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

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 44-page Report and Recommendation (the "Report") (D.I. 370),[1] dated May 23, 2017, recommending that the Court deny the portion of Defendants' motion for summary judgment related to induced infringement (D.I. 248);[2]

WHEREAS, on May 30, 2017, both GSK and Defendants objected to the Report (D.I. 384 ("GSK Objections" or "GSK Objs"); D.I. 387 ("Defendants Objections" or "Defs Objs"));

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

[2]The Report, and accordingly, this Order, solely relates to arguments in Defendants' motion related to the above-referenced issue.

WHEREAS, on June 6, 2017, both parties responded to the opposing Objections (D.I. 401 ("Defendants Response" or "Defs Resp"); D.I. 402 ("GSK Response" or "GSK Resp"));

WHEREAS, the Court has considered the parties' objections and responses *de novo*, *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. Both parties' Objections (D.I. 384; D.I. 387) are OVERRULED, Judge Burke's Report (D.I. 370) is ADOPTED, and the portion of Defendants' motion for summary judgment related to induced infringement (D.I. 248) is DENIED.

2. GSK agrees with the ultimate outcome of the Report, but objects to the Report's suggestion that there is no *per se* rule that a generic drug manufacturer's label including the patented indication, on its own, is sufficient to establish induced infringement. (GSK Objs at 2) For its position that this *per se* rule does exist, GSK cites *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1056-61 (Fed. Cir. 2010)[3] and *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 926-27 (Fed. Cir. 2011) (non-precedential). (*Id.*) The Report distinguished both cases based on their procedural posture as "pre-launch" cases, in which any infringement is necessarily hypothetical, as the proposed generic drug products involved in those cases had not yet been marketed. (Report at 25-26)

3. GSK objects that there is no difference between pre-launch and post-launch

[3]The Court in *AstraZeneca* did not find a label, on its own, sufficient to support a finding of induced infringement. *See* 633 F.3d at 1060-61 ("[T]he district court's specific intent finding was not based solely on the proposed label, but also on Apotex's decision to proceed with its plan to distribute the drug despite being aware that the label presented infringement problems.").

circumstances for purposes of finding inducement. (GSK Objs at 4) The Court has already largely rejected GSK's position in connection with its decision denying GSK's motion *in limine* that sought to preclude Teva from introducing evidence that doctors do not read (and cannot have been induced by) Teva's label. (*See* D.I. 379 at 1) ("Unlike in a Hatch-Waxman case, this case involves an already-marketed product; evidence as to how many, if any, physicians and patients read the label on Teva's product (and Teva's understanding of how often its label is read) is probative evidence of Teva's intent and of the amount of damages Teva may owe GSK.") GSK has provided no persuasive basis for the Court to reconsider these conclusions.

4. Additionally, a finding of induced infringement requires the patentee to show both specific intent by the alleged infringer and actual inducement, which generally means a "successful communication between the alleged inducer and the third-party direct infringer." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012); *see also Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016) ("*Power II*"). As the Report found, in the ANDA context (which was the context in which both *AstraZeneca* and *Eli Lilly* arose) – where a claim of induced infringement is filed before the generic has launched its product and, necessarily, before the generic has even attempted to communicate with any direct infringer – the focus must be on intent, rather than actual inducement. (Report at 24-25) Were it otherwise, no generic filer could ever be found liable for induced infringement in a pre-launch context, as no patentee could ever prove "a 'successful communication between the alleged inducer and third-party direct infringer'" without the generic drug having been launched. (*Id.*) "Here, in contrast to the timing of the *Eli Lilly* and *AstraZeneca* lawsuits, GSK filed these actions almost seven years ***after*** Defendants launched

their generic carvedilol products into the market." (*Id.* at 27) Hence, GSK's inducement claims "are not premised on a hypothetical . . . , but instead, must be supported by sufficient evidence as to what actually happened during the relevant time period." (*Id.*)

5. The Court disagrees with GSK's assessment that the Report "goes astray by suggesting that a generic drug manufacturer whose product labeling instructs others to use the product in an infringing manner might nonetheless escape inducement liability." (GSK Objs at 1) (citing Report at 24-27) A generic drug manufacturer who has launched its product and whose label instructs others to use that product in an infringing manner might nonetheless escape inducement liability if the patentee fails to prove the elements of an induced infringement claim, including "a successful communication between the alleged inducer [i.e., generic drug manufacturer] and third-party direct infringer [e.g., a prescribing physician]." As the Federal Circuit stated in *AstraZeneca*, if the generic manufacturer's label "instructs users to perform the patented method," then "[t]he proposed label ***may*** provide evidence of [the generic manufacturer's] affirmative intent to induce infringement." 633 F.3d at 1060 (emphasis added). If GSK wants the jury to find that Teva's label "would inevitably lead some [third parties] to practice the claimed method," *id.*, GSK is going to have to prove that – not merely assert it.

6. Defendants object to the Report's denial of summary judgment of no induced infringement, contending that Defendants' "undisputed direct evidence that doctors do not consult labels or other publications by generic companies in making prescribing decisions" outweighs GSK's circumstantial evidence to the contrary. (Defs Objs at 1) The Court disagrees with Defendants' assessment of the record; in the Court's view, Defendants' evidence ***is disputed*** (*see, e.g.*, GSK Resp at 8 (citing Dr. McCullough)), and Defendants are asking the Court to

improperly weigh evidence on a motion for summary judgment. Instead, as the Report recommended, the Court will leave it to the jury to weigh GSK's circumstantial evidence and Defendants' direct evidence. (Report at 31)

7. The Court agrees with Judge Burke that "so long as there is ***circumstantial evidence*** that could lead a factfinder to believe that the alleged acts of encouragement led to some amount of 'successful communication' between the alleged inducer (here, Defendants) and the third-party direct infringer (here, physicians prescribing Defendants' carvedilol), that should suffice to satisfy *Power II*'s requirements." (Report at 28-29) The Court further agrees with Judge Burke that "[w]hile it is true that Plaintiffs have not pointed to specific testimony from a direct infringer physician stating that she read Defendants' labels and that caused her to prescribe Defendants' generic carvedilol in an infringing manner, the law does not require that kind of direct (or 'hard') proof." (*Id.* at 31) Defendants may prevail at trial based on their view that GSK's "long chain of inferences" does not establish causation. (Defs Objs at 4) But that is a matter for the jury to decide after hearing the conflicting evidence (e.g., what the label instructs versus whether anyone read it, how Teva marketed its generic product versus whether cardiologists already knew to use carvedilol before GSK even obtained its patent, etc.) to be presented by both sides. The Court does not find, on the record before it, that "GSK's proposed inferences [are] unreasonable." (Defs Objs at 5)[4] Summary judgment must be denied.

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[4]Similarly, while Defendants are correct that the fact that Teva published certain information "does not ***compel*** an inference" that the publication caused any doctor to practice the claims (Defs Objs at 8 n.5) (emphasis added), the Court is not holding that the jury ***must*** draw such an inference. Instead, the Court is merely holding that the record permits a reasonable factfinder to draw competing material inferences, which compels the conclusion that summary judgment must be denied.

8. The Court has considered *de novo* each of the other arguments raised by the parties in their Objections and finds that each of them lacks merit and requires no further discussion.

June 9, 2017
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE