IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

REPORT AND RECOMMENDATION

Presently pending in this patent infringement case is Defendant Teva Pharmaceuticals USA, Inc.'s ("Defendant" or "Teva") motion (the "Motion") 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") in GSK's Second Amended Complaint ("SAC"). (D.I. 63) For the reasons set forth below, the Court recommends that Teva's Motion be DENIED.

I. BACKGROUND[1]

A. Factual Background

1. Approval of Carvedilol by the United States Food and Drug Administration ("FDA") and the '069 Patent

[1] In this Report and Recommendation, the Court will assume familiarity with the facts and procedural history detailed in a prior opinion in this action, *GlaxoSmithKline LLC v. Glenmark Generics, Inc., USA*, No. Civ.A. 14-877-LPS, Civ.A. 14-878-LPS, 2015 WL 3793757 (D. Del. Apr. 22, 2015), *report and recommendation adopted*, 2015 WL 4730913 (D. Del. Aug. 10, 2015).

Carvedilol is a drug belonging to a class of chemical compounds known as beta blockers, which may be used to treat, *inter alia*, hypertension. (D.I. 60 (hereinafter, "SAC") at ¶ 8) In 1993, GSK filed New Drug Application ("NDA") No. 20-297 on carvedilol tablets to manage hypertension, and it received FDA approval to market the drug for this purpose in 1995. (*Id.*) However, due to the crowded market for hypertension treatment, and due to clinical studies indicating that long-term administration of carvedilol decreased the risk of mortality in patients with congestive heart failure ("CHF"), GSK held off on launching the drug in the United States at that time. (*Id.*) Instead, it worked to obtain FDA approval to market carvedilol for the treatment of CHF. (*Id.*)

CHF is a chronic clinical condition that occurs when the diseased heart's ability to pump blood has been reduced, and the heart is therefore unable to deliver sufficient oxygen to meet the body's needs. (*Id.* at ¶ 9) The condition is the end stage of the cardiovascular disease continuum—a chain of events set off by several cardiovascular risk factors such as diabetes, hypertension and obesity. (*Id.* at ¶ 10) If CHF is left untreated, it will lead to end stage heart failure and death. (*Id.* (citation omitted))

In June 1995, GSK and its research partner filed a patent application directed to a method of using carvedilol to decrease the risk of mortality caused by CHF, which later issued in June 1998 as U.S. Patent No. 5,760,069 (the "'069 patent"). (*Id.* at ¶ 35) The '069 patent is entitled "'Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure.'" (*Id.*) In 1997, GSK's carvedilol tablets became the first beta blocker to receive FDA approval for the treatment of CHF—specifically, for the treatment of mild-to-moderate CHF of ischemic or cardiomyopathic origin, in conjunction with digitalis, diuretics, and ACE inhibitor, to reduce the

progression of disease as evidenced by cardiovascular death, cardiovascular hospitalization, or the need to adjust other CHF medications. (*Id.* at ¶ 21) After that, GSK began marketing and selling its carvedilol tablets under the brand name COREG® ("COREG"), promoting only the CHF indication. (*Id.* at ¶ 22) In 2001, the FDA approved carvedilol for the treatment of mild-to-severe CHF of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors and digitalis, to increase survival and also to reduce the risk of hospitalization due to CHF. (*Id.* at ¶ 27)

Despite these FDA-approved indications, there were patients with CHF, or that were likely to develop CHF, who had recently experienced a myocardial infarction (i.e., a heart attack) and who could not receive COREG. (*Id.* at ¶ 28) This was because the drug was not approved for use by a person who had recently had a heart attack, due to concerns that such a person's condition could worsen were the drug administered in that circumstance. (*Id.*) GSK hoped to expand the use of COREG to include these persons, and it conducted two studies in that regard: the Carvedilol Heart Attack Pilot Study ("CHAPS") and the CAPRICORN study. (*Id.* at ¶¶ 29-30) In 2003, in light of positive results from these studies, carvedilol received FDA approval for the treatment of left ventricular dysfunction ("LVD") following myocardial infarction ("post-MI LVD") in clinically stable patients. (*Id.* at ¶¶ 29-31)

GSK's label for COREG has three indications (the first two of which are most relevant for purposes of this Motion):

> **1 INDICATIONS AND USAGE**
>
> **1.1 Heart Failure**
>
> COREG® is indicated for the treatment of mild-to-severe chronic

> heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and, also, to reduce the risk of hospitalization *[see Drug Interactions (7.4) and Clinical Studies (14.1)]*.
>
> **1.2 Left Ventricular Dysfunction Following Myocardial Infarction**
>
> COREG is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤40% (with or without symptomatic heart failure) *[see Clinical Studies (14.2)]*.
>
> **1.3 Hypertension**
>
> COREG is indicated for the management of essential hypertension . . . .

(SAC, ex. F (emphasis in original))

2. The Hatch-Waxman Act, FDA Requirements and the Orange Book

The Hatch-Waxman Act, codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271 and 282, strikes a balance between the competing policy interests of "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002). A brand name drug manufacturer seeking FDA approval for a drug must submit an NDA that includes, *inter alia*, a statement of the drug's components and proposed labeling describing the uses for which the drug may be marketed. 21 U.S.C. § 355(b)(1); *Caraco Pharms. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). A brand name drug may be approved for multiple methods of use—either to treat different conditions or to treat one condition in different ways. *Caraco*, 132 S. Ct. at 1676. Once a drug

has been approved by the FDA, another company may seek permission to launch a generic version of the drug by filing an Abbreviated New Drug Application ("ANDA") with the FDA. 21 U.S.C. § 355(j); *Caraco*, 132 S. Ct. at 1676. The ANDA process circumvents the lengthy approval scheme in place for NDAs by permitting generic manufacturers to depend on the safety and efficacy studies completed for the previously-approved drug, so long as there is bioequivalency between the generic drug and the previously-approved drug. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012).

When evaluating an ANDA seeking to market a generic drug, the FDA considers whether the proposed drug would infringe a patent held by the brand name manufacturer of the drug. *Caraco*, 132 S. Ct. at 1675. "[T]he Hatch-Waxman Act creates a mechanism that allows for prompt judicial determination of whether the ANDA applicant's drug or method of using the drug infringes a valid patent." *Bayer*, 676 F.3d at 1318. In line with its goals of protecting patentees and facilitating approval of generic drugs, the Act dictates that a brand name manufacturer's NDA must identify specific patent information with respect to which a claim of patent infringement could "reasonably be asserted . . . [due to] the . . . use . . . of the drug." 21 U.S.C. § 355(b)(1)(G); *see also Bayer*, 676 F.3d at 1318. This requirement also applies to patents that issue subsequent to final approval of the NDA. 21 U.S.C. § 355(c)(2); *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003). The FDA lists these identified patents in a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations*, universally referred to in the industry as the "Orange Book." *Bayer*, 676 F.3d at 1318.

If the brand name manufacturer holds a method of use patent that gives it exclusive rights

over a particular method of using the drug subject to the NDA, FDA regulations require it to: (1) indicate "[w]hether the patent claims one or more methods of using the drug product for which use approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted" and (2) provide "[i]dentification of the specific section of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted[.]" 21 C.F.R. § 314.53(c)(2)(O)(i)(1)-(2). The manufacturer's descriptions of the method-of-use patents are referred to as "use codes." *Caraco*, 132 S. Ct. at 1676. The FDA then publishes these use codes, along with the corresponding patent numbers and expiration dates, in the Orange Book. *Id.*

3. Teva's ANDA and the '000 Patent

In March 2002, Teva filed ANDA No. 76-373 seeking to market generic carvedilol tablets. (SAC at ¶ 47) At this time, the Orange Book listed the '069 patent for COREG. (*Id.* at ¶ 48) A few months later, Teva notified GSK that its ANDA included a Paragraph IV certification asserting that the '069 patent was invalid and unenforceable. (*Id.* at ¶ 49) In November 2003, the then-owner of the '069 patent instituted a reissue proceeding before the United States Patent and Trademark Office ("PTO"). (*Id.* at ¶ 36) In January 2008, the '069 patent reissued as United States Patent No. RE40,000 (the "'000 patent"), entitled "'Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure.'" (*Id.*) Claim 1 of the '000 patent recites:

> **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,

> *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.*

(SAC, ex. E ("'000 Patent"), col. 8:30-40 (emphasis in original, representing additions to the claim during the reissue proceeding)) The '000 patent expired on June 7, 2015. (*Id.* at ¶ 40)

After the '000 patent issued, GSK "submitted patent information regarding the '000 patent and requested the withdrawal of the '069 patent from the Orange Book." (*Id.*) Specifically, GSK identified "decreasing mortality caused by congestive heart failure" as being covered by the '000 patent. (*Id.*) Accordingly, in February 2008, the '000 patent was listed in the Orange Book with patent use code U-233 ("decreasing mortality caused by congestive heart failure"). (*Id.*)

4. Approval of Teva's Product and its Product Label

An ANDA applicant is required to consult the Orange Book and take action relating to all pertinent patents. *Bayer*, 676 F.3d at 1318. If a patent listed in the Orange Book is a method-of-use patent, like the '000 patent, "the generic applicant can attempt to seek FDA approval to label its drug only for uses not covered by the patent" by submitting a "section viii statement" with its ANDA. (SAC at ¶ 45); *see also* 21 U.S.C. § 355(j)(2)(A)(viii); *Bayer*, 676 F.3d at 1318. These statements are referred to as "carve-outs" or "section viii carve-outs" because they are said to "limit[] the scope of the generic manufacture[r]'s ANDA to approved indications that are not claimed by valid patents listed in the Orange Book." *Astrazeneca Pharms. LP v. Apotex Corp.*, Civil No. 10-338 (RBK/KW), 2010 WL 5376310, at *2 (D. Del. Dec. 22, 2010); *see also Bayer*,

676 F.3d at 1318.[2] This process is meant to ensure that "one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 132 S. Ct. at 1682. If the section viii carve-out is approved, "the FDA will require the generic company to duplicate only the portions of the branded drug's label not protected by the applicable method-of-use patent, as identified in the patent use code." (SAC at ¶ 45); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1046 (Fed. Cir. 2010) ("*AstraZeneca 2010*").[3] The FDA takes the use code at face value—it does not independently assess the patent's scope or otherwise look beyond the use code description written by the brand. *Caraco*, 132 S. Ct. at 1677. The FDA has described its own role with respect to patent listing as "'ministerial[,]'" *id.* (internal citation omitted), as it "is not the arbiter of patent infringement issues[,]" *AstraZeneca 2010*, 633 F.3d at 1061. Section viii statements do not require notice to the patent-holder and therefore foreclose automatic initiation of patent infringement litigation. *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 345 n.7

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[2] The section viii carve-out stands in contrast to a paragraph IV certification, which is a generic drug manufacturer's other option when the Orange Books lists a method-of-use patent set to expire after the release of the generic drug. *Caraco*, 132 S. Ct. at 1676-77. An ANDA applicant should file a paragraph IV certification (instead of a section viii carve-out) when it is "seeking approval for exactly the same labeling as that in the NDA for which the patent was submitted." *Bayer*, 676 F.3d at 1318 (quoting Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003)). Such a certification states that a listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug[,]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and pursuant to 35 U.S.C. § 271(e)(2)(A), the filing of a paragraph IV certification is treated as itself an act of infringement that gives the brand name manufacturer an immediate right to file suit, *see Caraco*, 132 S. Ct. at 1677.

[3] However, one court has noted that the "FDA has consistently determined that it can approve [section viii] ANDAs for broad, general indications that may partially overlap with a protected method of use, so long as any express references to the protected use are omitted from the labeling." *Hospira, Inc. v. Burwell*, No. GJH-14-02662, 2014 WL 4406901, at *14 (D. Md. Sept. 5, 2014) (internal quotation marks and citation omitted).

(D.N.J. 2009).

Although Teva had originally submitted a Paragraph IV certification asserting that the '069 Patent was invalid, in or about August 2007, Teva amended its ANDA to a section viii statement, and did not include in its proposed label those portions of GSK's label directly "relating to the CHF indication." (SAC at ¶¶ 49-51; *see also* D.I. 69 at 3) Teva received FDA approval for its generic version of carvedilol on or about September 5, 2007, and until May 2011, the label for its generic carvedilol tablets "carved out" the CHF indication. (SAC at ¶¶ 51, 53 & ex. J; D.I. 64 at 7)[4]

5. The Orange Book and an "AB Rating"[5]

The Orange Book also contains a coding system to identify products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products. (D.I. 65, ex. B at xiii) One such code is an "AB rating." (*Id.*) The Orange Book states explicitly that when a generic drug product is "AB-rated" or has an "AB rating[,]" that means that the product is the therapeutic equivalent to a branded drug product only if the two are "pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling" of the generic product. (*Id.* at vii; *see*

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[4] In May 2011, Teva amended its label to fully conform with GSK's label for COREG, such that Teva's label now expressly included the CHF indication. (SAC at ¶ 53 & ex. G) This time period is not relevant for purposes of Teva's Motion.

[5] To the extent the information in this subsection is not contained in the SAC itself, it comes from the 2009 print version of the Orange Book (the version issued the year after the patent-in-suit was issued); excerpts from this version of the Orange Book were attached to a declaration filed by Teva in conjunction with the instant Motion. (D.I. 65, ex. B) The Court can consider the content of the Orange Book in resolving the Motion because it is expressly referred to throughout the SAC and is integral to GSK's allegations. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

also SAC at ¶ 66) The Orange Book also states that "[t]here may be labeling differences among pharmaceutically equivalent products that require attention on the part of the health professional" and that "[a]n FDA evaluation that [two] such [pharmaceutically equivalent] products are therapeutically equivalent is applicable only when each product is reconstituted, stored, and used under the conditions specified in the labeling of that product." (D.I. 65, ex. B at xiv)

B. Procedural Background

On July 3, 2014, GSK commenced this action, as well as a related action against Glenmark Pharmaceuticals Inc., USA ("Glenmark"), *GlaxoSmithKline LLC v. Glenmark Pharmaceuticals Inc., USA*, Civil Action No. 14-877-LPS-CJB. In these actions, GSK brought claims of indirect infringement (one count of induced infringement and one count of contributory infringement) against Teva and Glenmark (collectively, "Defendants") concerning the '000 patent. (Civil Action No. 14-877-LPS-CJB, D.I. 1; Civil Action No. 14-878-LPS-CJB, D.I. 1) Glenmark and Teva moved to dismiss the complaints, (Civil Action No. 14-877-LPS-CJB, D.I. 10; Civil Action No. 14-878-LPS-CJB, D.I. 10), and in response, GSK filed a First Amended Complaint ("FAC") in each action, (Civil Action No. 14-877-LPS-CJB, D.I. 14; Civil Action No. 14-878-LPS-CJB, D.I. 16). 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. (Civil Action No. 14-877-LPS-CJB, D.I. 16; Civil Action No. 14-878-LPS-CJB, D.I. 18)

In lieu of filing Answers to the FACs, Glenmark and Teva moved to dismiss GSK's FACs in their entirety (i.e., both the induced infringement and contributory infringement counts), pursuant to Federal Rule of Civil Procedure 12(b)(6). (Civil Action No. 14-877-LPS-CJB, D.I.

18; Civil Action No. 14-878-LPS-CJB, D.I. 20)[6] The Court thereafter issued a Report and Recommendation regarding the motions to dismiss, which recommended: (1) grant of the motions to dismiss as to GSK's claims regarding induced infringement during the time periods where the CHF indication was not on Defendants' labels, with leave to amend; (2) denial of the motions as to GSK's claims regarding induced infringement during the time periods where the CHF indication was on Defendants' labels; and (3) denial of the motions as to GSK's claims for contributory infringement. (Civil Action No. 14-877-LPS-CJB, D.I. 38; Civil Action No. 14-878-LPS-CJB, D.I. 39) The District Court later adopted the Report and Recommendation in its entirety, over Defendants' objections. (Civil Action No. 14-877-LPS-CJB, D.I. 54; Civil Action No. 14-878-LPS-CJB, D.I. 55)

GSK then filed its SAC in this action. (D.I. 60) In lieu of filing an Answer, on September 14, 2015, Teva filed the instant Motion, seeking dismissal of GSK's claims for inducement of infringement for the pre-May 2011 time period (i.e., when Teva's label carved out the CHF indication). (D.I. 63)[7] After Teva's Motion was fully briefed, (D.I. 70), the Court held oral argument regarding the Motion on March 1, 2016, (D.I. 132 (hereinafter, "Tr.")). Following

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[6] As was the case with Teva, when Glenmark's generic carvedilol tablets launched in September 2007, Glenmark's label carved out the CHF indication. (Civil Action No. 14-877-LPS-CJB, D.I. 59 at ¶ 49) However, it is alleged that between about August 2009 and about August 2010, Glenmark revised its label for generic carvedilol tablets to fully conform with and be identical (for all relevant purposes) to GSK's label for COREG, such that the label expressly included the CHF indication. (*Id.* at ¶¶ 51-52 & ex. G) Thereafter, it appears that Glenmark switched back to the version of the label that it had utilized prior to about August 2009. (*Id.* at ¶¶ 52, 59)

[7] Teva later filed an Answer to the SAC, (D.I. 105), in which it noted that the Answer was being "submitted subject to and without intending to waive Teva's [M]otion[,]" (*id.* at 1).

oral argument, GSK submitted a supplemental letter brief on March 3, 2016. (D.I. 124)

Meanwhile, in April 2015, with Defendants' motions to dismiss the FACs then pending, the Court entered a Scheduling Order governing these related cases. (Civil Action No. 14-877-LPS-CJB, D.I. 37; Civil Action No. 14-878-LPS-CJB, D.I. 38) Discovery has been ongoing, with fact discovery having been completed on July 1, 2016. (Civil Action No. 14-877-LPS-CJB, D.I. 121; Civil Action No. 14-878-LPS-CJB, D.I. 151) A five-day trial is scheduled to begin on June 12, 2017. (Civil Action No. 14-877-LPS-CJB, D.I. 37; Civil Action No. 14-878-LPS-CJB, D.I. 38)

II. LEGAL STANDARDS

A. Motion to Dismiss

The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In assessing the plausibility of a claim,

the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

B. Induced Infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." In order to prove induced infringement, the patentee "must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012) (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010)); *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1292-93 (Fed. Cir. 2008) ("Thus, 'inducement requires evidence of culpable conduct, *directed to encouraging* another's infringement, not merely that the inducer had knowledge of the direct infringer's activities.'") (emphasis added) (citation omitted). Moreover, the United States Court of Appeals for the Federal Circuit has recognized that "mere knowledge of possible infringement by others does not amount to inducement; specific intent *and action* to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (emphasis added); *see also Novartis Pharms., Corp. v. Wockhardt USA LLC*, Civil Action No. 12-cv-3967, 2013 WL 5770539, at *9 (D.N.J. Oct. 23, 2013) (noting that inducement involves the taking of "'affirmative steps'") (internal citations omitted).

To survive Teva's Motion, then, GSK's SAC must contain facts that make out a plausible claim of inducement as delineated above: "facts plausibly showing that [Teva] specifically

intended [third parties] to infringe the ['000 patent] and knew that the [third party's] acts constituted infringement." *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012). "This does not mean, however, that [GSK] must prove its case at the pleading stage." *Id.* (citations omitted).

III. DISCUSSION

Before assessing the sufficiency of GSK's current claim for induced infringement during the pre-May 2011 time period, the Court offers a brief review of its reasoning for dismissing GSK's prior allegations directed to this claim. *GlaxoSmithKline LLC v. Glenmark Generics Inc., USA*, No. Civ.A. 14-877-LPS, Civ.A. 14-878-LPS, 2015 WL 3793757 (D. Del. Apr. 22, 2015) ("*GlaxoSmithKline I*"), *report and recommendation adopted*, 2015 WL 4730913 (D. Del. Aug. 10, 2015). There, GSK had pointed to two paragraphs in its FAC as providing the requisite factual specificity in support of its claim:

> 55. In addition, even prior to its labeling change, [Teva] caused its generic carvedilol . . . tablets to be listed in the Orange Book with a therapeutic equivalence rating of "AB," which indicates that its generic copies are considered therapeutically equivalent to COREG® on all indications approved for the generic drug. *On information and belief, since the approval of its ANDA . . . [Teva] has actively promoted the "AB" rating of its generic carvedilol tablets and marketed them as therapeutically equivalent to and fully substitutable for GSK's COREG®* tablets indicated for treatment of CHF. Although the Orange Book states explicitly that an AB rating is limited to what is on the generic's approved label . . . [Teva] never informed the public that its generic carvedilol was not approved by the FDA for the CHF indication when it touted its generic copy as AB-rated and fully substitutable for COREG®.
>
> 56. On information and belief, [Teva] knew that when an AB-rated generic drug is available, many states and/or third party payers of prescription drugs (e.g., health insurance plans, Medicare and Medicaid programs) have adopted policies to encourage or

> require the substitution of the AB-rated generic drugs for the branded drugs, regardless of whether the generic drug label includes all the indications contained in the branded drug label. [Teva] also knew that unless informed otherwise, the market would assume that, like most-AB-rated generic drugs, [Teva's] generic carvedilol tablets were labeled identically to COREG® and included the CHF indication. *As a result, by promoting its generic carvedilol tablets as AB-rated and fully substitutable for COREG®* without informing the market that its generic carvedilol tablets were not approved for the CHF indication, [Teva] knew and intended that its generic carvedilol tablets would be substituted for COREG® for patients prescribed the drug for treatment of congestive heart failure in the direct infringement of the '000 patent.

GlaxoSmithKline I, 2015 WL 3793757, at *4-5 (quoting D.I. 16 at ¶¶ 55-56) (emphasis in opinion, but not contained in the text of the FAC itself). While GSK asserted that the sentences rendered in italics above made its inducement claims plausible, the Court disagreed. Instead, the Court explained that "these key sentences suffer from a particular lack of any meaningful factual content." *Id.* at *6. For instance, the Court noted that the sentences were silent as to "[w]hat type of 'market[ing]' and 'promoting' [was Teva] alleged to have engaged in that gives rise to the claim?" *Id.*

GSK now asserts that the allegations of its SAC "answer[] this question in spades." (D.I. 69 at 10) Teva disagrees, arguing that GSK's SAC "has not cured the defects" of GSK's prior complaint. (D.I. 64 at 19) More specifically, Teva argues that GSK has failed to plausibly allege that Teva possessed the specific intent to induce infringement in the relevant time period, or plausibly allege that Teva knew that infringement by third parties (here, medical professionals and/or patients) was occurring in the time period. (D.I. 64)

In explaining why it has sufficiently articulated a plausible claim, GSK points to two

primary aspects of the SAC. The first is the SAC's allegations regarding certain ways in which Teva actively promoted its generic carvedilol tablets (i.e., by publicizing the drug's "AB rating" and by disseminating certain press releases), both prior to and during the relevant time period. (D.I. 69 at 1-2) The second relates to the explicit contents of Teva's carve-out label. (*Id.*) While keeping in mind that GSK's theory of inducement is based on "the totality" of its allegations, (*see, e.g.*, Tr. at 56-58), for ease of discussion, the Court will analyze these two different sets of allegations in turn. After doing so, the Court will also touch on some additional allegations in the SAC that, in the Court's view, further bolster GSK's claim.

1. Teva's Active Promotion of its Generic Carvedilol Tablets

In the SAC, GSK includes a number of allegations regarding certain ways in which Teva actively promoted its generic carvedilol tablets prior to and during the relevant time period:

> 62. . . . Teva caused its generic carvedilol 3.125 mg, 6.25 mg, 12.5 mg and 25 mg tablets to be listed in the Orange Book with a therapeutic equivalence rating of "AB," which indicates that its generic copies are considered therapeutically equivalent to COREG® on all indications approved for the generic drug. On information and belief, since the approval of its ANDA No. 76-373, Teva has actively promoted on its website and other marketing materials the "AB" rating of its generic carvedilol tablets and marketed them as therapeutically equivalent to and fully substitutable for GSK's COREG® tablets indicated for treatment of CHF.
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> 63. For example, Teva's June 9, 2004 press release announcing the tentative approval of its generic carvedilol tablets states, "Carvedilol Tablets are the AB-rated generic equivalent of GlaxoSmithKline's COREG® Tablets and are indicated for treatment of *heart failure* and hypertension." [] Teva's press release stated that COREG®'s annual sales were approximately $670 million. [] Those sales, of course, included sales used to treat patients with CHF symptoms.
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> 64. On September 6, 2007, Teva announced final FDA approval for

its generic version of GSK's COREG® tablets and that COREG®'s U.S. sales were approximately $1.7 billion annually. [] Again, the sales number included sales of COREG® used to treat patients suffering from CHF symptoms.

65. On information and belief, Teva registered its generic Carvedilol Tablets with data aggregators (e.g., Red Book) as AB-rated to COREG®. And Teva's Product Catalog,[8] which is available on Teva's website, has identified Teva's Carvedilol Tablets as "AB Rated and bioequivalent to COREG® Tablets."

66. Although the Orange Book states explicitly that an AB rating is limited to what is on the generic's approved label . . . Teva never informed the public that its generic carvedilol was not approved by the FDA for the CHF indication when it touted its generic copy as AB-rated and fully substitutable for COREG®.

67. On information and belief, Teva knew that when an AB-rated generic drug is available, many states and/or third party payers of prescription drugs (*e.g.*, health insurance plans, Medicare and Medicaid programs) have adopted policies to encourage or require the substitution of the AB-rated generic drugs for the branded drugs, regardless of whether the generic drug label includes all the indications contained in the branded drug label. Teva also knew that unless informed otherwise, the market would assume that, like most AB-rated generic drugs, Teva's generic carvedilol tablets were labeled identically to COREG® and included the CHF indication. As a result, by promoting its generic carvedilol tablets as AB-rated and fully substitutable for COREG® without informing the market that its generic carvedilol tablets were not approved for the CHF indication, Teva knew and intended that its generic carvedilol tablets would be substituted for COREG® for patients prescribed the drug for treatment of CHF resulting in the direct infringement of the '000 patent.

(SAC at ¶¶ 62-67 (internal citations omitted) (emphasis in original)) These allegations raise a

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[8] With regard to the reference to Teva's Product Catalog, that catalog also notes that the "AB" code and other similar codes are "published in FDA's Orange Book[.]" (D.I. 65, ex. C) As is further noted below, the Orange Book, in turn, explains that a generic drug product is the therapeutic equivalent of a branded drug only for those uses listed on the generic product's label. (D.I. 64 at 13 n.7)

few different issues, which the Court will assess below.

a. The "AB rating"

As it did when addressing Defendants' motions to dismiss the FAC, here again GSK seems to suggest that alleging the mere fact that Teva promoted its drug as "AB rated" to COREG should be enough to set out a plausible claim for inducement, given the way some in the market can sometimes misperceive what it means for a drug to be "AB-rated" to another drug. (D.I. 69 at 10-12)[9] In dismissing GSK's induced infringement claim in the FAC for the pre-May 2011 time period, the Court explained its view as to why simply making the bald statement that Teva was actively "promoting its generic carvedilol tablets as AB-rated and fully substitutable for" COREG—standing alone—was not sufficient to plausibly allege Teva's intent to induce infringement. To that end, the Court stated that "[i]t is hard to conclude that Defendants' obtaining an AB rating in the Orange Book for their product, standing alone, could amount to sufficient 'action' to encourage infringement of a patented use [i.e., the CHF indication] *not listed* on their label—when the Orange Book affirmatively instructs that a generic drug product is the therapeutic equivalent of a branded drug only for those uses *listed* on the Defendants' label." *GlaxoSmithKline I*, 2015 WL 3793757, at *5 (emphasis in original).

The Court remains unconvinced that this conclusion was incorrect. "Obtaining [an] AB rating is a perfectly lawful step, created and regulated by the FDA." *Organon Inc. v. Teva Pharms., Inc.*, 244 F. Supp. 2d 370, 379 (D.N.J. 2002). Indeed, at least one court has noted that

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[9] The new allegations in the SAC on this topic (as compared to what was in the FAC) simply add some detail about the particular locations where Teva published these statements about the "AB rating" (such as on its website or in materials produced by data aggregators).

advertising a product as an "AB-rated bioequivalent" to a brand name drug is "the only realistic way [for an entity like Teva] to market their product at all." *Id.*; *see also* (Tr. at 15-16). Moreover, the FDA is the entity that has given meaning to the term "AB rated." And in the Orange Book, the FDA has explained that meaning: if a drug (like Teva's generic carvedilol) is "AB-rated" to COREG, then it is bioequivalent to COREG, and it is therapeutically equivalent to COREG *but only for the conditions or uses specified in the labeling for Teva's product.* (D.I. 65, ex. B at xiii, xiv; SAC at ¶ 66)

So although GSK alleges that Teva is suggesting to third parties that its generic product was "therapeutically equivalent to and *fully substitutable* for" COREG, (SAC at ¶ 62 (emphasis added)), under the circumstances here, Teva's simple claim that its product is "AB-rated" to COREG (again, if there were not anything more alleged) could not amount to meaningful evidence in support of that claim.[10] If anything, where a section viii carve-out is utilized, a generic manufacturer's statement that its product was "AB-rated" to a branded drug would typically be, as a definitional matter, more akin to a statement that its drug was *not* "fully substitutable" for the branded drug (e.g., *not* therapeutically equivalent for any use that was

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[10] Indeed, were this not the case, then the concept behind the utilization of a section viii carve-out would seem to be frustrated. Any generic drug manufacturer who utilized such a carve out, but nevertheless stated that its product was "AB-rated" to a branded drug product, would be potentially liable to the branded patent-holder for infringement as to the carved-out method of use. *Cf. AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) ("*AstraZeneca 2012*") (finding the plaintiffs' argument that "Section viii [carve-outs] . . . ignore market realities because even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available" to be "unpersuasive" because that position would, "in practice[] vitiate" the statute permitting such carve-outs "by enabling [] infringement claims [pursuant to 35 U.S.C. § 271(e)(2)] despite the fact that [defendant's] Section viii statements and corresponding proposed labeling explicitly and undisputedly carve out all patented indications for [the drug]").

carved out of the generic's label).[11]

In so concluding, the Court acknowledges GSK's allegations, (*see, e.g.*, SAC at ¶ 67), that despite the above-referenced meaning of an "AB rating," third parties would nevertheless see Teva's statements about that rating and substitute Teva's generic drug for GSK's branded version—without any concern for whether the generic drug label actually includes all of the indications that are contained in the branded drug label. And GSK further alleges that "[o]n information and belief" Teva knew this, and that it intended to take advantage of this reality, by promoting the "AB rating" so that this would come to pass. (*Id.*) But in the Court's view (again, absent any other evidence that speaks to a generic manufacturer's intent), a finding in this context that the promotion of an "AB rating" could amount to a plausible induced infringement claim would go too far. It would rely too heavily on the mindset or misconceptions of *third parties* in an attempt to ascribe wrongful intent to the alleged inducer. *Cf. Warner-Lambert Co.*, 316 F.3d at 1364 ("[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven."). Perhaps if there were facts pleaded in a section viii carve-out case stating that the alleged inducer affirmatively took other actions to tell physicians or consumers that its product was "fully substitutable" for the branded drug product (e.g., facts indicating that the generic's representatives used those very words when describing how its product could be used as compared to the branded drug), that would be different. Or perhaps the conclusion would be different in a case like this if the branded

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[11] Moreover, to the extent that Teva was (via its Product Catalog) pointing third parties *to* the Orange Book in explaining where an "AB rating" comes from, (SAC at ¶ 65; D.I. 65, ex. C), then Teva was directing the third parties to the very publication that would further make the above-referenced distinctions clear.

manufacturer offered more than "information and belief" that the generic manufacturer's intent was to engage in a concerted effort to prey upon these market-based misconceptions as to what an "AB rating" means. But none of those kinds of allegations are in the SAC.[12]

All of the above is to say that, if GSK's only allegations as to Teva's specific intent to induce infringement related to Teva's promotion of its drug as "AB rated" to COREG, then the Court would not find that GSK had made out a plausible claim of induced infringement in the relevant time period. But this is not all that GSK pleaded in the SAC.[13]

b. The press releases

GSK also points to the two press releases (one from June 2004 and one from September

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[12] If the "AB-rating"-related allegations were all that GSK had here, then its induced infringement claim for the pre-May 2011 time period would also not be saved by its further allegations as to what Teva *did not* do in the relevant time period. That is, one of GSK's allegations is that Teva did not affirmatively inform the public that its drug was only "AB-rated" for hypertension and post-MI LVD (and that its drug was *not* "AB-rated" for COREG's CHF-only indication). (Tr. at 77, 80-81; *see also* SAC at ¶ 67) But the Federal Circuit has recently rejected a similar line of argument in which the patentee suggested that the generic manufacturer's label "needs to contain a 'clear statement' to show that it was avoiding [the patented] indication." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015) (citation omitted). The Federal Circuit explained that such a requirement would "turn[] the legal test on its head. [The patentee] needs to show that [the generic manufacturer/defendant] took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Id.*

[13] Below, the Court will set out why other allegations in the SAC help to make out a plausible claim of induced infringement in the relevant time period. In light of that conclusion, the Court does not agree with Teva that GSK's allegations regarding Teva's trumpeting of an "AB rating" amount to a "theory" that "must be dismissed" or otherwise stricken from the SAC. (Tr. at 17) Despite what is said above, it is possible that evidence of Teva's marketing of its drug as "AB rated" *combined with* the other facts alleged in the SAC (and other facts further developed during discovery) could be a part of a winning induced infringement argument for GSK. Again, the Court's point here is simply that if GSK's allegations regarding the "AB rating" were all that it had, that could not be enough to withstand a motion to dismiss.

2007), identified in paragraphs 63 and 64 of the SAC, as further evidence of Teva's specific intent to target the entire market for carvedilol—including the treatment of CHF patients. (D.I. 69 at 10 n.5 & 11; Tr. at 53-58) Teva counters that the press releases are irrelevant to the induced infringement inquiry, since they were published before the '000 patent issued. (D.I. 64 at 9-10; D.I. 70 at 7-8) The Court disagrees with Teva.

It is true, as Teva points out, (D.I. 70 at 8), that the Federal Circuit held in *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996), that "the general rule is that inducement of infringement under § 271(b) does not lie when the acts of inducement occurred before there existed a patent to be infringed." This was so even where the actor had knowledge of a pending patent application and the intent that, as a direct result of its actions, there would be direct infringement by others after the patent issues. *Nat'l Presto Indus.*, 76 F.3d at 1196. It is notable, however, that in *Nat'l Presto Indus.*, *all* of the relevant acts took place before the patent had issued; indeed, the patent issued on the very same day that the plaintiff filed suit against the defendant alleging, *inter alia*, induced infringement. *Id.* at 1194. In contrast to the facts at issue in *Nat'l Presto Indus.*, where there are acts of inducement that *continue* after the issuance of a patent, courts have indicated that acts occurring prior to the patent's issuance could still be relevant to an induced infringement claim. *See, e.g.*, *L.A. Biomed. Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, Case No. LA CV13-08567 JAK (JCGx), 2014 WL 11241786, at *3 (C.D. Cal. May 12, 2014) (declining to dismiss an induced infringement claim where culpable conduct began before the issuance of the patent because "the complaint contains allegations of continued culpable conduct after the issuance of the patent"); *CreAgri, Inc. v. Pinnaclife Inc.*, Case No.: 5:11-CV-06635-LHK, 2013 WL 3958379, at *4-5 (N.D. Cal. July 29,

2013) ("The Court is not persuaded that [the defendant's] activities cannot support an inference of intent simply because the activities began before the [asserted] [p]atent was issued. To the extent [the defendant] continued these activities after the patent was issued, the continued activities reflect an intent to infringe upon the [asserted] [p]atent.").

These rulings make good sense. The question is whether a party had the intent to and did encourage the wrongful act of patent infringement in the relevant time frame—*after* a patent has issued. *See Nat'l Presto Indus.*, 76 F.3d at 1194. And surely it seems possible that what the party did and said *before* the patent issued might at least *bear on* what its mindset was in the crucial post-issuance time period (so long as that party did, in fact, perform an inducing act in that post-issuance time period).[14]

In this case, as the Court will further discuss below, GSK *has* alleged acts of inducement that occurred after the issuance of the '000 patent. And so, for example, as to the September 2007 press release, although it was sent out prior to the issuance of the '000 patent in January 2008, the document can still bear on Teva's intent to capture the CHF market after the patent issued a few months later. That press release came at a time when Teva had amended its proposed label in a stated attempt to carve out the CHF indication. Despite this, the press release notes that COREG had annual sales of "approximately $1.7 billion in the United States"—a sales figure that undisputedly includes sales from the treatment of CHF patients. (SAC, ex. L; *see also id.* at ¶ 64; D.I. 69 at 11) It may be seen as a small piece of intent evidence in and of itself. But it is nevertheless *some* evidence that can be used to make the case that Teva targeted the CHF

[14] Indeed, when questioned further about this conclusion at oral argument, Teva's counsel did not appear to dispute the rationale behind it. (*See* Tr. at 12-15)

market after January 2008 (and thus then intended to take aim at *all* of the $1.7 billion in sales opportunities that were referred to in the September 2007 press release).[15]

2. Contents of Teva's Label

GSK's SAC also points to another type of conduct that is said to be evidence of inducement of infringement during the pre-May 2011 period: that relating to the content of and promotion of Teva's carved-out (or "skinny") label for its generic carvedilol tablets. Here, GSK asserts that certain language in that label—language relating to the indication for treatment of post-MI LVD—actually amounts to encouragement for doctors and patients to use Teva's drug to infringe the '000 patent. (SAC at ¶¶ 28-30, 52) In other words, GSK is alleging that the FDA-approved post-MI LVD indication is drafted in such a way that it "still included an indication *to reduce cardiovascular mortality in CHF patients* who also suffered from [p]ost-MI LVD[,]" such that "[b]y including the [post-MI LVD] indication on its skinny label, Teva was knowingly instructing and encouraging physicians to prescribe its generic carvedilol to patients, *including patients with CHF*, for a period of more than six months to reduce the risk of mortality." (D.I. 69 at 4 (emphasis added))[16] The specific portions of Teva's skinny label that GSK highlights in

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[15] As for the June 2004 press release, Teva notes that it was not only disseminated three and a half years prior to the issuance of the '000 patent, but it also was circulated at a very different stage—at a point when Teva was clearly planning to include the CHF indication on its label, because it had previously filed a Paragraph IV certification challenging the validity of the '069 patent. (Tr. at 13-14) The Court understands, however, that GSK is pointing to the 2004 press release simply to underscore its claim that for many years, in one way or another, Teva had designs on the CHF market for carvedilol. (*See id.* at 53-56) Therefore, the Court finds that it could amount to a relevant piece of evidence as to an induced infringement claim.

[16] It is fair to say that when GSK previously responded to Defendants' first motion to dismiss, GSK did not highlight this particular argument then as a reason why dismissal was inappropriate. (Tr. at 59) But the Court agrees with GSK that this should not preclude it from

making this argument are italicized below:

- From the "Indications and Usage" section:

  1.2 Left Ventricular Dysfunction Following Myocardial Infarction

  Carvedilol tablets are indicated *to reduce cardiovascular mortality in clinically stable patients* who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤40% (*with* or without *symptomatic heart failure*).

- From "Clinical Studies" section 14.2:

  CAPRICORN was a double-blind study comparing carvedilol and placebo in 1,959 patients with a recent myocardial infarction (within 21 days) and left ventricular ejection fraction of ≤40%, *with (47%)* or without *symptoms of heart failure*.

- From "Heart Failure/Fluid Retention" Section 5.4:

  Worsening *heart failure* or fluid retention may occur during up-titration of carvedilol.

- From "Patient Advice" section 17.1:

  Patients should consult their physicians if they experience signs or symptoms of *worsening heart failure* such as weight gain or increasing shortness of breath.

(SAC, ex. J (cited in SAC at ¶ 52) (emphasis added))

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relying on the argument now. Although GSK did not put the argument front and center in responding to the prior motion, the factual basis to support the theory was at least present in the FAC. (D.I. 124 at 1-2; *see also* D.I. 16 at ¶ 26 & ex. G) And in responding to the prior motion to dismiss, GSK did at times explain that there was overlap between the post-MI LVD patient population and the CHF patient population that take carvedilol. (*See* D.I. 124) Thus, when the Court ordered that GSK could amend its FAC to more fully plead additional facts showing why Defendants induced infringement during the pre-May 2011 time period, it is understandable that GSK would then set out additional facts relating to this theory in the SAC. (*Id.* at 2-3) Therefore, the Court cannot find a reason why permitting GSK to press this theory now is unfair to Teva.

Teva, however, argues to the contrary that GSK's theory cannot possibly amount to a plausible claim of induced infringement. More specifically, Teva states that the Federal Circuit has espoused the rule that "a generic drug's label cannot as a matter of law induce an allegedly patented use if the generic drug is not approved for that use." (D.I. 70 at 1; *see also* D.I. 64 at 16; Tr. at 29-30) In support of this argument, Teva relies heavily on the Federal Circuit's decisions in three cases: *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), *Allergan, Inc. v. Alcon Labs, Inc.*, 324 F.3d 1322 (Fed Cir. 2003), and *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012). (D.I. 64 at 16-17) In these three ANDA cases, the Federal Circuit held that the generic manufacturers' ANDAs could not form the basis of an induced infringement claim pursuant to 35 U.S.C. § 271(e)(2) where they sought approval to market generic forms of drugs for uses that were not covered by a valid patent.[17] *Allergan*, 324 F.3d at 1332-34; *see also Bayer*, 676 F.3d at 1319, 1326; *Warner-Lambert Co.*, 316 F.3d at 1360, 1362. It is true (as GSK notes) that the patented uses at issue in those three cases were not approved by the FDA, while here, COREG was FDA-approved for the patented use. ("GSK's Presentation" Slides at 22-24); *see Bayer*, 676 F.3d at 1326; *Warner-Lambert Co.*, 316 F.3d at 1353; *Allergan*, 324 F.3d at 1334. But the Federal Circuit has explained that this distinction would not have made a difference in the outcomes of the three cases cited above:

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[17] Of course, while these were ANDA cases where the generic manufacturer had not yet entered the market, once the generic drug does enter the market, the brand name companies have the ability to sue for induced infringement under Section 271(b). *See Astrazeneca Pharms. LP*, 2010 WL 5376310, at *14 ("If Plaintiffs believe that Defendants will induce doctors to infringe the [relevant patents] upon approval of Defendants' ANDAs, they must assert a 'traditional' inducement claim under Section 271(b),[] not a claim under Section 271(e)(2)."), *aff'd*, 669 F.3d 1370 (Fed. Cir. 2012). That is what has happened in this case.

> [T]he [Hatch-Waxman] Act allows generic manufacturers to limit the scope of regulatory approval they seek—and thereby forego Paragraph IV certification and a [Section] 271(e)(2) infringement suit—by excluding patented indications from their ANDAs. We see no reason why those provisions would, on the one hand, foreclose [Section] 271(e)(2) liability if an ANDA excludes a patented but *unapproved* use as in *Warner-Lambert*, and yet, under otherwise identical circumstances, allow [the brand drug company] to pursue [Section] 271(e)(2) claims based on the patented, *FDA-approved* uses that were carved out in this case.

AstraZeneca 2012, 669 F.3d at 1379-80 (emphasis in original).

It could be, as GSK argues, that the results in these three ANDA cases can be distinguished on the ground that there, there was *no reasonable dispute* that the patents-in-suit "did not cover the uses of the drugs-in-suit described in the accused infringers' proposed labels." (D.I. 69 at 13)[18] But what the three cases *cannot* stand for is the proposition that Teva puts forward: that an induced infringement claim against a generic manufacturer can *never* be successful if (1) the generic has attempted to utilize a section viii carve-out; (2) has asserted to the FDA that in doing so, it is not seeking approval for a different, patented use for the drug; and (3) the FDA permitted the generic to go to market with the carved-out label. This is made clear

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[18] *See Bayer*, 676 F.3d at 1320 (the asserted patent claimed a method of use consisting of simultaneously achieving an anti-androgenic effect, and anti-aldosterone effect and a contraceptive effect, while the use set forth in the "Indications and Usage" section of the generics' proposed label was for the prevention of pregnancy in women who elect to use an oral contraceptive); *Allergan*, 324 F. 3d at 1323-24, 1328 (explaining that the generics did not seek FDA approval for the methods of using the drug at issue claimed in the asserted patents); *Warner-Lambert*, 316 F.3d at 1354-55 (noting that the generic manufacturer submitted an ANDA for approval to market a drug for a use not covered by an existing patent); *see also AstraZeneca 2012*, 669 F.3d at 1379-80 (noting that the brand name company has not alleged that the generics' ANDAs seek FDA approval for uses of rosuvastatin calcium covered by the asserted patents and that the generics' proposed labeling "explicitly and undisputedly carve[d] out all patented indications for rosuvastatin calcium").

by the Federal Circuit's holding in *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010).

In that case (referred to herein as "*AstraZeneca 2010*"), the FDA had approved the plaintiffs' ("AstraZeneca") NDA for a budesonide inhalation suspension; the Orange Book entry for AstraZeneca's product included a listing of the two AstraZeneca-owned patents-in-suit. *See AstraZeneca 2010*, 633 F.3d at 1046. The two patents included method and product claims directed to administering the drug once daily. *Id.* at 1046-47. AstraZeneca's label for the drug, however, indicated that the drug was approved for administration once or twice daily, that the drug was available in three strengths (0.25 mg, 0.5 mg and 1.0 mg per 2 mL vial), and that it shared a table of recommended starting doses based on patient history. *Id.* at 1047. The label also warned that patients should "'titrate down'" or "'downward-titrate'" to the "'lowest effective dose'" of the medication, in order to avoid any adverse effects from excessive use of the drug. *Id.* It was undisputed that the FDA required all manufacturers of the drug product to include this downward-titration language in the labels of their products. *Id.*

The defendant ("Apotex") later submitted an ANDA seeking FDA approval to manufacture and sell a generic version of the drug in question for twice-daily use—a type of use that was clearly "not claimed in" the patents-in-suit. *Id.* Apotex's ANDA included a proposed label for the generic drug that was identical to the branded label in most respects, but "would contain no explicit mention of once-daily administration." *Id.* The label did, however, retain the FDA-mandated downward-titration language that was in AstraZeneca's label, and the label indicated that the generic drug would be available in only two strengths (0.25 mg and 0.5 mg per

2 mL vial). *Id.*

The day after Apotex's ANDA was approved, AstraZeneca initiated a declaratory judgment action and moved for a preliminary injunction barring Apotex from distributing its generic drug. *Id.* at 1047-48. Among AstraZeneca's claims was that the downward-titration statements in Apotex's proposed label (e.g., "'it is desirable to downward-titrate to the lowest effective dose once [the desired clinical effect] is achieved'") would effectively instruct consumers to use the drug once daily such that it would induce infringement of the patents-in-suit. *Id.* at 1048, 1057.

The district court agreed with AstraZeneca. Because the recommended starting dose for certain patients was 0.5 mg daily administered twice daily in divided doses, the district court reasoned that the first step in titrating down from such a dose would be to 0.25 mg once daily (since there was no way of decreasing the amount of each dose below 0.25 mg). *Id.* at 1057. It thus found that the "downward-titration language would necessarily lead patients to use a 0.25 mg vial of the drug once-daily." *Id.* The district court came to this conclusion even though: (1) the FDA had previously issued a letter agreeing that the downward-titration language in Apotex's ANDA did *not* teach once-daily use and was *not* protected by the patents-in-suit; and (2) the FDA had required Apotex to include the downward-titration statements in its proposed label. *Id.* at 1048, 1057-59.

The Federal Circuit affirmed the district court's conclusion in this regard. In doing so, it noted that inducement of infringement requires evidence of "'active steps'" to encourage direct infringement, and that such active steps could include "'advertising an infringing use or

instructing how to engage in an infringing use[.]'" *Id.* at 1059 (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)); *see also Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 634 (Fed. Cir. 2015). The *AstraZeneca 2010* Court found that the "pertinent question is whether the proposed label instructs users to perform the patented method[; if it does, then] the proposed label may provide evidence of [a generic manufacturer's] affirmative intent to induce infringement." 633 F.3d at 1060. The Federal Circuit agreed that Apotex's label provided such evidence, because it "would inevitably lead some customers to practice the claimed method." *Id.* The *AstraZeneca 2010* Court also relied on the fact that there was evidence that Apotex knew that its "label presented infringement problems" but that it utilized the label nonetheless. *Id.* at 1060-61.[19] The Federal Circuit's decision was not impacted by the fact that Apotex had relied on the FDA's statements that the downward-titration language did not teach once-daily use and was not protected by the patents-in-suit, since "the FDA is not the arbiter of patent infringement issues." *Id.* at 1061.

The decision in *AstraZeneca 2010* indicates that 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.

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[19] This evidence included the fact that (although Apotex strongly felt that its label did not encourage infringement) after AstraZeneca expressed concern to Apotex about the label, Apotex sent the FDA proposed amendments to the label. *AstraZeneca 2010*, 633 F.3d at 1058. These proposed amendments further emphasized that Apotex was encouraging only twice-daily use of the drug, not once-daily use. *Id.* at 1058-59. The FDA rejected those proposed changes. *Id.*

See United Therapeutics Corp. v. Sandoz, Inc., Civil Action Nos. 12-CV-01617, 13-CV-316, 2014 WL 4259153, at *9, *14, *21 (D.N.J. Aug. 29, 2014) (explaining that an ANDA label that actually instructs physicians to practice the patented method may constitute evidence of the generic drug company's intent to induce physicians to engage in infringing conduct, even where a generic company employed a section viii carve-out, but only if the "instructions [are] such that a court can 'infer from those instructions an affirmative intent to infringe the patent'") (citation omitted); *cf. L.A. Biomed. Research Inst.*, 2014 WL 11241786, at *5 (distinguishing *Warner-Lambert* as a case where "the label itself did not give rise to any inference of inducement because the alleged infringing use was unrelated to the language on the label"). And that is exactly what GSK argues happened here. GSK is asserting in the SAC that, despite "carving out" the CHF indication, Teva's skinny label "still instructed and encouraged administering Teva's generic carvedilol tablets long term (extending for more than six months unless terminated by unintended adverse events) to decrease a risk of mortality caused by CHF"—an allegedly infringing use. (SAC at ¶ 52; *see also* D.I. 69 at 13; Tr. at 65 ("[A]ll [of the above-italicized] instructions, including the studies, and that parenthetical in [the post-MI LVD] indication, are relating to patients with CHF and encouraging the physicians to treat their patients who have [post-MI LVD] but are also symptomatic with CHF.")) In other words, the '000 patent "is alleged to cover the use of carvedilol described in Teva's skinny label[.]" (D.I. 69 at 13; *see also* GSK's Presentation Slide at 24)

Taking the decision in *AstraZeneca 2010* into account, the Court agrees with GSK that it is plausible that Teva's promotion of its skinny label encouraged infringement of the '000 patent

during the relevant time period. Most critically, the post-MI LVD indication in Section 1.2 of Teva's label conveys that Teva's generic carvedilol tablets are indicated "to reduce cardiovascular mortality in clinically stable patients . . . with . . . symptomatic heart failure." (SAC at ¶ 52 & ex. J at Section 1.2) This excerpt from the post-MI LVD instruction is similar to the carved-out CHF indication, which instructs that carvedilol tablets "are indicated *for the treatment of* mild-to-severe *chronic heart failure* of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors and digitalis, *to increase survival*[.]" (*Id.*, ex. F at Section 1.1 (emphasis added)) In light of the similarity in the wording of the two indications (along with the other language from Teva's label quoted in paragraph 52 of the SAC), it is plausible that Teva's skinny label alone could "inevitably lead some consumers to practice the claimed method." *AstraZeneca 2010*, 633 F.3d at 1060.[20]

Indeed, in its briefing, Teva never really provided an argument as to why this conclusion is an *implausible* one. (*See* D.I. 64, 70)[21] At oral argument, the Court thus put this question to

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[20] As for Teva's argument that "[t]here is no allegation [in GSK's SAC] from which this Court can reasonably infer that Teva knew that it was (allegedly) inducing infringement of the '000 patent by including the [p]ost-MI LVD [indication] on its label[,]" (D.I. 64 at 18), the Court does not agree. GSK alleges in the SAC that Teva knew about the '069 and '000 patents, and that Teva generated its section viii carve-out label. (SAC at ¶¶ 49, 50, 52, 71) From these allegations, 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.

[21] Instead, much of Teva's briefing on this issue was focused on the argument that treating *post-MI LVD* is not an infringing use of the '000 patent. (*See, e.g.*, D.I. 64 at 14; D.I. 70 at 6) But at oral argument, even Teva's counsel acknowledged that GSK is not asserting that "treatment of [post-MI LVD] is, in and of itself, an infringing use." (Tr. at 20) Instead, what GSK is alleging is that Teva knew of the '000 patent (as well as the original '069 patent), (SAC at ¶ 71; *see also* D.I. 69 at 8), and that Teva knew that at least some of its generic carvedilol tablets would be administered in an infringing manner because Teva's skinny label "instructed and

Teva's counsel—why was this an implausible theory? In response, Teva argued that the above-referenced language in the skinny label that relates to heart failure is unproblematic, because (1) "[*Warner-Lambert*, *Allergan* and *Bayer*] stand for the proposition that the label cannot induce infringement of an indication for which the label has not been approved" and (2) no wording on the label could induce infringement since "the two conditions [CHF and post-MI LVD] [indicate] two completely different uses of the drug." (Tr. at 29-30; *see also id.* at 33)

The Court has above explained why it does not think the first of these two responses is a sufficient answer—in that it does not believe that there exists any such hard-and-fast "proposition" of the kind that Teva suggests. As for the second reason, it is true that the CHF indication and the post-MI LVD indication are two separate indications on GSK's COREG label. But it is also true that the SAC alleges a clear relationship between the two conditions. In describing GSK's motivation for seeking approval for COREG to be administered for the post-MI LVD indication (following COREG's approval for treating CHF), the SAC alleges that there were "*patients with CHF*, or that were likely to develop CHF, *that could not receive COREG® because they recently experienced a myocardial infarction* (i.e., a heart attack) and COREG® [at one point] was not approved for use following a recent heart attack due, at least in part, to concerns about worsening the patient's condition." (SAC at ¶ 28 (emphasis added)) According to GSK, then, while these may be two different uses for carvedilol, they are not two completely unrelated uses. Rather, post-MI LVD patients with CHF are a subset of CHF patients, and

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encouraged physicians to administer carvedilol to *[CHF] patients*[,]" (D.I. 69 at 9 (emphasis added)).

"[t]here's a very closely related synergy between these two and really [the post-MI LVD indication] is sort of a special application of the CHF treatment." (Tr. at 62; *see also* SAC at ¶ 29 (explaining that a heart attack "can cause CHF" and that many patients in the CHAPS and CAPRICORN studies, who had recently suffered a heart attack, "likely had CHF"); *id.* at ¶ 33 ("Patients with LVD after a heart attack may also have signs of CHF, and many will eventually develop CHF."); *id.* at ¶ 52 (stating that portions of Teva's skinny label note that certain patients using Teva's product may experience symptoms of heart failure); Tr. at 51 (explaining that post-MI LVD and CHF are "very intimately related"); *id.* at 68 (same))[22] In fact, GSK asserts that the post-MI LVD indication was only broken out as a separate indication because physicians were concerned about giving COREG to CHF patients who had just suffered heart attacks, and so GSK "went out and had to do a separate study [] to alleviate the concerns of the doctors and the FDA." (Tr. at 68-69)

For all of these reasons, the Court agrees that it is plausible that certain language in Teva's label could instruct the administration of carvedilol in order to decrease a risk of mortality in patients surviving a heart attack with CHF.[23]

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[22] At oral argument, Teva's counsel acknowledged that "there is admittedly overlap" between the CHF and post-MI LVD patient groups. (Tr. at 25; *see also id.* at 86)

[23] The facts with respect to Teva's label here are in contrast with those in a number of cases (at various stages of the litigation process) where the branded drug company unpersuasively pointed to the label as inducing infringement for carved out uses. *See, e.g.*, *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, — F. Supp. 3d — , Civ. No. 14-1268-SLR, 2016 WL 2904593, at *7 (D. Del. May 18, 2016) (finding that the generic's label, indicated only for prophylaxis of gout flares, "is not a sufficient catalyst to constitute 'active steps taken to encourage direct infringement'" of the branded drug company's patented uses of treating acute gout flares, where the generic's label merely stated "'[i]f you have a gout flare while taking

3. Lack of Alleged Substantial Non-infringing Uses for Carvedilol

There is one other set of allegations referenced in passing by GSK in responding to the Motion, (D.I. 69 at 4), that the Court finds is relevant to the plausibility of the induced infringement claim at issue. In its SAC, GSK alleges facts that plausibly suggest that: (1) despite COREG's multiple approved indications, GSK has marketed the drug in the United States only for the CHF indication; (2) uses of carvedilol tablets for the other two indications (hypertension and post-MI LVD) are not substantial; and (3) Teva is aware that its generic carvedilol tablets were not suitable for substantial non-infringing use. (*See* SAC at ¶¶ 22, 32, 34, 52, 61; *cf. id.* at ¶ 83) Taken together and considered in the context of the other relevant allegations (and in the light most favorable to GSK), the Court finds that these allegations can further suggest Teva's intent to induce use of its generic drug for the patented treatment of CHF during the pre-May 2011 time period. (D.I. 69 at 4 ("All the while, Teva undoubtedly knew that

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Mitigare, tell your healthcare provider'") (internal citations omitted); *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 486 (D.N.J. 2015) ("Critically, Otsuka does not claim that any individual Defendant instructs and/or encourages the infringing use of its aripiprazole product *in either of the key sections of the package inserts*: 'INDICATIONS AND USAGE' or 'DOSAGE AND ADMINISTRATION.'") (emphasis added); *Acorda Therapeutics Inc. v. Apotex Inc.*, Civil Action No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *19 (D.N.J. Sept. 6, 2011) (concluding that the generics' proposed labels failed to demonstrate specific intent where there was "no explicit instruction to use the capsules with food to reduce somnolence" as the court "is unwilling to infer intent based upon information that must be pieced together in a puzzle"); *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 599 (D. Mass. 2005) (rejecting the patentee's active inducement claim where the plaintiff argued that the "Warnings" and "Precautions" sections of the generic company's proposed labeling contained information intended to encourage doctors to prescribe the drug at issue for the patented use of treating heart failure, but the labeling actually appeared to discourage doctors from prescribing the drug for patients with congestive heart failure).

COREG® was until that time administered almost exclusively, if not entirely, to reduce the risk of mortality caused by CHF—the only use GSK actively promoted for years.") (citation omitted))

By way of further explanation, in *Warner-Lambert* the Federal Circuit rejected the brand name manufacturer's induced infringement claim against a generic manufacturer who sought approval to market a drug for non-patented uses. In that case, the drug at issue had many uses, and only a small fraction of the prescriptions written for the drug were for the patented indication. *Warner-Lambert*, 316 F.3d at 1365. This fact was particularly relevant to the *Warner-Lambert* Court, as it explained that:

> Especially where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent. Where there are many uses for a product, as the record reflects to be true of gabapentin, and fewer than 1 in 46 sales of that product are for infringing uses, we are not in a position to infer or not infer intent on the part of [the generic] without any direct evidence.

Id.[24] In other words, the magnitude of the substantial non-infringing uses for the drug prevented

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[24] *See also Otsuka*, 99 F. Supp. 3d at 495 (stating that "in the event a product has substantial noninfringing uses, the Court cannot infer intent to induce infringement, even if these Defendants had 'actual knowledge' that some of their products would infringe the [asserted] patent") (quoting *Warner-Lambert*, 316 F.3d at 1365); *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, 72 F. Supp. 3d 539, 545 (D. Del. 2014) (noting that the use of the drug for the non-patented indication was "substantial" and "[t]herefore, specific intent [to induce infringement] cannot be inferred from the knowledge (actual or based on 'market realities'[]) that a generic product may be used in infringing ways. There must instead be affirmative evidence of specific intent and action to induce infringement."), *aff'd*, 785 F.3d 625 (Fed. Cir. 2015); *Acorda Therapeutics Inc.*, 2011 WL 4074116, at *19 (noting that where 75% of prescriptions for the drug at issue were not for the patented indication, and therefore it was likely a "large portion of [the generic's] capsules that are so prescribed do not infringe the patent. . . . [then] it makes little sense for [the generic's] intent to be to infringe the patent rather than to sell a commodity where the vast majority of sales are non-infringing"); *Organon*, 244 F. Supp. 2d at 382 (granting

an inference of intent to induce infringement on the part of the generic manufacturer. To the Court, this suggests that the converse is true as well—that where a brand name drug is alleged to *not* have substantial noninfringing uses, it could be inferred that a generic company's knowledge that some users of its product may be infringing the patent, (*see* SAC at ¶ 73), evidences intent to induce infringement.

4. Conclusion

Taking all of the above together, the SAC alleges that Teva has taken specific acts to induce infringement in the pre-May 2011 time period by disseminating its skinny label, the contents of which could instruct third parties to infringe the '000 patent. Moreover, GSK has alleged at least some other facts that (read in the light most favorable to it) paint Teva as an entity that: (1) had been long planning to encourage this infringing use of carvedilol; and (2) would have significant financial incentive to do so, since the amount of non-infringing uses of the drug are minimal. In the Court's view, these pleaded facts are enough to allege a plausible induced infringement claim in the relevant time period. *Twombly*, 550 U.S. at 570; *cf. Acorda Therapeutics Inc. v. Apotex Inc.*, Civil Action No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *16 (D.N.J. Sept. 6, 2011) (explaining in an opinion following a bench trial that whether the court can appropriately make an inference of specific intent based on instructions in a drug label "depends on how explicitly the instructions suggest the infringement, any direct evidence, the

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summary judgment of no induced infringement where the plaintiff failed to meet its burden of adducing facts sufficient to prove that the generic manufacturers acted or will act with the intent to induce infringement where, *inter alia*, "there is a significant market for non-infringing uses of [the drug at issue]").

[c]ourt's fact-finding conclusions and the surrounding circumstances").[25]

IV. CONCLUSION

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[25] With all of this said, this conclusion is *not* the same as a determination that GSK will ultimately be able to prove its induced infringement claim as to the pre-May 2011 time period. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1420 ("'The issue is not whether [GSK] will ultimately prevail but whether [GSK] is entitled to offer evidence to support the claims.'") (citation omitted). Teva, for example, has pointed to some possible challenges that GSK faces in proving the claim.

For one thing, it is not clear on this record why, although GSK "[a]bsolutely" wrote the content of the post-MI LVD indication of its label intending to encourage the use of COREG for congestive heart failure, (Tr. at 73), GSK did *not* submit a use code for purposes of the Orange Book indicating that the '000 patent covered the post-MI LVD indication, (SAC at ¶ 40). Patent owners list patents along with use codes in the Orange Book in order to give notice to the FDA and generic companies of patents and their corresponding uses upon which the patentee could reasonably bring suit. *See Organon*, 244 F. Supp. 2d at 374 n.6; *see also Allergan*, 324 F. 3d at 1339 (explaining that "the general purpose of the Patent Listing Provision [] is to give notice to a potential infringer (direct or induced) of patents upon which the patentee could reasonably bring a suit"). The Federal Circuit has noted that these provisions "encourage broad disclosure"—"the category of claims as to which infringement could reasonably be asserted is plainly broader than the category of claims that are infringed." *Bayer*, 676 F.3d at 1325.

Additionally, the Court notes that while the patented method of use calls for the administration of carvedilol, *inter alia*, "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[,]" ('000 patent, col. 8:33-35), the post-MI LVD indication in Teva's label does not mention any such therapeutic agents, (SAC, ex. J at Section 1.2). Meanwhile, the CHF indication on COREG's label does reference the administration of the drug "usually in addition to diuretics, ACE inhibitors, and digitalis[.]" (*Id.*, ex. F at Section 1.1) However, the Court does note that at least the "Heart Failure/Fluid Retention" section of Teva's skinny label states that if "[w]orsening heart failure" occurs during up-titration, "diuretics should be increased[.]" (*Id.*, ex. J at Section 5.4; *see also id.* at "Patient Information"—"What are carvedilol tablets?" section (noting that "Carvedilol tablets are used, often with other medicines . . . [t]o treat patients who had a heart attack that worsened how well the heart pumps")) In light of this, and because this issue was not really a focal point of the parties' Motion-related arguments, the Court cannot conclude that it is implausible that Teva's label instructs physicians to utilize this portion of the patented method. But the issue may be one, among others, that Teva raises again at the proof stage.

For the foregoing reasons, the Court recommends that Teva's Motion be DENIED.

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 within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). 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 Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

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.

Dated: July 20, 2016

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE