**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,<br><br>Plaintiffs,<br><br>v.<br><br>GLENMARK PHARMACEUTICALS INC., USA,<br><br>Defendant. | : | C.A. No. 14-877-LPS-CJB |
| GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC.,<br><br>Defendant. | : | C.A. No. 14-878-LPS-CJB |

**MEMORANDUM ORDER**

WHEREAS, Magistrate Judge Burke issued a 31-page Report and Recommendation (the "Report") (D.I. 383),[1] dated May 30, 2017, recommending that the Court (i) deny the portion of Defendants' motion for summary judgment related to GSK's claim for lost profits (D.I. 248); (ii) deny Defendants' motion to exclude (a) the opinions offered by GSK's damages expert, Dr. Robert S. Maness, concerning lost profits, and (b) the results of the survey of doctors conducted by GSK's survey expert, Dr. Brian C. Reisetter (D.I. 248); and (iii) grant GSK's motions to

[1]All references to the docket index (D.I.) are to the *Teva* action, C.A. No. 14-878, unless otherwise noted.

exclude (a) portions of the opinions offered by Glenmark's damages expert, Dr. DeForest McDuff, and (b) portions of the opinions offered by Teva's damages expert, Dr. Sumanth Addanki (Civil Action No. 14-877 (hereinafter, "Glenmark Action") D.I. 209; D.I. 246);

WHEREAS, on June 3, 2017, Defendants objected to the Report (D.I. 394 ("Defendants Objections" or "Defs Objs"));

WHEREAS, on June 7, 2017, GSK responded to Defendants Objections (D.I. 407 ("GSK Response" or "GSK Resp"));

WHEREAS, the Court has considered the parties' objections and responses as they relate to case-dispositive matters *de novo*, and has considered their objections and responses as they relate to non-dispositive matters for clear errors of law and clearly erroneous findings of fact, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Defendants' Objections (D.I. 394) are OVERRULED, Judge Burke's Report (D.I. 383) is ADOPTED, the portion of Defendants' motion for summary judgment related to lost profits and the portion of Defendants' motion to exclude related to the above-referenced issues (D.I. 248) are DENIED, and GSK's motions to exclude related to the above-referenced issues (Glenmark Action D.I. 209; D.I. 246) are GRANTED.[2]

2. Defendants object to the Report on two grounds: (1) it wrongly permits GSK to

[2]Defendants' request for oral argument (D.I. 399; Defs Objs at 1) is DENIED. The Court finds that oral argument is not necessary in order to resolve the parties' disputes. Moreover, Judge Burke already heard extensive oral argument, briefing on the objections was completed only two days ago, and trial begins barely three days from today.

present a lost profits calculation that contemplates a "but-for" world that excludes non-party manufacturers' generic carvedilol products, and (2) it allows GSK to present its lost profits case without any showing of causation. (Defs Objs at 1) The Court is persuaded by neither of Defendants' contentions.

3. Defendants insist that the but-for world to which comparisons must be made in order to assess GSK's claim for lost profits damages is a world in which non-party manufacturers of generic carvedilol would have existed,[3] and from which direct infringers (i.e., physicians) would have obtained carvedilol. It follows, then, that GSK lost no profits due to Defendants' allegedly infringing conduct, because even absent Defendants' infringement, GSK would still have lost those same sales – albeit to non-party manufacturers, rather than to Defendants.

4. However, as the Report explained, "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." (Report at 13) The undisputed evidence is that Defendants' generic carvedilol is interchangeable with the generic carvedilol of the non-party manufacturers; therefore, the generic carvedilol of these non-party manufacturers is an ***infringing alternative*** – and ***not*** a non-infringing alternative. These non-parties' products, thus, would not exist in the but-for world, which must be constructed to include "likely outcomes with ***infringement factored out of the economic picture***." *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (emphasis added).

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[3]"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." (Report at 9)

5. That there is no evidence that the non-party generic manufacturers could be held liable for ***induced infringement***, while Defendants are charged only with ***induced infringement***, does not alter this conclusion. The issue for the lost profits calculation is whether the product is non-infringing, not whether the alternative supplier has been, or could be, successfully sued for infringement. As GSK correctly states: "It doesn't matter whether the ***sales*** by other generic suppliers would be non-infringing, because the ultimate ***use*** of those products by doctors ***would*** be infringing and thus not a permissible consideration." (GSK Resp at 7; *see also id.* at 1 ("The 'but for' world can consider only non-infringing alternatives. Here, doctors could not use generic carvedilol from other suppliers to perform the patented method without infringing, so this is not a permissible alternative."))

6. Accordingly, because the but-for world is one in which no infringing alternatives exist, other generic carvedilol products that directly infringe the '000 patent must be excluded, even if the sales of those products are not induced by Defendants. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 1 Fed. App'x. 879, 882-83 (Fed. Cir. 2001) ("[S]ection 271(b) of title 35 states that 'whoever actively induces infringement of a patent shall be liable as an infringer.' Thus, appropriate relief against one inducing infringement may be the same as the relief against a direct infringer."); *Alt Ana Pharma AG v. Teva*, 2013 WL 12157835, at *8 (D.N.J. May 14, 2013) ("[T]the presence of other infringing generics in the marketplace does not defeat [plaintiff's] entitlement to lost profit damages on [defendant's] sales.").

7. As the Report found (at 14 n.6), because GSK's motions to exclude the opinions of Drs. McDuff and Addanki are the converse of Defendants' lost profits motion – presenting the same question of whether other generic carvedilol products should be included in the but-for

world and arguing that Drs. McDuff and Addanki based their opinions on a misapplication of the law – these motions are granted, and the opinions at issue are excluded, based on the reasoning of the Report and that contained in this Order.

8. Turning to Defendants' attack on the lost-profits opinions of Dr. Maness, Defendants fault the expert for relying on a survey that fails to address whether Defendants ***actually*** induced the infringing prescriptions of carvedilol. (*See* Defs Objs at 2-3) Because the survey fails to ask "whether Defendants' actions caused the doctors' prescribing decisions and, if so, how many of their carvedilol prescriptions were caused by Defendants," it follows – in Defendants' view – that the survey "provides ***no*** evidence that Teva or Glenmark ***caused*** the infringing use, let alone any evidence of the ***amount*** they allegedly caused." (*Id.* at 2) However, as the Report explained, Dr. Maness began his lost profits calculation by using the physician survey to determine the amount of Defendants' sales that were potentially infringing (Report at 15, 27) and then confined his lost profits calculation to that determined amount (*see* GSK Resp at 4-5). This method, including reliance on the survey undertaken by GSK expert Dr. Reisetter, is not so unreliable as to warrant being excluded. Instead, Defendants' criticisms go to the weight the factfinder should give to the opinion.[4]

9. The Court has considered each of the other arguments raised by Defendants in their Objections and, applying the appropriate standard of review, finds that each of them lacks

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[4]While Defendants are correct that the survey did not show the amount of potentially infringing sales that were actually caused by Defendants' inducement, the survey was only meant to ascertain the number of Defendants' sales that were (allegedly) directly infringing. (*See* Report at 28 n.10) GSK will be permitted to present its circumstantial evidence that the sales were induced by Defendants' conduct and "consequently seek damages . . . across the entire category." (*See, id.*) (citing *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274-75 (Fed. Cir. 2004))

merit and requires no further discussion.

June 9, 2017
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE