IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 39-page Report and Recommendation (the "Report") (D.I. 191), dated July 20, 2016, recommending that Defendant Teva Pharmaceuticals USA, Inc.'s ("Defendant" or "Teva") motion ("Teva's Motion to Dismiss") (D.I. 63), seeking to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited's (collectively, "GSK") induced infringement claim relating to the period between January 2008 and May 2011 ("the Pre-May 2011 Period" or "the Relevant Period") in GSK's Second Amended Complaint ("SAC") be denied;

WHEREAS, on August 8, 2016, Teva objected to the Report ("Objections") (D.I. 194), specifically objecting to the Report's conclusions that: (1) Teva's carved-out ("skinny") label could instruct third parties to infringe U.S. Patent No. RE40,000 (the "'000 patent") and (2) the SAC's allegations make it plausible that Teva knew the skinny label would induce infringement;

WHEREAS, on August 25, 2016, GSK responded to Teva's Objections ("Response")

(D.I. 197), asserting that the Report correctly found that the SAC met the applicable pleading standards and sufficiently alleged facts to show that the claims of induced infringement in the Relevant Period were plausible;

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. Teva's Objections (D.I. 194) are OVERRULED, Judge Burke's Report (D.I. 191) is ADOPTED, and Teva's Motion to Dismiss (D.I. 63) is DENIED.

2. Teva argues that the Report commits legal error by concluding that Teva's skinny label could instruct third parties to infringe the '000 patent, as Teva's generic carvedilol product was never approved by the FDA for the alleged patented use – relating to treatment of congestive heart failure ("CHF") – since Teva specifically carved out that patented use from its label. (Objections at 3-4) Teva argues that the Report wrongly found plausibility in the allegation that Teva's label "could" lead to infringement by some third parties based, in part, on Teva's label's statements relating to treatment of a different condition – left ventricular dysfunction following myocardial infarction ("Post-MI LVD"). (*Id.* at 6) According to Teva, this is legal error, notwithstanding any overlap between treatment of CHF and treatment of Post-MI LVD. (*Id.* at 6-7) (citing *Warner-Lambert Co. v. Apotex, Corp.*, 316 F.3d 1348, 1364-65 (Fed. Cir. 2003); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1324, 1327-28 (Fed. Cir. 2003); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1323-24 (Fed. Cir. 2012))

However, as the Report explained, "there can, in fact, be situations where a generic

manufacturer seeks and obtains a section viii carve-out for a use of a drug that is (according to the FDA) a 'different' use from a patented use – and yet the generic's label could nevertheless be written in such a way that it evidences active steps to induce patent infringement." (Report at 30) Here, Teva's label carves out use of the drug for CHF but expressly includes instruction on use of Teva's product to treat Post-MI LVD. That Post-MI LVD portion of the label includes statements that, for reasons explained in the Report, could plausibly be found to be knowing, intentional instructions to use Teva's product to treat CHF. (*See id.* at 31-34) While the plausibility of this allegation is supported by the relatedness of the patented use (treatment of CHF) and the unpatented use (treatment of Post-MI LVD), that relatedness is not the sole basis on which the Report's (correct) conclusion of plausibility is based.

3. Teva accuses the Report of permitting "an expansion of the law on inducement in the context of generic pharmaceuticals" that "simply cannot be squared with firmly rooted" law. (Objections at 1) For this contention, Teva relies primarily on three Federal Circuit decisions, which Teva insists are "unequivocal" in holding that "based on Teva's skinny label there can be no claim for inducement of a patent that requires the intentional treatment of CHF." (*Id.* at 4) (citing *Warner-Lambert*, 316 F.3d at 1364-65; *Allergan*, 324 F.3d at 1334; *Bayer*, 676 F.3d at 1324) Contrary to Teva's characterization, the Court agrees with GSK that the ***ANDA*** cases on which Teva relies at most establish that ***were this an ANDA case*** (it is not), and ***were GSK's allegations based solely on the label*** (they are not), GSK's inducement theory might lack merit as a matter of law. (*See* Response at 3) ("Those Hatch-Waxman cases deal with a markedly different circumstance – proving infringement under 35 U.S.C. § 271(e)(2) based on the proposed generic product and accompanying labeling, as set out in an ANDA, ***before any***

product is ever sold.")

4. Teva further argues that the Report incorrectly concluded that Teva knew its label was inducing infringement. (Objections at 7) Teva claims that the only use code GSK associated with the '000 patent was "decreasing mortality caused by congestive heart failure," which relates only to treating CHF and not to Post-MI LVD. (*Id.* at 8-9) Teva concludes that because GSK did not itself believe that the '000 patent could be asserted against the Post-MI LVD indication, there is no way Teva could have known that this indication would infringe the patent. (*Id.* at 9)

GSK responds that the use code covered ***all*** infringing uses of carvedilol to decrease the risk of mortality caused by heart failure, including Post-MI LVD patients who also had heart failure. (Response at 9) Thus, GSK maintains that the SAC sufficiently alleges Teva knew its label was inducing infringement: Teva knew of the '000 patent (and its parent patent) when it created its carve-out label and "had those patents in mind when it acted affirmatively in preparing its skinny label, an act which would have involved considerations of what uses might infringe." (*Id.* at 8)

The Report concludes that, based on the SAC, "it is plausible that Teva knew that certain language in its label would induce infringement of GSK's patent directed to a method of decreasing mortality caused by CHF." (Report at 32 n.20) The Court agrees. The SAC contains allegations that Teva knew of the patents and generated its carve-out to avoid infringing the CHF indication. (SAC at ¶¶ 49, 50, 52, 71) But it further alleges that Teva's label includes language for post-MI LVD, which directs patients to take the generic product "to reduce cardiovascular mortality in clinically stable patients . . . with . . . symptomatic heart failure." (SAC at ¶ 52) It

alleges still further that there are no substantial non-infringing uses for carvedilol, as GSK only marketed the drug for the CHF indication (in the United States) and uses for the other indications (Post-MI LVD and hypertension) are not substantial – all of which Teva is alleged to have known as it crafted its label. (SAC at ¶¶ 22, 32, 34, 52, 61, 80, 83) All of this, taken as true, supports a conclusion that GSK has plausibly alleged that Teva specifically intended third parties to infringe the '000 patent during the Relevant Period and knew that the third parties' acts would constitute infringement, which is all that must be found at this stage in order to deny Teva's motion. *See In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012); *see also* Report at 13-14.

5. Finally, the Court stresses (as did the Report) that in denying Teva's motion, the Court is not concluding that GSK will ***prove*** induced infringement. Instead, the Court is merely concluding that GSK has pled a plausible claim of induced infringement, one that must be subjected to the rigors of discovery and evidentiary proceedings. Much of Teva's attack on the Report misses the mark as it appears to be based on Teva's view (which may ultimately be correct, but which is unavailing on a motion to dismiss) that GSK will fail to ***prove*** induced infringement.

March 20, 2017
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE