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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September 10, 2019

ANDREWS, U.S. DISTRICT JUDGE:

Currently pending before the Court is Defendants' Motion for Judgment as a Matter of Law and New Trial or Remittitur.[1] (D.I. 336). The parties have fully briefed the issues. (D.I. 337, 343, 349). For the following reasons, I will deny Defendants' motion.

I. BACKGROUND

On July 27, 2016, Plaintiff Vectura Limited sued Defendants GlaxoSmithKline LLC and Glaxo Group Limited for direct and induced infringement of U.S. Patent No. 8,303,991 ("the '991 patent"). (D.I. 1). The '991 patent relates to pharmaceutical compositions for inhalation. (D.I. 82 at 1). Before trial, Plaintiff narrowed their infringement case to assert direct infringement of claim 3 of the '991 patent ("the asserted claim"). (D.I. 307). Plaintiff also pursued a claim of willful infringement of the asserted claim. (D.I. 307 at 11). Defendants asserted a noninfringement defense and an invalidity defense under 35 U.S.C. § 103. (*Id.*; D.I. 320 at 2).

Claim 3 of the '991 patent depends from claims 1 and 2. Together, the claims 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.
>
> 3. Composite active particles as claimed in claim 2, wherein the additive material includes magnesium stearate.

[1] Plaintiff's motion for supplemental damages, enhanced damages, an ongoing royalty, pre- and post-judgment interest, and attorney's fees (D.I. 338) is also pending.

('991 patent, cls. 1-3).

After a five-day trial, the jury returned the following verdict: (1) Defendants infringed claim 3 of the '991 patent, (2) claim 3 was not invalid for obviousness, (3) Plaintiff was entitled to an ongoing royalty payment of three percent for a total sum of $89,712,069 through December 31, 2018, and (4) Defendants' infringement was willful. (D.I. 321). The parties have now filed post-trial motions. Defendants renew their request for JMOL of no infringement, invalidity for obviousness, and no willful infringement, or in the alternative, a new trial. Defendants also request a new trial on damages or remittitur.

II. LEGAL STANDARDS

A. Judgement as a Matter of Law

Judgment as a matter of law is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. Fed. R. Civ. P. 50(a)(1). "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, 'granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.'" *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted).

"To prevail on a renewed motion for JMOL following a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (alterations in original). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be

accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984).

In assessing the sufficiency of the evidence, the Court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor and, in general, view the record in the light most favorable to him." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991). The Court may "not determine the credibility of the witnesses [nor] substitute its choice for that of the jury between conflicting elements in the evidence." *Perkin-Elmer*, 732 F.2d at 893. Rather, the Court must determine whether the evidence supports the jury's verdict. *See Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998); *Gomez v. Allegheny Health Servs. Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995) (describing standard as "whether there is evidence upon which a reasonable jury could properly have found its verdict"); 9B *Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure* § 2524 (3d ed. 2008) ("The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury might reasonably find a verdict for that party.").

Where the moving party bears the burden of proof, the Third Circuit applies a different standard. This standard "'requires the judge to test the body of evidence not for its insufficiency to support a finding, but rather for its overwhelming effect.'" *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976) (quoting *Mihalchak v. Am. Dredging Co.*, 266 F.2d 875, 877 (3d Cir. 1959)). The Court "'must be able to say not only that there is sufficient evidence to support the finding, even though other evidence could support as well a contrary finding, but additionally that there is insufficient evidence for permitting any different finding.'" *Id.* at 1177 (quoting *Mihalchak*, 266 F.2d at 877).

B. New Trial

Federal Rule of Civil Procedure 59(a)(1)(A) provides, in pertinent part: "The court may, on motion, grant a new trial on all or some of the issues—and to any party— . . . after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court . . . ." Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. *See Zarow-Smith v. N.J. Transit Rail Operations, Inc.*, 953 F. Supp. 581, 584–85 (D.N.J. 1997).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. *See Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem. Corp.*, 9 F.3d 282, 289 (3d Cir. 1993) (reviewing district court's grant or denial of new trial motion under the "abuse of discretion" standard). Although the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law—in that the Court need not view the evidence in the light most favorable to the verdict winner—a new trial should only be granted where "a miscarriage of justice would result if the verdict were to stand," the verdict "cries out to be overturned," or where the verdict "shocks [the] conscience." *Williamson*, 926 F.2d at 1352–53.

III. DISCUSSION

A. Infringement

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent . . . ." 35 U.S.C.

§ 271(a). A two-step analysis is employed in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. *See id.* The trier of fact must then compare the properly construed claims with the accused infringing product. *See id.* at 976. This second step is a question of fact. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

1. Judgment as a Matter of Law

When an accused infringer moves for JMOL of noninfringement, such relief may be granted only if at least one limitation of the claim in question does not read on an element of the accused product. *Bayer*, 212 F.3d at 1247. I must give deference to the jury's factual findings and view the record in the light most favorable to the non-moving party, Plaintiff. *Williamson*, 926 F.3d at 1348.

Defendants argue that JMOL of noninfringement is appropriate because (1) there is insufficient evidence to support a finding that the accused products satisfied the dispersion limitation and (2) Plaintiff failed to prove the presence of the claimed composite active particles ("CAPs"). (D.I. 337 at 2). Plaintiff asserts that it presented substantial evidence supporting the jury's infringement verdict. (D.I. 343 at 2). I agree with Plaintiff that the jury's infringement verdict is supported by substantial evidence.

a. The Dispersion Limitation

Defendants assert that there is insufficient evidence to supporting the jury's implied factual finding that the accused products satisfied the dispersion limitation. (D.I. 337 at 3-4). The dispersion limitation is found in the following claim language: "wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device." ('991 patent, cl. 1). I construed this limitation to mean "wherein a composition that contains one or more [CAPs] has increased dispersion of the active material upon activating a delivery device for inhalation into the lungs by a patient, as compared to the same composition wherein unmodified active particles are substituted for the [CAPs]." (D.I. 169 at 2). Defendants argue that to satisfy its burden, Plaintiff was required to present evidence isolating the impact of the CAPs on the overall dispersion of the composition as required by the Court's claim construction. (D.I. 337 at 3-4).

The Federal Circuit has made clear that it does not require a party to show evidence of a direct comparison to satisfy its burden of proof on infringement even where the court's claim construction requires a comparison to satisfy the claim limitation. *See Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372-73 (Fed. Cir. 2009). In *Martek*, the Federal Circuit recognized that even where there is a functional claim limitation requiring comparison, "circumstantial evidence may be sufficient" to satisfy the patentee's burden of proof. *Id.* As the patentee had presented other evidence supporting the infringement verdict, the lack of direct comparative testing did not require JMOL of noninfringement. *Id. Brigham & Women's Hosp., Inc. v. Perrigo Co.*, 761 F. App'x 995 (Fed. Cir. 2019) does not state otherwise. In *Brigham*, clinical testing was the only evidence put forward to prove infringement; there was no other direct

or circumstantial evidence in the record.[2] *Id.* at 1003-04. The Federal Circuit determined that the clinical testing did not measure the claim limitation and the patentee has not established a correlation between the claimed limitation and the metric tested. *Id.* (studies measured adequate relief beginning at fifteen minutes, rather than immediate relief starting within five to ten minutes).

Here, Plaintiff submitted comparison testing and other circumstantial evidence to the jury. (D.I. 352 at 154:11-156:10; D.I. 353 at 317:7-327:10; PTX-185). Defendants assert that Study 2 cannot support the infringement verdict under *Brigham*. (D.I. 337 at 4-5). However, Defendants merely reiterate the same arguments made at trial. Defendants challenge the usefulness of Study 2 because it did not test the accused products and Plaintiff did not establish that the Study was representative of the actual products. (*Id.*). But Plaintiff did submit evidence that Blend 6 was representative of the accused products. (D.I. 353 at 316:12-327:10; PTX-185 at 4; PTX-129 at 21; PTX 123 at 12). And unlike *Brigham*, where the testing submitted did not test the appropriate metric, here, Study 2 does provide a comparison of dispersion between a formulation with CAPs and a formulation without CAPs to show "increased dispersion of the active material . . . as compared to the same composition wherein unmodified active particles are substituted for the [CAPs]". (PTX-185). There is more than a mere speculative correlation between the testing provided and the accused products. (D.I. 353 at 325:15-326:14, 390:12-391:3, 407:22-410:15). Defendants also challenged the representativeness of the Study and the blends in front of the jury. (*Id.* at 360:6-365:2, 404:5-406:21; D.I. 354 at 574:1-576:17). The jury was entitled not to credit this testimony. (D.I. 307 at 7-8). As is required on a motion for JMOL, I must give Plaintiff the benefit of all logical inferences that can be made from the evidence in the record. Here, a

[2] The Federal Circuit discounted the inventor's testimony that he himself took the product after litigation began and experienced immediate relief as "uncorroborated, conclusory, and interested testimony" insufficient to carry the patentee's burden of proof. *Brigham*, 761 F. App'x at 1005.

reasonable juror could have credited Dr. Zhou's testimony over that of Defendants' expert, Dr. Colombo, determined that Study 2 was representative of the accused products, and thus, concluded that the dispersion limitation was met.

Defendants also challenge the sufficiency of the evidence with regard to the accused products with umeclidinium as the active ingredient. (D.I. 337 at 10). Dr. Zhou testified at trial that the results of Study 2, which tested only blends with the active ingredient vilanterol, were equally applicable to compositions using umeclidinium. (D.I. 353 at 324:16-23). The jury was entitled to credit this testimony, especially where there was an absence of any contradictory evidence.

Thus, there is substantial evidence in the record supporting the jury's finding that the dispersion limitation was satisfied by the accused products.

b. The CAPs Limitation

Defendants assert that Plaintiff failed to prove that the accused products satisfy the CAPs limitation because Plaintiff's expert testimony established, at best, "co-association," which does not satisfy the claim construction. (D.I. 337 at 11). At claim construction, I construed the claim term "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).

Defendants continue to assert that "co-association" cannot show that the additive is "fixed" to the active particle. However, Defendants focus upon the wrong inquiry. As I stated, "fixed" is not a technical term. (Pretrial Hr'g Tr. at 21:17-18). Plaintiff was required to establish that the additive magnesium stearate was "fixed to the active particle such that it does not separate in the airstream." (D.I. 169 at 1). Plaintiff has done so. Plaintiff presented testimony of SEM-EDX,

ToF-SIMS, and SPAMS testing to show that the accused products satisfy the CAPs limitation. (D.I. 352 at 188:19-190:10, 194:10-199:11, 201:12-204:23, 211:17-212:5; D.I. 353 at 327:12-335:12, 336:15-353:13, 379:8-11). Dr. Zhou repeatedly testified that magnesium stearate was sufficiently coated or fixed to the active particles such that the magnesium stearate and the active did not separate in the airstream. (D.I. 353 at 328:23-329:15, 341:11-22, 345:2-14, 350:2-19, 351:18-352:16). This is substantial evidence supporting the jury's implied factual finding that the accused products satisfy the CAPs claim limitation.

Thus, there is substantial evidence supporting the jury's factual findings that the accused products satisfy each and every claim limitation, as construed by the Court. Therefore, Defendants' Motion for JMOL of noninfringement is denied.

2. New Trial

Defendants, in the alternative, request a new trial on infringement for two independent grounds: (1) that the verdict was against the clear weight of the evidence and (2) to ensure that the parties are held to the same standard of proof. (D.I. 337 at 12).

First, even without being required to evaluate the evidence in the light most favorable to Plaintiff, I that the jury's infringement verdict was not against the clear weight of the evidence for the same reasons stated above.

Second, the parties have been held to the same standard of proof. In granting summary judgment of no anticipation, I determined that Defendants' expert did not "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." (D.I. 254 at 5 (quoting *Schumer v. Lab. Comput. Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002)). Dr. Colombo's report did not even address whether or not the dispersion limitation was met by the Musa reference. (D.I. 254 at 6-7).

Defendants argue that Dr. Zhou committed a similar error at trial. (D.I. 337 at 13). He did not. As I noted above, there was substantial evidence supporting a factual finding that the dispersion limitation was met, including evidence of a direct comparison between a blend without CAPs and a blend with CAPs. Thus, I do not believe there is any reason warranting a new trial on the issue of infringement. Defendants' motion for a new trial on infringement is denied.

B. Obviousness

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007). "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *KSR*, 550 U.S. at 406 (internal citation and quotation marks omitted).

A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed. Cir. 2012). "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

1. Judgment as a Matter of Law

A party must prove obviousness by clear and convincing evidence. *Allergan, Inc. v. Barr Labs., Inc.*, 501 F. App'x 965, 971 (Fed. Cir. 2013). Because obviousness, "like any other ground of invalidity, must be established by clear and convincing evidence," Defendants' burden on a JMOL motion is "doubly high: it must show that no reasonable jury could have failed to conclude that [Defendants'] case had been established by clear and convincing evidence." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1353 (Fed. Cir. 2003) (internal citation omitted).

Defendants have not shown that "no reasonable jury could have failed to conclude that [obviousness] had been established by clear and convincing evidence." *Id.* "Obviousness is a question of law based on underlying questions of fact." *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1298 (Fed. Cir. 2010). On JMOL, I must defer to the jury's underlying factual determinations, *Williamson*, 926 F.3d at 1348, but review the legal question *de novo*. *Pannu*, 155 F.3d at 1348. I note that the parties do not appear to dispute the level of ordinary skill in the art. (D.I. 337 at 15; D.I. 343 at 12-23 (not addressing *Graham* factor #3)).

a. Kawashima and Magnesium Stearate Inhalation References

Defendants' own expert, Dr. Colombo, testified that the Kawashima reference disclosed CAPs containing all the elements of claim 1, but used a colloidal silica as an additive, rather than magnesium stearate. (D.I. 354 at 722:15-723:2, 723:15-724:17, 741:11-14). Plaintiff's validity expert, Dr. Smyth testified that colloidal silica and magnesium stearate have substantial differences such that a person of ordinary skill in the art would not have thought to substitute magnesium stearate for the colloidal silica in the disclosed CAPs of Kawashima. (D.I. 355 at 901:22-905:3). Specifically, Dr. Smyth testified that colloidal silica was hydrophilic which served the purpose of

permitting drug particles to be better absorbed by patients because of the aqueous environment of the lungs. (*Id.* at 901:22-903:15). In contrast to the colloidal silica used in Kawashima, as Dr. Smyth testified, magnesium stearate is hydrophobic, which at the time of invention, counseled against its use in inhalation because hydrophobic additives may not be cleared from the aqueous environment of the lungs. (*Id.* at 903:16-904:16). Dr. Colombo agreed that magnesium stearate was hydrophobic. (D.I. 354 at 726:20-24).

Regarding the magnesium stearate inhalation references, there is testimony in the record indicating that (1) use of magnesium stearate in inhalation formulations was "not very common" at the time the asserted patent was filed (*id.* at 739:9-13), and (2) that the inhalation references using magnesium stearate solely used it to coat lactose carrier particles, rather than the active ingredient (*id.* at 737:7-783:23). Additionally, Plaintiff presented evidence that at the time the asserted patent was filed, there was concern about using magnesium stearate in inhalation formulations where it would be delivered to the lungs. (D.I. 355 at 903:16-904:16, 907:1-909:8).

Defendants assert that the Musa reference shows there were no safety concerns, and thus, that the safety concerns cannot "teach away" from the combination. (D.I. 337 at 18). But testimony in the record indicates that the safety studies in Musa did not address the use of magnesium stearate in an active particle, but rather a lactose carrier. (D.I. 355 at 913:15-916:22). Dr. Smyth testified that the studies in the Musa patent would have indicated to a person of ordinary skill in the art that magnesium stearate was not reaching the lungs when coating the lactose carrier. (*Id.* at 916:4-6). Dr. Smyth testified that Musa therefore does not refute the safety concerns with using magnesium stearate in a manner that ensures delivery to the lungs, i.e., being coated on an active particle. (*Id.* at 916:17-22). Thus, *Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326,

1333 (Fed. Cir. 2014) is inapposite because the jury could have determined that Musa did not contradict the negative teachings of other references.

Thus, there was substantial evidence to support the jury's implicit factual finding that the Kawashima reference would not have motivated a person of ordinary skill in the art to use magnesium stearate in CAPs.

b. Fults and Magnesium Stearate Inhalation References

Similarly, Dr. Colombo opined that the Fults reference disclosed CAPs satisfying all elements of claim 1, but used fatty acids (like stearic acid) as the additive rather than magnesium stearate. (D.I. 354 at 729:2-10). Dr. Smyth testified that magnesium stearate was not amenable to the method described in the Fults reference and thus a person of ordinary skill would not have been motivated to combine Fults with magnesium stearate. (D.I. 355 at 905:21-906:25). Dr. Colombo, on cross-examination, admitted that magnesium stearate was not amenable to the Fults method. (D.I. 354 at 789:6-790:24).

Combined with the testimony cited above on the magnesium stearate inhalation references, substantial evidence supports the jury's implied factual finding that the Fults reference would not have motivated a person of ordinary skill in the art to use magnesium stearate in CAPs.

c. Secondary Considerations

Defendants assert that Plaintiff did not offer any evidence of the required nexus between the Novartis license and the '991 patent, and thus that the Novartis license could not be considered as relevant evidence of secondary considerations. (D.I. 337 at 16). Thus, Defendants argue there was no secondary considerations for the jury to consider. (*Id.*).

I disagree. Plaintiff introduced evidence of secondary considerations supporting non-obviousness by introducing the Novartis license of the '991 patent. (D.I. 352 at 80:7-13, 82:19-

87:16, 159:2-21; D.I. 353 at 481:24-482:12, PTX-64, PTX-279, PTX-284). I believe this evidence is sufficient to support a nexus between the Novartis license and the '991 patent. *See Impax Labs. Inc. v. Lannett Holdings Inc.*, 893 F.3d 1372, 1381 (Fed. Cir. 2018) (court could independently analyze corroborating evidence to show nexus between patent and licensing).

Thus, after drawing all logical inferences in favor of the non-moving party on the underlying factual questions, I determine that a reasonable jury could conclude that the asserted claim was not proven to be obvious over the prior art. Thus, I will deny Defendants' Motion for JMOL of obviousness.

2. New Trial

Defendants argue in the alternative that a new trial should be granted because Plaintiff's introduction of evidence regarding the safety concerns surrounding use of magnesium stearate in inhalation at the time of the invention, including possible fatalities, prejudiced the jury. (D.I. 337 at 19). Specifically, Defendants complain that Plaintiff's introduction of this testimony was an "improper scare tactic[] to try to rebut the overwhelming trial record." (*Id.* at 1).

I disagree. First, I note that Defendants did not object to this testimony at trial or otherwise move to exclude such evidence as either irrelevant under Federal Rule of Evidence 402 or more prejudicial than probative under Rule 403.[3] Second, the toxicity of magnesium stearate as discussed in the prior art is relevant to whether a person of ordinary skill in the art would have been motivated to combine the Kawashima and/or Fults references with magnesium stearate. Plaintiff submitted substantial evidence regarding toxicity outside of the "fatality" theory that the

[3] Defendants did move in its motion *in limine* no. 2 to exclude similar evidence arising in the context of the French regulatory approval process. However, the primary objection to that evidence was that it was not prior art. (Pretrial Hr'g at 29:2-6). I reserved decision on the issue until trial (D.I. 306 at 2), and Plaintiff ultimately did not offer the document.

jury could have credited. Additionally, Plaintiff also emphasized that inhalation of magnesium stearate has now been established as safe. (D.I. 355 at 916:23-917:21). Therefore, I do not think this testimony was so prejudicial as to outweigh its probative value. Thus, I will deny Defendants' motion for a new trial on obviousness.

C. Willful Infringement

Defendants ask for JMOL of no willful infringement, or in the alternative, a new trial, for two reasons: (1) the jury was improperly instructed on the standard, and (2) under either standard, there was insufficient evidence to support a finding of willfulness. (D.I. 337 at 20).

I gave the jury the following instruction on willful infringement:

> In addition, to prove willful infringement of a claim, Vectura must persuade you that it is more likely true than not true that GSK intentionally ignored or recklessly disregarded that claim. You must base your decision on GSK's knowledge and actions at the time of infringement. Evidence that GSK had knowledge of the patent at the time of infringement by itself is not sufficient to show willfulness. Rather, to show willfulness, you must find that GSK engaged in additional conduct evidencing deliberate or reckless disregard of Vectura's patent rights.
>
> In deciding whether GSK willfully infringed, you should consider all of the facts surrounding the infringement including: whether GSK intentionally copied Vectura's patented technology in developing the accused products; whether GSK knew, or should have known, that its conduct involved an unreasonable risk of infringement; and whether GSK had a reasonable belief that at the time of infringement that its products did not infringe the asserted patent or that the patent was invalid.

(D.I. 319 at 6).

First, the jury instruction was not error. Defendants proposed that I instruct the jury using language taken directly from *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016). (D.I. 355 at 953:8-11; D.I. 317 at 6). However, as I explained then, the jury instruction on willful infringement was (1) taken from the Northern District of California's Model Patent Jury

Instructions, and (2) is a more accurate statement of the law of willful infringement. (*Id.* at 953:19-25). As I have previously noted,

> An infringer's subjective bad faith alone may support an award of enhanced damages under *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016). A patentee need only prove subjective willfulness alone – i.e., proof that the defendant acted despite a risk of infringement that was either known or so obvious that it should have been known to the accused infringer. . . . To determine whether willful infringement has occurred, the correct inquiry is the "subjective willfulness" of the infringer, not whether the infringement itself was "egregious."

Zimmer Surgical, Inc. v. Stryker Corp., 365 F. Supp. 3d 466, 491-92 (D. Del. 2019) (cleaned up). The "egregiousness" of the accused infringement should be considered when a court determines whether enhanced damages are appropriate. *See Valinge Innovation AB v. Halstead New England Corp.*, 2018 WL 2411218, at *8 (D. Del. May 29, 2018) (discussing *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992)). I believe this logic also applies to Defendants' request for an instruction that the infringement be "wanton, deliberate, consciously wrongful, flagrant or in bad faith." Thus, a new trial on willful infringement is not warranted.

Second, Plaintiff put forward substantial evidence supporting the jury verdict of willful infringement. The jury heard the following evidence: (1) Defendants met with one of the inventors, the inventor discussed mechanofusion with Defendants, and the conversation led Defendants to take action with regard to their vilanterol products (D.I. 354 at 569:8-19, 593:3-594:8); (2) Dr. Zhou testified that Defendants knew how to create a product that did not infringe (D.I. 353 at 324:2-7, 383:16-384:11); (3) despite pre-suit communications from Plaintiff to Defendants about infringement, Defendants did not explain why it believed it was not infringing or undertake any investigation into whether or not its products infringed (D.I. 352 at 1:14-107:3, PTX-69, PTX-70, PTX-464, PTX-465, PTX-466, PTX-468, PTX-470, PTX-473, PTX-475, PTX-470, PTX-480); and (4) Defendants' own pre-suit testing provided information from which

Defendants would have known their products infringed the asserted patent (D.I. 352 at 209:10-210:22).

Drawing all logical inferences in favor of Plaintiff, the non-moving party, as I am required to do on a motion for JMOL, there was substantial evidence in the record supporting the jury's determination that Defendants willfully infringed the asserted patent. Thus, I will deny the motion for JMOL of no willful infringement.

D. Damages

Defendants move for a new trial on damages for two reasons: (1) legal errors in the analysis of Plaintiff's damages expert and (2) prejudice from Plaintiff's "repeated references to 'billions' of dollars" and minimization of Defendants' damages figure in comparison to sales revenue. (D.I. 337 at 21-22, 33-34).

1. Ms. Schenk's Damages Analysis

Defendants assert a new trial on damages should be granted because (1) Ms. Schenk failed to properly apportion the value of the patented feature and claimed the entire market value of the accused inhalers as the royalty base and (2) when relying on comparable licensing agreements, Plaintiff's damages expert did not account for technical and economic differences between those agreements and the hypothetical negotiation. (*Id.* at 21-22). Plaintiff argues that (1) Defendants have waived any objections to Ms. Schenk's testimony by not moving pretrial under *Daubert* or *in limine* and (2) that Ms. Schenk's damages theory was proper. (D.I. 343 at 24).

I agree with Plaintiff that Ms. Schenk's damages theory was proper. The Federal Circuit has endorsed a reasonable royalty analysis that begins with comparable licenses, as Ms. Schenk did here. *See Commonwealth Sci. & Res. Org. v. Cisco Sys. Inc.*, 809 F.3d 1295, 1301-04 (Fed. Cir. 2015) ("Where the licenses employed are sufficiently comparable, this method is typically

reliable because the parties are constrained by the market's actual valuation of the patent."). "[C]omparable license agreements are not inadmissible solely because they express the royalty rate as a percentage of total revenues . . . ." *Id.* at 1302-03. Thus, Ms. Schenk's use of the total sales of the accused products was not improper, nor did she fail to account for the value of the patented feature as the proper apportionment or valuation of the patent can be derived from comparable licensing agreements.

Additionally, as to the question of whether Ms. Schenk appropriately accounted for variables and the degree of comparability, those "are factual issues best addressed by cross-examination." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012). Ms. Schenk provided testimony addressing the variables of technical and economic comparability of the license agreement between the parties to the '991 patent.[4] (D.I. 449:1-450:7, 451:34-452:7, 481:10-23; *see also* D.I. 352 at 88:24-89:20, 107:4-20 (fact witnesses)). She also provided testimony explaining how she justified certain departures from the license agreement. (D.I. 353 at 448:18-452:23, 481:10-18, 516:5-21, 517:15-519:10). Thus, a new trial is not warranted based upon Ms. Schenk's damages theory.

2. Prejudice Warranting New Trial

Defendants also request a new trial because Plaintiff's "repeated references to 'billions' of dollars were highly prejudicial" and were exacerbated by Plaintiff's minimization of Defendant's damages figure. (D.I. 337 at 33-34).

The Federal Circuit has cautioned against allowing "[a]dmission of such overall revenues" because it "only serve[s] to make a patentee's proffered damages amount appear modest by

[4] I also note that Defendants' expert agreed that the 2010 license agreement was a comparable license for the purposes of a reasonable royalty. (D.I. 355 at 845:5-15, 858:11-859:8).

comparison, and to artificially inflate the jury's damages calculations." *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 67-68 (Fed. Cir. 2012). Further, the Federal Circuit has also cautioned against permitting a patentee to deride an accused infringer's damages calculation by emphasizing how small the amount is in terms of the overall revenues. *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320-21 (Fed. Cir. 2011).

Here, Plaintiff repeatedly emphasized the amount of revenues made by Defendants and the relative smallness of the damages award they were requesting. *See* D.I. 352 at 23:10-12 ("This case is about GSK using Vectura's patented technology without Vectura's permission, making billions in profits, and refusing to give Vectura its fair share); *id.* at 55:6-12 ("GSK made more than $1.5 billion on the three accused products in the US in 2018 alone, and more than 75 percent of that was gross profits to GSK. Vectura is not asking for 30 percent, not asking for 10 percent, not even asking for five percent. Vectura is asking for three percent of GSK's net sales, only what it is fairly owed.").

On the second day of trial, Defendants indicated that they objected to Plaintiff being able to repeatedly introduce the large revenue number going forward in trial. (D.I. 353 at 430:19-431:2, 435:3-436:2). After dealing with their various objections, I directed that Plaintiff should take care not to emphasize the sales number beyond what was strictly required by the law. (D.I. 353 at 439:21-440:6). I also instructed the parties that I would police the testimony given, thereby indicating that Defendants would not need to make an individual objection to every instance where the "billions" figure was mentioned. (*Id.* at 440:3-5).

Plaintiff also repeatedly minimized Defendants' damages number. The following exchange between Plaintiff's counsel and Defendants' expert, Dr. Kerr, on cross-examination bears significant similarity to the exchange cited in *Uniloc*. 632 F.3d at 1320-21.

Q. [Plaintiff]. You think a three-percent royalty rate is holding GSK over a barrel?

A. [Kerr]. Absolutely, it is, because --

Q. For a formulation that they need to use, and they don't have an alternative for?

A. Absolutely, it is holding them over a barrel --

Q. For --

A. -- because it comes to a $90 million -- it implies that the value of the '991 patent is $90 million during the damages period --

Q. Okay.

A. -- when the entire value of 400 patents was no more than 30 million --

Q. So --

A. -- and in the U.S. only 20 million.

Q. But Dr. --

A. You have to get down to one patent.

Q. So Dr. Kerr, if GSK -- GSK has sold $3 billion in infringing sales so far; right?

A. I don't know the number off the top of my head.

Q. And you saw Ms. Schenk put a number on the screen. It was $3 billion; right?

A. I don't recall that, but I'll take your word for it.

Q. If they can't use the patented invention, they might not be able to make any of those sales; right?

A. Right. That's why they would have a hypothetical negotiation, and they would enter into a business deal to get the right to it and why they did it in 2010.

Q. And so it's your testimony that a three-percent royalty would be putting GSK over a barrel when they had $3 billion worth of infringing product at stake?

A. Yes. They would have been -- it's the equivalent of holding them hostage. You can't sell and make money unless you get our patent. That's not the -- what the hypothetical negotiation is supposed to be. It's supposed to be a business deal.

. . . Q. So Dr. Kerr, what we did is we've looked at the total payments that would be made under your alternative and we divided them by the license sales, and we came up with an effective royalty rate of 0.0187 percent of sales. Do you see that?

A. I see your calculation.

(D.I. 355 at 886:18-888:24).[5]

[5] In the middle of this exchange, I called counsel to sidebar to make my own objection to the continued reference to the $3 billion figure, per my previous statement to the parties that I would stop any instances of testimony that emphasized the figure beyond what was required under the law.

Before closings, I instructed the parties that "I [did not] want to hear the overall sales figure mentioned" during closing arguments. (*Id.* at 961:20-21). Plaintiff responded, "Understood, your Honor, you don't want to hear the $3 billion mentioned. I probably mentioned it enough today that I think they'll remember." (*Id.* at 961:22-24). Yet, in closings, Plaintiff again emphasized the relative smallness of the damages award it was requesting in comparison to Defendants' sales and profits on the accused products. Plaintiff's counsel stated,

> And now GSK's damages expert, Dr. Kerr, said asking for three percent is holding GSK over a barrel. But that's GSK's own doing. GSK decided to use Vectura's own patent. It put itself in that situation. And three percent is not holding GSK over a barrel. A three percent royalty is a small portion of GSK's profits, which are in excess in 75 percent of its sales, as shown here on this slide. Breo is 77 percent profits, Anoro 86.5 profits, and Incruse, 91.8 percent profits. Those are the profits that GSK makes on the sales of its products. A three percent royalty is fair and just compensation.
>
> So in the end, the question you'll be asking is under the circumstances, what is a reasonable royalty? Is it Ms. Schenk's three percent or Dr. Kerr's 0.0178 percent?

(D.I. 356 at 1023:18-1024:6).

Plaintiffs argue that *Uniloc* is inapposite because in that case there was no basis for referring to the entire market value. (D.I. 343 at 28). *Uniloc* addressed the use of the overall revenues as a check on the "reasonableness" of a damages award. 632 F.3d at 1321. Even where the overall revenue of the patented product is relevant to the analysis because of comparable license agreements, parties must "carefully tie proof of damages to the claimed invention's footprint in the market place." *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010). Here, the proper apportionment of the patent's contribution to the accused products was disputed by the parties. (D.I. 353 at 478:9-480:2; D.I. 355 at 851:14-863:11, 868:7-869:10). Plaintiff's arguments at trial do not appear to be focused on proving the value of the patented invention (CAPs using magnesium stearate), but rather advancing the "pennies on the dollar"

argument which I cautioned against. (D.I. 353 at 439:23-440:3). *Uniloc* cautions against the use of the entire market value to "lend[] legitimacy to the reasonableness of [the] damages calculation." 632 F.3d at 1321. Plaintiff repeatedly made such arguments to the jury without acknowledging the necessary apportionment or value attributed to the patented invention. (D.I. 356 at 1023:4-1024:6). This is the improper jury argument about which the Federal Circuit has repeatedly expressed concern. *See Uniloc*, 632 F. 3d at 1320 (reliance on entire market value "cannot help but skew the damages horizon for the jury"); *LaserDynamics*, 694 F.3d at 67-68.

However, I agree with Plaintiff that *Uniloc* and *LaserDynamics* present a different posture than the case here. In both *Uniloc* and *LaserDynamics*, the entire market value was introduced as either a "check" on another calculation which examined the smallest salable patent-practicing unit, *Uniloc*, 632 F.3d at 1297, 1320, or where the reasonable royalty calculation was not based upon the smallest salable patent-practicing unit, *LaserDynamics*, 694 F.3d at 67-68. There was no legitimate reason for the jury to hear the large total revenue figures in those cases. In contrast, in this case, there was no smallest salable patent-practicing unit, and the total revenue was an appropriate base that the jury needed to hear to understand Plaintiff's damages expert's analysis. Therefore, I do not find the introduction of the total revenue figure to be so prejudicial that the damages verdict "cries out to be overturned." *Williamson*, 926 F.2d at 1352-53. Thus, I will deny Defendants' Motion for a new trial on damages.[6]

[6] Defendants also assert that a new trial should be granted on all issues for prejudice resulting from the repeated references to "billions" of total sales. I disagree. It is not apparent to me from either the briefing or the record that any error involving the damages case would have infected the remainder of the trial such that the infringement and invalidity issues would need to be retried.

IV. CONCLUSION

For the foregoing reasons, I deny Defendants' motion for JMOL or a new trial as to infringement, invalidity, willful infringement and damages.

An accompanying order will be entered.

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

ORDER

For the reasons stated in the accompanying memorandum opinion, IT IS HEREBY ORDERED that Defendants' Motion for Judgment as a Matter of Law, or in the alternative, New Trial or Remittitur (D.I. 336) is DENIED.

Entered this 10 day of September, 2019.

United States District Judge