in Fairfield, Connecticut. Plaintiff's ultrasound business began with larger console ultrasound systems. Recently, it has taken advantage of advances in electronics to offer systems in increasingly smaller packages. In the mid 1990s, plaintiff designed and sold the LOGIQ 100, a portable ultrasound product that weight about twenty pounds. In 2002, plaintiff sold the first of its compact ultrasound systems.

Defendant SonoSite, Inc. is a corporation organized and existing under the laws of the state of Washington, having its principal place of business in Bothell, Washington. Defendant is a spinoff from a company known as ATL, which led a consortium that developed and filed the '412 patent application.

### ***B. Ultrasound Technology***

In 1994, ultrasound systems were typically large, cart-based units weighing 200-700 pounds, some costing in excess of \$200,000. Not only were they expensive, but they were not readily carried from patient to patient.

Generally, an ultrasound system contains a number of parts, including a beamformer and a transducer. The transducer converts electrical signals into sound waves that are transmitted into tissue. The tissue echo signals are received back at the transducer where they are converted to electrical signals and go to the beamformer. The beamformer creates data for display of the ultrasound image.

In late 1994, the Defense Advanced Research Projects Agency, or DARPA, requested proposals for the development of a portable ultrasound instrument that could be used on the battlefield to give a quick and accurate diagnosis of a soldier's condition so that remedial therapy can begin. The government provided grants to three companies, Terason/Teratech, ATL and Q-Dot, to develop new high-quality, low-power handheld ultrasound technology.

In 1995, ATL, the University of Washington and two semiconductor companies, Harris Semiconductor and VLSI Technology, formed a consortium to develop a new handheld device with a digital beamformer that would produce high-quality images for use in military and commercial applications. On June 27, 1995, the consortium completed its handheld ultrasound development plan. It was the only one of three companies to do so. The other two companies, Terason and Q-DOT, chose to implement a device with CCD technology, a type of analog beamformer. In early 1996, DARPA approved the consortium's plan and awarded it a \$6 million grant. In the spring of 1998, defendant's company was formed as spinoff from ATL that worked on handheld ultrasound technology. In 1999, defendant released its first commercial product, the SonoSite 180v.

By the end of the 1980s, a couple of manufacturers, including ATL, had commercialized the first, diagnostic ultrasound systems with digital beamformers. In the early 1990s, Hewlett Packard, Toshiba and Acuson began working on digital ultrasound systems.

## C. '412 Patent

U.S. Patent No. 5,722,412 (the '412 patent) is entitled "Hand Held Ultrasonic Diagnostic Instrument." The inventors are Lauren S. Pflugrath and Jacques Souquet. They conceived the original idea for the patent some time in the early 90s and filed an application for the '412 patent on June 28, 1996. The patent issued on March 3, 1998 and was assigned to defendant SonoSite.

The '412 patent "is directed to an ultrasound system that is extremely lightweight and highly portable." According to the specification, the patent discloses a handheld diagnostic ultrasound instrument that contains many of the advanced features of the premium ultrasonic diagnostic instruments, such as speckle reduction, color Doppler and three-dimensional imaging capabilities. '412 Pat., col. 1, lns. 24-34. The specification of the '412 patent describes the preferred embodiment as a two-part unit, with one part containing a transducer, beamformer and image processor, and the other containing a display and power source.

Defendant contends that two of plaintiff's products infringe claims 11-14 and 16-18 of the '412 patent. Claim 11 of the '412 patent is the only independent claim. Claim 11 discloses:

A handheld ultrasound system comprising:

an array transducer; and

a sampled data beamformer for delaying and combining samples of echo signals received by elements of said array transducer,

wherein said array transducer and said beamformer are located in one or more enclosures weighing less than ten pounds (4.5 kilograms).

'412 pat, col. 23, lns. 9-17. Claims 12-14 and 16-18 depend from claim 11. They disclose:

12. The handheld ultrasound system of claim 11, further comprising a digital filter coupled to the output of said beamformer and located in the same enclosure as said beamformer.

13. The handheld ultrasound system of claim 11, further comprising an image processor coupled to the output of said digital filter and located in the same enclosure as said digital filter.

14. The handheld ultrasound system of claim 13, further comprising an image display coupled to the output of said image processor.

\* \* \*

16. The handheld ultrasound system of claim 11, wherein said beamformer is a digital beamformer which delays and combines digital echo signals.

17. The handheld ultrasound system of claim 16, further comprising a digital filter and an image processor located in a common enclosure with said digital beamformer.

18. The handheld ultrasound system of claim 17, wherein said image processor includes a digital scan converter.

'412 pat., col. 23, lns. 17-40. The asserted claims do not require any of the advanced features described in the specification, such as color Doppler imaging, three-dimensional display capabilities and synthetic aperture formation.

#### ***D. Prosecution of the '412 Patent***

Defendants disclosed two references during the prosecution of the '412 patent that described handheld ultrasound systems. One was a manual for a handheld ultrasound product called the "Minivisor," introduced in 1979. The other was the specifications for the ULTRA PCI system from Advanced Medical Products of Columbia, South Carolina.

On February 24, 1997, the examiner rejected all of the claims under 35 U.S.C. s. 102(e) or s. 103 as obvious in light of U.S. Patent No. 5,590,658 (the Chiang patent). The Chiang patent states that the "total weight of the [ultrasound] system preferably does not exceed ten pounds." The Chiang patent discloses CCD technology, which is an analog type of sampled data beamformer. The examiner stated that the Chiang patent had all the claimed features except for a curved linear array, the digital filter and image processor in a single enclosure, which were requirements of pending dependent claims of the '412 application. The examiner also stated that a curved linear array was known in the art and he found it obvious to include a digital filter and image processor in a common enclosure.

The examiner cited U.S. Patent No. 5,295,485 (the Shinomura patent) as disclosing a handheld diagnostic ultrasound imaging system. The Shinomura patent discloses a device designed to be held in one hand and weighing 1 kilogram, or 2.2 pounds.

During prosecution of the '412 patent, the applicants sought to establish that they had an earlier invention date than the Chiang '658 patent application by submitting a Declaration of Prior Invention under 37 C.F.R. s. 1.131 with excerpts from a June 25, 1995 grant application.

On June 23, 1997, the prosecuting attorney submitted an amendment to overcome the Chiang and Shinomura references. The applicants amended claims 1 and 4 (which became issued claim 11), such that the "beamformer" limitation that combines echo signals was amended to be a "sampled data beamformer" that delays and combines "samples" of echo signals. The prosecuting attorney further wrote that

The Chiang et al. patent is directed to a scan head which includes a beamformer producing an analog electrical signal and an interface. As such, it is directed to a different invention than that of the present application, which claims an array transducer with a sampled data beamformer, which in a preferred embodiment is a digital beamformer. The Shinomura et al. device is unclear as to the nature of its beamformer but it appears, like Chiang et al., to be a conventional analog beamformer because the signals produced by the device must be A/D converted prior to being recorded or stored in the memory card 4A.

File History (FH) of '412 pat., dkt. # 116 at 216-17. On March 3, 1998, the patent examiner's office issued a notice of allowance for the '412 patent application.

## ***E. Plaintiff's Accused Products***

Plaintiff has designed two new ultrasound systems, the Venue 40 and the lightweight Venue 40, that are allegedly infringing. Plaintiff intended to launch the Venue 40 in April 2009 and the lightweight Venue 40 "some time after trial in this litigation." (The parties do not say whether plaintiff has begun selling the Venue 40.) Plaintiff is testing the Venue 40 prototype units at its research facility in Milwaukee, Wisconsin and has initiated the process of manufacturing units for sale.

Both systems have three main components: a console, a probe and a docking station. The 3S-SC and 12L-SC probes are intended to be used with the Venue 40 system. The 3S-SC probe contains a phased array transducer. The 12L-SC probe contains a linear array transducer. The 3S-SC probe weighs 0.72 lbs (0.325 kg) and the 12L-SC probe weighs 0.83 lbs (0.375 kg). Both systems include a sampled data beamformer for delaying and combining samples of echo signals received by elements of an array transducer from any of plaintiff's array probes.

The term "enclosure" means a surrounding case or housing to protect the contained equipment. The "enclosure" containing the sampled data beamformer is the outer case of the console and protects the contained electronic equipment from liquid splashes. The "enclosure" containing the transducer array is the probe handle of either the 3 S-SC and 12L-SC probes. The transducer elements are located within the probe handle, which is splash-proof and protects the contained equipment.

### ***1. The Venue 40***

The Venue 40 console is slightly larger than a laptop computer. It contains electronics and internal structural components, including a digital beamformer, LCD screen, battery module, image processor, and fan assembly. Two images of the Venue 40 system are shown below:

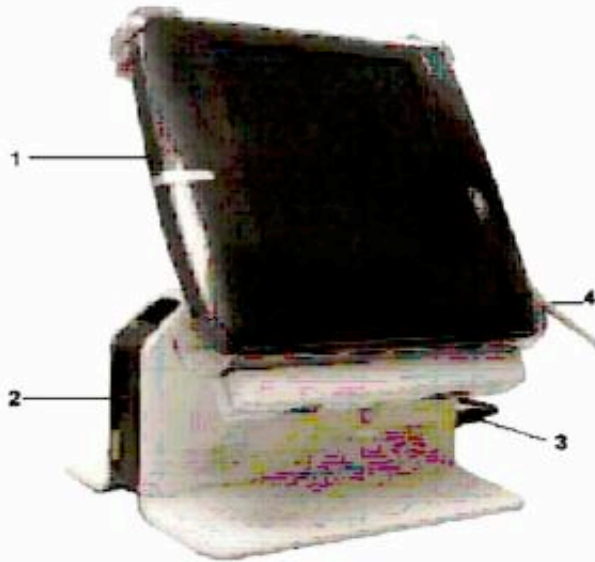


Figure 2-1. Venue 40 system (with docking station)

1. Venue 40
2. Docking station
3. Power cord
4. Probe

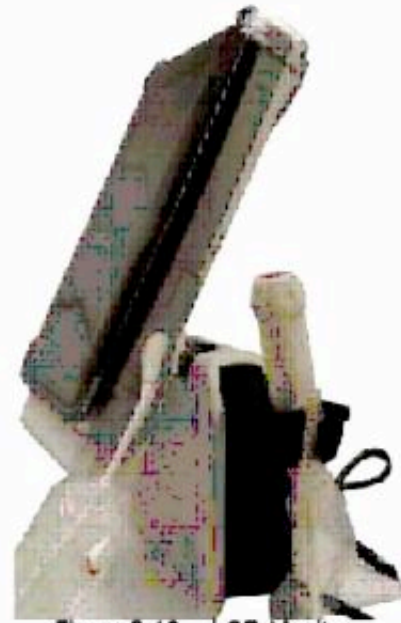
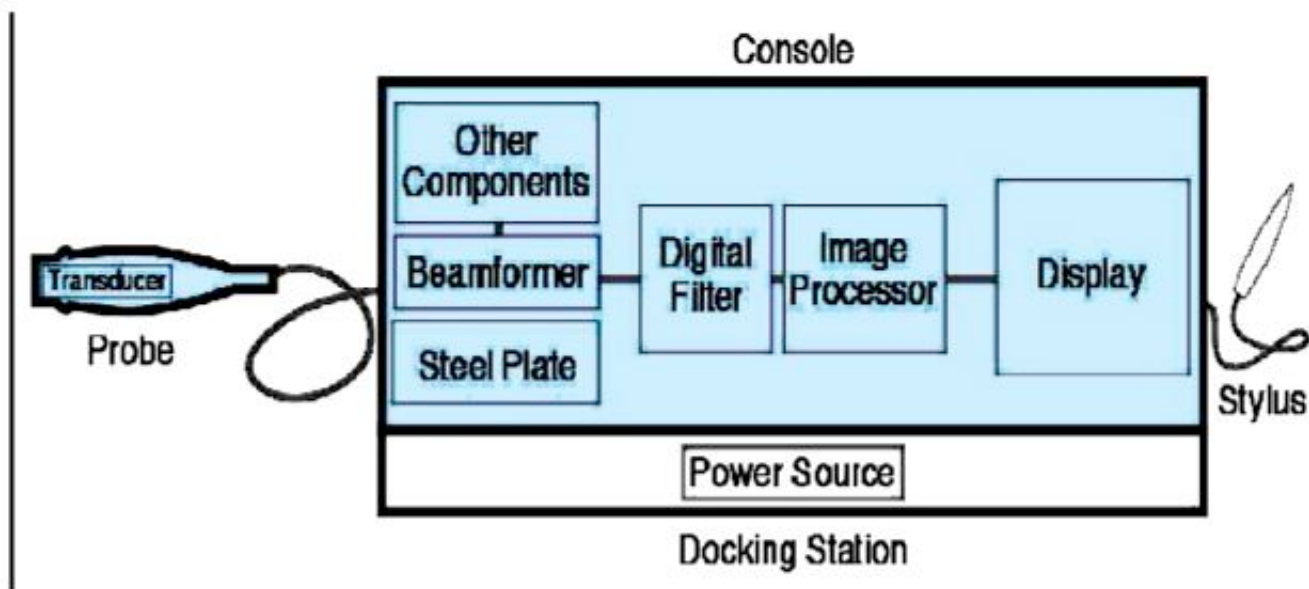


Figure 2-18. LCD Monitor

The Venue 40 console is operated with a touch stylus that is not part of the contents of the beamformer or transducer enclosures. It is secured to a docking station during operation. Power to operate the system is provided via the docking station cord, which is plugged into an AC power source or in certain instances, via a battery module. A battery module avoids powering the system down between dockings, to provide power in the event power from the dock is interrupted and for limited emergency uses when no dock is available. Below is a diagrammatic representation of the configuration of the components of the Venue 40, the console with attached stylus and probe in the docking station:





The Venue 40 system includes a steel plate that is attached to a metal bracket within the console. This steel plate weighs 2.85 lbs (1.29 kg), and the bracket weighs 0.95 lbs (0.43 kg). The steel plate is part of the contents of the beamformer enclosure. To remove the steel plate, 19 screws must be removed and a number of electronic links must be disconnected. The metal plate in the Venue 40 console was not designed to be removed. Removing it from the console would void the warranties.

With the 3S-SC probe or 12L-SC probe, the total weight of the Venue 40 console exceeds ten pounds.

## ***2. The lightweight Venue***

The lightweight Venue 40 will be manufactured with the metal bracket, but without the steel plate. With the 3S-SC or 12L-SC probes, it will weigh less than 10 pounds. The weight of the entire console assembly of the lightweight Venue 40 is approximately 6.04 lbs.

(If the Venue 40 and the lightweight Venue 40 infringe independent claim 11, plaintiff does not deny that they also infringe the asserted dependent claims 12-14 and 16-18. Plaintiff's expert acknowledges that the parties have no infringement disputes concerning the limitations of the dependent claims.)

## ***F. Prior Art***

The general movement toward digital beamformers began in the late 1980s, when all types of technology were becoming digital. The industry shift toward digital beamformers gained momentum in the mid 1990s. In 1995, Klein Biomedical Research, a well known analyst in the ultrasound industry, predicted that digital beamformer technology would become standard on most high, premium and super high performance systems by 1998 and that digital beamformer technology would migrate to mid-range systems in 1996.

Irex and Varian sold the first two commercial ultrasound products with digital beamformers in the mid 1980s. In 1987, ATL introduced a digital beamformer for its Ultramark 8 Systems. In 1988, it introduced additional ultrasound products with digital beamformers.

## ***1. The Minivisor***

The Minivisor from Organon Technika is recognized as the first commercial handheld ultrasound device; it weighed approximately 3.3 pounds. The Minivisor was developed in the late-1970s and sold commercially in the early-1980s. It has no analog or digital beamformer, digital filter, image processor or scan converter. The inventors of the '412 patent disclosed the Minivisor during the prosecution of the patent. The examiner made no comment related to the Minivisor.

## ***2. The O'Donnell Reference***

In 1988, Matthew O'Donnell, who at the time was employed at plaintiff's Research and Development Center, published a paper entitled "Applications of VLSI Circuits to Medical Imaging." (the O'Donnell Reference) The paper discusses a custom VLSI circuit used for digital beamforming and contains a photomicrograph (a photograph taken through a microscope) of a mixed digital and analog beamforming chip that is between 1 and 2 cm in length on each side.

Plaintiff's engineers discussed the same type of chip in another paper, S. Karr et al., "A Mixed Analog-Digital Chip for a Phased-Array Signal Processor," 1988 IEEE International Solid States Circuits Conference. In 1990, a number of individuals from plaintiff's Corporate Research & Development Center, including Dr. O'Donnell, published a paper entitled "Real-Time Phased Array Imaging Using Digital Beamforming And Autonomous Channel Controls." The paper stated that "[a]ll controls and signal processing needed for a single channel of the array imager have been integrated into a single custom VLSI circuit." Schafer Decl., dkt. # 132, at para. 56.

## ***3. The Karaman Reference***

In May of 1995, Dr. O'Donnell co-authored a publication with Mustafa Karaman entitled "Synthetic Aperture Imaging For Small Scale Systems," published in IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 42, No. 3. (the Karaman Reference) The Karaman Reference discusses the use of a digital beamformer in a small scale system, including "personal computer based and pocket size handheld imaging devices." It was published more than one year before the filing of the '412 patent application and it states:

In this paper we explore an alternate application of digital beamformers: handheld systems. The fundamental hypothesis of this work is that the same digital technology developed for high channel count systems can be used to dramatically reduce the size and cost of low channel count systems capable of reasonable image quality.

Personal computer based and pocket sized hand-held imaging devices, may have widespread applications in medicine. In particular, a hand-held scanner may complement a stethoscope as a general diagnostic device.

Schafer Decl., dkt. # 132-11, at 13.

The Karaman Reference describes a pocket size handheld or personal computer-based ultrasound instrument using digital beamforming synthetic aperture and processing techniques. Synthetic aperture imaging provides many of the imaging capabilities of a larger system with a reduced number of channels. The Karaman authors conducted experiments using computer simulation to "create" digital imaging systems, but

never actually designed a handheld, digital ultrasound device.

#### ***4. Plaintiff's 1986 handheld ultrasound project***

In 1985 and 1986, a group of plaintiff's engineers developed plans for a new handheld ultrasound system. In March 1986, plaintiff gave a presentation to five doctors of the Albany Medical College Medical Staff relating to its new project. Plaintiff never reduced the project to practice and terminated it some time in 1986.

#### ***G. Enablement***

ATL developed a prototype for DARPA embodying the elements of claim 11 of the '412 patent and weighing approximately 1 lb., 2 oz. It was functional and produced an ultrasound image as of 1998. Defendant's first commercial product, the SonoSite 180, weighed 5.4 pounds. Since then, defendant has released additional handheld ultrasound systems ranging in weight from 3.5 to 8.5 pounds.

Claims 11 through 14 require a "sampled data beamformer for delaying and combining samples of echo signals received by elements of said array transducer." '412 pat., col. 23, lns. 9-28. A digital beamformer is a type of sampled data beamformer.

Figure 6 of the '412 patent shows that each analog echo signal output is coupled to the input of an analog-to-digital converter shown as item 310 ("A/D"). An analog-to-digital converter is a device that converts an analog signal, that is, a continuously varying signal, into a series of digital values representing the values of the analog signal, that is, analog samples, at discrete intervals of time. The specification provides the following additional written description of this method of sampling analog signals:

Each echo signal output is coupled to the input of an A/D converter 310, where the echo signals are converted to digital data. The digital data from each element (or each pair of elements in a folded aperture) is shifted into a first in, first out (FIFO) register 312 by a clock signal A/D CLK. The A/D CLK signal is provided by a dynamic focus timing circuit 314 which defers the start of the clock signal to provide an initial delay, then controls the signal sampling times to provide dynamic focusing of the received echo signals.

'412 pat., col. 6, lns. 52-61. An analog-to-digital converter samples each digitized samples (whether or not an initial delay is provided) and then shifts it into a first in, first out (FIFO) register operating under the control of the clock signal, thereby delaying digital samples of the echo signals received by elements of the array transducer.

#### ***H. Best Mode***

The inventors of the '412 patent chose certain vendors, Harris and VLSI, to build the ASICs that would implement the transducer and beamforming circuitry. They did so in part because of the vendors' business relationship with ATL. The inventors of the '412 patent chose Harris to build the analog ASIC that was used for the transducer array. Harris was one of the few companies in the United States capable of designing the analog ASIC that the inventors of the '412 patent intended to use for the transducer circuitry. The inventors chose VLSI to build the digital ASIC that was used for the digital beamformer. The patent application did not disclose any of the chosen ASIC vendors. (The parties dispute whether other manufacturers were capable of producing ASIC in the manner required by the '412 patent.)

ASICs are an electronic element used by the inventors to create the handheld ultrasound instrument. The inventors disclosed the use of ASICs in the patent specification. The patent is not directed to the manufacture of ASICs or improvements in ASIC manufacturing. The non-asserted claims 9-10 and 22-24 mention "integrated circuits" and "application specific integrated circuits" and the specification states that in the preferred embodiment the ultrasound system is fabricated on four types of ASICs.

The inventors planned to use ball grid array technology for connecting the ASIC to the printed circuit board. With ball grid arrays, ASICs had little balls on the bottom, which made it easier and less expensive to manufacture the printed circuit board. Ball grid array technology is not disclosed in the '412 patent.

## OPINION

### *A. Infringement*

Although plaintiff brought this suit as an action to declare the '412 patent invalid as a matter of law, a challenge to a claim's invalidity is not an independent cause of action but a defense to a claim for infringement. Because defendant has filed a counterclaim for infringement of claims 11-14 and 16-18 of the '412 patent, I will address the infringement issue first. If the accused products do not infringe the asserted claims, then plaintiff's invalidity claims are non-justiciable; there would no longer be any concrete dispute between the parties. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007) ("Our decisions have required that the dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.' "); *but see Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1344-45 (Fed.Cir.2005) (holding that district court erred in concluding that it lost jurisdiction to hear counterclaim for unenforceability after jury returned verdicts on invalidity and infringement and plaintiff executed covenant not to sue); *Silicon Graphics, Inc. v. ATI Technologies, Inc.*, 573 F.Supp.2d 1108, 1110-13 (W.D.Wis.2008) (recognizing that district court have jurisdiction to hear invalidity claims even after infringement claims have been dismissed).

The parties have filed cross motions for summary judgment on the question of infringement. Plaintiff contends that neither of its products infringes claims 11-14 and 16-18 of the '412 patent directly or under the doctrine of equivalents. Defendant contends that both products infringe claims 11-14 and 16-18 of the '412 patent.

[2] [3] [4] [5] " Summary judgment on the issue of infringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents." *U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1374-1375 (Fed.Cir.2007) (quoting *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed.Cir.2005)). Patent infringement analysis involves two steps. First, the patent claims must be interpreted or construed to determine their meaning and scope. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995). Second, the properly construed claims are compared to the process or device accused of infringing. *Id.* To establish infringement, defendant must prove that each claim element is present in the accused product, either literally or by equivalence. *Dawn Equipment Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1015 (Fed.Cir.1998). Conversely, plaintiff can prevail by demonstrating that at least one element of the asserted claim is absent from their devices.

As an initial matter, defendant concedes that it has not advanced any claim that plaintiff's products infringe under the doctrine of equivalents. Accordingly, plaintiff's motion for summary judgement on this issue will be granted. In addition, the parties agree that if plaintiff's product infringes claim 11, it also infringes the remaining dependent claims 12-14 and 16-18. Dft.'s PFOF, dkt. # 184, at 28-29.

[6] The only remaining question is whether the Venue 40 or the lightweight Venue 40 infringes claim 11. The undisputed facts show that the accused products contain an array transducer and a sampled data beamformer. In addition, the parties have agreed that the preamble, "a handheld ultrasound system," is not a limitation of the patent. However, the parties dispute whether the accused products meet the ten pound limitation found in claim 11.

The relevant passage of claim 11 reads as follows: "Wherein said array transducer and said beamformer are located in one or more enclosures weighing less than ten pounds." 412 pat., col. 23, lns. 14-16. This term was construed in the court's November 26 claim construction order. In that order, I resolved the parties' dispute over the indefiniteness of the term. I concluded that a limiting construction exists, finding that "wherein said array transducer and said beamformer are located in one or more enclosures weighing less than ten pounds" meant "wherein the array transducer and the beamformer are located in one or more enclosures, the enclosure(s) with the claimed ultrasound components weighing altogether less than ten pounds (4.5 kilograms)." Order, Dkt. # 82, at 12.

Now defendant asserts that claim 11 contains additional limitations previously unaddressed by the parties. Defendant argues that claim 11 directs an individual to weigh "the enclosures containing the beamformer and the array transducer plus all of the ultrasound components in those same enclosures that are connected and enable other components of the system to operate," Dft.'s Br., dkt. # 144, at 15, to determine whether a product falls within the claimed ten pound weight limit. Essentially, defendant is inviting the court to construe additional disputed claim terms of the '412 patent. Because resolution of the infringement question requires determining what elements of the ultrasound system must be weighed to met the ten pound limitation of Claim 11, I will accept the parties' invitation.

[7] [8] [9] [10] When construing disputed terms in a claim, a court should generally give the terms their ordinary and customary meaning. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). The ordinary and customary meaning of a term "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corporation*, 415 F.3d 1303, 1313 (Fed.Cir.2005). The person of ordinary skill in the art reads a term both in the context of the claim in which it appears and "in the context of the entire patent, including the specification." *Id.* (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)). A patent's prosecution history can be relevant to construing disputed terms of a patent because it "provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317.

[11] Defendant argues that the court's use of the phrase "component of an ultrasound system" in the November 26 order indicates that only the "functional" portions of the ultrasound system are to be weighed in order to determine the ten pound limitation. Defendant's contention is unfounded. The court never identified which components needed to be measured in order to infringe claim 11. Defendant has offered no support for its proposed construction in the claim language, the specification or the prosecution history or anywhere else.

Moreover, defendant's provided construction cuts against the stated aim of the '412 patent to create a

compact, handheld ultrasound system. '412 pat., col. 1, lns. 4-30. Excluding the weight of non-functional elements such as screws or housing used to protect electronic equipment could increase the total weight of a system and therefore increase the weight. In other words, if all the "functional components" weighed less than ten pounds and the nonfunctional components were unlimited, the '412 patent would cover any products that weighed in excess of ten pounds. I will not adopt defendant's construction requiring that one weigh only the "functional" or "operational" elements of the ultrasound system. If the inventors had intended to include this limitation, they would have included language to this effect in either the claim terms or specification.

Contrary to defendant's proposed construction, claim 11 appears to include as part of the ten pound limitation all the elements identified in claim 11: the transducer, beamformer and enclosure(s) plus whatever is located within the enclosures. The specification indicates that "it would be desirable ... to be able to compact the entire ultrasound system into a scan-head size unit ... [that] retain[s] as many of the features of today's sophisticated ultrasound system as possible." '412 pat., col. 1, lns. 24-29. In fact, the purported novelty of the '412 patent is that it is lightweight. This principle should drive the analysis. Because the original inventors of the patent were trying to reduce the weight of the ultrasound system as much as possible to increase its portability, a construction of claim 11 that insures that the claimed invention weighs as little as possible would be in keeping with the patent's aim. Therefore, the language of claim 11 would include within the weight calculation all the components contained within the enclosures, whether functional or not. To determine whether a product infringes the '412 patent's ten pound limitation, I conclude that "wherein said array transducer and said beamformer are located in one or more enclosures weighing less than ten pounds" found in claim 11 requires a person to weigh the beamformer, array transducer, the enclosure(s) and all the components contained therein.

Once the issue of construction is resolved, the parties' infringement dispute is rather straight forward. The undisputed facts show that plaintiff's Venue 40 weighs more than ten pounds and contains all the elements of claim 11, including a steel plate attached to a metal bracket within the Venue 40 console. (The steel plate weighs 2.85 lbs (1.29 kg) and the bracket weighs 0.95 lbs (0.43 kg).) The steel plate and the bracket are part of the contents of the beamformer enclosure. The plate was not designed to be removed. In order to remove it, one must unscrew nineteen screws and disconnect a number of electronic links and doing so would void the warranties.

Defendant contends that the steel plate should be excluded when weighing the Venue 40 for the purpose of infringement analysis. It argues that the steel plate is a non-functional element that plaintiff cannot add to its product simply to defeat infringement. *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1197 (Fed.Cir.2005) (adding features does not avoid charge of infringement if other claim terms are met). Defendant is incorrect.

Whether the steel plate is a "functional" component of the ultrasound system is not relevant to the infringement analysis. The limitation is not in the claim language. Once the steel plate is added to plaintiff's accused product, the Venue 40 no longer contains all the claimed elements of the '412 patent. Although defendant suggests that the steel plate is added merely for the purpose of insuring non-infringement, it has adduced no evidence of this. In addition, the undisputed facts show that removing the steel plate requires a dismantling of the product and voids the warranty. This suggests that the steel plate serves some function in the Venue 40. Inventors are not likely to go to such great lengths to add an entirely superfluous feature. By adding the steel plate, plaintiff chose to increase the weight of its ultrasound system. If the purported novelty of new ultrasound systems is their portability and weight, then every ounce or gram counts. Plaintiff

has chosen to add a plate that increases the weight of its product and could have the consequence of reducing its sales. Because the Venue 40 fails to meet the ten pound limitation of claim 11 of the '412 patent, plaintiff's motion for summary judgment will be granted on its claim for non-infringement.

[12] However, the lightweight Venue 40 does not contain the steel plate found in the Venue 40. Instead, the undisputed facts show that the lightweight Venue 40 console with the 3S-SC and 12L-SC probes console weighs less than 10 pounds. The weight of the entire console assembly of the lightweight Venue 40 is approximately 6.04 lbs. Unlike the Venue 40, it contains all the claimed elements of claim 11 and the dependent claims, which depend from claim 11.

Plaintiff only non-infringement argument is based on defendant's proposed construction regarding the "functional" components of the ultrasound. Plaintiff contends that if one weighs the "functional" elements of the lightweight Venue, which include elements found outside the enclosure, it weighs more than ten pounds. Plaintiffs are not using the appropriate construction of claim 11. Because plaintiff has failed to put forth any additional explanation for its contention that the lightweight version of the Venue 40 does not infringe and the undisputed facts show that it contains an array transducer, a sampled data beamformer and that the entire unit weighs less than ten pounds, I find that plaintiff's lightweight Venue 40 infringes claim 11 of the '412 patent. Further, because the parties agree that if either product infringes claim 11, that product also infringes claims 12-14 and 16-18, I conclude that as a matter of law the lightweight Venue 40 infringes all the asserted claims of the '412 patent. Defendant's motion for summary judgment will be granted on its claim of infringement as it relates to the lightweight Venue 40 system.

### ***B. Invalidity***

[13] Because one of plaintiff's accused products infringes the asserted claims of defendant's '412 patent, I must address whether the patent is invalid as a matter of law, as alleged by plaintiff. As a general rule, patents are presumptively valid. 35 U.S.C. s. 282. The party that moves to invalidate a patent must prove invalidity by clear and convincing evidence. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed.Cir.1983). In its complaint, plaintiff alleged that defendant's '412 patent is invalid under 35 U.S.C. s.s. 102, 103 and 112. Although plaintiff never explicitly identified the theories of invalidity it was alleging, plaintiff has moved for summary judgment on four grounds: anticipation, obviousness, enablement and indefiniteness. It argues that the '412 patent is invalid because prior art references anticipated the patent claims or rendered the patent obvious and that the patent fails to properly describe the claimed invention.

Defendant has also moved for summary judgment on plaintiff's general claims of invalidity. Defendant argues that plaintiff has failed to provide evidence proving that the '412 patent is invalid for failing to enable the claimed invention or to meet the "best mode" or "written description" requirement.

Although I address each invalidity argument independently below, I will summarize the rulings here. With respect to plaintiff's arguments of anticipation and obviousness, I conclude that plaintiff has failed to show as a matter of law and by clear and convincing evidence that any of the prior art references render any claim of the '412 patent anticipated or obvious. With respect to its enablement and indefiniteness arguments, I conclude that plaintiff has failed to adduce evidence establishing either that claim 11 fails to enable the claimed invention or that there is no limiting construction. Therefore, plaintiff's motion for summary judgment on enablement and indefiniteness will be denied and I will enter judgment in defendant's favor on these grounds. Defendant's motion for summary judgment regarding the "best mode" and "written description" requirement will be granted because plaintiff has failed to introduce any evidence to support its

claim of invalidity on those grounds. Last, I find that defendant has failed to establish that the inventors conceived of the invention covered by the '412 patent prior to the issuance of the Chiang patent; however, I agree that defendant has failed to prove that plaintiff's 1986 ultrasound project was prior art under 35 U.S.C. s. 102.

### **1. Anticipation**

[14] [15] [16] One ground on which a patent may be invalidated is anticipation. "Claimed subject matter is 'anticipated' when it is not new; that is, when it was previously known." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed.Cir.2008). Under 35 U.S.C. s. 102(b), a prior art reference is anticipatory if it was published a year before the filing of a patent application and either explicitly or inherently discloses each limitation of a patent. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed.Cir.2007); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed.Cir.2001). "Invalidation on this ground requires that every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention." *Sanofi-Synthelabo*, 550 F.3d at 1082. "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed.Cir.2005) (quoting *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed.Cir.2002)). "Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it." *MEHL/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed.Cir.1999).

Plaintiff contends that at least three prior art references anticipate the claims of the '412 patent. One is an article published in May of 1995, one year before the filing of the '412 patent, entitled "Synthetic Aperture Imaging for Small Scale Systems," authored by Mustafa Karaman and Matthew O'Donnell, also known as the Karaman Reference. This article was not disclosed to the patent examiner who approved the '412 patent. Plaintiff has moved for summary judgment on the ground that the Karaman Reference anticipates the asserted claims of the '412 patent. Plaintiff has also identified two additional prior art references that allegedly anticipate claim 11 of the '412 patent: the Chiang patent and plaintiff's abandoned 1986 ultrasound project. Defendant denies that these references are prior art.

In addition, defendant has moved for summary judgment on the ground that the Chiang patent does not anticipate claims 12-14 and 16-18 of the '412 patent. Plaintiff has never asserted that the Chiang patent anticipates these dependent claims. (Plaintiff alleges only that the Chiang patent anticipates claim 11. Neither party has moved for summary judgment on this claim.) Therefore, defendant's motion on this ground will be denied because the parties do not dispute this issue.

#### **a. The Karaman Reference**

[17] The Karaman Reference discusses the way ASICs could assist in reducing the size and weight of medical imaging devices, specifically, ultrasound systems. The Karaman Reference states:

In this paper we explore an alternate application of digital beamformers: handheld systems. The fundamental hypothesis of this work is that the same digital technology developed for high channel count systems can be used to dramatically reduce the size and cost of low channel count systems capable of reasonable image quality.

Personal computer based and pocket sized hand-held imaging devices, may have widespread applications in



medicine. In particular, a hand-held scanner may complement a stethoscope as a general diagnostic device.

Schafer Decl., dkt. # 132-11, at 13 (emphasis added). The undisputed facts show that the article describes a pocket size handheld or personal computer-based ultrasound instrument using digital beamforming synthetic aperture and processing techniques. Plaintiff's expert Dr. Schafer conducted a claim by claim analysis illustrating Karaman's anticipation of both claim 11 and the dependent claims of the '412 patent. The only disputed issue is whether the reference anticipates claim 11. It does not.

First, the Karaman Reference does not disclose a "sampled data beamformer." A sampled data beamformer is a beamformer that receives both digital and analog echo signals, combines and converts these signals and then outputs a digital signal. Plaintiff's expert identifies portions of the Karaman Reference that teach a person of ordinary skill in the art that the beamformer(s) described in the article are digital. McAlhany Decl., Exh. 16, dkt. # 126-21, at 3-4. The article refers repeatedly to digital beamformers:

-> "Digital beam formers now permit high precision imaging with a very simple system architecture." Schafer Decl., Exh. 37, dkt. # 132-11, at 13;

-> "Synthetic aperture imaging enables flexible beam forming through digital processing." *Id.*, at 19;

-> "Digital beam forming ASICs can be used effectively for real-time processing of synthetic aperture data." *Id.*, at 23.

However, plaintiff does not identify any passage that indicates that the article also discusses analog beamformers. The only "evidence" submitted by plaintiff to prove the existence of a "sampled data beamformer," that is, one that receives both digital and analog echo signals and outputs a digital signal, is the conclusory testimony of its expert, which is insufficient to establish a dispute of material fact. *CytoLogix Corp. v. Ventana Medical Systems, Inc.*, 424 F.3d 1168, 1176 (Fed.Cir.2005) ("Substantial evidence of invalidity must meet certain minimum requirements; '[g]eneral and conclusory testimony ... does not suffice as substantial evidence of invalidity.' "); *Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1473 (Fed.Cir.1997) ("An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself."); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed.Cir.1983) (expert testimony alone cannot serve as a basis for a finding of anticipation). Because the Karaman Reference fails to discuss both digital and analog beamformers, it fails to meet a limitation of claim 11 of the '412 patent.

Further, the Karaman Reference does not discuss the ten pound weight limitation found in claim 11. It makes no reference to the weight of the theoretical ultrasound system. Plaintiff contends that the article's reference to a "pocket sized" device inherently discloses the "ten pound limitation" because one of skill in the art in 1995 would have understood this term to mean a device weighing less than ten pounds. Plaintiff also argues that defendant bears the burden of proving that the term "pocket sized" did not mean less than ten pounds to a person of ordinary skill in the art in 1995. Plaintiff is mistaken on both counts.

To succeed on an anticipation claim as a matter of law, the moving party bears the burden of proving by clear and convincing evidence that the undisputed facts show that the prior art reference anticipates. In this case, it was plaintiff's burden to establish that the ten pound limitation is taught by the Karaman Reference. Again, the only evidence plaintiff offers to support its claim is the testimony of its own expert that "pocket

sized" means less than ten pounds. This testimony alone is not clear and convincing evidence that the ten pound limitation is taught. It is not clear from the undisputed facts that the Karaman reference anticipates the '412 patent as a matter of law. Therefore, plaintiff's motion for summary judgment on its claim of invalidity based on anticipation will be denied.

## **b. The Chiang patent**

Defendant has moved for summary judgment on the ground that the Chiang patent does not anticipate the '412 patent as a matter of law because it is not a prior art reference under 35 U.S.C. s. 102(e). According to defendant, the inventors of the '412 patent conceived the invention disclosed by the '412 patent in September of 1994, one year before the filing of the Chiang patent; therefore, it is not a prior art reference and plaintiff's invalidity claim based on the Chiang patent must be dismissed. *Bausch & Lomb, Inc. v. Barnes-Hind-Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed.Cir.1986).

[18] [19] "Conception is the formation 'in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice.' " *Kridl v. McCormick*, 105 F.3d 1446, 1449 (Fed.Cir.1997). "A conception must encompass all limitations of the claimed invention ... and 'is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.' " *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed.Cir.2003) (internal citation omitted).

[20] Plaintiff denies that defendant can establish conception prior to the Chiang patent. It argues that defendant has not proved that the inventors conceived an ultrasound system in which the array transducer and beamformer were present in two separate enclosures, as required by claim 11 of the '412 patent.

Although the inventors state in their declarations that they conceived an ultrasound system in which the transducer and beamformer were in separate enclosures, inventor testimony alone is insufficient to establish conception. *Singh*, 317 F.3d at 1341; *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572 (Fed.Cir.1996) (patentee must provide evidence corroborating inventor's testimony); *Cooper v. Goldfarb*, 154 F.3d 1321 (Fed.Cir.1998)("In order to establish an actual reduction to practice, an inventor's testimony must be corroborated by independent evidence.").

To bolster the inventors' assertions, defendant has offered three documents created between September 1994 and June 6, 1995 that allegedly demonstrate that the inventors had contemplated separating the transducer and the beamformer. The documents created in September and October of 1994 state that "[t]he elimination of the scanhead cable allows the ASIC design to improve the impedance match between the array element and the receiver for a possible performance improvement of 3dB." *Cox Decl.*, Exh. 37, dkt. # 138-38, at 6; *see also Cox. Decl.*, Exh. 35, dkt. # 138-36, at 5. According to defendant's expert, this passage indicates that the inventors intended to separate the elements because it discusses eliminating the scan head cable. The third document is a proposal submitted to DARPA that states that a likely implementation of the device would consist of two units where the transducer is separated from the LCD display.

However, none of these documents directly corroborate the testimony of defendant's expert. They do not identify exactly what is being separated. It appears that two elements are to be separated, but it is not evident that the inventors intended to separate the transducer from the beamformer. Because defendant must establish that it conceived a ultrasound in which the transducer and beamformer were in separate enclosures, this lack of proof is fatal to its argument. In addition, defendant turns to its expert to explain the documents

instead of identifying passages in the text to support the argument. *Motorola, Inc.*, 121 F.3d at 1473 (parties cannot simply rely on expert to explain anticipatory reference). Because defendant has failed to supply independent evidence of conception, its motion for summary judgment on plaintiff's contention that the Chiang patent was not prior art for the '412 patent will be denied.

### **c. Plaintiff's 1986 ultrasound project**

[21] Defendant also moves for summary judgment on the ground that plaintiff's handheld ultrasound project is not prior art for purposes of the '412 patent because, among other grounds, it was not publicly known. However, plaintiff contends that it does not intend to argue that its handheld project was prior art, but that a presentation plaintiff made to five doctors on March 6, 1986 at Albany Medical College is prior art that is relevant to its obviousness defense. Ultimately, the difference is immaterial because plaintiff has failed to meet its evidentiary burden.

[22] "In order to invalidate a patent based on prior knowledge or use, that knowledge or use must have been available to the public." *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed.Cir.1998). All plaintiff offers to support its claim that the document entitled "Meeting on Hand Held Ultrasound Concept," Schafer Decl., exh. 25, dkt. # 132-8, was actually presented at Albany College on March 1986 is the following statement by plaintiff's expert: "[i]t is my understanding, based on documents that I have reviewed, that when [plaintiff] presented its handheld ultrasound project to physicians at Albany Medical College in March 1986 to elicit comments on the desirability and marketability of its handheld ultrasound project, [plaintiff] determined that there was no market at that time for their under-ten-pound ultrasound system." Schafer Decl., dkt. # 132, at 87. There is no evidence from any individual with first hand knowledge regarding the subject matter of the presentation. Plaintiff's evidence falls short of showing that it made the document "Meeting on Hand Held Ultrasound Concept" public. Without any evidence in the record to show that this document was available to the public before the filing of the '412 patent, I cannot find it prior art under 35 U.S.C. s. 102(e). It is plaintiff's burden to provide sufficient facts to survive a motion for summary judgment by the moving party. In this case, plaintiff has failed to meet its burden. Therefore, I will grant defendant's motion for summary judgment on plaintiff's contention that the Albany College presentation was a prior art reference.

## **2. Obviousness**

[23] [24] Plaintiff also argues that the '412 patent should be invalidated because the Karaman Reference, the Minivisor, a compact ultrasound system created in the 1970s, and the O'Donnell Reference made the claimed innovation obvious. A court may invalidate a patent for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that 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 to which said subject matter pertains." 35 U.S.C. s. 103(a). The "obviousness" analysis is an objective one and requires a district court to consider: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent art. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966)). The main question under s. 103 is "whether the combined teachings of the prior art, taken as a whole, would have rendered the claimed invention obvious to one of ordinary skill in the art." *In re Napier*, 55 F.3d 610, 613 (1995).

In this case, plaintiff advances two general theories of obviousness. First, even if the Karaman Reference does not disclose the ten pound limitation in claim 11 or the digital filter limitation in claim 12, these

alterations would have been "obvious to try." Second, the combination of the Minivisor and the O'Donnell Reference would have rendered the innovation of the '412 patent obvious because the Minivisor contains all the claimed elements of the patent except a sampled data beamformer that is taught by the O'Donnell Reference.

[25] With respect to the Karaman Reference, plaintiff offers no evidence that it would have been obvious to choose either the ten pound limitation for the ultrasound system or a digital filter to filter the output of the beamformer. Instead, plaintiff relies on conclusory statements from its expert. This is insufficient evidence to support a finding of invalidity. *CytoLogix Corp.*, 424 F.3d at 1176. The Karaman Reference does not render the claims of the '412 patent obvious as a matter of law.

[26] Although plaintiff contends that the Minivisor discloses all of the asserted claims of the '412 patent with the exception of a sampled data beamformer, it has put forth no evidence establishing that the Minivisor or any other prior art reference makes the dependent claims obvious. Instead, plaintiff argues that because defendant's expert has failed to offer testimony to show why the dependent claims are not obvious, plaintiff is entitled to judgment. Plaintiff mistakes the placement of the burdens. It has the burden of proving the obviousness of each claim it contends is invalid. It has offered no evidence. Therefore, its motion for summary judgment will be denied on its contention that the dependent claims of the '412 patent are invalid for obviousness.

[27] As to independent claim 11, plaintiff contends that the Minivisor and the O'Donnell Reference would have rendered the '412 patent obvious. There is no dispute that the Minivisor is a compact single enclosure system that weigh less than ten pounds, but this is not enough.

First, the Minivisor does not contain an "array transducer" as conceived by the '412 patent. The transducer in the Minivisor functions as individual transducer elements and not as an array. Plaintiff has not shown that including the more "modern" array transducer would have been obvious to try in light of the Minivisor.

Second, the parties dispute whether the addition of a sampled data beamformer would have been an obvious innovation to make in the Minivisor. Plaintiff contends that a 1988 article entitled "Applications of VLSI Circuits to Medical Imaging," written by Matthew O'Donnell, known as the O'Donnell Reference, reveals a digital chip for beamforming that is small enough to fit in an compact ultrasound system. In light of the O'Donnell Reference, plaintiff says, one of ordinary skill in the art would have added digital beamforming chips to the Minivisor to create the same invention claimed in the '412 patent. In addition, plaintiff argues, the DARPA project was a market incentive for the inventors of the '412 patent to seek the most modern and smallest electronics to insert into an ultrasound system to create the claimed invention of the '412 patent.

Plaintiff's claim of "obviousness" is a bit strained. Allegedly, the 1988 O'Donnell Reference taught one of ordinary skill in the art how to create a single enclosure ultrasound system weighing less than ten pounds. However, plaintiff offers no evidence that an ultrasound system was created using this teaching in the eight years before plaintiff filed its patent application. If the technology to create a miniature digital beamformer existed and was an obvious innovation in 1988, why would it take nearly eight years before any company in the ultrasound business created a compact system?

Also, the government provided grants to at least three companies to develop new handheld ultrasound technology. Of the three companies receiving funding, only the inventors of the '412 patent developed a handheld ultrasound system using a digital beamformer. The other companies chose to implement a device

with a type of analog beamformer, or the more "antiquated" technology. If, as plaintiff asserts, the use of digital beamforming technology was an obvious choice for constructing a mini-ultrasound system, why did only one company chose this route? Perhaps the answer is that the claimed innovation was not as obvious as plaintiff's expert suggest. Regardless, plaintiff has failed to establish by clear and convincing evidence that the '412 patent was an obvious innovation in light of the Minivisor and other prior art references. Therefore, plaintiff's motion for summary judgment of invalidity of claim 11 of the '421 based on obviousness will be denied.

### **3. Enablement**

[28] [29] 35 U.S.C. s. 112, para. 1, requires that the specification of every patent contain a written description of the invention "and of the manner and process of making and using it ... as to enable any person skilled in the art" to make and use the same. This language has been interpreted to include two separate requirements: the patent must enable the claimed invention and the patent must contain a written description of the invention. The enablement requirement "is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed.Cir.2008) (citing *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed.Cir.2003)). However, the written description requirement is broader than requiring merely an explanation of "how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed.Cir.1991); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002) ("What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue."). In this case, plaintiff argues that the '412 patent fails to meet both requirements.

#### **a. Lack of enablement**

Plaintiff contends that claim 11 of the '412 patent is too broad and fails to enable all ultrasound systems under ten pounds. Specifically, because the '412 patent does not provide a method for creating a "weightless" ultrasound device or, at the very least, include a lower limit for the claimed ultrasound system, it fails to meet the enablement requirement and is invalid under s. 112. *Sitrick*, 516 F.3d at 999 ("A patentee who chooses broad claim language must make sure the broad claims are fully enabled."). Defendant has filed a cross motion for summary judgment, asserting that plaintiff has failed to adduce sufficient evidence to prove lack of enablement.

[30] [31] [32] "[A] patent claim is presumed enabled unless proven otherwise by clear and convincing evidence." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1317-18 (Fed.Cir.2007). The enablement requirement does not "say that the specification ... must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp.*, 344 F.3d at 1244; *see also Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.Cir.1997) ("[A] specification need not disclose what is well known in the art."). However, "it does mean that, when a range is claimed, there must be *reasonable enablement of the scope of the range*." *AK Steel Corp.*, 344 F.3d at 1244 (emphasis added). "Open-ended claims are not inherently improper; ... [t]hey may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit." *Scrapps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1572 (Fed.Cir.1991).

[33] The question is not whether claim 11 enables a weightless ultrasound system but, as the Federal Circuit suggests in *AK Steel Corp.*, 344 F.3d at 1244, whether the hypothetical person of ordinary skill in the art would be able to make an ultrasound system weighing between ten pounds and a reasonable lower limit. In this case, there is an inherent limit to the possible range: a weightless ultrasound machine is not within the reasonable range of possible embodiments. Although plaintiff argues that the inventors of the '412 patent should have been required to supply a lower limit, the enablement requirement is not this strict.

The undisputed facts show that the inventors of the '412 patent were able to make a single enclosure prototype weighing 1.2 pounds that contained all the claimed elements of the '412 patent. Also, the Shinomura patent, which discloses a compact ultrasound system, disclosed a device weighing 2.2 pounds. Therefore, a person of ordinary skill in the art would have understood that the claimed ultrasound system contained a lower weight limit in the range of 1 to 2 pounds.

In addition, defendant has provided evidence that ultrasound systems weighing less than ten pounds have been constructed using the disclosure of the '412 patent. The one pound prototype created by the inventors as well as the five pound SonoSite 180 were created using the claimed elements of the '412 patent. With this proof that the '412 patent enables systems within the claimed range, defendant is entitled to judgment that the '412 patent is not invalid for lack of enablement. Accordingly, I will deny plaintiff's motion for summary judgment on its claim of invalidity for lack of enablement and grant defendant's motion on the same issue.

#### **b. Written description requirement**

Plaintiff also contends that the '412 patent fails to comply with the "written description" requirement of 35 U.S.C. s. 112 because it fails to describe the claim term "sampled data beamformer." In the court's claim construction order, I determined that a sampled data beamformer "delay[s] and combine[s] analog or digital samples of echo signals or both such samples received by elements of said array transducer." Order, dkt. # 82, at 8. Plaintiff argues that because the invention claimed in the '412 patent only combines and outputs digital signals and fails to disclose any beamformer that combines samples of analog signals alone, the '412 patent does not properly describe the claimed invention or properly enable a "sampled data beamformer."

According to the Court of Appeals for the Federal Circuit, the written description requirement requires "the patent specification to 'describe the claimed invention so that one skilled in the art can recognize what is claimed.'" *Koito Manufacturing Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1154 (Fed.Cir.2004) (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed.Cir.2002)). "[T]he patent's 'disclosure must allow one skilled in the art to visualize or recognize the identity of' the subject matter purportedly described." *Koito Manufacturing Co.*, 381 F.3d at 1154. "The disclosure as originally filed does not, however, have to provide in haec verba support for the claimed subject matter at issue." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1364 (Fed.Cir.2003).

[34] Defendant has moved for summary judgment on this issue, arguing that plaintiff has failed to present any evidence that the '412 patent fails to describe a beamformer that combines signals that are either analog and digital or both. In support of its position that the patent describes the claimed invention, defendant cites a passage from the specification that describes how beamforming occurs in the invention. Beamforming is conducted by the front end ASIC where the echo signals are combined and converted. '420 pat., col. 6, lns. 48-52. The specification adds:

Each echo signal output is coupled to the input of an A/D converter 310, where the echo signals are

converted to digital data. The digital data from each element (or each pair of elements in a folded aperture) is shifted into a first in, first out (FIFO) register 312 by a clock signal A/D CLK. The A/D CLK signal is provided by a dynamic focus timing circuit 314 which defers the start of the clock signal to provide an initial delay, then controls the signal sampling times to provide dynamic focusing of the received echo signals.

'412 pat., col. 6, lns. 52-61. The A/D converter is present to convert analog echo signals into digital data. Therefore, according to defendant, the specification discloses an analog beamformer.

In this case, the only evidence plaintiff has offered to support its claim that the '412 patent does not disclose a "sampled data beamformer" is the following statement:

There is nothing in the '412 patent or original claims that suggests that the inventors considered a sampled data beamformer that delays and combines analog samples (or both analog and digital samples) to be part of their invention. Dr. Souquet has testified that neither he nor anyone else at ATL did any work on analog sampled data beamformer technology during his time at ATL.... In addition, Dr. Souquet testified that, in his view, CCD technology (a type of analog sampled data beamforming technology) never really worked.

Schafer Decl., dkt. # 132, at 72-73, para. 236. Plaintiff relies entirely on its expert's conclusory statement that the patent fails to disclose an analog beamformer. To succeed in showing the existence of a genuine issue of material fact, plaintiffs must do more than state the legal standard and then declare that it has been satisfied. *Mid-State Fertilizer v. Exchange National Bank*, 877 F.2d 1333, 1338-39 (7th Cir.1989) (expert affidavits cannot contain mere conclusory statements but must reveal "a process of reasoning beginning with a firm foundation"). Further, plaintiff makes no effort to address the passage of the specification cited by defendant showing that the patent describes an analog beamformer. Therefore, because plaintiff has failed to introduce any evidence that the patent fails to describe the existence of an analog beamformer, defendant's motion for summary judgment on plaintiff's claim that the '412 patent is invalid for failing to comply with the written description requirement will be granted.

#### ***4. Best mode requirement***

[35] Defendant seeks summary judgment on plaintiff's claim that the '412 patent is invalid because the inventors failed to comply with the "best mode" requirement. Defendant argues that plaintiff's claim should be dismissed for its failure to introduce any evidence to support its claim. I agree with defendant.

[36] [37] 35 U.S.C. s. 112 states that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." A patent that fails to comply with the best mode requirement may be invalidated. *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1320-21 (Fed.Cir.2006). To establish that a patentee has failed to comply with the best mode requirement, the party claiming invalidity must show (1) "whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention," *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306, 1320 (Fed.Cir.2002), and (2) "whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention." *Id.* The first question is subjective and focuses on the inventor's state of mind; the second question is objective and depends on the level of skill in the relevant art. *Id.*; *Northern Telecom Ltd.*

v. Samsung Elec. Co., 215 F.3d 1281, 1286 (Fed.Cir.2000).

[38] [39] "The best mode requirement does not 'demand disclosure of every preference an inventor possesses as of the filing date.' " Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353, 1364 (Fed.Cir.2008) (citing Bayer AG, 301 F.3d at 1314-15.). However, it does require "disclosure of an inventor's *preferred embodiment* of the claimed invention." Pfizer, Inc., 518 F.3d at 1363 (emphasis added). Moreover, the "best mode requires inventors 'to disclose aspects of making or using the claimed invention [when] the undisclosed matter materially affect[s] the properties of the claimed invention.' " Id.

Plaintiff argues that the inventors of the '412 patent failed to disclose preferred methods of creating the claimed ultrasound system. Specifically, the '412 patent specification does not indicate that the inventors preferred (1) the use of a ball grid array for circuitry connections versus the use of pin grid array; (2) the use of a 0.5 micron CMOS 3.3 volt process to construct the front end ASIC of the system; and (3) two ASIC vendors, who allegedly were the only ones able to perform the militarization needed to create the '412 invention. It is undisputed that this information was not disclosed in the patent specification, but plaintiff has failed to provide any evidence that this undisclosed information was a preferred embodiment or whether it materially affected the properties of the claimed invention.

Plaintiff cites the deposition testimony of '412 inventor Lauren S. Pflugrath for support that defendant's predecessor, ATL, failed to disclose either the ball grid array or the 0.5 micron CMOS 3.3 volt process fabrication method. When discussing the method for constructing the "front end ASIC," Pflugrath stated that in order to balance, cost and size ATL chose the .5 micron CMOS 3.3 volt process:

Q: What I'm getting at is are there other ways that you could have implemented the front end ASIC other than that process?

A: Yes.

Q: And what are those?

A: You could in a smaller process, of course. This, this .5 micron was in here for costing reasons, trying to determine cost, power. It's a bunch-this document is a design trade-off type document where you are trading power and cost and size. So this isn't the only way you could do it. There's other ways. But this is a way that seemed to fit with cost, power and size.

Pflugrath Dep., dkt. # 111, at 62-63. The .5 micron process was not the only option in creating the claimed invention of the '412 patent. Pflugrath also stated that the ball grid array was chosen for its cost and size:

Q: Is a- was a ball grid array preferable in your mind in 1995 than a pin grid array?

A: Yes, for size.

Q: Why is that?

A: Because the way it, it can mount on the circuit board, it's more automated for manufacturing, less expensive.



Q: Did ATL use the ball grid array technology for the handheld ultrasound product that it was developing?

A: Yes.

Q: Did ATL use the pin grid array in any capacity for the handheld ultrasound project?

A: No.

Q: And why was that?

A: Size, cost.

Pflugrath Dep., dkt. # 111, at 87.

With regard to both the volt .5 micron process and ball grid array, Pflugrath admits that these were the preferred ways of constructing the claimed invention, but this is not the end of the inquiry. Inventors are not required to disclose all the preferred ways but the preferred embodiment. Pflugrath did not say whether this was the preferred embodiment and plaintiff offers no further evidence to establish this point. In addition, in both instances, this was the preferred method because of factors including cost, power and size. Plaintiff did not say whether using different chips or grid arrays would materially alter the invention. In the absence of such testimony, I cannot find that the inventors' failure to disclose this information was a violation of the best mode requirement.

In support of its contention that defendant failed to reveal preferred ASIC vendors necessary to create the claimed invention of the '412 patent, plaintiff cites the following line from defendant's proposal to DARPA: "Without the miniaturization capabilities of VLSI and Harris, the ultrasound system design and manufacturing knowledge of ATL, and the research and application knowledge of the University of Washington, [the handheld ultrasound project] would not have been possible." Cox Decl., dkt. # 138-4, at 32. This passage is not evidence proving the point plaintiff seeks to establish: that VLSI and Harris were the only vendors who could produce the ASICs required to make the claimed invention. At best, this statement proves that these two companies had the miniaturization technology defendant needed and that they were integral in developing the patent. No reasonable factfinder could infer from this one statement that Harris and VLSI were the only vendors capable of providing the necessary technology.

Moreover, plaintiff has failed to show that the ASICs provided by these vendors were necessary to either the preferred embodiment or that they had a material effect on the invention. Because plaintiff has failed to produce any evidence showing that the inventors of the '412 patent failed to disclose the best mode for the claim invention, defendant's motion for summary judgment on plaintiff's claim that '412 patent is invalid for failure to disclose the best mode will be granted.

## ***5. Indefiniteness***

[40] [41] Plaintiff's last invalidity argument is a renewed motion to find claim 11 of the '412 patent invalid for indefiniteness. Plaintiff asks this court to reconsider the indefiniteness claim on the basis of defendant's contention that for a product to infringe the weight limitation of claim 11, the "functional" components of the ultrasound system and the enclosure must be weighed. In order to prevail on a claim of "indefiniteness," the moving party must show that the "claim is insolubly ambiguous, and no narrowing construction can

properly be adopted." Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375 (Fed.Cir.2001). However, "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree," id., the claim is sufficiently clear to avoid indefiniteness. Because I have construed the disputed term, I am not persuaded that claim 11 is not insolubly ambiguous and I will deny plaintiff's motion for summary judgment on its claim that the '412 is invalid for indefiniteness.

## **ORDER**

IT IS ORDERED that:

1. Defendant SonoSite, Inc.'s motion, dkt. # 107, to exclude the supplemental expert opinion and report of Dr. Schafer, dkt. # 108-3, is GRANTED.

2. Plaintiff General Electric Company's motion for summary judgment, dkt. # 124, is GRANTED on the following grounds:

-> Plaintiff's Venue 40 system does not infringe claims 11-14 and 16-18 of the '412 patent; and

-> Neither plaintiff's Venue 40 system or the lightweight Venue 40 system infringes claims 11-14 and 16-18 of the '412 patent under the doctrine of equivalents.

The motion is DENIED in all other respects.

3. Defendant's counterclaim of direct infringement regarding the Venue 40 system and defendant's counterclaim of infringement under the doctrine of equivalents are DISMISSED.

4. Defendant's motion for summary judgment, dkt. # 127, is GRANTED on the following grounds:

-> Plaintiff's lightweight Venue 40 system infringes claims 11-14 and 16-18 of the '412 patent;

-> The '412 patent is not invalid for failure to meet the enablement, written description or best mode requirement; and

-> The document entitled "Meeting on Hand Held Ultrasound Concept" is not prior art under 35 U.S.C. s. 102(e).

The motion is DENIED in all other respects.

The trial will be limited to plaintiff's claims that the '412 patent is invalid for anticipation, obviousness or both.

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