IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

VLADIMIR PANCHEV, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 1:12-cv-641 (GBL/IDD)
v.	)	
	)	
DAVID KAPPOS, Director, United States Patent and Trademark Office,	)	
	)	
	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

THIS MATTER is before the Court on Defendant's Motion for Summary Judgment. (Doc. 20.) This case concerns Plaintiffs' United States Patent Application 10/496,322 ("the '322 Application"), which seeks the issuance of a patent with claims directed at a method for treating tumors with formic acid. (*See* Administrative R. A1 [hereinafter Admin. R.], Doc. 13-3.) This case presents three issues.

The first issue is claim construction. Plaintiffs assign error to the United States Patent and Trademark Office's ("USPTO") construction of their claim term "tumor" to encompass warts. Upon *de novo* review, the Court construes Plaintiffs' term language to encompass any and all abnormal growths, including warts. The Court reaches this construction for two reasons. First, the Court's construction is consistent with the ordinary and customary meaning of the term as it is used in the claim language and correlates with contemporaneous dictionary definitions, including those to which Plaintiffs cited during prosecution. Second, the Court's construction is

consistent with Plaintiffs' intent, as evidenced by the use of the term in the specification. For these reasons, the Court construes "tumor" to mean any abnormal growth.

The second issue is whether the Director of the USPTO is entitled to summary judgment as to Plaintiffs' claim that the USPTO erred in concluding that their claimed method was obvious over two prior art references, Agholme and Schwartz. The Court concludes that Plaintiffs' Application is obvious over the cited references for two reasons. First, construing "tumor" to encompass warts, Plaintiffs' Application would have been obvious because the treatment of warts, a benign tumor, with formic acid is taught by the Agholme reference. Second, the germicidal properties referenced in Schwartz, which teaches the addition of iodine for its antiseptic benefits, would have been an obvious combination with the ablation of undesirable tissue taught by Agholme. As a result, the Court finds no material issue with respect to the obviousness of Plaintiffs' claims and the Court grants the Director summary judgment on this count.

The third issue is whether the Director is entitled to summary judgment as to Plaintiffs' claim that the USPTO erred in concluding that their specification's disclosure fails to enable their claims. The Court grants the Director's Motion for Summary Judgment on this claim because Plaintiffs' specification fails to provide the requisite specificity to fully disclose how to use the novel aspects of their claims sufficient to enable one of ordinary skill in the art to practice the claimed method without undue experimentation. Further, the Court's *de novo* review of Plaintiffs' newly admitted, post-filing evidence does not alter this conclusion because the scientific abstracts and the experimental data of a single treatment remain inadequate to surmount the deficiencies of Plaintiffs' Application insofar as the specification fails to explain how its teaching could be implemented to treat all types of tumors. Therefore, Plaintiffs' claims

fail for lack of enablement and the Court grants the Director's Motion for Summary Judgment on this count.

I. BACKGROUND

This case concerns Plaintiffs Vladimir Panchev, Marieta Pancehva, and Adelina Pancheva's '322 Application entitled, "Medium for Radical Treatment of Tumors, Inflammatory Processes, Fungal Infections and other Affections of the Tissues, Diagnostic and Prophylactic and Method of its Implementation." (Admin. R. A1.) Plaintiffs are Bulgarian citizens, proceeding *pro se*, seeking review of the USPTO's rejection of their claims pursuant to 35 U.S.C. § 145.

A. The '322 Application

Plaintiffs filed the '322 Application on May 20, 2004, seeking claim priority to an earlier Bulgarian application filed on December 12, 2001.[1] Specifically, Plaintiffs seek method claims generally directed to treating tumors with formic acid based on their alleged discovery that the more permeable blood vessels of diseased tissues, such as tumors, are uniquely penetrable, such that the blood coagulation properties of formic acid are able to penetrate the vascular system to necrotize the targeted diseased tissue. In other words, Plaintiffs' Application seeks a patent for a method applying a known chemical to abnormal growths, in which Plaintiffs purport that the method kills the growth by restricting its blood supply while preserving the surrounding healthy

[1] Plaintiffs' Application was filed under the Patent Cooperation Treaty ("PCT"), an international agreement permitting inventors to streamline their patent application process in multiple signatory countries. *Helfgott & Karas, P.C. v. Dickerson*, 209 F.3d 1328, 1330 (Fed. Cir. 2000). (*See generally* Admin. R. A1-16.) The Court's analysis, however, is not affected by Plaintiffs' PCT filing because U.S. patent laws are territorial in nature, such that Plaintiffs' Application must comply with the patentability requirements of Title 35 of the United States Code.

tissue. Plaintiffs' Application, therefore, seeks a patent on a method of treating all benign and malignant tumors.

Plaintiffs assert their field of invention as "the treatment of tumor[s] and other diseased tissues with increased permeability of their blood vessels." (Admin. R. A260, Doc. 13-4.) The method of treatment claimed is "based on the different degree of protection that ensure [sic] that blood vessels of healthy and of the tumor tissue against [sic] the influence of blood-coagulation enhancing substances . . . ." (Admin. R. A261.) Plaintiffs propose their method based on (1) the "[a]typicity of the tumor tissue . . . in direct proportion of its malignity[;]" (2) the superior vascular protection of healthy tissue; (3) the blood coagulation properties of formic acid; (4) the reduced risk of side effects from formic acid exposure; and (5) the rapid absorption rate of formic acid's water solutions, which Plaintiffs purport allow for the treatment of internal tumors without the need of syringe, sound, or surgical intervention. (Admin. R. A262.)

The specification of Plaintiffs' Application generally provides that their invented method can be used to treat tumors with formic acid, to which iodine may be added to accelerate absorption. (Admin. R. A263.) Plaintiffs qualify their method by stating that their method is case dependent and depends on the treating physician's qualifications but that generally a 10% solution with the addition of a 5% iodine concentration is sufficient for malignant tumors. (*Id.*) The treatment of Plaintiffs' method consists of rubbing the concentrated medium directly on the tumor or an accessible surface of the contiguous healthy tissue. (*Id.*) Repeated application and monitored absorption is instructed, such that the tumor is sufficiently saturated with formic acid solution and the tumor is necrotized. (*Id.*) Plaintiffs warn of a "caustic effect" on tissues, however, with too high of a concentration resulting in toxicity. (*Id.*) For benign tumors, Plaintiffs' Application teaches the mechanical irritation of the tissue. (*Id.*)

Additionally, the Plaintiffs' specification provides details of one example of the method of treatment. Specifically, Plaintiffs mention the treatment of a 52-year-old woman, Plaintiffs' relative, with "two side fibrous mastopathy" three times a day over the course of ten days. However, Plaintiffs' specification provides no other details of treatment, nor does Plaintiffs' Application specify how to use its claimed method beyond its fibrous mastopathy reference. Notwithstanding Plaintiffs' sparse specification, Plaintiffs purport that their method opens "unlimited possibilities for tumor treatment in other organs" through inhalation, puncture, and by surgical reach. (Admin. R. A265.)

Plaintiffs' Application claims:

1. A method of radical treatment of benign and malignant tumors:

> [C]omprising administration to the affected place a medium, representing water solution of formic (methanoic) acid in all possible proportions, by means of repeatedly administering the solution to that tissue, or the nearest to it accessible tissue, with respective awaiting its absorption until the diseased tissue necrotizes;
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> [T]herapeutically based on the strong blood-coagulation enhancing properties of this acid, the rapid absorption of its water solutions in human's and animal's tissues, and the increased permeability of the blood vessels of the affected tissue, compared to the blood vessels of the healthy one; and
>
> [W]atching over eventual harm of the healthy tissue, and over symptoms of excessive increase of formic acid concentration in the entire body.

2. The method of claim 1, wherein the used medium contains iodine on about 5%.

3. A method of radical treatment of benign and malignant tumors based on the different permeability of the blood vessels of the tumor and the healthy tissues against the blood-coagulation enhancing substance, which represents the method of claim 1, or claim 2;

> [C]omprising an attack against the tumor blood vessels externally through rub in, inhalation, spraying and other methods of repeated supply of the formic acid solution to the affected tissue, or to the nearest to it accessible tissue, and aiming its necrosis through destroying selectively its vascular system in coagulating the blood in it, before the concentration of formic acid in the healthy tissue could reach levels, dangerous for it;
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> [B]ased on the increased permeability of the blood vessels of the tumor tissue, compared to the blood vessels of the healthy one, and even destroying by need the nearest to the tumor healthy tissue;
>
> [B]y temporary interrupting the treatment, if healthy tissue becomes affected, or symptoms of nausea appear and taking more fluids until the latter symptoms fully disappear.

B. The USPTO Examination

On June 28, 2007, and following preliminary exchanges with the USPTO Examiner, Plaintiffs amended claims 1-3. These claims were originally directed to the "treatment, diagnostic and prophylactic of benign and malignant tumors, inflammatory disease states, pathologically affected tissues, fungal infections, and blood stopping . . . ." (Admin. R. A195, Doc. 13-3.) Ultimately, claims 1-3 were amended to state "treatment for benign and malignant tumors."[2] Notwithstanding Plaintiffs' amendment, the Examiner finally rejected Plaintiffs' Application, reasoning that Plaintiffs' specification did not enable claims 1-3 and that the claims were nonetheless obvious over two prior art references, Agholme and Schwartz.

On August 17, 2007, the Examiner issued a Non-Final Office Action rejecting Plaintiffs' claims. (*Id.* at A201.) Applying the *Wand* factors, the Examiner based his enablement rejection

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[2] Plaintiffs' November 15, 2007 Response to the Examiner's August 17, 2007 Non-Final Office Action states that their June 27, 2007 amendment mistakenly deleted "of benign and malignant tumors" from claim 1. In their Response, Plaintiffs restored this language. (Admin R. A240, Doc. 13-4.)

on his finding that Plaintiffs' specification did not "reasonably provide enablement for: 1) any and all radical treatments; 2) all possible proportions of formic acid; and 3) a method of treating any and all benign and malignant tumors." (Admin. R. A206.) Further, the Examiner explained that, based on Plaintiffs' specification, one skilled in the art would be unable to practice the method without undue experimentation commensurate with the broad scope of Plaintiffs' claims. (*Id.*) Specifically, the Examiner noted that Plaintiffs' claims are broad in that they purport to treat all benign and malignant tumors with all possible proportions of formic acid, yet Plaintiffs' specification only provides details related to treating fibrous mastopathy. (*Id.*) The Examiner recognized that the level of skill by one of ordinary skill in the art is relatively high due to the complexity of cancer research. (*Id.* at A207.)

Applying the factors set forth in *Graham*, the Examiner based his obviousness rejection on his finding that, as to claim 1, the Agholme reference, and as to claims 2 and 3, Agholme in view of Schwartz, rendered Plaintiffs' claims unpatentable because both references taught Plaintiffs' method and that the combination of the two would have been obvious to one skilled in the art. (*Id.* at A211.) The Agholme reference teaches the method of treating warts with acids, including formic acid. (*See* Def.'s Ex. A, Doc. 21-1.) Specifically, Agholme claims the method of treating skin warts wherein the preparation of formic acid into a medium is applied onto the skin. The Agholme method is based on the effect of the treatment on the blood capillaries of the wart, such that the capillaries are degraded and ultimately ablated or removed. (*Id.*) The Schwartz reference discloses the antiseptic composition of iodine for topical application to skin. (Def.'s Ex. B, Doc. 21-2.) Schwartz teaches that the addition of iodine can provide desired germicidal properties to a number of mediums. (*Id.*) The Examiner opined that one of ordinary skill would have been motivated to combine Agholme with Schwartz because chemical ablation

of warts with formic acid, taught by Agholme, would have caused a high risk of infection, thus practitioners would have wanted to prophylactically counter the risk by the addition of iodine, which is taught by Schwartz. (Admin. R. A211-212.) For these reasons, the Examiner finally rejected claims 1-3 for obviousness. (*Id.* at A295-308.)

C. The Administrative Appeal

On June 11, 2008, the Examiner entered final rejections on Plaintiffs' claims 1-3. (*Id.*) Plaintiffs appealed to the United States Patent and Trademark Office Board of Patent Appeals and Interferences ("the Board"). The Examiner filed his Answer to Plaintiffs' appeal in which he reiterated his reasons for rejecting Plaintiffs' claims. (*Id.* at A591-603.) Specifically, the Examiner maintained his position that Plaintiffs' specification failed to enable Plaintiffs' broad claims of treating all benign and malignant tumors and that Plaintiffs' claims were obvious over Agholme and Schwartz. Plaintiffs contested the Examiner's finding that the specification only taught treatment of fibrous mastopathy but asserted that they treated breast cancer instead. In support of this, Plaintiffs submitted an image of a mammogram as purported evidence of the treatment of a malignant lesion.

With respect to obviousness, Plaintiffs presented three arguments. First, Plaintiffs argued that Agholme's teaching of wart treatment was distinct from their Applications' treatment of vascular supported tumors. Thus, Plaintiffs asserted that chemical ablation of warts was not the same method of necrotizing tumors. Second, Plaintiffs argued that "warts" were not encompassed within the meaning of "tumors," highlighting that neither Agholme nor Schwartz reference "tumor." Additionally, Plaintiffs challenged the Examiner's rejection of both lack of enablement and obviousness, arguing that to reject on both grounds was inherently contradictory because a claim that fails to enable cannot also be obvious. Plaintiffs further argued that one of

ordinary skill in the art would not have been motivated to combine Agholme and Schwartz for the same reasons that they combine iodine, namely increasing vascular permeability.

The Board affirmed the Examiner's rejection for lack of enablement and obviousness. (Admin. R. A623). Treating claim 1 as representative of Plaintiffs' claims, the Board adopted the Examiner's factual findings with respect to the scope of Plaintiffs' claims and concluded that the claims' scope was incongruent with the limited specification provided in Plaintiffs' Application.[3] The Board reasoned that the Examiner was correct in citing the complex field of treating cancer to find that undue experimentation would be required to treat different forms of cancer under Plaintiffs' inadequate specification. Thus, the Board affirmed the Examiner's enablement rejection.

On the issue of obviousness, the Board affirmed the Examiner's decision, concluding that, giving Plaintiffs' claims the broadest interpretation, "tumor" would encompass "wart," a papilla virus-induced skin growth. Based on this finding, the Board concluded that the Agholme

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[3] The Court notes that Defendant candidly points to the fact that the Board improperly cited to Plaintiffs' pre-amendment claims on review. Indeed, as discussed, Plaintiffs amended claims 1-3 to remove "other pathological tissues," among other claim language, in their attempt to surmount the Examiner's rejections. However, in its opinion, the Board cites the claim language as it appeared prior to Plaintiffs' amendments. The Court agrees with the Director, however, that the Board's error is harmless and does not preclude this Court's review. The Board cited its reasons for rejection based on claim language contained in both the final and pre-amendement language. Therefore, the Board's reasoning makes clear that their conclusion would have been the same had they cited the narrower, amended claims. Notwithstanding this error, Plaintiffs' argue that they are entitled to this Court's review of earlier, broader claims based on the Examiner's restriction requirement during prosecution. A restriction requirement is a requirement that an inventor "elect" one invention to prosecute when the Examiner believes the claims cover multiple inventions. *See Manual of Patent Examining Procedure* ("MPEP") § 802.02. However, Plaintiffs failed to properly challenge that restriction requirement at the administrative level and have therefore not exhausted that claim. A challenge to the restriction requirement can only be achieved by filing a petition with the USPTO during prosecution and Plaintiffs elected not to do so. Therefore, the Court rejects Plaintiffs' attempt to bring the early, broader claims subject to the Examiner's restriction requirement within the purview of the present appeal.

reference rendered claim 1, and thus dependent claims 2 and 3, obvious. Further, the Board affirmed the Examiner's finding that Agholme in view of Schwartz rendered its claims obvious, concluding that the reasons for combining the references do not need to be the same. The Board opined that the antiseptic properties taught by Schwartz combined with the chemical ablation of warts taught by Agholme would have been an obvious combination. Additionally, the Board concluded that a claim could be rejected for both lack of enablement and obviousness because, "a claim may not be enabled for everything it encompasses, but may still be rendered unpatentable by prior art that teaches only one embodiment that is encompassed by the claimed subject matter." (Admin. R. A627.) Thus, the Board affirmed the Examiner's rejection for obviousness.

D. The Present Civil Action

Pursuant to 35 U.S.C. § 145, Plaintiffs filed their Complaint on January 19, 2012 in the United States District Court for the District of Columbia, seeking review of the Board's decision rejecting their claims for lack of enablement and obviousness. (*See* Doc. 1.) On May 14, 2012, upon Defendant's motion for improper venue, the case was transferred to this Court pursuant to 28 U.S.C. § 1406(a), as the Eastern District of Virginia retains exclusive jurisdiction over original civil actions brought under § 145. (*See* Doc. 5.) Following transfer, Defendant answered Plaintiffs' Complaint, denying Plaintiffs' allegation that the USPTO acted arbitrarily or capriciously in rejecting Plaintiffs' Application. (Doc. 9.)

1. Plaintiffs' New Evidence

Pursuant to the recent Supreme Court's decision in *Kappos v. Hyatt*, 132 S. Ct. 1690 (2012), Plaintiffs seek *de novo* review with respect to several of the USPTO's factual findings underpinning its rejections for lack of enablement and obviousness. Plaintiffs seek this review

by presenting several new exhibits that were not presented to the Examiner during prosecution or to the Board on appeal. First, Plaintiffs attach three images to its Complaint, which purportedly show the results of Plaintiffs' experiment as taught in their specification. Plaintiffs aver that the experiment was performed on a breast carcinoma by exactly following their specification. Rebutting the USPTO's finding that their specification only teaches the treatment of fibrous mastopathy, Plaintiffs submit these images as evidence of their treatment of cancer. (Pls.' Opp'n at 5, Doc. 24.) No other experimental data or explanation accompanies Plaintiffs' images.

Next, Plaintiffs submit four scientific abstracts, which they collectively authored, dated between 2011 and 2012. (*See* Pls.' Exs. 1-4, Doc. 12.) The abstracts were submitted to various scientific conferences and published in the respective conferences' materials. "Abstract 1" is entitled, "The Easiest Way to Selectively Kill Cancer is to Destroy Selectively Its Vasculature" and was presented at the 8th Annual Cancer Drugs & Research Conference on January 27-28, 2011. (Pls.' Pretrial Disclosures at 1, Doc. 12; Pls.' Ex. 1, at 2-3, Doc. 12-1.) The abstract references a therapy directed to the vasculature of tumors and discusses in general terms formic acid's disruptive effect on tumor vascularization through its effect on carbon dioxide levels. (Pls.' Ex. 1, at 2-3.)

"Abstract 2" is also entitled, "The Easiest Way to Selectively Kill Cancer is to Destroy Selectively Its Vasculature" and was presented at the 2nd International Cancer Immunotherapy and Immunomonitoring Conference held in Budapest, Hungary on May 2-5, 2011. (Pls.' Pretrial Disclosures at 1; Pls.' Ex. 2, Doc. 12-2.) The text of the abstract is nearly identical to that of Abstract 1. Distinguishing the two, however, is the final sentence which reads "10% solution is enough to kill immediately malignant tumor and in particular, breast carcinoma, on which we

first implemented the therapy, after several years of experiments on benign tumors." (Pls.' Ex. 2, at 3, Doc. 12-2.) In all the other respects, Abstract 2 is identical to Abstract 1.

"Abstract 3" is entitled "Inflammation is a manifestation of the CO2-induced increase of the postcapillary venules' pressure" and was presented at the 10th World Congress on Inflammation in Paris, France on June 25-29, 2011. (Pls.' Pretrial Disclosures at 1; Pls.' Ex. 3, Doc. 12-3.) This abstract similarly discusses Plaintiffs' research on CO2 influence on the vascularization of diseased tissues. Plaintiffs explain that the subjects of their experiment were used to "treat inflammation and cancer, using, as well the discovered by us [sic]: (1) Extremely strong penetrative feature of formic acid molecules via biological membranes; (2) Its strong blood coagulating feature; [and] (3) Its strong bactericidal and virucidal feature." (Pls.' Ex. 3, at 3, Doc. 12-3.) Further, Abstract 3 discusses the treatments selective killing of malignant tissues with 10% formic acid solution. (*Id.*)

"Abstract 4" is entitled "The capillary pumps regulate muscle blood flow by the myocytes' CO2 and heat production and the mechanical impact of their contraction." This abstract was published in "Physiology 2012, Edinburgh, UK Book of Abstracts, p. 225P, poster 318." (Pls.' Pretrial Disclosures at 1; Pls.' Ex. 4, at 1, Doc. 12-4.) In their abstract, Plaintiffs discuss their research directed to heat transfer in muscle cells. Plaintiffs discuss their hypothesis of CO2's critical role in thermal-heat regulation and the means by which they conducted experiments to test the pressure-temperature relationship against various CO2 concentrations. (Pls.' Ex. 4, at 2-3.) Notably, Abstract 4 does not reference the treatment of tumors, cancers, or any specific disease.

2. The Director's Expert Report

On October 23, 2012, Defendant filed its instant Motion for Summary Judgment. (Doc. 20.) In support of his Motion, the Director proffers the expert testimony of Dr. Gregory Thatcher, Chair in Medicinal Chemistry in the Department of Medicinal Chemistry and Pharmacognosy, at the University of Illinois College of Pharmacy. (*See* Thatcher Expert Report, Def.'s Ex. H, Doc. 21-8.) Dr. Thatcher has thirty-five years of experience in the chemical sciences and twenty-five years of experience as a scientist in the field of drug development. (*Id.* ¶ 11.) His research is directed at medicinal chemistry, chemical biology, proteomics, chemical toxicology, and cell and molecular biology, leading to numerous publications in the related arts. (*Id.* ¶¶ 1-2; 8.) Dr. Thatcher also has experience in drafting patent applications and responding to office actions related to pharmaceuticals directed at the treatment of ischemia, neurodegenerative diseases, epilepsy, and the treatment of Alzheimer's disease. (*Id.* ¶¶ 5-6.)

Dr. Thatcher opens his report by discussing the physiology of tumors and the chemical properties of formic acid. Specifically, Dr. Thatcher explains that a tumor is "an abnormal growth of body tissue." (*Id.* ¶ 17.) His understanding is that "tumor," as used in the '322 Application, means "abnormal growth of tissue, wherein tumors can be cancerous (malignant) or noncancerous (benign)." (*Id.* ¶ 40.) He further explains that, because tumors significantly differ "in type, subtype, location, etiology, and progression," they cannot be categorically classified into a single class of similar conditions. (*Id.* ¶ 18.) Notably, Dr. Thatcher reports that "[w]arts are indeed closely associated with many more recognizable tumors, benign and malignant" and are highly vascularized structures. (*Id.* ¶ 41-42.) Dr. Thatcher also offers his testimony on the chemical properties of formic acid and iodine. (*See id.* ¶¶ 23-28.) He reports formic acid as a "carboxylic acid with known uses as an antiseptic, in particular as an antibacterial, and

preservative." (*Id.* ¶ 23.) Thatcher explains that formic acid acts as an oxidizing agent that forms formaldehyde and methanol. (*Id.*) He further explains that formic acid is a known treatment of warts, which contains a reduced product of formaldehyde, which is also known for its antiseptic and virucidal properties. (*Id.* ¶ 24-26.) Additionally, Thatcher acknowledges that a wide range of iodine concentrations are known virucidal agents and are known for their "effective treatment of warts by daily application." (*Id.* ¶ 28.)

In evaluating Plaintiffs' claims, Dr. Thatcher opines that one skilled in the relevant art of drug development would "have knowledge of the aberrant cell growth underlying tumor formation and mechanisms by which drugs may perturb growth and potentially modify symptoms associated with tumors." (*Id.* ¶ 31.) Additionally, Dr. Thatcher believes a person of ordinary skill in the art to comprise a team of persons holding a Ph.D., Pharm.D., or M.D., with specific knowledge in chemistry, physiology, and cancer biology. (*Id.*)

Dr. Thatcher offers his opinion on several aspects of Plaintiffs' claims and specification as presented in the '322 Application. First, Dr. Thatcher understands Plaintiffs' claims to be directed at a broad method of treating "every kind" of pathological alteration of tissues based on the broad language used in Plaintiffs' specification. (*Id.* ¶ 33.) Based on his review of the specification, Dr. Thatcher highlights that Plaintiffs do not disclose examples of their method "beyond that of a human subject stated to have a 'malign formation' of the left breast and a 'fibrous mastopathy' of 5.7 to 7.4 mm dimensions." (*Id.* ¶ 34.) He explains that a fibrous mastopathy is an increase in fibrous connective tissue that usually refers to a benign tumor. (*Id.* ¶ 35.) Noting that Plaintiffs fail to provide sufficient data to conclusively identify whether they treated a benign or malignant tumor, Dr. Thatcher states that, to one skilled in the art, Plaintiffs disclosure "purports to teach that a human mammary tumor . . . when treated with the method

described may undergo a change in dimensions." (*Id.* ¶ 36.) He interprets Plaintiffs' claims to broadly treat "any and all tumors . . . regardless of the tumor formation, malignancy, or stage of infiltration." (*Id.*) Dr. Thatcher's review also leads to his determination that Plaintiffs' specification covered all possible solutions of iodine and formic acid. (*Id.*)

Second, Dr. Thatcher opines that Plaintiffs' claims and specification do not enable their method to one skilled in the art. Specifically, he states that the method "cannot be practiced . . . without undue experimentation because of the lack of clarity, detail, and guidance in the example and specification." (*Id.* ¶ 15.) Dr. Thatcher highlights the fact that Plaintiffs' specification offers "no limitation, direction, or guidance . . . on the selection of administration routes, amount, dosing, frequency, or excipients." In his opinion, Plaintiffs guidance to one skilled in the art is insufficient or entirely absent. (*Id.* ¶ 52.) Additionally, with respect to the single "working example" Plaintiffs disclose, Dr. Thatcher states that it is "poorly described, leaving one of skill in the art unclear as to the type of tumor treated, the exact result of the treatment, and almost all details associated with practice of the invention in the worked example." (*Id.* ¶ 53.) More specifically, Dr. Thatcher explains that Plaintiffs' example "leaves out several details that would be important to one of skill in the art, including: the grade of tumor; the subtype and genotype of the tumor; [and] the patient profile," specifically noting that Plaintiffs' data and images which they provide are "virtually unusable" to one skilled in the art. (*Id.* ¶ 53.) Based on his experience, it is impossible from Plaintiffs' disclosure to predict the treatment of varying malignant tumors without more experimentation. (*Id.* ¶ 57.)

Third, Dr. Thatcher opines that Plaintiffs' method is an obvious combination of known prior art references. Based on his review of Agholme and Schwartz, Dr. Thatcher agrees that the two references are within the scope and content of the prior art and would have taught one of

ordinary skill in the art that topical application of formic acid can be applied to treat warts. (*Id.* ¶ 72.) Additionally, in his opinion, there exists prior art that suggests a link between the treatments of cancers with formaldehyde, which is an active component of formic acid solutions disclosed in Plaintiffs' specification. (*Id.* ¶ 55.) Further, Dr. Thatcher explains that Plaintiffs' claims are obvious by "prior art that teaches use of formic acid solutions in treatment of a subset of benign tumors (i.e., warts) and the use of iodine as an antiseptic adjuvant." (*Id.* ¶ 16.) He cites both Agholme and Schwartz, among others, to support his opinion as to the obvious nature of Plaintiffs' claims. (*See id.* ¶¶ 54-55, 67, 78, 86.)

Lastly, Dr. Thatcher comments on Plaintiff's new evidence. In his experience, abstracts such as those submitted by Plaintiffs are typically submitted many months in advance of scientific conferences and are not peer-reviewed before publication. (*Id.* ¶ 94.) With respect to the substance of the abstracts, however, Dr. Thatcher reports that each of the four abstracts is "essentially the same work" recast in four different publications. (*Id.* ¶ 95.) Specifically, he explains that "[e]ach abstract appears to report the same single experiment: measurement of the pressure-temperature relationship of CO[2] dissolved in aqueous saline solution." (*Id.* ¶ 95.) Dr. Thatcher notes, however, that the purported data referenced by the abstracts has already been reported in the scientific literature and thus does not appear to present anything novel, making it "of uncertain relevance" to Plaintiffs' Application. (*Id.*)

3. Plaintiffs' Rebuttal Expert Report

In response to the Director's expert, Plaintiffs submit their own "expert" report. (*See* Pls.' Expert Report, Def.'s Ex. I, Doc. 21-9.) Plaintiffs assert themselves as electrical engineers who work in the fields of animal and plant physiology and medicine with a particular focus on blood and plant sap circulation and cell division, which they purport is within the field of their

invention. (*Id.* at 1.) Plaintiffs open their report by pointing to additional abstracts accepted at two conferences, both of which took place in 2011. (*Id.* at 2.) Plaintiffs also highlight additional publications published in the *Journal of Applied Physiology*, which concern their research of arteriovenous pumps. (*Id.* at 3.) Additionally, Plaintiffs reference another patent application of "similar significance" to the Application presently in dispute, which is apparently on appeal before the Board following claim rejections. (*Id.* at 4-5.) However, Plaintiffs do not provide any other details on their additional references.

Plaintiffs' report largely challenges Dr. Thatcher's qualification as an expert. (*Id.* at 6.) Plaintiffs opine that Dr. Thatcher does not have the requisite experience or knowledge in the field of blood circulation, which is the field of endeavor of their invention. (*Id.*) Further, Plaintiffs highlight Dr. Thatcher's lack of experience in cancer or benign tumor research and therefore believe him to be "inappropriate" expert "due to the lack of competence in the subject matter . . . ." (*Id.*) However, Plaintiffs acknowledge that Dr. Thatcher actually supports their position of nonobviousness in two respects. First, Dr. Thatcher acknowledges that, because formic acid is comprised of antiseptic components, the addition of iodine, as taught by Schwartz, is unnecessary. Second, Plaintiffs aver that Dr. Thatcher's opinion is consistent with their position to the extent that warts fall outside the definition of benign tumor. (*Id.*)

Next, with respect to Dr. Thatcher's opinion of obviousness, Plaintiffs state that his conclusion is unfounded because it is based on an entirely "senseless combination between prior arts" in light of Plaintiffs' disclosure that formic acid itself contains antiseptic properties, such that the Schwartz addition of iodine would be unnecessary to achieve the prophylactic measures sought by its addition. (*Id.* at 6-7.) Further, Plaintiffs believe Dr. Thatcher's report to be

predicated on an incorrect assumption that warts are a subset of tumors. (*Id.*) In this regard, Plaintiffs proffer their previous position presented to the USPTO.

Lastly, with respect to Dr. Thatcher's opinion on Plaintiffs' lack of enablement, Plaintiffs attest that he failed to review their exhibits, which included examples of treating and diagnosing conditions beyond that disclosed in the specification. Specifically, Plaintiffs assert that the three images of killing a human skin benign tumor were not examined or commented on in Dr. Thatcher's report. (*Id.* at 8.) Therefore, Plaintiffs challenge Dr. Thatcher's opinion that their claims were unsupported by sufficient experimental data to fully enable their claims.

In sum, the record before the Court in this § 145 proceeding consists of the administrative record, comprising the prosecution history, Plaintiffs' appeal to the Board, including the Examiner's responses and the Board's, Plaintiffs' petition for rehearing, and the parties' newly admitted evidence, including the parties' expert designations and respective reports. It is on this comprehensive record that the Court now rules on the Director's pending Motion for Summary Judgment (Doc. 20), determining whether Plaintiffs are entitled to the issuance of the patent subject of the '322 Application. Having considered the entire record, and for the reasons that follow, the Court answers this question in the negative.

II. STANDARD OF REVIEW

a. Summary Judgment

Under Federal Rule of Civil Procedure 56, the Court must grant summary judgment if the moving party demonstrates that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c) (2013).

In reviewing a motion for summary judgment, the Court views the facts in a light most favorable to the nonmoving party. *Boitnott v. Corning, Inc.*, 669 F.3d 172, 175 (4th Cir. 2012)

(citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)). Once a motion for summary judgment is properly made and supported, the opposing party has the burden of showing that a genuine dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Bouchat v. Baltimore Ravens Football Club, Inc.*, 346 F.3d 514, 522 (4th Cir. 2003) (citations omitted). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." *Emmett v. Johnson*, 532 F.3d 291, 297 (4th Cir. 2008) (quoting *Anderson*, 477 U.S. at 247-48).

A "material fact" is a fact that might affect the outcome of a party's case. *Anderson*, 477 U.S. at 248; *JKC Holding Co. v. Wash. Sports Ventures, Inc.*, 264 F.3d 459, 465 (4th Cir. 2001). Whether a fact is considered to be "material" is determined by the substantive law, and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248; *Hooven-Lewis v. Caldera*, 249 F.3d 259, 265 (4th Cir. 2001).

A "genuine" issue concerning a "material" fact arises when the evidence is sufficient to allow a reasonable jury to return a verdict in the nonmoving party's favor. *Resource Bankshares Corp. v. St. Paul Mercury Ins. Co.*, 407 F.3d 631, 635 (4th Cir. 2005) (quoting *Anderson*, 477 U.S. at 248). Rule 56(e) requires the nonmoving party to go beyond the pleadings and by its own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

b. Judicial Review under 35 U.S.C. § 145

In addition to the summary judgment standard of review, this Court's review under 35 U.S.C. § 145 is guided by the deference afforded to the USPTO's findings of fact. *Johnson v. Rea*, No. 1:12-CV-440, 2013 WL 1499052, at *2 (E.D. Va. Apr. 9, 2013). Section 145 provides that "[a]n applicant dissatisfied with the decision of the Patent Trial and Appeal Board in an appeal under section 134(a) may, unless appeal has been taken to the United States Court of Appeals for the Federal Circuit, have remedy by civil action against the Director in the United States District Court for the Eastern District of Virginia . . . ." 35 U.S.C. § 145. In a civil action under § 145, "the court may adjudge that [the] applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the [USPTO], and as the facts in the case may appear and such adjudication shall authorize the Director to issue such a patent on compliance with the requirements of law." *Id.* Unlike applicants who seek review to the Federal Circuit, applicants who first seek review in this Court by civil action may present new evidence relevant to disputed issues of fact that was not presented to the PTO. *Hyatt*, 132 S. Ct. at 1696. When the Court does so, it "must make *de novo* factual finding that take account of both the new evidence and the administrative record before the [US]PTO." *BTG Int'l Ltd. v. Kappos*, No. 1:12-CV-682, 2012 WL 6082910, at *4 (E.D. Va. Dec. 6, 2012) (quoting *Hyatt*, 132 S. Ct. at 1701) (internal quotation marks omitted). The evidentiary rules applicable to all civil actions govern § 145 actions, such that § 145 proceedings are subject only to the Federal Rules of Evidence and the Federal Rules of Civil Procedure. *Hyatt*, 132 S. Ct. at 1699-1700. The Court retains discretion, however, to determine what weight to afford an applicant's newly admitted evidence by considering the proceedings before the USPTO and whether the applicant had an opportunity to present the new evidence during those proceedings. *Id.* at 1700. If the

applicant presents no new evidence, this Court reviews the USPTO's decision under the deferential standard provided by Administrative Procedure Act ("APA"). *Johnson*, 2013 WL 1499052, at *2. Thus, under the latter standard, the Court will only set aside a Board decision that is arbitrary, capricious, or otherwise not in accordance with law. *Id.* (citing 5 U.S.C. § 706(2)(a) and *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005)).

III. DISCUSSION

The Court grants Defendant's Motion for Summary Judgment because there are no material factual disputes with respect to the USPTO's findings that Plaintiffs' claims are obvious over two prior art references and are not enabled by their specification. The new evidence submitted to the Court bears little weight on the underlying factual findings and is this insufficient to displace the USPTO's findings. Additionally, because the Court construes Plaintiffs' patent claims to encompass "any abnormal growth" despite the newly admitted evidence, the Court agrees with the Director's conclusion and holds that Plaintiffs' claims are unpatentable as obvious under Agholme and Schwartz. The Court further holds that Plaintiffs' Application fails to enable the broad scope of their claims. Therefore, the Court holds that Plaintiffs' claims are unpatentable under 35 U.S.C. §§ 103 and 112 and that the Director is entitled to summary judgment as a matter of law. Each of these issues are discussed in turn.

A. Claim Construction

The first step of any invalidity analysis is to perform claim construction. *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). Claim construction is a question of law to be determined by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). The court begins by considering the language of the claims themselves. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). The

words of the claim "are generally given their ordinary and customary meaning," which "is the meaning that term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312–13 (internal quotation marks omitted). In addition, during prosecution, "claims are to be given their broadest reasonable interpretation consistent with the specification, [and] claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Acad. Sci. Tech. Ctr.*, 367 F.3d 1359, 1363 (Fed. Cir. 2004). A court should also consider the prosecution history of the patent because it "provides evidence of how the [USPTO] and the inventor understood the patent." *Id.* at 1317 (citations omitted). References before the USPTO during patent prosecution are part of the intrinsic record. *V-Formation, Inc. v. Benetton Grp.*, 401 F.3d 1307, 1311 (Fed. Cir. 2005). Lastly, courts may "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1322-23 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996)) (internal quotation marks omitted).

Plaintiffs' first claim, as amended,[4] provides:

> 1. A method for radical treatment of *benign and malignant tumors*; comprising administration to the affected place a medium, representing water solution of formic (methanoic) acid in all possible proportions, by means of repeatedly administering the solution to that tissue, or to the nearest to it accessible tissue, with respective awaiting its absorption until the diseased tissue necrotizes, therapeutically based on the strong blood-coagulation enhancing properties of this acid, the rapid absorption of its water solutions in human's and animal's tissues, and the increased

[4] On appeal, the Board reviewed the validity of Plaintiffs' claims in light of Plaintiffs' pre-amendment language, which included "benign tumor, *as well as pathologically affected tissues*." However, Plaintiffs amended their claims by deleting the latter "pathologically affected tissues" language from claim 1. Thus, that claim language was not before the Board. Notwithstanding this error, the Board affirmed the Examiner's rejection for obviousness on the ground that "benign tumor" also encompasses "warts," which is the basis for Plaintiffs' review in this Court.

> permeability of the blood vessels of the affected tissue, compared to the blood vessels of the healthy one; and watching over eventual harm of the healthy tissue, and over symptoms of excessive increase of formic acid concentration in the entire body.[5]

Plaintiffs' specification teaches the "treatment of tumors, inflammatory processes, fungal infections and other affections of the tissues, diagnostic and prophylactic and method of its implementation." (Admin. R. A624.) Further, the specification explains that "[t]he treatment is provided by rub in the medium with a tampon impregnated with it, directly in the tumor (by the skin ones) . . . until the tumor is saturated with formic acid . . . ." (*Id.* at A625.) The method is claimed to combat "each sort of tumor formations, independently of their malignity, stage of infiltration or location." In teaching the treatment of fibrous mastopathy of the breast, Plaintiffs explain that "the medium can be applied for treatment of every kind of inflammatory processes, fungal infections, and other pathological alterations of the tissues—external and internal and for blood-stopping as well." (*Id.* at A626.) Plaintiffs provide examples of treating "skin eczemas, pus furuncles, dandruf[f], inflammations of the mouth cavity, the larynx, the gingivas, the sinuses, dental granuloma, inflammations of the joints and of the nerves, nail-fungy, etc." (*Id.*)

The parties' invalidity dispute centers on the construction of "tumor." The Board affirmed the Examiner's construction that "tumor" encompasses "warts" insofar as "tumor" is broad enough to encompass any abnormal growth. The Director asserts this position with respect to claim construction and urges the Court to adopt the USPTO's construction. Plaintiffs propose that "tumor" is limited to vascularized tissue, such that warts, which they argue are not vascular, are not tumors. Upon considering the meaning of and interchangeable use of the terms

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[5] The Board treated claim 1 as representative to Plaintiffs' claims. (*See* Admin. R. A623, Doc. 14-1.) In this § 145 litigation, however, Plaintiffs have not assigned error to the Board's treatment of claim 1 as representative of their disputed claims. Therefore, the Court will treat claim 1 as representative. *See Alberts v. Kappos*, No. 10-1727, 2013 WL 204694, at *6, ___ F. Supp. 2d ___ (D.D.C. Jan. 18, 2013).

"tumor" and "wart," as well as the dictionary definitions of such terms, the Court adopts the Director's construction.

The Court finds that Plaintiffs' claims encompass any abnormal growth, a conclusion supported by examining the Plaintiffs' claims and specification. Beginning with the claims' language, Plaintiffs' claims do not define "tumor" but rather sparsely reference "tumor" as the condition to which Plaintiffs' method is directed. The term "tumor" appears in the claim language four times, and in neither instance do the claims shed any light on the term's meaning, let alone any limitation to its meaning. Specifically, Plaintiffs' claims twice disclose the method of treating "benign and malignant *tumors*." Plaintiffs further describe the method's dependency on the "permeability of the blood vessels of the *tumor* and the healthy tissues." Claim 3 twice references "*tumor* blood vessels" and the "permeability of the blood vessels of the *tumor* tissue." Additionally, claim 3 describes destroying the nearest "*tumor* healthy tissue," if necessary. Thus, the ordinary and customary meaning of "tumor" is not apparent from the claims' language.

The specification is dispositive, however, because where, as here, the claims themselves do not conclusively define the term, the Court must look to the specification to understand its full meaning. The specification compels the conclusion that "tumor" should be broadly construed to mean "any abnormal growth." Claims must be read in light of the specification. *Wyeth v. Sandoz*, 570 F. Supp. 2d 815, 820 (E.D.N.C. 2008). Indeed, the specification "is the single best guide to the meaning of a disputed term." *Conceptronic*, 90 F.3d at 1582. Here, Plaintiffs reference "tumor" in connection with a number of conditions. Specifically, Plaintiffs describe the "treatment of tumors, inflammatory processes, fungal infections and other affections of the tissues," "tumor formations, independently of their malignity, stage of infiltration or location," and "every kind of inflammatory processes, fungal infections, and other pathological alterations

of the tissues." The broad language that Plaintiffs employ in their specification frames the context of their invention as a method of treating a broad spectrum of conditions. At times, Plaintiffs describe the treatment of a "tumor" or "tissue," indicating Plaintiffs' interchangeable use of the terms with "tissue," seemingly broader than "tumor." In each instance, "tumor" can be read broadly to encompass any abnormal growth. Plaintiffs claim their invented method broadly treats tumors without limiting the invention to a particular subset of tumors. The Court cannot "allow the claim language to become divorced from what the specification conveys is the invention." *Retractable Techs, Inc. v. Becton*, 653 F.3d 1269, 1305 (Fed. Cir. 2011). Therefore, "tumor" within the context of Plaintiffs' specification encompasses any abnormal growth.

The Court's construction is also consistent with the contemporaneous medical literature and understanding of the term. In claim construction, the Court is permitted to use dictionaries and treatises to define claim terms. *See Phillips*, 415 F.3d at 1322. The Director cites two sources defining "tumor" as "any swelling or tumefaction" and "growth of tissue caused by uncontrolled cell proliferation . . . benign or malignant." (*See Stedman's Medical Dictionary* 1393 (27th ed. 2000), Def.'s Ex. N; *Dictionary of Medical Terms for the Nonmedical Person* 568 (4th ed. 2000), Def.'s Ex. O, Doc. 28-1.) These definitions are consistent with the Court's construction insofar as neither definition uses restrictive language to limit the term's meaning, but rather demonstrate that the term is broad enough to encompass a number of disorders affecting tissues. Moreover, the Director's expert opines that a person with ordinary skill in the art would have understood at the time of Plaintiffs' application, "tumor" to mean "abnormal growth of body tissue." (Thatcher Expert Report at 9, Def.'s Ex. H.) The medical literature at the time of the invention correlates to Dr. Thatcher's report and is thus a reliable corroboration of his understanding of the term as it was understood in the art at the time.

The Court rejects Plaintiffs' proposed construction because their construction seeks to impermissibly limit the term's meaning and also conflicts with Plaintiffs' previous position as to the term's meaning. Plaintiffs propose that "tumor" be construed as "diseased vascular tissue," citing a number of definitions seemingly excerpted from various medical sources. While the Court agrees that "tumor" can encompass vascular tissues, the Court dismisses Plaintiffs' attempt to limit its meaning because the claim language does not limit or even reference vascularization. Additionally, Plaintiffs' specification asserts that the method of treatment can be applied to conditions that are both vascular and non-vascular, but nonetheless teaches a method of treatment of a vascular tissue. Plaintiffs argue that their example, therefore, demonstrates their understanding that "tumor" means a vascular structure and that was their intent by using that example in their specification. In making such an argument, however, Plaintiffs seek to place an impermissible limitation on its claims through their specification. The Court must "'avoid the danger of reading limitations from the specification into the claim,' as 'persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.'" *The Fox Grp. Inc. v. Cree, Inc.*, 819 F. Supp. 2d 490, 498 (E.D. Va. 2011) (quoting *Phillips*, 415 F.3d at 1323). Finally, Plaintiffs' proffered definitions during prosecution provided that a tumor is "an abnormal mass of tissue that results when cells divide more than they should or not die when they should" and is "an abnormal benign or malignant new growth of tissue that possess no physiological function and arises from uncontrolled usually rapid cellular proliferation." These definitions do not mention the word vascular let alone the term's meaning to only vascular tissues but instead are consistent with the broader definition of "any abnormal growth." Thus, Plaintiffs' own position during prosecution is inconsistent with the restricted definition they now urge the Court to adopt.

For these reasons, the Court adopts the Director's construction and finds that "tumor," in the context of the '322 Application, means any abnormal growth.

B. Obviousness

Having construed "tumor" to mean any abnormal growth, the Court grants the Director summary judgment as to the USPTO's obviousness rejection because Plaintiffs' claimed method would have been obvious over Agholme as to claim1 and, and Agholme in view of Schwartz as to claims 2 and 3.

1. Applicable Law

Section 103(a) of Title 35 of the United States Code provides that a patent may not be obtained if the differences between the claimed invention "as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Obviousness is a question of law to be decided by the Court and "is focused on the scope of the patent in suit, not the patentee's goal in creating the patent." *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409, 440 (E.D. Va. 2011) (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007)). The factors guiding the obviousness inquiry are (1) the scope and content of the prior art; (2) the level of skill in the art; (3) differences between the claimed invention and the prior art; and (4) any relevant secondary considerations, including commercial success, long-felt but unsolved needs, and the failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *DyStar Textilfarben GmbH & Co. v. C.H. Patrick Co.*, 464 F.3d 1356, 1360–61 (Fed. Cir. 2006).

A patent "is not proved obvious merely by demonstrating that each of the elements was, independently, known in the prior art." *Teleflex*, 550 U.S. at 418. "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining

them is more likely to be nonobvious." *Id.* at 416. An inventor's decision to act contrary to the accepted wisdom of the art is indicia of nonobviousness. *See United States v. Adams*, 383 U.S. 39, 52 (1966). However, if a person of ordinary skill, who is typically able to combine the teachings of multiple patents, is able to "implement a predictable variation" based on that combination, then such variation is unpatentable as obvious. *Johnson*, 2013 WL 1499052, at *3.

Finally, because Plaintiffs offer new evidence to support their position with respect to the Board's final rejection for obviousness, the Court employs a *de novo* standard as to the necessary factual findings, taking into account both Plaintiffs' new evidence and the administrative record. *Hyatt*, 132 S. Ct. at 1701; *Johnson*, 2013 WL 1499052, at *2.

2. Factual Findings

As to the first *Graham* factor—the scope and content of the prior art—the Court must bifurcate its factual inquiry. The "scope" of the prior art is comprised of those references within the relevant art that may be used to reject a claim as obvious; the "content" of the prior art is comprised of the disclosures those references teach one skilled in the art. *See Alberts v. Kappos*, No. 10-1727, 2013 WL 204694, at *7, ___ F. Supp. 2d ___ (D.D.C. Jan. 18, 2013) (treating the scope and content of the prior art as separate inquiries).

The Court finds the scope of the prior art to be those disclosures relevant to the method of treating abnormal benign and malignant growths, including Agholme and Schwartz. To fall within the scope of the prior art, the prior art must be "analogous" to the claimed invention. *Alberts*, 2013 WL 204694, at *7. The Federal Circuit has set forth a "twofold" test to determine whether a prior art reference is analogous. *Id.* (citing *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1572 (Fed. Cir. 1984)). Under the first prong, analogous prior art is that which is derived "from the same field of endeavor, regardless of the problem addressed...." *Id.* (quoting

Innovention Toys, LLC v. MGA Entm't, Inc., 637 F.3d 1314, 1321 (Fed. Cir. 2011)) (internal quotation marks omitted). The second prong, however, "still deems prior art analogous if it is 'reasonably pertinent to the particular problem with which the inventor is involved.'" *Id.* (quoting *Innovention Toys*, 637 F.3d at 1321). Thus, the second prong is broader and more inclusive than the first. "A reference is reasonably pertinent if . . . it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *Id.* (citing *Innovention Toys*, 637 F.3d at 1321).

The Court finds that Agholme and Schwartz easily satisfy these inquiries. With respect to Agholme, it meets the first test because its field of endeavor is analogous to that of Plaintiffs' claims. Plaintiffs claim their field of invention as "the treatment of tumor and other diseased tissues." (Admin. R. A260.) Similarly, the Agholme reference cites its field of invention as the treatment of mammalian warts caused by viruses. Though each seeks to solve a different problem, Plaintiffs' claims and the Agholme reference are similarly directed to the treatment of affected tissues through chemical ablation. Moreover, Agholme satisfies the second test as pertinent art because one skilled in the art would have found Agholme to be a reasonably pertinent source in addressing the problem to which Plaintiffs' method is directed. The chemical ablation of skin warts would have logically commended itself to one in the art seeking methods of ablating skin tumors. Thus, Agholme is properly within the prior art related to Plaintiffs' method.

Additionally, the Court finds that Schwartz satisfies the second test. Schwartz's teaching the application of a magnesium and iodine composition for its antiseptic properties would have been reasonably pertinent to inventors in this field because of the high infection risk associated with removing diseased tissue. It would have been logical for one of ordinary skill to consider

the Schwartz disclosure in addressing the problem sought to be resolved, namely the chemical removal of skin tissue. A reasonable practitioner in the art would have been interested in reducing the risk of infection and thus would have naturally searched for prophylactic measures that could reduce infection. Thus, the Schwartz reference is properly within the scope of the relevant prior art.

As to the content of the prior art, the Court finds that the prior art is circumscribed by Agholme's disclosure of the chemical ablation of skin warts with formic acid by topical application. The Court further finds that Schwartz discloses the composition and method of topically applying a combination of magnesium and iodine for the composition's antiseptic, disinfectant, and germicidal properties. Therefore, the content of the prior is defined by these references' disclosures.

Plaintiff's new evidence does not alter the Court's findings. First, as explained above, the experimental data submitted is at best Plaintiffs' attempt to distinguish warts from the condition they purportedly treated in their specification. However, the Court has already construed their claims to broadly include all abnormal growths, including warts. Thus, the experimental data has no bearing on whether Agholme and Schwartz are properly within the prior art because the Court's claim construction effectively renders the references analogous to their method and reasonably pertinent to Plaintiffs' claimed method. Second, Plaintiffs' abstracts are irrelevant for obviousness purposes because each abstract is dated years after the filing date of their Application and are thus not relevant to the prior art as it existed at the time of Plaintiffs' filing.

Graham's second inquiry requires the determination of the "level of ordinary skill in the pertinent art." *Graham*, 383 U.S. at 17. However, Plaintiffs do not submit any new evidence on

this issue, nor do Plaintiff's assert any substantive argument with respect to the Examiner or the Board's factual finding of the level of skill in the pertinent art. Nonetheless, the Court finds that the relevant level of skill possessed by one in the art would have knowledge and skill in medicinal chemistry, biochemistry, pharmacology, and biology. This finding is supported by Dr. Thatcher's report, which makes clear that one of ordinary skill in the related arts must possess a Ph.D., Pharm.D, or M.D. in the above-mentioned arts with significant skill and experience in cancer research.

Finally, with respect to the third *Graham* factor—the difference between the claimed invention and the prior art—the Court makes three findings. First, the Court finds that Agholme does not teach the method of treating all benign and malignant tumors, or fibrous mastopathy, as Plaintiffs disclose. Indeed, Agholme is limited to the treatment of skin warts. Second, the Court finds that Agholme does not teach the addition of iodine to its disclosed method of applying formic acid. Third, the Court finds that Schwartz does not teach the treatment of all benign and malignant tumors, but rather teaches only the general combination of formic acid to solutions for the purpose of adding antiseptic and germicidal properties to various topical mediums.

Again, the Court finds Plaintiffs' new evidence bears little weight in the latter factual inquiry. The images that purportedly show the treatment of breast cancer have no relevance to the comparison of the Plaintiffs' method to the prior art other than to show what the Court has already recognized, namely that Plaintiffs claim a treatment of cancer and Agholme's disclosure is limited to the treatment of warts. Furthermore, the abstracts are entirely irrelevant to this comparison because neither was published at the time of Plaintiffs' Application, and even if they were, each fails to sufficiently disclose a method pertinent to the Application at issue in this dispute.

Further, the secondary evidence with which Plaintiffs cite in support of nonobviousness does not impact the Court's analysis. Plaintiffs assert that their method resolves a long-felt but unmet need in the art. "[A]ny relevant secondary considerations, including commercial success, long-felt but unsolved needs, and the failure of others" may be considered by the Court in determining whether a claim is obvious. *Graham*, 464 F.3d at 18. It is commonsensical that the a cure for cancer is a long-felt and unresolved need, and the Court need not look further to come to that conclusion. However, as discussed more fully below, Plaintiffs' claims are not enabled by its specification and therefore insufficiently demonstrate that it resolved a need, especially a cure for cancer. Plaintiffs' broad claims that purport to treat all forms of cancer with all possible concentrations of a known chemical through the mere teaching of treating a single mammary cyst or tumor without supporting data is entirely insufficient to support such a claim. Thus, the Court is not persuaded that secondary considerations raise a material issue.

3. Legal Conclusion

Applying the *Graham* factors to Plaintiffs' Application, the Court agrees with the USPTO's conclusion of obviousness. The parties seem to agree that "wart" means at least "a raised growth on the surface of the skin" or "a horny projection on the skin." (*See* Admin. R. A633.) Thus, under the Court's previous construction of "tumor" as any abnormal growth, claim 1 would have been obvious over Agholme. One skilled in the art would have reasonably been able to apply the method of chemically removing a wart, a benign abnormal growth, which Agholme discloses, to removing a benign skin tumor, as the Court interprets that term. Thus, claim 1, which teaches the treatment of all tumors with formic acid of any concentration, is rendered obvious by the teachings of Agholme.

Similarly, claims 2 and 3 are obvious over Agholme in view of Schwartz. Specifically, claim 2, which incorporates the limitations of claim 1, is nearly identical to claim 1 with the exception it teaches the addition of a medium containing 5% iodine. Therefore, the Court must determine whether the combination of iodine to the formic acid solution taught by Agholme and claim 1 would have rendered claim 2 obvious to one skilled in the art. The Court concludes it does, however, because one of ordinary skill would have expected a benefit from the addition of antiseptic properties in treating tumors and warts due to the risks of infection associated with such treatments. Because claim 3 is nearly identical to claims 1 and 2, incorporating both claims' limitation, the Court also finds claim 3 obvious in view of Agholme and Schwartz.

For all of the above reasons, the Court finds that no genuine issues remain with respect to the USPTO's rejection of Plaintiffs' claim for obviousness. Thus, the Court grants the Director's Motion for Summary Judgment as to obviousness.

C. Enablement

The Court grants the Director summary judgment on Plaintiffs' enablement claim because the Plaintiffs' specification fails to fully enable the broad scope of their claims.

Section 112 of Title 35 of the United States Code governs a patentee's written description requirements. 35 U.S.C. § 112. Under § 112, a patentee is required to "describe, enable, and set forth the best mode" of practicing the claimed invention. *DNT, LLC v. Sprint Spectrum, LP*, 750 F. Supp. 2d 616, 623 (E.D. Va. 2010) (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002)). "In order to enable the claims of a patent pursuant to § 112, the patent specification must teach those of ordinary skill in the art 'how to make and use the full scope of the claimed invention without undue experimentation.'" *Id.* (quoting *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1224 (Fed. Cir. 2006)). The factors to be considered

in determining whether a specification meets the enablement requirements are set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* These factors are "are illustrative, not mandatory," and thus the Court need not consider each factor. *VS Technologies, LLC v. Twitter, Inc.*, No. 2:11-CV-43, 2011 WL 4744911, at *10 (E.D. Va. Oct. 5, 2011) (citing *MagSil Corp. v. Seagate Tech.*, 764 F. Supp. 2d 674, 678 (D. Del. 2011)). As with the obviousness inquiry, the Court reviews Plaintiffs' new evidence *de novo* in light of the administrative record. *Hyatt*, 132 S. Ct. at 1701.

1. Factual Findings

The Court finds that each of the *Wands* factors is relevant to the present dispute. With respect to the first, fourth, and sixth factors—the quantity of experimentation required, the nature of the invention, and the art's predictability—the Court agrees with the Director's expert, Dr. Thatcher. Specifically, the Court finds that the nature of Plaintiffs' claimed method, namely the treatment of cancer, requires a high level of experimentation due to the unpredictable nature of treating various cancers and tumors. Thus, one of ordinary skill would necessarily need precise information related to the type of tumor, its location and etiology, and the particular patient's profile to tailor specific treatment to individual cancers, each of which would be unique and dependent on a plethora of variables related to the individual patient. Indeed, it is commonsense that the numerous forms of cancer, some of which are resistant to treatments effective on others, requires a high level of experimentation, targeted study, and carefully supervised administration.

The fifth and seventh factors require the Court to consider the state of the art at the time of the invention and the relative skill of one of ordinary skill. The Court finds that the state of cancer treatment in 2001, the year in which Plaintiffs' Application was filed, was developing but nonetheless at a state in which no cure for cancer was known. Certainly, the surgical removal and chemical ablation of tumors, dependent upon its location, was known and practiced. Additionally, as thoroughly discussed, the treatment of warts through chemical ablation was known in the art, as well as the antiseptic properties of iodine. At the time of Plaintiffs' purported invention, one skilled in the art would have known the state of the art, comprising a team of professionals skilled in medicine, medicinal chemistry, and related arts with experience with treating cancer.

The second, third, and eighth factors require the Court to consider what is claimed and what is disclosed. As previously explained, Plaintiffs disclose a broad method of treating tumors with all possible concentrations of formic acid. Thus, Plaintiffs have not disclosed particular concentrations to be used on specific types of tumors, nor have Plaintiffs disclosed exact administration sites, doses, and frequency of treatments. Additionally, Plaintiffs explain the treatment of one tumor or mammary cyst, which still remains unclear even in light of Plaintiffs' newly admitted images. Plaintiffs' specification discloses no data beyond this one treatment yet alleges its applicability to treatment of all tumors, both benign and malignant.

As with the Court's obviousness findings, the Court similarly finds Plaintiffs' new evidence to be insufficient, at best, to this analysis and likely irrelevant. The images Plaintiffs present are entirely insufficient to constitute instruction or guidance useful to one of ordinary skill in the art to practice the claimed method, especially in light of the breadth of Plaintiffs' claims to treat all tumors. Three images of purported treatment of breast cancer without any

accompanying data falls short of the requisite disclosure needed to practice a treatment of all malignant tumors. Indeed, Plaintiffs fail to describe the treatment, the concentration of formic acid used, frequency of administration, or any pertinent information. Additionally, the abstracts are entirely irrelevant to the enablement analysis. Even if the abstracts had been published at the time of Plaintiffs' Application, which they were not, the abstracts still fail to fully enable Plaintiffs' claims because they do not disclose the requisite information needed to practice the method of which Plaintiffs claim.

ii. Legal Conclusion

Under the *Wands* factors, Plaintiffs' specification fails to fully enable the scope of their claims. Indeed, nearly every *Wands* factor weighs in the Director's favor. First, Plaintiffs seek to claim a method of treating any and all benign and cancerous abnormal growths with all possible proportions of formic acid. However, Plaintiffs' specification only discloses the treatment of fibrous mastopathy with an unknown concentration of formic acid. Plaintiffs concede that "cancer research is difficult," yet they seek to claim a method of treating cancer without any disclosure of how their method can treat all the numerous forms of cancer. A patentee must describe and enable one skilled in the art "to make and use the full scope of the claimed invention without undue experimentation." *DNT*, 750 F. Supp. 2d at 623 (quoting *Liquid Dynamics*, 449 F.3d at 1224) (internal quotation marks omitted). As the Examiner identified, the relative skill possessed by those of ordinary skill in the art of cancer research is high and cancer research requires exhaustive experimentation. Plaintiffs' bare disclosure is entirely inadequate to teach one skilled in the art how to treat cancer with formic acid of an unknown concentration. Moreover, Plaintiffs' specification fails to provide any specific data with respect to a method of treating any and all benign and malignant tumors. Thus, undue

experimentation would be required even by one with a relatively high skill level to properly practice Plaintiffs' method. Therefore, Plaintiffs' claims are not enabled under § 112, as the specification does not enable any person skilled in the art to use Plaintiffs' method commensurate in scope with Plaintiffs' broad method claims of treating all types of cancer.

IV. CONCLUSION

The Court concludes that no issues of fact remain as to the USPTO's rejection of Plaintiffs' Application for lack of enablement and obviousness. Accordingly, for the foregoing reasons,

IT IS HEREBY ORDERED that Defendant's Motion for Summary Judgment (Doc. 20) is **GRANTED**; and

IT IS FURTHER ORDERED that Plaintiffs' Complaint is **DISMISSED with prejudice.**

IT IS SO ORDERED.

ENTERED this 25th day of June, 2013.

Alexandria, Virginia
6/25/2013

/s/
Gerald Bruce Lee
United States District Judge