

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC :

Plaintiff, :

v. :

C.A. No. 17-775-LPS

HOSPIRA, INC., :

Defendant. :

REDACTED - PUBLIC VERSION

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MEMORANDUM OPINION

September 28, 2018
Wilmington, Delaware



STARK, U.S. District Judge:

Plaintiff Belcher Pharmaceuticals, LLC (“Belcher”) sued Defendant Hospira, Inc. (“Hospira”), alleging infringement of U.S. Patent No. 9,293,197 (“’197 Patent”). (D.I. 1) Pending before the Court is Hospira’s motion for partial summary judgment of non-infringement of the ’197 patent under the doctrine of equivalents. (D.I. 55) (“Motion”) For the reasons stated below, the Court will deny Hospira’s Motion.

I. BACKGROUND

Belcher holds approved New Drug Application (“NDA”) No. 205029 for Epinephrine Injection USP, an injection product formulated with epinephrine at a concentration of 1 mg/mL. (D.I. 1 ¶¶ 13, 14) The product is indicated to “increase mean arterial blood pressure in adult patients with hypotension associated with septic shock, for emergency treatment of allergic reactions (Type 1), including anaphylaxis, and for induction and maintenance of mydriasis during intraocular surgery.” (*Id.* ¶ 14)

The ’197 Patent is listed in the U.S. Food and Drug Administration’s (“FDA”) Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Belcher’s epinephrine injection product. (*Id.* ¶ 15) The patent’s title is “More Potent and Less Toxic Formulations of Epinephrine and Methods of Medical Use;” it issued on March 15, 2016 and is assigned to Belcher. (*Id.* ¶¶ 15, 16)

Hospira submitted its own NDA (No. 209359) to the FDA, seeking approval of an injection product, Abboject™ Syringe, which is a formulation containing epinephrine at a

concentration of 1mg/10mL (the “NDA Product”). (*Id.* at ¶¶ 8, 17)¹ Hospira notified Belcher that Hospira has submitted NDA No. 209539 to the FDA (the “Notice Letter”). (*Id.* at ¶¶ 17-18) The Notice Letter advised that Hospira has filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) concerning the ’197 patent. (*Id.* at ¶ 19) The Notice Letter stated that Hospira is seeking FDA approval to engage in the commercial manufacture, use, or sale of the NDA Product before the expiration of the ’197 Patent, in accordance with the Paragraph IV Certification. (*Id.* at ¶¶ 17-19)

Belcher timely sued Hospira, within the statutorily imposed deadline of 45 days after receiving Hospira’s Notice Letter containing the Paragraph IV Certification. (*Id.* at ¶¶ 18, 21) Belcher’s complaint alleges a single count contending that any future manufacture, sale, offer for sale, and/or importation of Hospira’s NDA Product, once it is approved by the FDA, would infringe the ’197 Patent. (*Id.* at ¶¶ 22-26)

Hospira initially filed a motion to dismiss for failure to state a claim (D.I. 11) and a motion for sanctions (D.I. 15) under Federal Rules of Civil Procedure 12(b)(6) and 11, respectively. The Court heard oral argument and denied both motions. (*See* D.I. 52) Thereafter, the Court entered a schedule to resolve the parties’ claim construction disputes and the issue of the availability of a claim for infringement under the doctrine of equivalents (“DOE”) in relation to Hospira’s NDA product. (*See* D.I. 53) After receiving full briefing on claim construction and DOE (*see* D.I. 56, 65, 70, 71, 75, 79, 80), the Court heard oral argument on both issues on April

¹Hospira has represented to the Court that the FDA has tentatively approved its NDA Product, and the statutory stay triggered by Belcher’s commencement of this litigation is the only remaining impediment for Hospira to market the NDA Product. (*See* D.I. 56 at 1; *see also* D.I. 50)

11, 2018. (*See* D.I. 87) (“Tr.”))

II. LEGAL STANDARDS

A. Summary Judgment

Under Rule 56(a) of the Federal Rules of Civil Procedure, “[t]he 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.” The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by “citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials,” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating

party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). The “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial”). Thus, the “mere existence of a scintilla of evidence” in support of the nonmoving party’s position is insufficient to defeat a motion for summary judgment; there must be “evidence on which the jury could reasonably find” for the nonmoving party. *Anderson*, 477 U.S. at 252.

B. Non-Infringement

Hospira seeks partial summary judgment of non-infringement under the doctrine of equivalents. (D.I. 55) Summary judgment of non-infringement may be granted only if a reasonable fact finder could only conclude that one or more limitations of the claim(s) in question do not read on an element of the accused product, either literally or under the doctrine of equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) (“Summary judgment of noninfringement is . . . appropriate where the patent owner’s proof is deficient in meeting an

essential part of the legal standard for infringement, because such failure will render all other facts immaterial.”). Thus, summary judgment of non-infringement can only be granted if, after viewing the facts in the light most favorable to the patentee, there is no genuine issue as to whether the accused product is covered by the claims (as construed by the Court). *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

C. Doctrine of Equivalents

The Supreme Court has explained that the “scope of a patent is not limited to its literal terms, but instead embraces all equivalents to the claims described.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 732 (2002) (internal citation omitted). Two frameworks are available for application of the DOE: the “function-way-result test,” which asks whether the accused product performs “substantially the same function in substantially the same way to obtain the same result” as the patented invention, and the “insubstantial differences test,” which asks “whether the accused product or process is substantially different from what is patented.” *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017) (citing *Graver Tank & Manufacturing Co., Inc. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950)). The DOE tests are to be applied to the individual claims of a patent, not to the patented invention as a whole. *See Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997).

The doctrine of prosecution history estoppel “limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution.” *Intendis GMBH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1364–65 (Fed. Cir. 2016). This “can occur during prosecution in one of two ways, either

(1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." *Id.* at 1364.

The ensnarement doctrine also limits the application of the doctrine of equivalents. That is, the patentee may not assert "a scope of equivalency that would encompass, or ensnare, the prior art." *Id.* at 1363; *see also Tate Access Floors v. Interface Architectural Res.*, 279 F.3d 1357, 1366-67 (Fed. Cir. 2002) (noting there can be no finding of infringement under DOE where alleged infringer is practicing prior art). "Hypothetical claim analysis is a practical method to determine whether an equivalent would impermissibly ensnare the prior art." *Intendis*, 822 F.3d at 1363. This is a two-step process. "The first step is to construct a hypothetical claim that literally covers the accused device." *Id.* (internal quotations omitted). "Next, prior art introduced by the accused infringer is assessed to determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art." *Id.* (internal quotation marks omitted) "In short, we ask if a hypothetical claim can be crafted, which contains both the literal claim scope and the accused device, without ensnaring the prior art." *Id.*

III. DISCUSSION

The issue presented by Hospira's motion is whether Belcher can rely on the doctrine of equivalents to extend the epinephrine concentration limitation – which is stated in precise numerical terms in the asserted claims – beyond its literal scope, to establish infringement of the '197 patent. According to Hospira, prosecution history estoppel and ensnarement preclude Belcher from pressing its DOE theory. (D.I. 56 at 2-3; D.I. 75 at 1) Belcher responds that neither of those doctrines is applicable here. (D.I. 65 at 5-16) The Court agrees with Belcher, for

the reasons explained below.

A. Prosecution History Estoppel

Hospira contends that during prosecution of the '197 patent, the patent applicants made arguments and amendments narrowing the scope of the asserted claims to a final epinephrine concentration of exactly 1 mg/mL, thereby relinquishing the subject matter of Hospira's NDA Product, which has a target epinephrine concentration in the final product of just 0.1 mg/mL (D.I. 56 at 8-14; D.I. 75 at 2-8) Belcher argues that prosecution history estoppel does not apply because the patent examiner did not rely on the arguments and amendment at issue, the specification discloses the use of different concentrations of epinephrine beyond those recited in the claims, and the amendment was made to clarify rather than narrow the claim scope. (D.I. 65 at 5-12)

The Court concludes that prosecution history estoppel does not preclude Belcher from asserting a claim under the doctrine of equivalents. While the '197 patent's claims recite specific concentrations of epinephrine, the prosecution history does not reveal applicants unmistakably surrendering concentrations beyond those recited in the claims. *See Intendis*, 822 F.3d at 1365 ("Argument-based estoppel only applies when the prosecution history evinces a clear and unmistakable surrender of subject matter.") (internal brackets and quotation marks omitted). In responding to a Section 112 indefiniteness rejection, the applicants clarified that the purpose of the invention is to avoid using excess epinephrine concentration during manufacturing, which the patent refers to as "overages." (*See, e.g.*, '197 patent, 2:15-17; 2:20-23; 2:33-36; *see also* D.I. 57 Ex. A at A66 (explaining that "approximately 1.0 to 1.06 mg/mL l-epinephrine describes how the formulation is *compounded* during manufacturing; a narrow concentration range during the

production step of compounding; to result in a drug product of 1 mg/mL epinephrine sterile solution after the steps of filling, sterilization, and over its shelf life”) (emphasis in original); *see also id.* at A67 (explaining that “importance of the current invention is that the concentration of 1 mg/mL l-epinephrine is maintained as best as possible in a drug product . . . without using high overages during manufacturing which would result in increased side effects and inaccurate dosing to patients”)² By these statements, the applicants did not expressly disavow subject matter. *See Intendis*, 822 F.3d at 1365 (“Applicants’ clarifying statement . . . did not clearly and unmistakably disavow claim scope to distinguish prior art.”). While the arguments mention specific epinephrine concentrations, the applicants made those arguments simply “to demonstrate that a compounding step may encompass approximately 1.0 to 1.06 mg/mL l-epinephrine when a concentration of 1 mg/mL l-epinephrine is a preferred final concentration.” (D.I. 65 at 7) Moreover, the specification expressly states that formulations with “any desirable concentration of l-epinephrine” can be produced by the disclosed invention. ’197 patent, 5:36-41.

Hospira contends that “amendment-based estoppel” applies because the applicants narrowed the scope of the claims and surrendered subject matter by removing the term “approximately” from the original claim limitations that had recited “approximately 1.0 to 1.06 mg/mL.” (D.I. 56 at 12-14; D.I. 75 at 4-8) The Court, however, does not view this amendment as a narrowing amendment. *See U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1379 (Fed. Cir. 2007) (“[T]erms like ‘approximately’ serve only to expand the scope of literal

²*See also* ’197 patent, 2:50-53 (noting that “[t]here exists a great need for a liquid formulation of l-epinephrine . . . with minimal overage” and “[t]he present invention fulfills this great medical need”); *id.* at 4:58-59 (noting that “overages could greatly be reduced” using claimed invention); *id.* at 5:55-57 (“These improved epinephrine formulations have no need for high overages, and use minimal overages, if any to assure reliable dosage.”).

infringement, not to enable application of the doctrine of equivalents.”); *Warner–Jenkinson*, 520 U.S. at 32-33 (permitting consideration of DOE with respect to claim reciting pH range “from approximately 6.0 to 9.0”). Rather, the Court views the amendment as a clarifying amendment, for the same reason that the Court concluded the applicants’ arguments are clarifying statements. (See D.I. 57 Ex. A at A66-67) The amendment was made to clarify the significance of using minimal overage of epinephrine relative to the desired final concentration while manufacturing the claimed formulation. See *Festo*, 535 U.S. at 736–37 (2002) (“If a § 112 amendment is truly cosmetic, then it would not narrow the patent’s scope or raise an estoppel.”). Hence, like the applicants’ arguments, the Court finds that the amendment does not surrender subject matter and it does not give rise to estoppel. See *Intendis*, 822 F.3d at 1365 (“Amendment-based estoppel does not apply because the amendment was not a narrowing amendment made to obtain the patent.”).

In this case, whether the epinephrine formulation of Hospira’s NDA Product is “equivalent” to the epinephrine formulation claimed in the ’197 patent is a question of fact. Hence, the Court will deny Hospira’s Motion.

B. Encompassing or Ensnaring the Prior Art

“Ensnarement bars a patentee from asserting a scope of equivalency that would encompass, or ‘ensnare,’ the prior art.” *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009); *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990) (“[T]here can be no infringement if the asserted scope of equivalency of what is literally claimed would encompass the prior art.”).

Hospira contends that prior art U.S. Patent Application Publication 2008/0269347 (“347

publication”), entitled “Epinephrine Formulations,” discloses a formulation materially identical to Hospira’s NDA Product. (D.I. 56 at 5-6) Belcher counters that the ’347 publication fails to disclose the claimed adrenalone levels under a hypothetical claim analysis. (D.I. 65 at 12-14) Hospira replies that there is “reason to believe” that the prior art formulation disclosed in the ’347 publication “inherently possesses the claimed adrenalone levels,” and Belcher has not met its burden to show otherwise. (D.I. 75 at 8-10)

The record reveals a genuine dispute of material fact regarding whether the ’347 publication inherently possesses the claimed adrenalone levels in the ’197 patent. While Hospira contends that “because they have [REDACTED] [REDACTED] the ’347 formulation and Hospira’s NDA Product necessarily have the same characteristics – including the same impurity levels” (D.I. 56 at 18), Belcher points to evidence suggesting that “[s]ince the formation of adrenalone is intrinsically linked to non-inherent properties as part of manufacturing processes and the ’347 Publication does not disclose its method of manufacturing, the ’347 Publication cannot anticipate any hypothetical claim that includes any percentage of adrenalone” (D.I. 65 at 15). A reasonable fact-finder, viewing such competing evidence, could find for either Belcher or Hospira on this dispute. Therefore, again, the Court will deny Hospira’s Motion.

IV. CONCLUSION

For the reasons stated above, the Court will deny Hospira’s motion for partial summary judgment. (D.I. 55) An appropriate Order follows.