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 are the following motions: (1) Defendants' motion for summary judgment against GSK's claim for lost profits ("Defendants' Lost Profits Motion"), (Civil Action No. 14-877-LPS-CJB (hereinafter "*Glenmark* Action"), D.I. 214; Civil Action No. 14-878-LPS-CJB (hereinafter "*Teva* Action"), D.I. 248); (2) Defendants' motion to exclude: (a) the opinions offered by Plaintiffs' damages expert, Dr. Robert S. Maness,

concerning lost profits; and (b) the results of the survey of doctors conducted by Plaintiffs' survey expert, Dr. Brian C. Reisetter, ("Defendants' Motion to Exclude"), (*id.*);[1] (3) Plaintiffs' motion to exclude portions of the opinions offered by Glenmark's damages expert Dr. DeForest McDuff pertaining to the but-for world, lost profits, and GSK's litigation strategy and the veracity of GSK's claims of infringement, ("Plaintiffs' Motion to Exclude McDuff") (*Glenmark* Action, D.I. 209); and (4) Plaintiffs' motion to exclude portions of the opinions offered by Teva's damages expert Dr. Sumanth Addanki pertaining to the but-for world, lost profits, and GSK's litigation strategy and subjective beliefs, ("Plaintiffs' Motion to Exclude Addanki") (*Teva* Action, D.I. 246).[2] The Court recommends that Defendants' Lost Profits Motion be DENIED; Defendants' Motion to Exclude be DENIED; Plaintiffs' Motion to Exclude McDuff be GRANTED; and Plaintiffs' Motion to Exclude Addanki be GRANTED.

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. 60, 211) On October 16, 2014, Chief Judge Leonard P. Stark referred

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[1] The Court notes that Defendants' Lost Profits Motion and Motion to Exclude are included in Defendants' "Combined Motion for Summary Judgment and to Exclude Certain Expert Testimony" in which they, *inter alia*, move for summary judgment with respect to other issues. (*Glenmark* Action, D.I. 214; *Teva* Action, D.I. 248) This Report and Recommendation solely addresses Defendants' arguments as to the above-referenced issues.

[2] For simplicity's sake, the Court will hereafter refer to the "D.I." number in the *Teva* Action, unless otherwise indicated.

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; D.I. 18)

Briefing on the instant Motions was completed on March 3, 2017. (*Glenmark* Action, D.I. 274, 272; D.I. 313, 311) The Court held oral argument on the Motions (and various other summary judgment and *Daubert* motions filed in the case) on March 24, 2017. (D.I. 335 (hereinafter, "Tr.")) A 5-day trial is set to begin in the *Teva* Action (Civil Action No. 14-878-LPS-CJB) on June 12, 2017. (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: (1) Report and Recommendation on Defendants' motion for summary judgment of invalidity, issued on May 2, 2017, (D.I. 346); and (2) Report and Recommendation on Defendants' motion for summary judgment of no induced infringement, issued on May 23, 2017, (D.I. 370).

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. 249 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

[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. 73, ex. B) Citation to the patent will simply be to the "'000 patent."

> 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,
>
> > *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 a reissue proceeding.

II. DISCUSSION

A. Legal Standards

1. Summary Judgment

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. 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).

2. *Daubert* Motions

Federal Rule of Evidence 702 governs the admissibility of qualified expert testimony,

providing that an expert witness may testify if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. Rule 702's requirements have been examined in detail by the Supreme Court of the United States in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and have been said to embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *see also B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010).[4] As to the motions here that relate to the admissibility of expert testimony, what is largely at issue is the reliability and "fit" of that testimony.

With regard to the requirement of reliability, Rule 702 mandates that the relevant expert testimony "must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590; *see also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). This reliability requirement applies not only to an expert providing "scientific" knowledge, but also to one providing "technical" or "other specialized" knowledge in a case (i.e., testimony that may not necessarily be categorized as "scientific"). *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 146-47 (1999). Such testimony should amount to "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. In examining

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[4] In applying Rule 702 to a patent action, the Court will look to the law of the regional circuit. *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1371 (Fed. Cir. 2015).

whether the reliability factor has been met, a court's focus must be on "principles and methodology" rather than on the conclusions generated by the expert. *Id.* at 595; *see also Daddio v. Nemours Found.*, 399 F. App'x 711, 713 (3d Cir. 2010).

As to the "fit" requirement, it "goes primarily to relevance" as the testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue" and have "a valid . . . connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591-92 (internal quotation marks and citations omitted); *see also Schneider*, 320 F.3d at 404. The standard for fit, however, is not a high one; it is met "when there is a clear 'fit' connecting the issue in the case with the expert's opinion that will aid the jury in determining an issue in the case." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009) (citations omitted).

Overall, "Rule 702 embodies a 'liberal policy of admissibility.'" *B. Braun Melsungen AG*, 749 F. Supp. 2d at 222 (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008)). Nonetheless, the burden is placed on the party offering expert testimony to show that it meets each of the standards for admissibility. *Id.* (citing *Daubert*, 509 U.S. at 592 n.10).[5]

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[5] Although the Court held oral argument on the pending summary judgment and *Daubert* motions, (D.I. 335), neither party sought an evidentiary hearing as to the *Daubert* Motions at issue here or suggested that the factual record was insufficiently developed such that a hearing of that type was required. The United States Court of Appeals for the Third Circuit has held that a trial court need not conduct an evidentiary hearing on a *Daubert* challenge if the record is sufficient to allow the Court to make a determination on the issues in dispute. *See, e.g., Oddi v. Ford Motor Co.*, 234 F.3d 136, 151-55 (3d Cir. 2000); *Maldonado v. Walmart Store No. 2141*, Civil Action No. 08-3458, 2011 WL 1790840, at *13 n.10 (E.D. Pa. May 10, 2011). Here, the relevant expert reports were provided to the Court, as was certain deposition testimony regarding those reports. The parties also ably addressed issues relating to the relevant expert reports in their briefing. In light of this, the Court has determined that the record before it is sufficient to allow for a decision on the admissibility of the expert opinions at issue in these Motions under *Daubert*. *See, e.g., Furlan v. Schindler Elevator Corp.*, 516 F. App'x 201, 205-06

3. Lost Profits Damages

Pursuant to 35 U.S.C. § 284 ("Section 284"), a patentee is entitled to "full compensation" for any damages it suffered as a result of infringement. *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983). Such compensation "includes any foreseeable lost profits the patent owner can prove." *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). The issue of whether lost profits are available in a particular situation is a question of law. *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1293 (Fed. Cir. 2007).

The goal of an award of lost profits damages is to "place the patentee in the same position it would have occupied had there been no infringement." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1285 (Fed. Cir. 2017). "To recover lost profits as opposed to royalties, a patent owner must prove a causal relation between the infringement and its loss of profits." *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993). The burden rests on the patent owner to "show a reasonable probability that, 'but for' the infringement, it would have made the sales that were made by the infringer." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc). The "but for" inquiry requires a reconstruction of the market as it would have developed absent the infringing product, to determine what (here, GSK) would have made. *Grain Processing*, 185 F.3d at 1350; *see also Mentor Graphics*, 851 F.3d at 1285 ("[T]he fact finder's job is to determine what would the patent holder have made (what would his profits have been) if the infringer had not infringed."). While this is a hypothetical enterprise in that it requires the patentee to project economic results that did not occur, the Federal Circuit has explained that it nevertheless "requires sound economic proof of

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(3d Cir. 2013); *Oddi*, 234 F.3d at 151-55; *Maldonado*, 2011 WL 1790840, at *13 n.10.

the nature of the market and likely outcomes with infringement factored out of the economic picture." *Grain Processing*, 185 F.3d at 1350. While damages may not be based on speculation, they need not be proved with unerring precision either. *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1579 (Fed. Cir. 1992).

The *Panduit* test, set out in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978), establishes an acceptable (though non-exclusive) framework for a patentee to show "but for" causation. *Rite-Hite*, 56 F.3d at 1545. Under the *Panduit* test, the patentee must make a showing of: (1) demand for the patented product; (2) absence of acceptable non-infringing alternatives; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of profit it would have made. *Panduit*, 575 F.2d at 1156. If the patentee establishes each of the *Panduit* factors, the court may reasonably infer that the claimed lost profits were caused by the infringing sales, thus establishing a patentee's *prima facie* case with respect to "but for" causation. *Rite-Hite*, 56 F.3d at 1545. The burden then shifts to the alleged infringer to show that the inference is unreasonable for some or all of the lost sales. *Id.*

B. Analysis

1. Defendants' Lost Profits Motion

It is undisputed that, at all times relevant to the lost profits analysis, there were generic carvedilol tablets available from at least eight different generic manufacturers that were approved by the United States Food and Drug Administration. (*See* D.I. 265 (hereinafter, "Riley Decl. Vol. II"), ex. 15 at 94-96, 107, 125; D.I. 266 (hereinafter, "Riley Decl. Vol. III"), ex. 27 at ¶ 75) It is also undisputed that only Teva and Glenmark have been sued to date by GSK for infringement of the '000 patent (the generic manufacturers of carvedilol not sued by GSK will be hereinafter

referred to as "the other generic suppliers"). (*See* Riley Decl. Vol. II, ex. 15 at 107) And it is undisputed that in the relevant damages period, these generic manufacturers made far more sales of carvedilol than GSK. (*Id.* at 89-91, 148) GSK is claiming lost profits damages for the entire damages period at issue in these cases. (*See, e.g.*, Riley Decl. Vol. III, ex. 27 at ¶ 20)

The crux of the dispute between the parties with respect to Defendants' Lost Profits Motion revolves around the presence of these other generic suppliers, which had carvedilol tablets on the market at all times relevant to the lost profits analysis. For purposes of lost profits damages, the parties disagree on whether "the [] generic [carvedilol] products [supplied by the other generic suppliers] should be considered as part of [the] but-for market[.]" (D.I. 249 at 28)

On the one hand, GSK's damages expert, Dr. Maness, did not consider the other generic suppliers' carvedilol products as being present in the market (i.e., as non-infringing alternatives to GSK's COREG) in the but-for world. In doing so, he explained that: "I am informed that under the law . . . the administration of a different generic carvedilol [from one of the other generic suppliers] to replace an infringing prescription of Defendant[s'] carvedilol would still infringe the '000 patent claims, and thus cannot be a non-infringing alternative in a lost-profits analysis." (Riley Decl. Vol. III, ex. 27 at ¶ 75) On the other hand, in their analysis of GSK's claim for lost profits, Defendants' damages experts have offered opinions that in the but-for world, absent the presence of Defendants' generic carvedilol tablets, sales of Defendants' products would have been replaced not by GSK's COREG, but by sales of carvedilol tablets from the other generic suppliers. (*See, e.g.*, Riley Decl. Vol. III, ex. 26 at 76-77; D.I. 262, ex. A at ¶ 52 (Dr. Addanki opining that "in the but-for world. . . . patients [would have been] treated with generic carvedilol products instead of Coreg for all uses"); D.I. 254, ex. A at ¶ 27 (Dr. McDuff

opining that in the "but-for market . . . competing generic carvedilol products [] would have earned the accused sales even if [Defendants] were not selling [their] product for CHF use"))

In their Lost Profits Motion, Defendants move for summary judgment that GSK is not entitled to lost profits damages, asserting that GSK's lost profits theory is "fundamentally flawed" because it is based on the incorrect legal assumption that the other generic suppliers' carvedilol tablets that existed in the relevant time period cannot be considered in reconstructing the but-for world. (D.I. 249 at 26, 28; *see also* Tr. at 120) Defendants' view is that "[t]here can be no legitimate dispute . . . that [the other generic suppliers] provided acceptable substitutes for Defendants' products at lower price than GSK would have provided[,]" and that these suppliers' carvedilol tablets constituted acceptable non-infringing alternatives that should defeat GSK's claim for lost profits damages. (D.I. 249 at 30) Such tablets constitute non-infringing alternatives, according to Defendants, because the charge here against Defendants is one of *induced* infringement, and so that (i.e., inducement) is the only thing that must be factored out in the but-for world. (Tr. at 106-07) Accordingly, Defendants argue that, for purposes of the lost profits analysis, it is irrelevant that physicians may ultimately directly infringe the '000 patent by administering the generic carvedilol tablets supplied by the other generic suppliers to patients in accordance with the patented method. (*Id.* at 107) This is so because, according to Defendants, "the but-for test [is an] exacting standard that . . . . [is] supposed to isolate the *challenged conduct* which here is only inducement and [to ask] if the challenged conduct hadn't occurred . . . would [GSK] have made more profits[?]" (*Id.* at 107-08 (emphasis added); *see also id.* at 123 (Defendants' counsel explaining that their "harmful act is nothing other than inducement and any direct infringement *that flows from inducement*. But if you have a lot of prescriptions that are

happening that don't flow from inducement, then you don't take them out of the but-for world because it's *not what we did wrong*") (emphasis added))

In response, GSK asserts that it is Defendants' position that is wrong as a matter of law. According to GSK, this is because as part of GSK's inducement claim, it must establish, *inter alia*, direct infringement of the method claims by physicians, (D.I. 297 at 29), and "[t]he law actually says *all* of the infringement is excluded in the but-for world[,]" (Tr. at 115 (emphasis added); *see also* GSK's Lost Profits, Survey Evidence, Convoyed Sales (hereinafter, "Damages") Slide Presentation, Slide PDX-106 ("No court has permitted an assumption of infringement (of any type) in the but-for world")). GSK continues that "[a]ny use of carvedilol under the conditions specified by the '000 patent is infringing[,]" and therefore "the administration of any generic carvedilol by a doctor according to the claimed methods [including those tablets from the other generic suppliers] directly infringes, and must be excluded from the lost profits analysis." (D.I. 297 at 3, 29-30)

The Court is not convinced that Defendants' position is correct as a matter of law. Defendants have not pointed the Court to any case standing for the proposition that—in the context of a claim for induced infringement of a method of use patent—a proper lost profits damages analysis would treat a use that would directly infringe the patent as a "non-infringing alternative," so long as the plaintiff does not show that that use was also induced by another. (Tr. at 121-22; D.I. 311 at 4, 6; *see also* Tr. at 148 (GSK's counsel asserting that "[i]f your Honor were to decide that because this is an inducement case, direct infringement is allowed in the but-for world, that would be the first case ever to do that and it would go against decades and decades and decades of law that says that all infringement is excluded"); GSK's Damages Slide

Presentation, Slide PDX-106) Meanwhile, the law is clear that a lost profits analysis must be based on a world in which infringement of the asserted patent does not exist, and therefore it does not allow for infringing alternatives to be available in the hypothetical "but for" world. Indeed, the Federal Circuit has repeatedly observed that the "but for" world must be constructed to demonstrate "likely outcomes *with infringement factored out of the economic picture*[.]" *Grain Processing*, 185 F.3d at 1350 (emphasis added). Yet here, Defendants want the Court to permit them to argue that, for purposes of the lost profits analysis, a "non-infringing alternative" can be an alternative that actually infringes. To say it is to understand why it cannot be so.

Case law certainly supports the proposition that in the but-for world, a defendant cannot argue that the sale of its own product would have been replaced by the sale of some other party's infringing product, for purposes of calculating lost profits damages. For instance, in *Bros Inc. v. W.E. Grace Mfg. Co.*, 320 F.2d 594 (5th Cir. 1963), the United States Court of Appeals for the Fifth Circuit reviewed the lower court's decision to reduce a patent infringement damages award for lost profits by two thirds on the basis that there were two other infringing companies selling the same product and "had not the Infringer wrongfully appropriated and sold the patented machines, 2/3rds of them would probably have been sold by these two competitors." 320 F.2d at 598. The Court rejected this approach, explaining that the consequence of such a "novel and startling" holding "is strange [because] [i]n effect it is that an admitted infringer who has made substantial profits from purloining another's patent is not made to account for his acknowledged acts because had he not poached, another would or, at any rate, sales of similar products would have been made, not by the patent owner, but by others"); *see also Alt Ana Pharma AG v. Teva Pharms. USA, Inc.*, Civil Action No. 04-2355 (JLL), 2013 WL 12157835, at *8 (D.N.J. May 14,

2013) ("[T]he presence of other infringing generics in the marketplace does not defeat [plaintiff's] entitlement to lost profit damages on [defendant's] sales."); *cf. State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989) (in affirming that lost profits can be based on a market share approach where there are multiple competitors, noting that "[i]f . . . other competitors were likely infringers of one or the other of [the plaintiff's] patents, [the plaintiff] would have been entitled to their shares of the market on top of its own, and a correspondingly greater share of [the defendant's] sales").

Because the Court believes that GSK's approach of factoring out the infringing administration of the other generic suppliers' carvedilol in its lost profits damages analysis was legally correct, the Court recommends that Defendants' Lost Profits Motion be denied.[6]

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[6] In Plaintiffs' Motion to Exclude McDuff and Motion to Exclude Addanki, Plaintiffs first request that the Court exclude the portions of Dr. McDuff's and Dr. Addanki's Rebuttal Reports that "pertain to generic carvedilol being available and/or used to infringe in the but-for world." (*Glenmark* Action, D.I. 210 at 16; D.I. 247 at 15) The arguments to this effect that GSK makes in these motions are "the converse of" Defendants' Lost Profits Motion and thus present the same question—"[h]ow should all of the other real-world generic carvedilol products be treated in the but-for world?" (D.I. 292 at 1 (emphasis omitted); *see also* Tr. at 105) Plaintiffs argue that because Dr. McDuff's and Dr. Addanki's opinions at issue (i.e., those that "assume[] [that in the but-for world] the underlying direct infringement by the physician may still occur by simply administering another version of generic carvedilol") are "predicated on a faulty application of the law[,]" they must be excluded. (*Glenmark Action*, D.I. 210 at 6, 8-9; D.I. 247 at 6, 8-9) As set out above, the Court agrees, and therefore recommends that these portions of Plaintiffs' motions be granted. *Cf. DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1308-09 (Fed. Cir. 2006) (affirming the lower court's exclusion of expert testimony where the expert failed to consider the effect of the availability of a non-infringing substitute in his lost profits analysis); *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996) ("Incorrect statements of law are no more admissible through 'experts' than are falsifiable scientific theories."). As GSK notes, this holding would not preclude Defendants' experts from offering their alternative opinions in which they did assume that generic carvedilol was not an available substitute. (*Glenmark* Action, D.I. 210 at 3 n.3; D.I. 247 at 3 n.3)

In their Motions, Plaintiffs also argue for exclusion of Defendants' experts' opinions regarding GSK's litigation strategy and its effect on GSK's lost profits damages. (*Glenmark*

2. Defendants' Motion to Exclude

Defendants next assert that "to show entitlement to lost profits, Dr. Maness must show that there was direct infringement, that Defendants induced *and* caused a particular amount of that infringement, and that the sales attributable to that induced direct infringement would have gone to GSK in the properly constructed but-for world." (D.I. 249 at 33) In their Motion to Exclude, Defendants argue that the lost-profits opinions of Dr. Maness should be excluded because GSK has no competent evidence to show the *amount* of additional sales it would have made in the but-for world. (*Id.* at 32) They point to three primary reasons why Dr. Maness' opinions purportedly fail to provide a reasonable basis for establishing GSK's lost profits and should therefore be excluded. The Court will take these up in turn.

a. Defendants' Argument that Key Portions of Dr. Maness' Opinions are Based Solely on an Unreliable Survey

The first step of Dr. Maness' lost profits calculation was to determine the amount of Defendants' infringing sales, for which he relied upon the results of a survey of physicians conducted by GSK's survey expert, Dr. Reisetter (the "Reisetter Survey"). (Riley Decl. Vol. III,

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Action, D.I. 210 at 11-16; D.I. 247 at 10-15) The Court agrees with the reasoning set out by GSK, and therefore, the Court recommends that Plaintiffs' Motions be GRANTED and that these opinions be excluded. Briefly, the Court notes that: (1) at least some of the opinions at issue as to this portion of Plaintiffs' motions relate to Defendants' incorrect legal argument that carvedilol from the other generic suppliers need not be factored out of the but-for world, and are therefore not relevant in light of the Court's conclusion on that issue; and (2) though Teva asserts that certain of these opinions are relevant to its equitable defenses, those defenses are exclusively for the District Court to decide and therefore (absent some further ruling by the District Court) would not be relevant for the jury trial in the *Teva* Action. To the extent that Defendants argue that these portions of their experts' testimony is relevant for some other purpose (e.g., "whether the lost profits methodology offered by GSK's expert . . . is plausible" or as to "disputed issues about . . . the proper quantification of damages"), (D.I. 292 at 25, 26), the Court does not understand how that is so, and thus cannot rely on any such argument as a basis to deny this part of the Motions.

ex. 27 at ¶ 58; Riley Decl. Vol. II, ex. 15 at 56) With the Reisetter Survey, Dr. Reisetter asked approximately 200 cardiologists and primary care physicians 23 questions, including 10 questions regarding their prescribing history for carvedilol and other medications used to treat CHF during the time period of 2007 through 2015. (Riley Decl. Vol. III, ex. 32; *see also* D.I. 249 at 34) Survey participants were required to have prescribed carvedilol at least 20 times per month for the pertinent period. (Riley Decl. Vol. III, ex. 28 at ¶ 48) The Reisetter Survey instructed respondents to "provide your best estimate for each question[,]" (Riley Decl. Vol. III, ex. 32 at GSK01005127), and participants were told "[p]lease do not guess [or] consult another person or resource[,]" (*id.*, ex. 31 at 232). Dr. Maness then utilized the survey results to calculate Defendants' allegedly infringing sales. (*Id.*, ex. 27 at ¶ 58)

Courts generally accept survey evidence that is reliable. *See, e.g.*, *Hartle v. FirstEnergy Generation Corp.*, Civil Action No. 08-1019, 2014 WL 1317702, at *5 (W.D. Pa. Mar. 31, 2014) (citation omitted). The United States Court of Appeals for the Third Circuit has explained that while "mere technical unreliability goes to the weight accorded a survey, not its admissibility[,]" a survey may be properly excluded where its "methodology was fundamentally flawed[.]" *Citizens Fin. Grp., Inc. v. Citizens Nat'l Bank of Evans City*, 383 F.3d 110, 121 (3d Cir. 2004); *cf. United States v. H & R Block, Inc.*, 831 F. Supp. 2d 27, 34 (D.D.C. 2011) (explaining that with respect to surveys, "technical deficiencies that can be adequately explored on cross-examination generally go to the weight, rather than the admissibility, of the evidence, unless the methodological deficiencies are so sweeping or fundamental as to render the survey wholly unreliable and therefore inadmissible").

In their Motion to Exclude, Defendants argue that: (1) the Reisetter Survey is

fundamentally flawed and unreliable, and therefore the survey and its results (i.e., the opinions of Dr. Reisetter) should be excluded; (2) without the Reisetter Survey, Dr. Maness has no reliable basis for calculating GSK's lost profits damages, and therefore Dr. Maness' lost profits opinions should be excluded under *Daubert*; and (3) summary judgment of no lost profits should thus be granted. (D.I. 249 at 33-43; D.I. 313 at 17-23) More specifically, Defendants argue that the Reisetter Survey suffers from the following fundamental flaws, which render the survey inadmissible:

(1) The survey does not match the critical facts of the case in that Dr. Reisetter (a) failed to provide respondents with the Court's claim construction of CHF; and (b) failed to identify the correct time period, in that the survey defined the pertinent period for which respondents were to provide answers as beginning January 2007 through the end of 2015, though the patent was not issued until January 2008, and it expired in June 2015. (D.I. 249 at 35-36)

(2) The survey participants did not constitute a randomly-chosen, probability-based sample that accurately reflected the relevant population (i.e., all physicians who prescribed carvedilol), and therefore no inferences regarding the relevant population can be reliably drawn from the survey results. (*Id.* at 36-37)

(3) The survey was conducted using an incorrect, unrepresentative sample population (i.e., in utilizing a baseless cardiologist/primary care physician ratio). (*Id.* at 37-39)

(4) The survey suffers from recall bias in asking participants to recall specific information regarding hundreds of patients that occurred between 1 and 9 years ago, without referring to any records. (*Id.* at 39-42)

(5) The survey's low response rate suggests a non-response bias that prevents Dr. Reisetter from being able to extrapolate the results of the survey to the wider population. (*Id.* at 42-43)

For the reasons discussed below, the Court concludes that each of Defendants' criticisms are more appropriate for jury consideration, and are not so fundamental as to render the survey wholly unreliable such that it should be excluded.

With regard to Defendants' initial complaint (regarding the Reisetter Survey's failure to provide respondents with the Court's claim construction for CHF, and the time period captured by the survey's questions), it does not clearly demonstrate the survey's unreliability. As to the failure to include the Court's construction of CHF in the Reisetter Survey, GSK puts forward evidence that the construction, (D.I. 165 at 44), is "materially the same as the accepted medical definition of the term[,]" (D.I. 297 at 38 (citing D.I. 299 (hereinafter, "McCann Decl. Vol. II"), ex. 83, 88)). To the extent that Defendants' experts opine that "congestive heart failure" has a broader meaning that survey respondents may have applied in formulating their answers, (D.I. 249 at 35 (citing D.I. 253, ex. A at ¶¶ 26-30; D.I. 260, ex. A at ¶¶ 22-23)), that is a criticism that should go to the jury. So too should disputes about the time period that Dr. Reisetter used for the survey. Two-thirds of responding physicians indicated that their prescribing practices did not change over time, (McCann Decl. Vol. II, ex. 73 at 238), and of those that did change their prescribing practices, their prescriptions of carvedilol for CHF are said to have increased only slightly over time in comparison to prescriptions of carvedilol for other diseases, (*id.*, ex. 59 at ¶¶ 44-45, Tables 6 & 7).[7]

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[7] The sole case that Defendants cite in support of exclusion of the survey on these bases, (D.I. 249 at 36 (citing *M2M Sols. LLC v. Motorola Sols., Inc.*, Civil Action No. 12-33-RGA, 2016 WL 767900, at *6 (D. Del. Feb. 25, 2016)), is inapposite to the facts here. In that case, the Court excluded a damages opinion that was "entirely" based on a survey "completely unrelated" to the accused technology. 2016 WL 767900, at *5-6. The Court held that it could not allow the plaintiff to present damages testimony to the jury "whereby a non-technical expert extrapolates from a survey unrelated to the patented invention to calculate how many customers

Defendants' next criticism of the Reisetter Survey is based on the fact that the group of physicians invited to participate did not constitute a "randomly chosen probability based sample that accurately reflected the relevant population" (i.e., a "probability sample"), but instead were selected from a large panel of physicians, and thus constituted a "non-probability sample," or "quota sample." (D.I. 249 at 36-37; *see also* Riley Decl. Vol. III, ex. 31 at 81) In order to generate the sample of physicians used for the Reisetter Survey, Dr. Reisetter relied on Reckner Healthcare ("Reckner"), a national market research firm with large existing panels of physicians; Reckner, in turn, drew the participants from these panels (utilizing various processes). (McCann Decl. Vol. II, ex. 59 at 16 at ¶ 47) According to Defendants, Dr. Reisetter's use of a non-probability sample is a fatal flaw that renders his survey unreliable because it cannot be extrapolated to the relevant population, and therefore no inferences with respect to the relevant population can reliably be drawn. (D.I. 249 at 36-37)

However, when questioned about the differences in probability samples and non-probability samples at his deposition, Dr. Reisetter testified that in his experience, when using a quota sample, "you get answers that quite valid and easy to validate through, for example, other market research that a company might be doing." (McCann Decl. Vol. II, ex. 73 at 85) After completion of the survey, Dr. Reisetter checked the results against existing market research on the subject; that research provided "an estimate or a calculation or an analysis of the percentage of [prescriptions of carvedilol written for] CHF [and] [t]he numbers consistently have been 50 to 65 percent[,]" which matched up to his survey results. (*Id.* at 85-86)

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use the patented features of the accused products." *Id.* at *6. Here, in contrast, the survey was prepared for this litigation, relates directly to prescribing practices for carvedilol, and is relevant to the issues involved in these cases.

Courts have routinely rejected criticisms similar to Defendants' here as a ground to exclude survey evidence (at least with regard to "opinion" surveys). (D.I. 297 at 40 (citing cases)) While Defendants suggest that this criticism amounts to grounds for exclusion when the survey at issue is a "factual" survey (as here), as opposed to an "opinion" survey, they do not cite to a case that recognizes the differences in such surveys, nor one that applies a different standard depending upon which category the survey at issue fell into. (*See* GSK's Damages Slide Presentation, Slide PDX-122) Here, then, the Court concludes that Defendants' critique regarding the Reisetter Survey's usage of a non-probability sample goes to the weight of the evidence rather than to its admissibility. *See, e.g.*, *Dataquill Ltd. v. Huawei Techs. Co. Ltd.*, 2:13-CV-633, 2:13-CV-634, 2015 WL 12912360, at *2-3 (E.D. Tex. June 11, 2015) (rejecting defendant's argument that a survey should be excluded because, *inter alia*, the expert used a "so-called quota sample rather than a probability sample[,]" where "such perceived deficiencies can be adequately addressed through vigorous cross-examination");[8] *cf. Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs.*, 532 F. Supp. 1040, 1053-55 (D.N.J. 1980) (following a bench trial, excluding one survey but keeping in another that was a "stratified quota sample[,]" explaining that while the court would not give it "as much weight as [the court] would a probability sample[,]" it would give it some weight where it was undertaken to determine the percentage of time that physicians disallowed substitution of the brand name drug at issue for a generic, the expert testified that in at least 25 studies the results obtained from such a quota sample "were similar to the findings generated by a probability sample[,]" and where the

[8] Although it is not clear from the opinion, that case was a patent infringement case, and the survey at issue was offered in support of a damages calculation. *See DataQuill Ltd. v. Huawei Techs. Co.*, Civil Action No. 13-00633-JRG, D.I. 125 (E.D. Tex. Apr. 9, 2015).

technique had historically been used in the pharmaceutical market research field).

Defendants next argue that the Reisetter Survey is fatally flawed in its failure to properly define the appropriate sample population, by "arbitrarily impos[ing] a 60/40 ratio of cardiologists to primary care physicians." (D.I. 249 at 37-38; D.I. 313 at 20) Dr. Reisetter explains in his report that the sample universe comprised physicians who had initiated prescriptions of carvedilol for patients during the relevant time frame, and that "[p]revious research identified that [60%] of carvedilol prescriptions written to initiate therapy" were by cardiologists, with the vast majority of the remainder being initiated by primary care physicians. (McCann Decl. Vol. II, ex. 59 at 15 at ¶ 43) The "research" that Dr. Reisetter referred to consists of a one-page internal GSK PowerPoint slide from a deck of "Back-Up Slides" dating from approximately 2004. (*Id.* at nn.35-36; *see also id.*, ex. 71 at GSK00873620) The first slide in the deck states that the data (in general) was collected from ImpactRX Promotion Research Organization, (*id.*, ex. 71 at GSK00873613), and Dr. Reisetter testified that before he prepared his report, he had a "basic understanding of what ImpactRX . . . information was and how the data was collected[,]" (Riley Decl. Vol. III, ex. 31 at 111), and why he felt it was appropriate to use that data, (McCann Decl. Vol. II, ex. 73 at 307-13). While the evidentiary base for this 60/40 ratio of cardiologists to primary care physicians seems a bit thin, the Court does not have the record to conclude that the ratio is so fundamentally flawed as to discredit the overall survey results. To the extent Defendants dispute that Dr. Reisetter relied upon the proper ratio (they do not dispute that those two types of physicians constituted the proper sample), those objections go to the weight of Dr. Reisetter's testimony, not its admissibility under Rule 702.

Defendants also assert that Dr. Reisetter made matters worse by (1) "arbitrarily limiting

his total number of subjects to 200 (rather than the 700+ shown in the slide)" and (2) excluding from his group of primary care physicians any physician who had not achieved certain estimated monthly patient or prescription numbers. (D.I. 249 at 39) However, Teva's survey expert testified that he did not "have any problem with [a sample size of] 200," (McCann Decl. Vol. II, ex. 75 at 45), and Dr. Reisetter reasonably explained that his survey focused on physicians "who most commonly prescribe carvedilol. . . . because those physicians would likely be most informed as to the reasons carvedilol was initially chosen as the most appropriate agent[,]" (*id.*, ex. 59 at 14 at ¶¶ 41-42). For these reasons, the Court is not persuaded that any such flaws with the make-up of the sample are fatal. These critiques too go the weight of the evidence and may be sufficiently attacked through "[v]igorous cross-examination [and] presentation of contrary evidence[.]" *Daubert*, 509 U.S. at 596; *see also Hartle*, 2014 WL 1317702, at *6 (explaining that "arguments with respect to . . . nonrepresentative and nonrandom sampling . . . are 'technical flaws' that go to the weight rather than admissibility of the survey") (citations omitted).

With respect to Defendants' concerns about recall bias, as GSK points out, the survey did not ask physicians to recall a specific event such as their treatment of a particular patient. Instead it questioned physicians as to their treatment of CHF patients in the aggregate over the period from 2007-2015. (D.I. 297 at 43) This difference is important. In *In re: Autozone, Inc.*, No.: 3:10-md-02159-CRB, 2016 WL 4208200 (N.D. Cal. Aug. 10, 2006), for example, a district court concluded that a survey was unreliable and therefore inadmissible because, *inter alia*, it "asks respondents to recall very specific events that occurred between three and a half and eleven years ago[,]" while noting in contrast that "class members might reliably remember whether they were 'authorized and permitted' to take one/two/three rest breaks when they worked Short/Mid/Long

shifts[.]" 2016 WL 4208200, at *19. The questions in the Reisetter Survey seem more analogous to the latter type of question. Moreover, if the physicians did have trouble recalling the details relevant to the survey questions, they could respond with "don't know." (McCann Decl. Vol. II, ex. 59 at Questionnaire, Pages 6-18) Furthermore, the respondents were asked whether or not their prescribing habits with respect to carvedilol changed substantively over the period of 2007 to 2015, (*id.* at Questionnaire, Page 8; *see also id.*, ex. 73 at 238, 275-76), and Dr. Reisetter testified that approximately two-thirds of the physicians responded that their habits did not change, (*id.*, ex. 73 at 238). Under these circumstances, the Court is not convinced that concerns of recall bias amount to a fundamental flaw that renders the Reisetter Survey inadmissible. *See, e.g.*, *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 855-56 (Fed. Cir. 2010) (affirming the district court's admission of a survey offered to quantify damages based on the number of actual users of the accused functionality over the defendant's argument that, *inter alia*, "questions regarding estimates of [] usage [of the accused functionality] going back several years" rendered the survey unreliable where the defendant "presented expert testimony and attacked the . . . survey . . . on cross-examination").

Defendants' final argument here—that the Reisetter Survey must be excluded because the low response rate indicates a high likelihood of non-response bias—also goes to the weight that should be afforded the survey. Dr. Reisetter sought a sample size of 200 physicians, (McCann Decl. Vol. II, ex. 59 at 16 at ¶ 46), and he instructed Reckner to contact 20,000 physicians by email to participate, (*id.*, ex. 73 at 133-34). Of those, 482 physicians expressed interest (a response rate of 2.3%) and 238 were ultimately qualified to participate. (D.I. 255, ex. A at ¶ 34; D.I. 249 at 42; D.I. 297 at 45) Another court has explained that, with respect to an internet

survey, a similar response rate of 2.16% "appears, by any standard, to be quite low[,]" which "could point toward non-response bias or diminish the validity of the results." *Univ. of Kansas v. Sinks*, No. 06-2341-JAR, 2008 WL 755065, at *4 (D. Kan. Mar. 19, 2008). Even so, the *University of Kansas* Court declined to exclude the survey at issue, explaining that while it presented "significant flaws[,]" those flaws "may be adequately brought to the jury's attention through rigorous cross-examination and the presentation of [the movant's] expert[.]" *Id.* at *5; *see also H & R Block*, 831 F. Supp. 2d at 34-35. The Court reaches the same conclusion here. In doing so, the Court notes that when asked if he took any steps to assess for non-response bias, Dr. Reisetter testified that one appropriate method is to "look at early responders versus late responders to see if there's differences between the [responses of] the two groups," and that in comparing pretest and survey data for the first question of the Reisetter Survey, he concluded that there are "no significant differences between early responders and late responders in the group." (McCann Decl. Vol. II, ex. 73 at 153-54) Defendants' expert Dr. Russell S. Winer confirmed that this is, among others, a "common way[] that people try to check for non-response bias. They look at early respondents versus late respondents, for example, are there any differences there[.]" (*Id.*, ex. 75 at 122) So while Defendants cite to evidence on their side that indicates that the low response rate here could be problematic, (D.I. 249 at 42-43), the record is not one-sided on this point.[9]

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[9] The Court agrees with GSK that the facts in *In re: Autozone* with respect to the survey's low response rate presented some additional concerns that do not appear to be present here. (D.I. 297 at 45) For example, the *In re: Autozone* Court credited the defendants' expert's testimony that individuals who affirmatively refused to participate in the survey outnumbered those who responded by almost two-thirds, which is a "'red flag'" especially in the context of a survey conducted in the litigation context and when one does not know why the "self-selection" took place. 2016 WL 4208200, at *18 (citation omitted). Additionally, the Court explained that

In sum, while Defendants have pointed out certain flaws in the methodology of the Reisetter Survey, they go to the survey's weight, and may be adequately brought to the jury's attention through cross-examination and via the testimony of Defendants' survey experts.

b. Defendants' Argument that GSK has No Reliable Evidence Showing How Much of Any Alleged Direct Infringement was Caused by Defendants' Alleged Inducement

Defendants next assert that, assuming there is a finding of liability for induced infringement, in order to then "obtain damages, GSK bears the burden of proving *how much* direct infringement was induced by Defendants." (D.I. 249 at 43 (emphasis in original); *see also* Tr. at 35 (Defendants' counsel asserting that "[t]here is a requirement under the law that when you have damages in an inducement case, you can't just say that any sale by the Defendants forms a basis for damages. You have to show sales that are tied to the . . . actual inducement in this case")) Defendants assert that GSK has failed to present any evidence with respect to this step of the lost profits damages calculation, thus rendering GSK's lost profits opinion speculative and unreliable. (D.I. 249 at 43-44) In support of this position, Defendants point to two Federal Circuit decisions: *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 1 F. App'x 879 (Fed. Cir. 2001) and *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.* ("*Power I*"), 711 F.3d 1348 (Fed. Cir. 2013). (D.I. 249 at 43-44; Tr. at 36)

In response, Plaintiffs contend that Defendants are "really misapplying the law [with respect to] causation [and] what the law actually requires from a damages perspective on the

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the survey recipients were told that there was a class action lawsuit and that the information they provided would help to resolve it, which raised the problem of self-interest bias in the small number of individuals that did respond, as a sample that includes even a small number of interested parties can produce biased results. *Id.*

issue of causation." (Tr. at 38) With the proper law applied, they assert that their damages calculation comports with the law. (*Id.* at 39-40)

In the Court's view, the holdings of these cases do not compel a finding that summary judgment here must be granted against Plaintiffs' lost profits damages claim. In *Chiuminatta*, for example, following a finding on summary judgment that defendants induced infringement of the asserted method of use patent through sales of the defendants' Green Machine saw, the district court had granted summary judgment of damages to the patentee for each Green Machine saw sold by the defendants. 1 F. App'x at 881-83. The claimed method was directed to cutting grooves in concrete that had not yet hardened to its rock-like hardness state, with one such element requiring the cutting step to occur within a specific concrete hardness range. *Id.* at 882. The defendants appealed the district court's grant of damages for sales of each saw, asserting that "some sales of the Green Machine saw did not lead to any direct infringement, because the purchasers did not use the saw during the patented time frame" and that it was therefore "incorrect to assess damages for each sale of a Green Machine, absent sufficient proof that each such potentially inducing sale actually led to *an act of direct infringement*." *Id.* at 883 (emphasis added). The Federal Circuit explained that the *Panduit* lost profits analysis *presumes* a direct relationship between a sale and an infringing act, but in "cases in which there is a question whether *every sale leads to an instance of direct infringement*, a patentee must, in addition to establishing that the four factors of the *Panduit* test are satisfied, establish the connection between sales and direct infringement." *Id.* at 883-84 (emphasis added). The *Chiuminatta* Court concluded that the defendants had put forward sufficient evidence suggesting that the Green Machine saw had substantial non-infringing uses, and that they had therefore raised an issue of

material fact as to whether *each* sale of a Green Machine saw induced the purchaser to directly infringe the patent. *Id.* at 884. The Court warned, however, that the holding was not meant to imply that the patentee "is required to demonstrate a one-to-one correspondence between units sold and directly infringing customers[,]" and the Court reiterated that "[p]roof of inducing infringement or direct infringement may be shown by circumstantial evidence." *Id.*

Here, unlike the import of the district court's grant of summary judgment that was reversed in *Chiuminatta*, GSK is not contending that every sale of Defendants' carvedilol results in direct infringement of the patented method. Rather, GSK's damages expert relied on the Reisetter Survey to determine the amount of Defendants' sales that did directly infringe the patented method. (*See, e.g.*, Riley Decl. Vol. III, ex. 27 at ¶ 16) GSK's counsel asserts that therefore, they did "exactly what the *Chiuminatta* case says you're supposed to do, and not just say . . . all of the sales are subject [to] an inducement lost profits claim[.]" (Tr. at 40) Though Defendants' counsel asserts that GSK failed to provide "proof" in order for "their expert to opine that all of [the claimed] damages are tied into the alleged wrongdoing, the inducement[,]" (*id.* at 47), such proof may be in the form of circumstantial evidence, *Chiuminatta*, 1 F. App'x at 884. As the Court recently found in its Report and Recommendation recommending denial of Defendants' Motion for Summary Judgment of No Induced Infringement, "Plaintiffs are entitled to present the jury with their circumstantial evidence" regarding inducement. (D.I. 370 at 32) Just as the *Chiuminatta* Court found a dispute of material fact as to whether every sale of the accused product in that case induced the customer to directly infringe the patent, so too should the damages issue here be one for the jury. *Cf. Hilgraeve, Inc. v. Symantec Corp.*, 272 F. Supp. 2d 613, 621 (E.D. Mich. 2003) (rejecting the Defendants' *Chiuminatta*-based argument that any

recovery of damages for plaintiff's induced infringement claim must be limited to instances where the plaintiff can affirmatively prove acts of direct infringement by users of defendants' products, explaining that "Plaintiff may rely upon circumstantial evidence to prove damages from inducement. Of course, should the jury in this case find Defendant liable for inducing infringement based on circumstantial evidence, it remains to be seen whether that same evidence will be sufficient to establish damages."); *see also Black & Decker v. Bosch*, No. 04 C 7955, 2006 WL 3883286, at *2 (N.D. Ill. Dec. 18, 2006) ("Based on the *Chiuminatta* decision that a patentee is not required to demonstrate one-to-one correspondence between units sold and directly infringing customers, [the plaintiff] was not required to set forth proof that each sale of the [accused product] induced the purchaser to directly infringe the patents-in-suit.").[10]

c. Defendants' Argument that GSK has No Reliable Evidence of the Amount of Infringing Sales Allegedly Induced by Defendants that GSK Would Have Captured

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[10] The Court also agrees with GSK that the decision in *Power I* is not really helpful to Defendants' argument here. (Tr. at 43-44) In that case, the plaintiff's expert had used worldwide sales data for Samsung mobile phones to estimate sales of the accused product, which was power circuits that were incorporated into Samsung's mobile phone *chargers*. 711 F.3d at 1372. On appeal, the *Power I* Court agreed with the defendant that the expert's damages testimony was unreliable because, *inter alia*, it relied upon too many speculative assumptions, including that (1) the sales data upon which he relied only mentioned mobile *phones*, not chargers in which the accused product was incorporated, and thus his analysis "assumed that each of Samsung's phones shipped with a charger[;]" and (2) he assumed not only that each shipment included a charger, but that each of the chargers incorporated an infringing power circuit, where the evidence showed that at least some chargers could have incorporated other power circuits. *Id* at 1373-74. Here, the Reisetter Survey was meant to reliably ascertain the number of sales of Defendants' carvedilol tablets that directly infringe the patented method, and GSK is entitled to present its circumstantial evidence that those sales were induced by Defendants' conduct. *See, e.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004) ("Plaintiffs who identify an entire category of infringers (e.g., the defendant's customers) may cast their theories of vicarious liability more broadly, and may consequently seek damages . . . across the entire category.").

Finally, Defendants argue that the Reisetter Survey (relied upon by Dr. Maness to determine the amount of sales that would have actually gone to GSK but-for Defendants' alleged inducement) "simply does not purport to supply the required information." (D.I. 249 at 44) The question intended to address the issue in the Reisetter Survey was Question 9, which asked:

> Consider this scenario: If generic carvedilol IR was not available for prescriptions (only branded Coreg IR) during that maintenance period, how would you have replaced those prescriptions among the following alternatives?

(Riley Decl. Vol. III, ex. 32 at GSK01005137) Defendants take issue with this question because "[e]ven assuming that a certain percentage of doctors answered that they would have prescribed GSK's Coreg, the ultimate question is what was actually dispensed to the patient at the pharmacy." (D.I. 249 at 45) And there is a "strong" possibility, according to Defendants' experts, that the prescription would have changed prior to being dispensed, so that the patient could receive a less expensive alternative. (*Id.* (citations omitted))

The Court concludes that Defendants' concern with respect to this survey question goes to the weight of the evidence. It is true that Defendants offer expert testimony that there is a chance that a patient would have requested to change a prescription after it was written, (*id.* (citing, *e.g.*, D.I. 262, ex. A at ¶ 82)), and from this they argue that "simply asking what the doctor would have prescribed is not a reliable predicate," (*id.*). The jury may reasonably be persuaded by this argument at trial, and may be correspondingly disinclined to accept some or all of GSK's position as to damages. Yet the jury could also reasonably conclude that, in light of the survey data indicating that only 43% of the generic carvedilol prescriptions would have been

captured by branded carvedilol, (*see, e.g.*, D.I. 261, ex. 1 at ¶¶ 90- 91),[11] the survey participants were aware of the reality (that patients might have requested of them cheaper alternatives to COREG) and that the response reflected the "physicians' understanding of the impact on price between generic and branded carvedilol, as well as the alternative generic drugs that were available at the time[,]" (D.I. 297 at 46; *see also* Riley Decl. Vol. II, ex. 15 at 177-78).

II. CONCLUSION

For the reasons set out above, the Court recommends that Defendants' Lost Profits Motion be DENIED; Defendants' Motion to Exclude be DENIED; and Plaintiffs' Motions to Exclude McDuff and Addanki 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 **June 3, 2017**; responses are due by no later than **June 7, 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

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[11] The results of the Reisetter Survey showed that the remaining 57% would have been captured by non-infringing alternatives, such as the administration of other beta-blockers, other medication, or no medication at all. (D.I. 261, ex. 1 at ¶ 90)

proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **June 6, 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 30, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE