IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA, Defendant.	)	Civil Action No. 14-877-LPS-CJB
GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	Civil Action No. 14-878-LPS-CJB

REPORT AND RECOMMENDATION

In these two patent infringement actions filed by Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited (collectively, "GSK" or "Plaintiffs") against Defendants Glenmark Pharmaceuticals Inc., USA ("Glenmark") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Defendants"), presently before the Court is Defendants' motion for summary judgment regarding Plaintiffs' claim of lost profits damages for "convoyed sales" (the "Motion").[1] (Civil Action No. 14-877-LPS-CJB (hereinafter "*Glenmark* Action"), D.I. 214;

[1] The Court notes that the Motion is included in Defendants' "Combined Motion for Summary Judgment and to Exclude Certain Expert Testimony" in which they, *inter alia*,

Civil Action No. 14-878-LPS-CJB (hereinafter "*Teva* Action"), D.I. 248) The Court recommends that Defendants' Motion be GRANTED.[2]

I. BACKGROUND

A. Procedural History

On July 3, 2014, GSK commenced these actions. (D.I. 1) GSK alleges that Defendants induce infringement of United States Patent No. RE40,000 (the "'000 patent") by making, offering to sell, selling, importing, and otherwise promoting and distributing generic carvedilol tablets. (*See, e.g.*, D.I. 59, 175) On October 16, 2014, Chief Judge Leonard P. Stark referred these cases to the Court to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (*Glenmark* Action, D.I. 16; *Teva* Action, D.I. 18)

Briefing on the instant Motion was completed on March 3, 2017. (D.I. 274) The Court held oral argument on the Motion (and various other summary judgment and *Daubert* motions filed in the case) on March 24, 2017. (D.I. 296) A 5-day trial is set to begin in the *Teva* Action (Civil Action No. 14-878-LPS-CJB) on June 12, 2017. (*Teva* Action, D.I. 38, 329, 350)

B. Factual Background

The Court hereby incorporates the discussion of certain factual background relating to this matter contained in its Report and Recommendation on Defendants' motion for summary judgment of invalidity, issued on May 2, 2017. (D.I. 299)

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move for summary judgment with respect to other issues. (*Teva* Action, D.I. 248, 249) This Report and Recommendation solely addresses Defendants' arguments as to the convoyed sales issue.

[2] The Court will cite to docket index (or "D.I.") numbers from the *Glenmark* Action (Civil Action No. 14-877-LPS-CJB) herein, unless otherwise noted.

The '000 patent, at issue in this case, contains 9 method claims directed to methods of decreasing mortality caused by congestive heart failure (or "CHF") in a patient in need thereof by administering carvedilol in a manner recited in the claims. ('000 patent)[3] GSK asserts all but claim 5 against Defendants in these actions. (D.I. 215 at 3) Claim 1 is the only independent claim of the '000 patent, and it reads:

> **1.** A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,
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> > *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

('000 patent, col. 8:30-40 (emphasis in original)) The italicized portion of the claim is the portion that was added during the reissue proceeding.

After holding a *Markman* hearing, the Court construed the term "maintenance period" as used in the claims to mean a "period of time over which the maintenance dose is taken into a patient's body." (D.I. 133 at 44 (internal quotation marks omitted)) "Maintenance dosages," in turn, were construed to mean "dosages to maintain the therapeutic effect following a period in which the patient's tolerance of the drug is monitored." (*Id.* (internal quotation marks omitted))

Chief Judge Stark later sustained Plaintiffs' objection to the Court's construction of

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[3] The '000 patent appears on the dockets in these actions more than once, including as an exhibit to the Joint Claim Construction Chart. (D.I. 68, ex. B) Citation to the patent will simply be to the "'000 patent."

"maintenance dosages," finding that the term should instead be construed to mean "dosages in the therapeutic amount given during the maintenance period[.]" (D.I. 251 at 2-4 (internal quotation marks and citation omitted)) In doing so, Chief Judge Stark noted that the patent contrasts a "maintenance dosage" of carvedilol (dosages used to maintain a therapeutic effect) with low "'starting' dosages administered to check a patient's tolerance before 'up-titrating' to the maintenance dose." (*Id.* at 3) The District Court concluded that "the record does not support viewing an initial or early dosage in an amount that turns out to be the 'maintenance dosage' as excluded from the meaning of 'maintenance dosage' (even if the physician is closely monitoring the patient's tolerance of this amount)" and that the term "maintenance dosage" should be understood to be contrasting only with "dosages of less than the final, therapeutic amount." (*Id.* at 3-4) For purposes of this Report and Recommendation, then, the Court will refer to non-infringing dosages of carvedilol of less than the final therapeutic amount, which are administered prior to the administration of a "maintenance dosage," to be dosages provided in the "initial monitoring period."[4]

There is currently an unresolved dispute between the parties as to whether sales of the accused products during the initial six months of the maintenance period constitute infringing sales. That dispute is the subject of a pending summary judgment motion filed by Defendants. (*See, e.g.*, D.I. 215 at 46-47) If the District Court ultimately grants Defendants' motion in that regard, Defendants' position is that Plaintiffs would not be entitled to convoyed sales damages during that time period, for the same reason they would not be entitled to such damages as to

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[4] The Court does so also because this is how the parties referred to these non-infringing dosages of the drug in their briefs. (D.I. 215 at 48-50; D.I. 258 at 48-50)

sales of drugs administered during the initial monitoring period. (*Id.* at 48 n.20)[5] The Court will herein refer to dosages of carvedilol provided in this period as those provided in "the initial six months of the maintenance period."

II. DISCUSSION

A. Legal Standard

A grant of summary judgment is appropriate where "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 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 & n.10 (1986). If the moving party meets this burden, the nonmovant must then "come forward with specific facts showing that there is a *genuine issue for trial*." *Id.* at 587 (emphasis in original) (internal quotation marks and citation omitted). If the nonmoving 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. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, 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).

However, in order 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.

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[5] If the District Court ultimately denies Defendants' motion, however, sales of the drug in this time period would be considered infringing sales.

2005) (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 and citation omitted). The "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." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Disputes over facts that could alter the outcome are "material," and a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. "If the evidence is merely colorable, . . . or is not significantly probative, . . . summary judgment may be granted." *Id.* at 249-50 (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion 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).

B. Analysis

Plaintiffs argue that sales of Defendants' carvedilol products used during (1) the initial monitoring period and (2) the initial six months of the maintenance period—even if those sales are not properly described as infringing sales—may still give rise to a damages award for lost profits. This is because, according to Plaintiffs, the sales of the drug would be considered to be

"convoyed sales." Defendants disagree, and with their Motion, they seek to preclude Plaintiffs from recovering damages for sales of the accused product during these time periods via a convoyed sales theory.

In *American Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262 (Fed. Cir. 2008), the United States Court of Appeals for the Federal Circuit well explained what constitutes a "convoyed sale":

> A "convoyed sale" refers to the relationship between the sale of a patented product and a functionally associated non-patented product. A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products "together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit." *Rite-Hite Corp. v. Kelley Co. Inc.*, 56 F.3d 1538, 1550 (Fed. Cir. 1998). "Our precedent has not extended liability to include items that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage." *Id.* Damages on these items would exceed that which suitably compensates for the infringement. *Id.*
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> A functional relationship does not exist when independently operating patented and unpatented products are purchased as a package solely because of customer demand. The fact that customers prefer that [patented and unpatented items] come from a single supplier for ease of purchase, repair, and uniform design and appearance, does not compel the conclusion that the [items] are "analogous to components of a single assembly or . . . parts of a complete machine."

514 F.3d at 1268. Here, obviously, dosages of carvedilol that are administered during the initial monitoring period and/or during the initial six months of the maintenance period (hereinafter, collectively referred to as the "pre-six month periods"), on the one hand, and dosages of carvedilol that are administered after the maintenance period has lasted for greater than six

months (hereinafter, the "post-six month period"), on the other hand, would not be considered to be "components of a single assembly or parts of a complete machine[.]" Unlike most cases involving a claim to convoyed sales, this case does not implicate an "assembly" or "machine" of any kind. But Plaintiffs nevertheless argue that dosages of Plaintiffs' carvedilol product COREG® that are given in the pre-six-month periods and in the post-six-month period "constitute a 'functional unit'" for convoyed sales purposes. (D.I. 258 at 48)

Here, the Court agrees with Defendants that Plaintiffs have "offered no admissible evidence in support of" this assertion. (D.I. 215 at 48) In support of their position, Plaintiffs point to the following portions of the record: (1) paragraphs 135 and 136 of the report of their infringement expert, Dr. Peter A. McCullough, which are said to describe "how and why" the pre-six-month periods and the post-six month period "constitute a 'functional unit[,]'" (D.I. 258 at 48 (citing D.I. 259, ex. 2 at ¶¶ 135-36)); and (2) paragraph 21 of the report of their damages expert Dr. Robert S. Maness, in which Dr. Maness "points to . . . technical support" for Plaintiffs' position—specifically, to the statements made in paragraphs 135-41 of Dr. McCullough's report on infringement, (*id.* (citing D.I. 260, ex. 80 at ¶ 21 & nn.20-21)). Thus, if there is to be any factual record support for Plaintiffs' "functional unit" argument, it will need to be found in paragraphs 135-41 of Dr. McCullough's report.

However, those paragraphs do not suffice to generate a genuine issue of material fact. The Court so concludes for two primary reasons.

First, it is notable that this portion of Dr. McCullough's report is not specifically about the issue of convoyed sales. In these paragraphs, Dr. McCullough does not use the term "functional unit," nor does he specifically assert that carvedilol tablets administered during the

pre-six-month periods and those administered during the post-six-month period constitute a "functional unit" of any kind. (D.I. 259, ex. 2 at ¶¶ 135-36; *see also* D.I. 215 at 48)

Second, what these paragraphs do basically establish is that (1) "the only purpose for administering carvedilol for heart failure during a[n initial] monitoring period is to determine a suitable maintenance dose for that patient's heart failure treatment regimen"; (2) that there is "no medical purpose for administering carvedilol and monitoring the patient's tolerance if the physician does not intend to ultimately put that patient on a carvedilol maintenance dose of maximally tolerated carvedilol"; and (3) the maintenance dose in such cases would almost certainly end up being administered for more than six months. (D.I. 259, ex. 2 at ¶¶ 135-38) In other words, the point of these paragraphs in Dr. McCullough's report is to establish that physicians administering Plaintiffs' COREG (or generic carvedilol) during the relevant period would not have prescribed the drug in the pre-six-month periods without intending to and actually continuing to prescribe the drug in the post-six-month period.

But as Defendants note, that kind of assertion misses the point when it comes to the test for convoyed sales. "The question here is not whether sales before and after the six-month maintenance period have some relationship . . . . [r]ather, the point is whether, if only *branded* [COREG] will be used for the period . . . after six months of maintenance . . . there is a functional relationship to *prior* sales requiring that only branded, and not generic, carvedilol be used during the [earlier] period of therapy as well." (D.I. 274 at 24 (emphasis in original)) Here, there is no dispute that generic carvedilol is and was fully interchangeable with the branded version (COREG). (D.I. 227, ex. 10 at 61 (Dr. McCullough testifying that "if I saw a generic product that was AB-rated . . . I had full confidence that, in fact, the generic drug was

therapeutically interchangeable with the branded drug"); *id.* at 64 (Dr. McCullough agreeing that "[i]n 2007, when the generic products first came on the market [he was] comfortable substituting . . . generic carvedilol for COREG in the patients [he] already had taking COREG")) And so, there is no reason why, for example, if a patient took COREG in a post-six-month period, that same patient necessarily would, "functionally," have had to have taken that same COREG product (as opposed to, for example, another company's generic carvedilol product) during the pre-six-month periods.

Nor is there any other articulation in the record supporting some other type of "functional unit" relationship. Defendants' non-infringement expert Dr. Randall Zusman explained that "there is no significant functional connection between one dose of carvedilol and any later doses thereof after a dose has been metabolized by the body" and thus that "[a]ssuming, for the sake of argument, that [he] was required to administer COREG[] to a particular patient once that patient reached the sixth month of their maintenance period, there is no functional tie between the COREG being administered after the six-month mark and the carvedilol that was administered previously during their up-titration period or the first six months of their maintenance period." (D.I. 221, ex. A at ¶¶ 135-36);[6] *see also Rite-Hite Corp.*, 56 F.3d at 1551 (noting that the convoyed sales doctrine was not implicated where although the unpatented and patented devices "may have been used together, they did not function together to achieve one result and each could effectively have been used independently of each other"); *Immersion Corp. v. HTC Corp.*, Civil Action No. 12-259-RGA, 2015 WL 834209, at *4 (D. Del. Feb. 24, 2015) ("If they can

[6] Plaintiffs assert that these statements of Dr. Zusman "smack[] of a factual dispute[,]" (D.I. 258 at 49), but point to no facts of record that actually put Dr. Zusman's position in this regard in dispute.

function independently, patented and unpatented products do not constitute a functional unit.").

For these reasons, the Court finds that there is no genuine issue of fact as to whether the patented and unpatented products at issue here amount to a "functional unit." *Cf. Immersion Corp.*, 2015 WL 834209, at *3-4 & n.4 (finding that plaintiff's damages expert had not sufficiently established that the patented products, which were haptic feedback devices and a haptic system that provides force feedback, had a functional relationship with plaintiff's unpatented product, a software package that mobile device manufacturers could use to incorporate haptic feedback in their devices, since the software package "is not the only means of implementing haptic effects" and the patented "products can function independently of [the software package]").

III. CONCLUSION

For the reasons set forth above, the Court recommends that Defendants' Motion be GRANTED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1) and D. Del. LR 72.1. The parties may serve and file specific written objections by no later than **May 18, 2017**; responses are due by no later than **May 25, 2017.** The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **May 18, 2017** for review by the Court, along with a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: May 11, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE