

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VECTURA LIMITED,

Plaintiff;

v.

GLAXOSMITHKLINE LLC and GLAXO
GROUP LIMITED,

Defendants.

Civil Action No. 16-638-RGA

MEMORANDUM OPINION

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March 18, 2019



ANDREWS, U.S. DISTRICT JUDGE:

Currently pending before the Court are Plaintiff's motion for partial summary judgment of no invalidity by anticipation (D.I. 126) and Defendants' motion for summary judgment of invalidity by lack of enablement. (D.I. 122). The parties have fully briefed the issues. (D.I. 190, 195, 208, 212, 216, 220). The Court heard oral argument on March 4, 2016. (Hr'g Trans.).

I. BACKGROUND

Plaintiff Vectura Limited sued Defendants GlaxoSmithKline LLC and Glaxo Group Limited on July 27, 2016 alleging infringement of U.S. Patent Nos. 8,303,991 ("the '991 patent") and 8,435,567 ("the '567 patent"). (D.I. 1). Plaintiff has narrowed its infringement allegations to claim 3 of the '991 patent and claim 3 of the '567 patent ("the Asserted Claims"). The patents-in-suit "relate to pharmaceutical compositions for inhalation and methods of making them." (D.I. 82 at 1). The asserted claims are dependent claims which cover only compositions where the additive is magnesium stearate. (D.I. 195 at 9).

On August 10, 2018, the parties made various motions for summary judgment. Plaintiff moved for partial summary judgment of no invalidity by anticipation. (D.I. 126). Defendants moved for summary judgment of non-infringement (D.I. 120) and of invalidity by lack of enablement (D.I. 122). On October 1, 2018, I issued my claim construction opinion, and subsequently, the claim construction order. (D.I. 167; D.I. 169). The parties had exchanged expert reports prior to the opinion, and my constructions of the claim terms differed from that of either party. I then permitted supplemental expert discovery between the parties and amended summary judgment briefing. (D.I. 176). The parties have exchanged supplemental expert discovery and amended their previous summary judgment briefing. At oral argument, I denied

Defendants' motion for summary judgment of non-infringement. (D.I. 246). I now address the parties' remaining dispositive motions.

II. LEGAL STANDARD

A. Summary Judgment

“The court shall grant summary judgment if the movant 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). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those “that could affect the outcome” of the proceeding, and “a dispute about a material fact is ‘genuine’ if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party.” *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party’s case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: “(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute” Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247–49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Anticipation

A patent claim is invalid as anticipated under 35 U.S.C. § 102 if "within the four corners of a single, prior art document . . . every element of the claimed invention [is described], either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (alterations in original). As with infringement, the court construes the claims and compares them against the prior art. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010). Anticipation "may be decided on summary judgment if the record reveals no genuine dispute of material fact." *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349 (Fed. Cir. 2010).

C. Enablement

The enablement requirement, considered a separate and distinct requirement contained in 35 U.S.C. § 112, ¶ 1, assesses whether "one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Because the enablement inquiry takes into account

what is known to one skilled in the art, the Federal Circuit has “repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art.” *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004). “Enablement is a legal question based on underlying factual determinations.” *Vasudevan Software Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 684 (Fed. Cir. 2015). Factors considered in assessing the enablement requirement 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.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). “A party must prove invalidity for lack of enablement by clear and convincing evidence.” *Vasudevan*, 782 F.3d at 684.

III. DISCUSSION

A. Anticipation

Plaintiff moves for summary judgment of no invalidity by anticipation.¹ (D.I. 126). Plaintiff asserts that no material dispute of fact exists and that the Staniforth and Musa references² do not expressly or inherently anticipate the asserted claims. (D.I. 195 at 11). Specifically, Plaintiff argues the following: 1) Defendants’ experts did not provide opinions on anticipation under the Court’s claim construction, 2) Defendants’ experts have not provided sufficient expert opinion or evidence to conclude that either Staniforth or Musa expressly or inherently discloses each limitation of the Asserted Claims, and 3) during Dr. Colombo’s

¹ Defendants have mooted part of Plaintiff’s motion by agreeing to withdraw Koishi 1984 and Koishi 1988 as anticipatory references. (D.I. 208 at 6 n.2).

² The Staniforth reference is WO 96/23485, an international patent application. (D.I. 208 at 9). The Musa reference is U.S. Patent No. 6,528,096. (*Id.*).

deposition, he admitted that Staniforth and Musa do not expressly anticipate and do not necessarily result in the claimed invention. (D.I. 195 at 11-12, 16). Defendants assert that there is a material factual dispute regarding whether Staniforth and Musa anticipate the claims and that Defendants' experts have put forth enough evidence that a reasonable jury could find in their favor on anticipation.³ (D.I. 208 at 7-8).

While the Federal Circuit has declined to state a "per se rule" that expert testimony is required to prove anticipation, *see Carrier Corp. v. Goodman Global, Inc.*, 64 F. Supp. 3d 602, 615 (D. Del. 2014) (citing cases), "[t]ypically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each element is disclosed in the prior art reference." *Schumer v. Lab. Comput. Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002). Defendants assert that their experts have met this requirement. (D.I. 208 at 14).

I disagree. I do not need to consider Plaintiff's first and third arguments because Defendants' expert opinions, taken in the light most favorable to Defendants, as required, do not satisfy the requirements to prove anticipation. Dr. Colombo's various reports do not "identify each claim element, state [his] interpretation of the claim element, and explain in detail how each element is disclosed in" either Staniforth or Musa. *Schumer*, 308 F.3d at 1315. Neither does Dr. Russell's SEM-EDX⁴ analysis. (*See* D.I. 142-1 at 44-45). Claim 3 of the '991 patent reads as follows:

³ Defendants note that these assertions are based upon Defendants' belief that Plaintiff's experts rely on an incorrect interpretation of my claim construction, mirroring Plaintiff's initial proposed constructions. (D.I. 208 at 7). As Defendants unequivocally state, "it is [Defendants'] position that under the proper interpretation of the Court's constructions of the composite active particle terms, [Plaintiff] has not shown that [Defendants'] accused products infringe the asserted claims and the Staniforth and Musa references do not anticipate the claims." *Id.*

⁴ SEM-EDX is Scanning Electron Microscopy with Energy Dispersive X-ray spectroscopy. (D.I. 208 at 3). It is "an analytical technique that can measure the topography of particles and, with certain limitations, the components thereof." (*Id.*).

3. Composite active particles as claimed in claim 2, wherein the additive material includes magnesium stearate.

('991 patent, cl. 3). It depends from claims 1 and 2, which read as follows:

1. Composite active particles for use in a pharmaceutical composition for pulmonary administration, each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material, wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm , and wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device.

2. Composite active particles as claimed in claim 1, wherein the additive material includes one or more of: an amino acid or derivative thereof; a peptide or derivative thereof, a phospholipid or derivative thereof, a surface active material; or a metal stearate and derivative thereof.

('991 patent, cls. 1-2). The asserted claims of the '567 patent are similar.

Dr. Colombo's expert reports focus solely on the Staniforth and Musa references' disclosure of a *single* claim limitation—composite active particles—and whether the disclosure satisfied Plaintiff's proposed claim construction of the term.⁵ (D.I. 125-1, Ex. 2 at ¶¶ 71, 79, 110-14 (opening report), Ex. 4 at ¶¶ 7-13 (reply report); D.I. 192-1, Ex. 6 ¶¶ 67-68 (supplemental rebuttal report)).⁶ While Dr. Colombo's expert report states that he believes the Staniforth and Musa references anticipate all claims of the asserted patents, he provides no accompanying analysis to support his conclusion. (D.I. 125-1, Ex. 2 at ¶ 71). For example, Dr. Colombo's analysis of the Staniforth or Musa references makes no mention of whether they

⁵ The term "microparticle[s]" which appears only in the '567 patent, has the same meaning as the term "composite active particle[s]" in the context of the claims. Plaintiff's proposed claim construction for this term was: "[a] single particulate entit[y/ies] made up of a particle of active material to which one or more particles of additive material are fused." (D.I. 167 at 5).

⁶ I construed "composite active particle[s]" to mean "[a] single particulate entit[y/ies] made up of a particle of active material to which one or more particles of additive material are fixed such that the active and additive particles do not separate in the airstream." (D.I. 169 at 1). Dr. Colombo's supplemental report focuses on this construction.

disclose an “additive material [that] promotes the dispersion of the composite active particles.” (’991 patent, cl. 1; D.I. 125-1, Ex. 2 at ¶¶ 71, 79, Ex. 4 at ¶¶ 7-13, D.I. 192-1, Ex. 6 ¶¶ 67-68).

Dr. Russell’s reports also focus solely on the “composite active particle” claim element and whether the Staniforth and Musa references disclose a blend with the requisite level of association between active and additive particles. (D.I. 142-1 at 44-45, 129-31). She provides no analysis of whether the references disclose an “additive material [that] promotes the dispersion of the composite active particles.” (’991 patent, cl. 1; D.I. 142-1 (no reference to dispersion)). The evidence of the experts, taken in the light most favorable to Defendants, is insufficient to show anticipation. Therefore, Plaintiff has demonstrated that Defendants failed to make a sufficient showing on an essential element of their case with respect to which they have the burden of proof. *See Celotex Corp.*, 477 U.S. at 322. Thus, I grant Plaintiff’s motion for partial summary judgment of no invalidity by anticipation.

B. Enablement

Defendants move for summary judgment of invalidity for lack of enablement. (D.I. 122). Defendants assert that there is no material dispute of fact that making the full scope of the asserted claims requires undue experimentation. (D.I. 190 at 7-8). More specifically, Defendants assert that the scope of the composite active particles covered by the asserted claims is unduly broad and enablement would require a person of ordinary skill in the art to 1) make each composite active particle, 2) test the particle to ensure that it is a composite active particle, 3) test the particle for dispersion, and 4) in connection with the ’567 patent only, test the particle for dissolution. (*Id.*). Plaintiff argues that the asserted claims are enabled and that Defendants have not met the clear and convincing evidence threshold to succeed on an invalidity defense at summary judgment. (D.I. 212 at 4). The parties’ briefing identifies material disputes of fact as

to 1) the quantity of experimentation necessary and 2) the predictability or unpredictability of the art. As there are material disputes as to the facts underlying the enablement analysis, I deny Defendants' motion for summary judgment.

First, the parties dispute whether the art is predictable or unpredictable. (D.I. 190 at 17; D.I. 212 at 21; Hr'g Trans. at 22:16-19; 44:18-20; 46:4-10; 47:22-48:2). Defendants argue that "the dispersion properties of a particular composition are unpredictable owing to . . . the complexity of particle-particle interactions." (D.I. 190 at 17-18). Plaintiff asserts that there is no evidence "suggesting that the properties of magnesium stearate could change . . . such that magnesium stearate somehow becomes unsuitable for promoting dispersion and delaying dissolution." (D.I. 212 at 22). Plaintiff also disputes whether the PowderHale report shows an inoperative embodiment. (*Id.* at 18-19).

Second, the parties dispute the quantity of experimentation necessary for a person of ordinary skill in the art ("POSA") to make the full scope of the claims. (D.I. 190 at 16-17; D.I. 212 at 20). Defendants assert that a POSA would need to engage in trial and error testing of the individual composite active particles within the scope of the claims to make the full scope of the claims. (D.I. 190 at 16-17). More specifically, Defendants argue that a POSA would have to engage in undue experimentation to determine which iterations of a composite active particle actually promote dispersion. (*Id.* at 17). Plaintiff argues that a POSA would be able to make the full scope of the claims with little experimentation for the following reasons: (1) "[t]here is no dispute that a POSA would know how to make composite active particles with magnesium stearate" (D.I. 212 at 5); (2) "[t]he specifications provide [] guidance on an 'optimum amount' of additive material to use" (*id.* at 11); (3) a POSA would understand from the specifications that SEM is an appropriate method to confirm that particles are composite active particles (*id.* at

15); (4) a POSA would understand from the prior art how to conduct SEM testing (*id.*); and (5) a POSA would understand how to adjust the myriad variables for dispersion (*id.* at 20-21, Hr'g Trans. at 42:11-20; 44:18-20; 49:14-18).

Given these material disputes of fact, a reasonable jury could determine that the art is predictable and that minimal experimentation is needed to make the full scope of the claims. Therefore, I deny Defendants' motion for summary judgment of invalidity.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's motion for partial summary judgment is GRANTED and Defendants' motion for summary judgment of invalidity is DENIED.

An accompanying order will be entered.