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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

TSI Incorporated, Plaintiff, v. Azbil BioVigilant Incorporated, Defendant.	No. CV-12-00083-PHX-DGC **ORDER**

Defendant Azbil BioVigilant, Inc. ("BioVigilant") has filed a motion for summary judgment. Doc. 227. The motion is fully briefed and neither party has requested oral argument. The Court will grant BioVigilant's motion.

I. Background.

BioVigilant and Plaintiff TSI, Inc. ("TSI") sell devices for detecting airborne biological particles. Biological aerosols can occur naturally or may be manmade, and they can become a health hazard, particularly in hospitals and war zones. The TSI devices at issue in this case detect bio-viable particles through a process known as "intrinsic fluorescence." The devices contact a particle with a laser beam and then detect and measure fluorescence emitted from biomolecules such as nicotinamide adenine dinucleotide (reduced form) ("NADH") and riboflavin, which are native to viable biological particles. The devices compare the intensity of each particle's fluorescence against pre-determined criteria to determine whether a given particle is viable (alive) or inert (not alive). Through this process, the devices can ascertain, in real time, whether

airborne particles are present in a given sample, whether the particles are bio-viable, and at what concentration they exist. TSI's complaint alleges that BioVigilant has directly infringed, induced others to infringe, and contributed to the infringement of the patent that covers TSI's devices.

On December 14, 2004, the United States Patent and Trademark Office issued United States Patent No. 6,831,279 ("the '279 Patent"), entitled "Laser Diode-Excited Biological Particle Detection System." Jim Yew-Wah Ho is the sole inventor named on the '279 Patent. TSI owns the '279 Patent, and asserts Claims 1-4, 6-7, 17-20, and 23-24 of the '279 Patent (collectively, the "Asserted Claims").

In the section of the '279 Patent entitled "DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT," the patent discloses use of a Nichia laser diode which emits beams at a frequency of about 402-405 nm. U.S. Patent No. 6,831,279 col.6 l.28-29. Lasers at this wavelength excite riboflavin. The patent explains that riboflavin is part of "a new range of biomolecules [that] can be used which are indicative of particle viability." U.S. Patent No. 6,831,279 col.3 l.3-5. The patent explains that "[o]ther laser diodes are available from the same manufacturer which range in output from 400 to about 450 nm, with others being developed." U.S. Patent No. 6,831,279 col.6 l.38-40. It acknowledges, however, that at the time the patent was filed, "laser diodes [were] not available at the wavelengths known to be most suited to excite the known reactive biomolecule NADH; however, they are currently available at slightly longer wavelengths." U.S. Patent No. 6,831,279 col.3 l.12-15.

II. Legal Standard.

A party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the evidence, viewed in the light most favorable to the nonmoving party, shows "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a

matter of law." Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Furthermore, the party opposing summary judgment "may not rest upon the mere allegations or denials of [the party's] pleadings, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see* Fed. R. Civ. P. 56(e).

There is no issue for trial unless there is sufficient evidence favoring the nonmoving party; if the evidence is merely colorable or is not significantly probative, summary judgment may be granted. *Anderson*, 477 U.S. at 249-50. However, because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions, not those of a judge," the evidence of the non-movant "is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255 (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970)).

III. Analysis.

BioVigilant argues that the Asserted Claims are invalid for two reasons. First, BioVigilant argues that the Asserted Claims are obvious. Second, it argues that the '279 Patent's disclosure is not sufficiently enabling. Because the Court agrees with the second argument, it need not reach the obviousness defense or BioVigilant's noninfringement arguments.

"By direction of 35 U.S.C. § 282, an issued patent is presumed valid." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 412 (2007). "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. BioVigilant must prove invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242, 180 L. Ed. 2d 131 (2011). The Court must apply this standard of proof in ruling on BioVigilant's motion for summary judgment. *See Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1311 (Fed.

Cir. 2011); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005).

The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, ¶ 1, which provides in relevant part:

> The 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[.]

Enablement is determined as of the effective filing date of the patent application. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the *full scope* of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (citation omitted) (emphasis added).

A. Scope of the Invention.

The doctrine of enablement does not require "that the specification itself 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. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *Genentech*, 108 F.3d at 1366 ("[A] specification need not disclose what is well known in the art."); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) ("Enablement is not precluded by some experimentation, such as routine screening."). But when a range of materials, properties, or other elements is claimed, the enablement requirement does necessitate that there be reasonable enablement of the scope of the range. *See AK Steel Corp.*, 344 F.3d at 1234. The Federal Circuit has provided this helpful explanation:

> Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention. This important doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage. The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.

MagSil Corp. v. Hitachi Global Storage Techs., Inc., 687 F.3d 1377, 1380-81 (Fed. Cir. 2012) (citations and quotation marks omitted); *see also Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

BioVigilant argues that the '279 Patent's specification is not enabling because "[a]ll of the Asserted Claims recite a laser diode for emitting a wavelength in a range of 320 nm and above," but no laser diodes capable of emitting lasers at wavelengths near the bottom end of that range existed at the time of filing. Doc. 227 at 13. The '279 Patent acknowledges that laser diodes were not available at wavelengths below 400 nm at the time it was filed. *Id.*; U.S. Patent No. 6,831,279 col.3 l.12-15. BioVigilant has presented deposition testimony in which Dr. Ho testified that, as of filing the '279 Patent, he was not aware of any laser diode that could excite biomolecules in the range of 321 to 405 nm. Doc. 227 at 13; Doc. 228, ¶ 115. The heart of BioVigilant's argument is that the '279 Patent claims an apparatus and method employing a laser diode that emits a laser having a wavelength from 320 nm to 500 nm, but that the '279 Patent does not enable the full scope of that range.

TSI reads the patent differently. TSI argues that a person skilled in the art in 2001 "would not have understood the invention to be a laser diode of a particular wavelength or to require a wavelength down to 320 nm." Doc. 229 at 13. TSI asserts that a person skilled in the art would have understood that "the laser diode should be selected such that

its wavelength is (1) above about 320 nm **and** (2) operative to excite biomolecules." *Id*. (emphasis in original). TSI's expert, Dr. Carrano, opined that "a person of ordinary skill in the art in 2001 would have understood that the scope of the asserted claims of the '279 Patent do not require a 'laser diode in the 320-375 nm range.'" Doc. 202 at 272. Dr. Carrano bases this opinion in part on his assertion that "a person of ordinary skill in the art would have known that laser diodes in the ultraviolet range did not exist in 2001," and that the '279 Patent disclosed this fact when it stated that "laser diodes [we]re not available at the wavelengths known to be most suited to excite the known reactive biomolecule NADH." *Id.* TSI thus asserts that it was not required to enable biological particle detectors using laser diodes at the bottom of the claimed wavelength range and that the single embodiment described in the specification was sufficient.

This Court must apply "the familiar axiom that '[c]laims should be so construed, if possible, as to sustain their validity.'" *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) (quoting *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 937 n.5 (Fed. Cir. 1983)). But the Federal Circuit "has consistently limited the axiom to cases where the construction is 'practicable' and does not conflict with the explicit language of the claim," and it has "admonished against judicial rewriting of claims to preserve validity." *Rhine*, 183 F.3d at 1342.

TSI's argument is essentially one of claim construction. TSI asks the Court to read the ranges set forth in its patent as limited to the ranges that were available in lasers at the time of the patent application. But this is not a proper basis for construing the language of the claim. The words of a claim are generally given the ordinary and customary meaning that the terms would have to a person of ordinary skill in the art at the time of the invention. *Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1342 (Fed. Cir. 2013). Courts "will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history." *3M Innovative Properties Co. v. Tredegar Corp.*, 725 F.3d 1315, 1333 (Fed. Cir. 2013).

The Claims in the '279 Patent claim specific segments of the identified range of wavelengths. Claim 1 claims an apparatus utilizing a laser diode "having a wavelength above about 320 nm." U.S. Patent No. 6,831,279 col.15 l.51-52. Claim 3 claims an apparatus employing a laser diode that "has a wavelength in the range of about 320 nm to about 420 nm." U.S. Patent No. 6,831,279 col.15 l.65-67. Claim 5 claims an apparatus utilizing a laser diode that "has a wavelength in the range of about 320 nm to about 360 nm." U.S. Patent No. 6,831,279 col.15 l.4-5. Claim 20 claims a wavelength "from about 320 nm to 500 nm." U.S. Patent No. 6,831,279 col.17 l.5. TSI's assertion that a person skilled in the art would have understood these words to require a laser diode of 402-405 nm is simply not plausible. The language of the Claims is not ambiguous – it identifies specific, numerical wavelengths. The fact that a person of ordinary skill in the art might have known that no such lasers existed when the patent was sought would not alter the meaning of the words; it would instead mean that the patent is overbroad and does not enable the full scope of the ranges it claims.

Claim construction is a matter of law. *Douglas Dynamics*, 717 F.3d at 1341. The Court concludes that a person of ordinary skill in the art would have understood the invention to cover an apparatus utilizing a laser diode that emitted a laser within the range of wavelengths specified in the patent.

This conclusion is supported by the Federal Circuit's decision in *MagSil*, 687 F.3d 1377. The patent at issue in that case concerned computer hard drives. The patent claimed that its invention produced "change in the resistance [of portions of the drives] by at least 10% at room temperature," which the district court and the federal circuit read to mean 10% or higher, stretching to infinity. *Id.* at 1382. Given this claimed range, the Federal Circuit noted that "[t]he specification must contain sufficient disclosure to enable an ordinary skilled artisan to make and use the entire scope of the claimed invention at the time of filing." *Id.* at 1381. Because the inventor at the time of filing had achieved changes in resistance only as high as 11.8%, the Federal Circuit held that the patent did not enable the entire scope of the claimed invention and was therefore invalid for lack of

enablement. *Id.* at 1380. The Federal Circuit affirmed the district court's grant of summary judgment in favor of the alleged infringer.

TSI argues that the ranges set forth in its patent are limited to the ranges that were available in technology at the time of the patent application – wavelengths of 402-405 nm. If this argument were correct, however, the Federal Circuit would have reached the opposite result in *MagSil*. Because the technology in existence at the time of the MagSil patent application had achieved a resistance change of only 11.8%, the claim in the patent would have been read to mean a range of 10% to 11.8% and the patent would have faced no enablement problems. The Federal Circuit did not adopt such an approach. It read the patent according to its plain terms as embracing a range in excess of 10%, and held that the patent was invalid because it did not enable such a broad range. The Federal Circuit observed that "MagSil's difficulty in enabling the asserted claims is a problem of its own making." *Id.* at 1384. By claiming an overly broad range in its patent, MagSil later found itself holding a patent that did not enable the full range it had claimed. The same is true here. By claiming a range of 320-500 nm, TSI's patent must either enable the entire range or face the same fate as MagSil's patent.

TSI cites *Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1309 (Fed. Cir. 2012), as authority that it has satisfied the enablement requirement. The defendant in *Edwards* challenged the validity of a patent covering a heart valve prosthesis, arguing that the patent was invalid for lack of enablement in humans because the valve had been implanted only in pigs at the time the patent application was filed. The validity issue was presented to the jury at trial, and the jury found infringement and awarded substantial damages. On appeal, the Federal Circuit noted the unique setting for medical device patents: "it has long been recognized that when experimentation on human subjects is inappropriate, as in the testing and development of drugs and medical devices, the enablement requirement may be met by animal tests or *in vitro* data." *Id.* at 1309. Because evidence was presented at trial showing that the product had been created and tested in animals in the way described by the patent, the appeals court found sufficient

evidence to sustain the jury's verdict on validity. *Id.*

Edwards is not helpful precedent in this case. The issue in *Edwards* – whether a product developed in animal tests can be patented and later applied to the product when used in humans – is a very different than the issue presented here. As the Federal Circuit noted, it involved practical considerations of the way in which medical products are developed. *Edwards* reached the pragmatic conclusion that products developed through animal tests can be patented for human use even though the product has not actually been used in humans. This case does not concern medical products, and *Edwards* does not include a specified range in the patent like this case or *MagSil*.

B. Undue Experimentation.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech*, 108 F.3d at 1365 (citation omitted); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) ("[T]he scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification to persons of ordinary skill in the art."). The Federal Circuit has held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." *See, e.g.*, *Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity of some experimentation. . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'") (footnotes, citations, and internal quotation marks omitted). In *Wands*, the Federal Circuit set forth a number of factors a court may consider in determining whether a disclosure would require undue experimentation: the quantity of experimentation necessary; the amount of direction or guidance presented; the presence or absence of working examples; the nature of the invention; the state of the prior art; the relative skill of those in the art; the predictability or unpredictability of the art; and the breadth of the claims. *Id*. at 737. The Federal Circuit has noted that not all of the factors

must be reviewed when determining whether a disclosure is enabling. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts."). "Whether undue experimentation is needed is not a single, simple, factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 858 F.2d at 737.

For several reasons, the Court concludes that a person skilled in the art would be required to engage in undue experimentation to practice the ranges claimed in each Asserted Claim.

First, a large amount of experimentation would have been necessary to develop diodes capable of emitting lasers near the bottom of the claimed ranges. BioVigilant's expert, Dr. Carlson, opined that "an extraordinary amount of experimentation would be required" and indicated that, even as of 2008, no laser diodes were available with emissions below 370 nm. Doc. 172, ¶ 107. TSI has not rebutted this evidence.

Second, there was little guidance or direction in the prior art or the specification. The specification and prior art do not explain how one of ordinary skill in the art could construct or obtain laser diodes with emissions in the claimed range of wavelengths. *Id*., ¶ 103.

Third, there were no working examples of laser diodes in the claimed range of wavelengths. This fact was confirmed by both BioVigilant and TSI's experts and by Dr. Ho, the inventor of the '279 Patent. *Id*., ¶¶ 103-04; Doc. 202 at 272.

Fourth, when the '279 Patent was filed, laser diodes were a relatively new breakthrough introduced by Dr. Shuji Nakamura. No working examples existed that were capable of wavelengths below 400 nm.

Fifth, according to TSI, a person of ordinary skill in the art would have "a multidisciplinary skill set, including an understanding of and experience with laser-excited native (intrinsic) fluorescence spectroscopy systems. Such a person would typically have a master's or doctorate degree in a relevant area, such as biochemistry,

chemistry, microbiology, physics, or electrical engineering, and one or more years of additional experience working with laser-excited native (intrinsic) fluorescence spectroscopy systems." Doc. 202 at 17. TSI's expert, Dr. Carrano, who is far more skilled than a person having ordinary skill in the art, reported that no laser diode existed in 2001 that was capable of emitting a laser with a wavelength near the bottom of the claimed range and that making one would be a "really hard thing to do." Doc. 227 at 13. A person of ordinary skill would not have had the necessary knowledge or training required to pioneer this laser diode technology and invent a laser diode capable of emitting lasers at an unprecedented wavelength.

Sixth, the Asserted Claims are very broad. Laser diodes were available for use in the claimed method and apparatus which emitted lasers at about 402-405 nm. The Asserted Claims, however, claim a range of wavelengths from 320-500 nm. These ranges would have required a person of ordinary skill in the art to develop laser diodes with emissions at a wavelength far below and even above the laser diodes that had been constructed in 2001.

The Court finds that the *Wands* factors weigh heavily in favor of a finding that the experimentation necessary to develop a suitable laser diode would have been undue. Because every single Asserted Claim employs a laser diode with emissions at wavelengths below 400 nm, a person of ordinary skill in the art would have needed to perform undue experimentation in order to practice each of the Asserted Claims.[1]

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[1] Claims 4, 6, 23, and 24 claim an apparatus or method utilizing a laser diode that has a wavelength operative to excite NADH, flavinoids, NADH, and riboflavin respectively. Dr. Carrano indicates in his report that "[t]he excitation wavelength of NADH was centered at around 340 nm, which falls within the ultraviolet spectrum" and that those with ordinary skill in the art "understood that using 340-360 nm as the selective NADH excitation wavelength would maximize the probability of exciting intrinsic fluorescence." Doc. 202 at 30. The evidence indicates that no laser diodes existed in 2001, or even 2008, capable of emitting lasers at the required wavelengths. Doc. 172, ¶ 107. Claims 6 and 24 are invalid as well because they also claim uses of a laser diode that emits a laser within portions of the range that are not enabled. For example, Dr. Carrano's report indicates that "riboflavin may also be detected by a system designed for NADH because riboflavin's fluorescence emission wavelengths partially overlap those of NADH." Doc. 202 at 49 (internal quotations omitted). Riboflavin, therefore, is fluoresced at wavelengths in the claimed range near 360 nm, which is a wavelength also not enabled by the '279 Patent. Claims 4, 6, 23, and 24 do not delineate

C. Conclusion.

The patent claims a wavelength range of 320-500 nm. Undisputed evidence establishes that no laser diodes existed at the time of the '279 patent application that would satisfy this full range. The undisputed evidence also shows that such laser diodes could not have been developed without undue experimentation. BioVigilant has established the invalidity of the patent on enablement grounds by clear and convincing evidence.

IT IS ORDERED that BioVigilant's motion for summary judgment (Doc. 227) is **granted**. In light of this ruling, the Court concludes that BioVigilant's counterclaims for declaratory relief are moot, and the Clerk is therefore directed to terminate this matter.

Dated this 21st day of April, 2014.

David G. Campbell
United States District Judge

what portions of the range they claim. They appear to be fallback positions written into the patent such that these Claims would survive in the event that the broader Claims were found invalid. Evidence has been presented, however, that renders each of these fallback Claims invalid for lack of enablement.