IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

REPORT AND RECOMMENDATION

In these two related actions filed by Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited (collectively, "GSK" or "Plaintiffs") against Defendant Glenmark Pharmaceuticals Inc., USA ("Glenmark") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Defendants"), GSK alleges induced infringement of United States Patent No. RE40,000 (the "Asserted Patent" or the "'000 patent"). Presently before the Court is Defendants' motion for summary judgment of no induced infringement (the "Motion"). (Civil Action No. 14-877-LPS-CJB (hereinafter "*Glenmark* Action"), D.I. 214; Civil Action No. 14-878-LPS-CJB

(hereinafter "*Teva* Action"), D.I. 248)[1] The Court recommends that Defendants' Motion be DENIED.[2]

I. BACKGROUND

A. Factual Background

1. The Parties

GSK manufactures and sells the drug carvedilol under the trade name COREG®. (D.I. 60 at ¶¶ 8, 22) SmithKline Beecham (Cork) Limited is the owner, by assignment, of the '000 patent, and GlaxoSmithKline LLC is the patent's exclusive licensee. (*Id.* at ¶¶ 37-38)

Defendants are engaged in the business of developing, manufacturing, and distributing generic versions of branded drug products throughout the United States. (*See, e.g.*, *Glenmark* Action, D.I. 61 at ¶ 47; *Teva* Action, D.I. 60 at ¶ 47; D.I. 105 at ¶ 47)

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 approval from the

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

[2] The Court notes that the Motion is included in Defendants' "Combined Motion for Summary Judgment and to Exclude Certain Expert Testimony" in which they, *inter alia*, move for summary judgment with respect to other issues in addition to induced infringement. (D.I. 248, 249) This Report and Recommendation solely addresses Defendants' arguments relating to induced infringement.

United States Food and Drug Administration ("FDA") for a drug must submit a New Drug Application ("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); *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 the "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (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 describes the method of use claimed by the patent submitted[.]" 21 C.F.R. § 314.53(c)(2)(i)(O)(1)-(2).[3] 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.*

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, a generic company 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. (D.I. 298 (hereinafter, "McCann Decl. Vol. I"), ex. 17 at ¶ 30); *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-

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[3] This is the language of the Federal Regulation that was in effect in 2008, when the '000 patent issued.

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.[4] 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 then requires 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 (often referred to as a "skinny label"). (McCann Decl. Vol. I, ex. 17 at ¶ 31); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1046 (Fed. Cir. 2010).[5]

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.

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[4] 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 Book 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 (an "ANDA case" or a "Hatch-Waxman case"), *see Caraco*, 132 S. Ct. at 1677.

[5] 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).

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*, 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 (D.N.J. 2009).

3. Discovery of Carvedilol as a Treatment for Congestive Heart Failure

Congestive heart failure (or "CHF"), which has been construed by the Court to mean "a condition that occurs as a result of impaired pumping capability of the heart and is associated with abnormal retention of water and sodium[,]" (D.I. 165 at 43), affects over 5 million people in the United States, (McCann Decl. Vol. I, ex. 2 at ¶ 23). More specifically, the hearts of people with CHF are diseased and/or damaged, thus impairing the ability of the left ventricle (i.e., the major pumping chamber) to fill with or eject blood. (*Id.* at ¶ 24) These patients' hearts are unable to deliver sufficient oxygenated blood throughout the body. (*Id.*) Symptoms of CHF include dyspnea (breathlessness), poor exercise intolerance, fatigue and edema (swelling of the legs). (D.I. 253, ex. A (hereinafter, "Rosendorff Decl.") at ¶ 28; McCann Decl. Vol. I, ex. 2 at ¶ 24) Historically, approximately half of the people that developed CHF died within 5 years of diagnosis. (*See* '000 patent, col. 1:55-57;[6] McCann Decl. Vol. I, ex. 2 at ¶ 23) Before 1997, the only treatments approved by the FDA for heart failure were diuretics, certain angiotensin converting enzyme ("ACE") inhibitors and digoxin/digitalis. (McCann Decl. Vol. I, ex. 2 at ¶ 25) These drugs were used to treat the symptoms of heart failure. (*Id.*) Controlled clinical trials

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[6] The '000 patent appears on the dockets in these actions more than once, including as an exhibit to the Joint Claim Construction Chart. (D.I. 68, ex. B) Citation to the patent will simply be to the "'000 patent."

demonstrated that ACE inhibitors reduced the risk of mortality from heart failure by about 20%. (*Id.*)

Carvedilol has been a known beta blocker since at least 1978. (U.S. Patent No. 4,503,067; McCann Decl. Vol. I, ex. 2 at ¶ 29) Beta blockers are compounds that prevent stimulation of the adrenergic receptors responsible for increased heart rate and contractility, which can cause the heart to pump slower or with less force. (McCann Decl. Vol. I, ex. 2 at ¶ 27) Historically, beta blockers were contraindicated in the treatment of CHF because of the medical community's "widely-held concern" that this type of drug would further reduce the diseased and/or damaged heart's ability to pump blood through the body. (*Id.* at ¶¶ 27-28; *see also* D.I. 299 (hereinafter, "McCann Decl. Vol. II"), ex. 53 at 50, 55 (Glenmark's expert Sean C. Beinart, M.D. noting that when he was in medical school in the "mid-'90s" he was taught "capital letters, beta blockers are contraindicated [for CHF]"); '000 patent, col. 3:56-60) For example, guidelines published in 1993 regarding the treatment of high blood pressure indicated that beta blockers were "[r]elatively or [a]bsolutely [c]ontraindicated" in patients with cardiac failure. (McCann Decl. Vol. I, ex. 3 at Table 8)

In the late 1980s, the named inventors of the '000 patent (Mary Ann Lukas-Laskey, Robert Ruffolo, Jr., and Neil Howard Shusterman of GSK's predecessor and Gisbert Sponer and Klaus Strein of Boehringer Mannheim GmbH) were investigating the possible uses of carvedilol (then in development as a drug to treat hypertension) to treat different diseases. (McCann Decl. Vol. I, ex. 2 at ¶ 30; '000 patent, col. 3:15-36) They pursued promising research suggesting that carvedilol could be used to successfully treat CHF, receiving approval from the FDA to initiate a clinical trial in 1992. (McCann Decl. Vol. I, ex. 2 at ¶ 30) According to Dr. Ruffolo, the

reaction from his colleagues was very negative, due to concerns that a beta blocker like carvedilol would actually hasten the death of those with CHF. (McCann Decl. Vol. II, ex. 81 at GSK00983250) One colleague told him that he was "'going to kill a lot of people with that drug.'" (*Id.*) GSK's Chief Executive Officer also received a letter protesting the studies of carvedilol in CHF patients as resembling "the studies done by the Nazi scientists in the death camps of World War II." (*Id.*; McCann Decl. Vol. I, ex. 4 at 86) In light of these concerns, GSK established a Data and Safety Monitoring Board ("DSMB") to monitor the trial and to stop it if carvedilol, in fact, was killing patients. (McCann Decl. Vol. I, ex. 4 at 87)

In February 1995, the DSMB did indeed terminate the clinical trial early, but based on the finding of a significant effect of carvedilol on *survival* in CHF patients. (*Id.*; *see also id.*, ex. 2 at ¶ 33; *id.*, ex. 6; *id.*, ex. 7; *id.*, ex. 8 at 329-30) The trial revealed that patients treated with carvedilol had an approximately 65% lower risk of death than those given placebo. (*Id.*, ex. 11 at GSK00776812; *see also id.*, ex. 8 at 243-44; '000 patent, col. 3:60-64) In light of this data, the DSMB believed that it would be "'unethical'" to maintain a placebo arm of the study. (McCann Decl. Vol. I., exs. 6-7; *see also id.*, ex. 4 at 87) The results of the clinical trial were published in *The New England Journal of Medicine*. (*Id*, ex. 11)

In November 1995, GSK sought FDA approval of carvedilol in combination with ACE inhibitors, digoxin or diuretics (the same regimen used in the clinical trial) to reduce the risk of mortality caused by heart failure. (*Id.*, ex. 13 at ¶ 34) The FDA initially rejected GSK's NDA, but after receiving additional confirmatory data and analysis, in May 1997 the FDA ultimately approved carvedilol as the first beta blocker for the treatment of CHF, as an adjunctive therapy. (*Id.* at ¶¶ 34-35; D.I. 297 at 5-6) The next month, GSK launched COREG. (McCann Decl. Vol.

I, ex. 14 at ¶ 10)

Beginning in 1997, GSK sponsored another clinical trial ("CAPRICORN") in order to obtain FDA approval for use in patients who had recently experienced a myocardial infarction (i.e., a heart attack) and who had a left ventricular ejection fraction of ≤40% (i.e., left ventricular dysfunction following myocardial infarction; hereinafter, "Post-MI LVD"). (*Id.*, ex. 2 at ¶ 89; D.I. 265 (hereinafter, "Riley Decl. Vol. II"), ex. 13 at ¶ 41) At the time of enrollment in CAPRICORN, 47% of the 1,959 patients had symptomatic heart failure. (McCann Decl. Vol. I, ex. 2 at ¶ 89; *see also* Riley Decl. Vol. II, ex. 13 at ¶ 42) Based on the positive results of CAPRICORN, in September 2002, GSK submitted a supplement to its NDA, seeking approval of the Post-MI LVD indication for COREG. (Riley Decl. Vol. II, ex. 13 at ¶ 43) On March 27, 2003, the FDA approved GSK's supplement, and the Post-MI LVD indication was added to the prescribing information for COREG. (*Id.*) Thus, by that date, the FDA had approved COREG for three indications, as follows:

> **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[, (hereinafter, the "heart failure indication")]
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> **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)[, (hereinafter, the "Post-MI LVD indication")]
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> **1.3 Hypertension:** COREG is indicated for the management of essential hypertension[, (hereinafter, the "hypertension

indication")]

(D.I. 60, ex. F at 1160; Riley Decl. Vol. II, ex. 13 at ¶ 44)

By 2005, the guidelines provided by the American College of Cardiology ("ACC") and the American Heart Association ("AHA") gave its highest recommendation for the use of carvedilol to reduce the risk of death in patients with CHF. (Riley Decl. Vol. II, ex. 14 at ¶ 98) And by 2007, carvedilol had become a medication routinely used in the treatment of CHF patients. (McCann Decl. Vol. I, ex. 13 at ¶ 50) Accordingly, in 2006-2007 (and prior to the entry into the market of Defendants' generic carvedilol in September 2007), sales of COREG peaked at approximately $1.6 billion per year. (*See* McCann Decl. Vol. II, ex. 82 at GSK00983295; D.I. 297 at 6)

4. '000 Patent

In June 1995, the inventors filed a patent application directed to a method of using carvedilol to decrease the risk of mortality caused by CHF, which issued as U.S. Patent No. 5,760,069 (the "'069 patent") entitled "Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure." (*See* '000 patent) The FDA published the '069 patent in the Orange Book as covering COREG for use in decreasing mortality caused by CHF. (McCann Decl. Vol. I, ex. 15)

In November 2003, GSK requested a reissue of the '069 patent, and on January 8, 2008, that patent reissued as the '000 patent. ('000 patent) In February 2008, GSK replaced the '069 patent in the Orange Book with the '000 patent, and it identified "[d]ecreasing [m]ortality [c]aused [b]y [c]ongestive [h]eart [f]ailure" as the method of use covered by the '000 patent to be included as the "use code" in that publication. (McCann Decl. Vol. I, ex. 16 at GSK00592217)

The '000 patent contains 9 method claims directed to methods of decreasing mortality caused by CHF in a patient in need thereof by administering carvedilol in a manner recited in the claims. ('000 patent) GSK asserts all but claim 5 against Defendants in these actions. (D.I. 249 at 3) Claim 1 is the only independent claim of the '000 patent, and it reads:

> **1.** A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with 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,
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> > *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

('000 patent, col. 8:30-40 (emphasis in original)) The italicized portion of the claim is the portion that was added during the reissue proceeding.

5. Defendants' Generic Carvedilol

In March 2002—during which time the Orange Book listed the '069 patent for COREG—Teva submitted ANDA No. 76-373, seeking to market generic carvedilol tablets. (McCann Decl. Vol. I, ex. 17 at ¶¶ 63-64) Teva's ANDA included: (1) a Paragraph IV certification asserting that the '069 patent was invalid and unenforceable; and (2) another certification that requested that Teva's ANDA not be finally approved until a second patent listed in the Orange Book as covering the compound carvedilol expired in March 2007, which included Teva's commitment not to launch its generic until that date. (*Id.* at ¶¶ 64-65) At the time, Teva apparently believed that it was the first generic applicant for COREG that included a Paragraph

IV certification in its ANDA, which could make it eligible for 180-day exclusivity against all other subsequent Paragraph IV filers. (*Id.* at ¶ 63; *see also id.* at ¶ 32)

On June 9, 2004, the FDA tentatively approved Teva's ANDA. (*Id.*, ex. 19) That same day, Teva issued a press release announcing the tentative approval of its generic carvedilol tablets. (D.I. 60, ex. K) The press release stated that "Carvedilol Tablets are the AB-rated generic equivalent of GlaxoSmithKline's COREG® Tablets and are indicated for treatment of heart failure and hypertension" and that COREG's annual sales were approximately $670 million. (*Id.*)

A few months before Teva's planned September 2007 launch, Teva apparently learned that other generic companies had chosen not to challenge the validity of the '069 patent. (McCann Decl. Vol. I, ex. 20) Instead, Glenmark and other generic companies had submitted section viii statements with their ANDAs, and therefore received FDA approval for labels that included the hypertension and Post-MI LVD indications, but that omitted the heart failure indication. (*See, e.g.*, *id.*; *id.*, ex. 25)[7] In late July 2007, Teva decided to amend its ANDA to include a section viii statement and to change its label to carve out the heart failure indication, as other generics had done. (*Id.*, ex. 22)

On September 5, 2007, the FDA approved the ANDAs of fourteen generic companies, including Teva and Glenmark. (D.I. 264 (hereinafter, "Riley Decl. Vol. I"), ex. 1) The FDA's press release announcing these approvals noted that "[t]he labeling of the generic products may differ from that of Coreg because parts of the Coreg labeling are protected by patents and/or

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[7] Glenmark's initial draft label for its ANDA included only the hypertension indication, (McCann Decl. Vol. I, ex. 30), but it subsequently amended the label to include both the hypertension and Post-MI LVD indications.

exclusivity." (*Id.*) At the time of launch, the labels for Teva's and Glenmark's generic versions of COREG included the hypertension and Post-MI LVD indications, but did not include the heart failure indication (the "Skinny Label Period"). (McCann Decl. Vol. I, exs. 25, 27) Both Defendants issued press releases announcing the FDA approval of their generic carvedilol tablets. (D.I. 60, ex. L; *Glenmark* Action, D.I. 59, ex. K) Teva's press release described its product as a "[g]eneric version of [GSK's] cardiovascular agent Coreg[]" and noted that COREG had annual sales of "approximately $1.7 billion in the United States[.]" (D.I. 60, ex. L) Glenmark's press release noted that "Coreg is a widely used medication that is FDA approved to treat high blood pressure, mild to severe chronic heart failure and left ventricular function following a heart attack." (*Glenmark* Action, D.I. 59, ex. K) And Defendants' product catalogs and websites listed their carvedilol tablets as "AB"-rated to Coreg. (*See, e.g.*, McCann Decl. Vol. I, exs. 31-34) By the end of 2007, more than 90% of all prescriptions for carvedilol tablets were being filled with a generic instead of COREG. (Riley Decl. Vol. I, ex. 2 at exs. 5A-B)

In May 2011, Teva amended its label to include the heart failure indication, and it has since used that full label. (McCann Decl. Vol. I, ex. 17 at ¶¶ 73-75) For a three-month period from June to August 2010, Glenmark's label also included the separate heart failure indication. (D.I. 249 at 23; D.I. 297 at 11; *see also* Riley Decl. Vol. II, ex. 20 at GCARV556189; *Glenmark* Action, D.I. 59, ex. G) According to Glenmark, this was the result of an error in which the heart failure indication was inadvertently added to Glenmark's package insert in the course of making an unrelated ANDA amendment to add different bottle sizes. (Riley Decl. Vol. I, exs. 17, 18, 20) When Glenmark became aware of the error in August 2010, it informed the FDA of the error, changed the label back to omit the heart failure indication, and collected and destroyed the

remaining incorrect package inserts still in its possession. (Riley Decl. Vol. II, ex. 20 at GCARV556189; *id.*, ex. 21; D.I. 266 (hereinafter, "Riley Decl. Vol. III"), ex. 23; D.I. 267 (hereinafter, "Riley Decl. Vol. IV"), ex. 41 at 226-28) The FDA determined that Glenmark's error did not create a safety issue and that Glenmark did not have to recall any of the mislabeled product that had already been dispersed. (Riley Decl. Vol. III, ex. 25; Riley Decl. Vol. IV, ex. 41 at 219-23)

B. Procedural History

On July 3, 2014, GSK commenced these actions, charging Defendants with one count of induced infringement and one count of contributory infringement with respect to the '000 patent. (*Glenmark* Action, D.I. 1; *Teva* Action, D.I. 1) Glenmark and Teva moved to dismiss the complaints, (*Glenmark* Action, D.I. 10; *Teva* Action, D.I. 10), and in response, GSK filed a First Amended Complaint ("FAC") in each action, (*Glenmark* Action, D.I. 14; *Teva* Action, D.I. 16).

In lieu of filing Answers to the FACs, Defendants 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). (*Glenmark* Action, D.I. 18; *Teva* Action, D.I. 20) The Court thereafter issued a Report and Recommendation[8] regarding the motions to dismiss, which recommended: (1) grant of the motions to dismiss as to GSK's claims regarding induced infringement during the Skinny Label Period, 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

[8] 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. (*Glenmark* Action, D.I. 16; *Teva* Action, D.I. 18)

infringement. (*Glenmark* Action, D.I. 38; *Teva* Action, D.I. 39) Chief Judge Stark later adopted the Report and Recommendation in its entirety, over Defendants' objections. (*Glenmark* Action, D.I. 54; *Teva* Action, D.I. 55)

GSK then filed its SACs in these actions. (*Glenmark* Action, D.I. 59; *Teva* Action, D.I. 60) In response, Glenmark filed an Answer, (*Glenmark* Action, D.I. 61), and Teva filed a motion seeking dismissal of GSK's claims for inducement of infringement with respect to the Skinny Label Period, (D.I. 63). On July 20, 2016, the Court issued a Report and Recommendation recommending that Teva's motion to dismiss be denied ("MTD R&R"). (D.I. 191); *see also GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, Civil Action No. 14-878-LPS-CJB, 2016 WL 3946770 (D. Del. July 20, 2016). Chief Judge Stark ultimately overruled Teva's objections and adopted the MTD R&R, (D.I. 328); *see also GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, C.A. No. 14-878-LPS-CJB, 2017 WL 1050574 (D. Del. Mar. 20, 2017), explaining 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[,]" 2017 WL 1050574, at *2 (emphasis in original).

Meanwhile, following a *Markman* hearing, (D.I. 147), the Court issued a Report and Recommendation on claim construction on June 3, 2016, (D.I. 165). On February 17, 2017, Chief Judge Stark overruled objections to that Report and Recommendation as to all but one term ("maintenance dosages"). (D.I. 290) Furthermore, in October 2016 and November 2016, respectively, GSK dismissed its contributory infringement counts against Teva and Glenmark, (*Glenmark* Action, D.I. 175; *Teva* Action, D.I. 211), leaving induced infringement as the sole

remaining count in each case.

Briefing on the instant Motion was completed on March 3, 2017, (D.I. 313), and the Court held oral argument on the Motion (and various other summary judgment and *Daubert* motions filed in the case) on March 24, 2017, (D.I. 335 (hereinafter, "Tr.")). A 5-day trial is set to begin in the *Teva* Action on June 12, 2017. (D.I. 38, 329, 350)

II. STANDARD OF REVIEW

A. Summary Judgment

A grant of summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). If the moving party meets this burden, the nonmovant must then "come forward with specific facts showing that there is a *genuine issue for trial*." *Id.* at 587 (emphasis in original) (internal quotation marks and citation omitted). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586-87; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d

Cir. 2005) (party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks and citation omitted). The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are "material," and a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. "If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." *Id.* at 249-50 (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials"; or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

B. Induced Infringement

Pursuant to 35 U.S.C. § 271(b) ("Section 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)) (certain internal quotation marks and citations 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 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.'") (citation omitted); *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).

Induced infringement is a question of fact, *AstraZeneca*, 633 F.3d at 1056, that must be proved by the patentee by a preponderance of the evidence, *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

III. DISCUSSION

Generic drug manufacturers such as Defendants cannot directly infringe a method of treatment patent like the '000 patent, since they do not themselves treat patients; instead, such manufactures may be held liable for infringement under Section 271(b) if they actively induce infringement of the patent at issue. *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 126 F. Supp. 3d 1037, 1039-40 (S.D. Ind. 2015). That is GSK's charge against Defendants in these cases—that Defendants have actively induced doctors to directly infringe the '000 patent by

administering Defendants' generic carvedilol tablets to patients with CHF in order to reduce the risk of death in those patients. (*See, e.g.*, D.I. 297 at 3, 25; McCann Decl. Vol. I, ex. 2 at ¶ 149) With their Motion, Defendants move for summary judgment of no induced infringement, contending that GSK has failed to produce any evidence establishing that: (1) Defendants' conduct *actually caused* physicians to administer carvedilol in an infringing manner; and (2) Defendants acted with the specific intent of inducing physicians to administer carvedilol in an infringing manner during the Skinny Label Period. (*See* D.I. 249 at 2-3; D.I. 313 at 10-15) The Court will address these arguments in turn.

A. Whether GSK Has Demonstrated that a Genuine Issue of Material Fact Exists Regarding Whether Defendants Caused Infringement of the '000 Patent

First, Defendants argue that GSK, in making out its induced infringement claims, bears the burden of proving that Defendants caused doctors to infringe the '000 patent, and that GSK has failed to provide any evidence that this actually happened. (D.I. 249 at 14-17; D.I. 313 at 10-12; Tr. at 9) This argument extends across the entire relevant period of infringement—equally applicable, according to Defendants, to both the Skinny Label Period and the period in which Defendants' products included the full label with the heart failure indication. (D.I. 249 at 14)

Defendants center their causation argument on the recent holding of the Federal Circuit in *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315 (Fed. Cir. 2016) ("*Power II*"). (D.I. 249 at 2, 14; D.I. 313 at 10-11; Tr. at 7) In that case, the district court had adopted a jury instruction regarding induced infringement that stated, *inter alia*:

> [I]n order to find inducement, you must find that the party accused of infringement intended others to use its products in at least some ways that would infringe the asserted claims of the patent. *However, that infringement need not have been actually caused by*

> *the party's actions. All that is required is that the party took steps to encourage or assist that infringement, regardless of whether that encouragement succeeded, or was even received.*

Power II, 843 F.3d at 1330 (emphasis in original). The Federal Circuit held that this instruction misstated the law of induced infringement, because it "left the jury with the incorrect understanding that a party may be liable for induced infringement even where it does not successfully communicate with and induce a third-party direct infringer." *Id.* at 1330-31. To the contrary, the Federal Circuit made clear that "a finding of induced infringement requires actual inducement"—i.e., "successful communication between the alleged inducer and the third-party direct infringer." *Id.* at 1331. While a plaintiff may rely on circumstantial evidence to prove such actual inducement, "the jury must still find that it occurred" in order for a plaintiff to prevail. *Id.*; *see also, e.g.*, *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004) ("To prevail under a theory of indirect infringement, [plaintiff] must first prove that defendants' actions led to direct infringement of the [patent-in-suit].").

Here, Defendants argue that summary judgment of no induced infringement must be granted because, contrary to the holding of *Power II*, "GSK has put forth no expert opinion nor other evidence that *any* doctor's prescription of carvedilol for the allegedly infringing purpose was *caused* by any act of Defendants." (D.I. 249 at 2 (emphasis in original)) That is, according to Defendants, regardless of any evidence GSK may set out about the content of Defendants' generic labels, or about Defendants' touting of their products' AB rating, or about the actions of Defendants' sales team and the low price of Defendants' drugs in comparison to COREG, GSK's induced infringement claims still fail as a matter of law—because GSK did not prove that any of this evidence actually "caused a single doctor to prescribe generic carvedilol for an infringing

purpose." (D.I. 313 at 11; *see also* Tr. at 10 (GSK did not show "communications with doctors [that] caus[ed] [] direct infringement")) Indeed, Defendants assert that the undisputed evidence establishes many other reasons why doctors prescribed carvedilol—none of them to include Defendants' conduct. (D.I. 249 at 2)

In that vein, Defendants first point to evidence establishing that by the time the '000 patent issued in January 2008, most prescriptions were already being filled by a generic carvedilol drug instead of COREG (and thus, these generic drugs were being administered absent infringement of the '000 patent). More specifically with respect to this pre-'000 patent period, Defendants cite to evidence establishing the following:

(1) Upon the launch of COREG in 1997, GSK spent years educating doctors on the use of carvedilol to treat CHF through "physician detailing" and the clinical studies it had conducted, (Riley Decl. Vol. II, ex. 13 at ¶¶ 39, 41, 45; Riley Decl. Vol. I, ex. 10 at 54-55 (GSK's expert Dr. Peter A. McCullough testifying that by 2007, doctors had learned that carvedilol was effective in reducing mortality in CHF patients from sources including GSK's prescribing information and promotional material));

(2) ACC/AHA treatment guidelines had, since 2005, given carvedilol its highest recommendation in treating CHF, (Riley Decl. Vol. II, ex. 14 at ¶ 98), and physicians would have followed such practice guidelines in prescribing carvedilol, (*id.* at ¶ 99);

(3) By the time Defendants' generic products came onto the market in September 2007, doctors had already been prescribing carvedilol to treat CHF for nearly a decade, (*id.*, ex. 13 at ¶ 50), thanks to the treatment guidelines and GSK's physician detailing, (*see, e.g.*, D.I. 257, ex. A (hereinafter, "Zusman Decl.") at ¶ 142); and

(4) Defendants launched their generic products four months *before* the '000 patent issued in January 2008, and by the end of 2007, more than 90% of all prescriptions were

> already being filled with a generic instead of COREG,
> (Riley Decl. Vol. I, ex. 2 at exs. 5A-B).

(D.I. 249 at 14-15; *see also* D.I. 313 at 10 ("It was [GSK's physician detailing and clinical studies, and the widely followed ACC/AHA guidelines] that caused physicians to prescribe carvedilol for the treatment of CHF, not Defendants' product labels, or other statements, after generics entered the market. GSK has offered no evidence to the contrary."); Tr. at 12-13)

Next, Defendants argue that even after the '000 patent issued, "there is no evidence that any doctor was specifically induced to prescribe Defendants' carvedilol, as opposed to the dozen other generic products on the market[,]" nor any evidence from which the Court may even draw a reasonable inference that Defendants' actions caused any doctors to directly infringe the patent. (D.I. 249 at 15-16; *see also* Tr. at 10) In support of this argument, Defendants point to Dr. McCullough's deposition testimony in which he described the typical practice of prescribing carvedilol. (D.I. 249 at 15-16) Dr. McCullough explained that, aside from circumstances in which he would write on the prescription "dispense as written" to inform the pharmacist that the patient should receive the branded product, he would simply write "carvedilol" on the prescription, along with the quantity and number of refills, without specifying a particular generic manufacturer. (Riley Decl. Vol. I, ex. 10 at 277-78) According to Dr. McCullough, physicians "are generally unaware of which generic manufacturer's carvedilol pharmacies carry at any given time." (Riley Decl. Vol. II, ex. 13 at ¶ 77 n.77)

Defendants also cite to the report of their expert Dr. Randall Zusman, which paints a picture of generic manufacturers simply launching their products out into the market with no corresponding communications with doctors. (D.I. 249 at 16 (citing Zusman Decl. at ¶¶ 141-49)) According to Dr. Zusman, doctors were not receiving or otherwise accessing Defendants'

carvedilol labels, reading them, and then making the decision to infringe the '000 patent by prescribing carvedilol according to the claimed method. (Zusman Decl. at ¶ 146; *see also* Tr. at 13 (Glenmark's counsel asserting at oral argument that Defendants' label "doesn't go to the doctors . . . . [instead, it] goes to the customer, the patient")) Instead, Dr. Zusman opined that with GSK having already done the work to educate doctors about the branded product COREG, doctors were thereafter simply writing prescriptions for "carvedilol" without regard to any specific generic manufacturer's drug:

> [I]n my opinion it is unlikely that the vast majority (if not all) prescribing physicians have ever seen or read [Defendants'] package insert. Unlike brand companies, generic pharmaceutical companies do not market or advertise their products (or the use of their products) to doctors. In my experience, doctors are informed by the use of the reference listed drug, or brand equivalent. Thus, for a generic drug, a doctor will prescribe based on the brand label or accepted off-label uses for the brand drug. In my medical practice, I cannot recall an instance in which I reviewed a generic product label or generic marketing materials including prescribing instructions. In fact, it is almost always the case that a doctor does not even know which generic will be used to fill a prescription for carvedilol.

(Zusman Decl. at ¶ 146)[9] In sum, Defendants assert that because "[t]here is no evidence that doctors even looked at [] Defendants' labels in making prescribing decisions or that Defendants' other communications were read by doctors, let alone influenced their prescriptions[,]" (D.I. 313

[9] GSK commissioned a survey of doctors with respect to their prescribing practices in regard to carvedilol for damages purposes, but did not ask "any question about what factors caused doctors to prescribe one product over another, or even whether doctors read generic labels." (D.I. 249 at 17; *see also* Defendants' Induced Infringement Presentation, Slide 7) Defendants assert that GSK's choice to not ask such questions is "revealing" and really underscores the market realities that were at play here, wherein "doctors don't rely on generic labels" in making prescribing decisions, and GSK (and everyone else) know this. (Tr. at 10-11; *see also* D.I. 249 at 17)

at 11), GSK has failed to meet its burden with respect to the causation element of induced infringement.

GSK makes few different arguments in response. First, at least as to the period in which Defendants' products included the full label with the heart failure indication, GSK seems to suggest that the Federal Circuit has set out a *per se* rule that if a generic manufacturer's label includes the indication that is patented, that, in and of itself, is "sufficient to establish induced infringement." (D.I. 297 at 25; Tr. at 19 ("The law is that the sale of a product specifically labeled for use in a patented method constitutes inducement."); Tr. at 26 (GSK's counsel asserting that "the law says that the labels alone . . . constitute actual inducement which is the claim element that Defendants are disputing on this motion"); GSK's Induced Infringement Presentation, Slides PDX-102, PDX-109 ("Under Federal Circuit Law, Defendants' Full Labels Induce Infringement")) In support, GSK cites to *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1047, 1056-61 (Fed. Cir. 2010), (D.I. 297 at 25), and to *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 926-27 (Fed. Cir. 2011), (GSK's Induced Infringement Presentation, Slide PDX-102). In *Eli Lilly*, for example, the Federal Circuit stated that "[w]e have long held that the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent[,]" and cited to *AstraZeneca* in support thereof. *Eli Lilly*, 435 F. App'x 926-27 (citing *AstraZeneca*, 633 F.3d at 1060).

At first blush, that particular statement could indeed suggest that if a defendant's product label tracks the patented method, the inquiry is over—the elements of an induced infringement claim have been satisfied. But a closer look at *AstraZeneca* and *Eli Lilly* establishes that in those cases, the Federal Circuit was not focused on the causation issue that is at the heart of

Defendants' Motion here (i.e., the question of whether GSK can establish a genuine dispute of material fact as to whether Defendants' labels were actually successfully communicated to doctors and caused them to infringe the '000 patent). Instead, the plaintiffs in these cases had filed suit much earlier than GSK here. In *AstraZeneca*, the plaintiff had initiated the declaratory judgment action underlying the appeal and moved for a preliminary injunction barring the defendant from distributing its generic drug the day after the defendant's ANDA was approved. 633 F.3d at 1047. And in *Eli Lilly*, the plaintiff filed suit after the defendant filed a Paragraph IV certification seeking to sell generic counterparts of the branded drug before the expiration of plaintiff's patent directed to use of the drug. 435 F. App'x at 919. And so the issue that these courts were confronting was whether the defendants' *proposed* labels could establish the requisite *intent* to encourage another's infringement.

The *Eli Lilly* Court ultimately affirmed the district court's grant of the plaintiff's motion for summary judgement of induced infringement. *Id.* at 927. The district court had explained "[i]n the context of ANDA filings the direct infringing acts are hypothetical—since the generic manufacturers have not yet distributed the product—so a court need only consider . . . . whether specific intent [to encourage another's infringement] exists." *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 676 F. Supp. 2d 352, 377 (D.N.J. 2009), *rev'd on other grounds*, 435 F. App'x 917 (Fed. Cir. 2011). Accordingly, the district court determined that direct infringement "will occur[,]" and explained that "[w]hether [d]efendants will induce infringement of [p]laintiff's patent depends on whether they have the requisite intent to cause direct infringement." 676 F. Supp. 2d at 377 & n.22. With respect to that issue, the district court concluded that the defendants "will be labeling the product in a manner which encourages direct infringement by others. . . . and such

evidence is sufficient to establish Defendants' *intent*." *Id.* at 378 (emphasis added). Likewise, the *AstraZeneca* Court was also focused on the intent element of induced infringement, explaining that "[i]n the context of specific intent, it is irrelevant that some users may ignore the warnings in the proposed label. The pertinent question is whether the proposed label instructs users to perform the patented method. If so, *the proposed label may provide evidence of [defendant's] affirmative intent to induce infringement*." 633 F.3d at 1060 (emphasis added).

The *Eli Lilly* and *AstraZeneca* Courts' particular focus on intent makes sense in light of the procedural posture of those cases—the defendants' products had not yet been launched into the market, and so the labels at issue were merely "proposed" labels. *See, e.g., Novartis Pharms. Corp. v. Breckenridge Pharm., Inc.*, — F. Supp. 3d. — , Civil Action No. 1:14-cv-1043-RGA, 2017 WL 1278672, at *3 (D. Del. Apr. 3, 2017) ("In Hatch-Waxman cases alleging that a proposed drug label will induce infringement by physicians . . . . a [proposed] package insert containing directives that will inevitably lead some consumers to practice the claimed method provides sufficient evidence for a finding of specific intent.") (internal quotation marks and citation omitted). A plaintiff in such a circumstance would be hard-pressed to prove a "successful communication between the alleged inducer and the third-party direct infringer" as called for by *Power II*, because it is not possible for there to *have yet ever have been* any "successful communication" or direct infringement. Thus, the analysis in such cases necessarily tends to focus on intent.[10]

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[10] That said, some courts, even in the pre-launch context, have at least given a nod to the causation element that Defendants focus upon here. *See, e.g., Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364, 1369 (Fed. Cir. 2017) (concluding that "evidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement" where the product labeling at issue consisted of

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. And so GSK's induced infringement claims are not premised on a hypothetical (i.e., what will happen if Defendants' proposed labels and generic products are launched into the market), but instead, must be supported by sufficient evidence as to what actually happened during the relevant time period.

In an attempt to meet this burden, GSK argues that: (1) under the law, it may prove actual inducement with circumstantial evidence directed to a class of direct infringers, (GSK's Induced Infringement Presentation, Slide PDX-106; Tr. at 21-22), and (2) it has put forward sufficient evidence to create a genuine issue of material fact on this element.

GSK is of course correct that it may rely on circumstantial evidence to establish a genuine issue of fact. As the *Power II* Court explained: "we have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring *hard proof* that any

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two documents, the Physician Prescribing Information and the Patient Information, and "there is testimony that the Physician Prescribing Information, as the name indicates, is directed at physicians"); *Novartis Pharms.*, 2017 WL 1278672, at *15-16 (concluding, following a bench trial in an ANDA case, that plaintiff proved by a preponderance of the evidence that the defendants' proposed labels induced infringement of the asserted patents where findings of fact established that "[a] physician would look to the indications and usage section of Defendants' proposed labels before prescribing [the drug at issue][,]" and would "refer to the dosage and administration section of Defendants' proposed label to determine the appropriate doses" of the drug at issue); *Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 682 (D. Del. 2016) (concluding, following a bench trial in an ANDA case, that plaintiff proved by a preponderance of the evidence that the defendants' proposed labels induced infringement of the asserted patent where "all that [plaintiff's] theory of inducement essentially requires is that a prescribing physician actually read [defendants'] labels. Neither parties' expert suggested that a prescribing physician would not read the drug's label before prescribing it to patients").

individual third-party direct infringer was actually persuaded to infringe by that material." *Power II*, 843 F.3d at 1331, 1335 (emphasis added); *see also, e.g.*, *Semiconductor Energy Lab. Co. Ltd. v. Chi Mei Optoelecs. Corp.*, 531 F. Supp. 2d 1084, 1114 (Fed. Cir. 2007) (holding that the jury should be permitted to consider "circumstantial evidence" of affirmative acts encouraging direct infringement). In Defendants' briefing, however, they appeared to be requiring more of GSK. That is, Defendants asserted that, for example, "[e]ven if there were evidence that physicians saw the label before prescribing the carvedilol, that is not sufficient to establish that the label induced infringement." (D.I. 249 at 17; *see also* D.I. 313 at 11 (Defendants arguing that "GSK cites no *evidence* that Defendants caused *a single doctor* to prescribe generic carvedilol for an infringing purpose") (certain emphasis added); Tr. at 22 (Plaintiffs' counsel asserting that "Defendants are trying to import a different standard [than that required by the law] and make us show that we have a doctor that says, I saw this material and that was the [proximate] cause as to why I wrote my prescription, and that's not the standard that we are held to")) In other words, Defendants appeared to suggest that GSK, in order to prove its claims, would also need to have: (1) at least one specific physician testify that he read a particular generic manufacturer's carvedilol label, and (2) that the label caused him to write a patient a prescription for that manufacturer's carvedilol.

If that is what Defendants were suggesting in their briefing, then the Court believes that they are stretching the law too far on this point. Again, 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. Indeed, by oral argument, Defendants' counsel agreed that "you don't have to call a series of doctors in, put them on the stand and have them [testify that they reviewed the generic label and that caused them to infringe], that's true. But you have to have circumstantial evidence . . . . You have to have some evidence." (Tr. at 32; *see also id.* at 17)

So that leaves the question of whether GSK has "some evidence" on this point—enough circumstantial evidence to withstand summary judgment. GSK asserts that its "[e]vidence of Defendants' [a]ctual [i]nducement" consists of: (1) Defendants' labels (both the full labels and the labels from the Skinny Label Period); and (2) Defendants' touting of the AB rating of their generic carvedilol for the entire infringement period from 2008-2015 in their product catalogs, websites, price sheets, Monthly Prescribing Reference ("MPR") and Generic Product Reference Guide. (D.I. 297 at 25-26; Tr. at 22-24; GSK's Induced Infringement Presentation, Slides PDX-108-13) On this score, the Court concludes that GSK has mustered at least enough evidence to survive.

With respect to the labels, a review of their content leads to the reasonable inference that they are directed to doctors (which, in turn, is circumstantial evidence that they are and were actually communicated to doctors, and that some number of doctors actually saw those labels). For example, the "Dosage and Administration" section of Defendants' full labels provides specific dosing instructions for physicians, and states that "Patients should be advised that initiation of treatment and (to a lesser extent) dosage increases may be associated with transient symptoms of dizziness or lightheadedness[.]" (*Teva* Action, D.I. 60, ex. G at 1195; *Glenmark* Action, D.I. 59, ex. F at 4) The labels further instruct that in heart failure patients with diabetes,

"[i]t is recommended that blood glucose be monitored when carvedilol dosing is initiated, adjusted, or discontinued" and that some diabetes patients "should be cautioned" about certain possibilities that could occur while taking carvedilol. (*Teva* Action, D.I. 60, ex. G at 1198; *Glenmark* Action, D.I. 59, ex. F at 6-7) There is a "Patient Advice" section of the label listing several items of which "[p]atients taking carvedilol tablets should be advised." (*Teva* Action, D.I. 60, ex. G at 1213; *Glenmark* Action, D.I. 59, ex. F at 24) And there is a separate section at the end of the label entitled "Patient Information" that the pharmacist is instructed to detach and give to the patient. (*Teva* Action, D.I. 60, ex. G at 1214; *Glenmark* Action, D.I. 59, ex. F at 25)

In his expert reports, Dr. McCullough walks through certain sections of the labels (including those referenced above), and his opinions reflect that the labels are directed at physicians. (*See, e.g.*, McCann Decl. Vol. I, ex. 2 at ¶¶ 85-96) For instance, he explains that his interpretation of the "Warnings and Precautions" section of Defendants' skinny label is that Defendants were "warning [] physicians not to discontinue therapy because of increased risks associated with abrupt cessation of therapy." (*Id.*, ex. 2 at ¶ 86; *id.*, ex. 35 at ¶ 147) As a second example, Dr. McCullough notes that Teva's full label and skinny label referenced a CAPRICORN clinical study and included a survival graph depicting study results, and he opines that "[p]hysicians looking at the CAPRICORN graph would have understood that survival benefits accrue after six months of therapy, and therefore carvedilol therapy would be administered for longer than six months." (*Id.*, ex. 2 at ¶ 138) And Dr. McCullough also testified that there were instances in the relevant period where he looked at prescribing information on Defendants' label before prescribing carvedilol to patients. (Riley Decl. Vol. I, ex. 10 at 62-63)

While 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. *Power II*, 843 F.3d at 1335. And so while Defendants' expert Dr. Zusman has stated that "in [his] opinion it is unlikely that the vast majority (if not all) prescribing physicians have ever seen or read Teva's package insert" and that he "cannot recall an instance in which [he] reviewed a generic product label or generic marketing materials including prescribing instructions[,]" (Zusman Decl. at ¶ 146), the factfinder will have to weigh his testimony against the evidence Plaintiffs have put forward on this point. That task is not within the Court's province in assessing Defendants' Motion.

As noted above, Plaintiffs also point to Defendants' marketing of their generic carvedilol's AB rating in various marketing materials as sufficient circumstantial evidence of the causation element of induced infringement. (D.I. 297 at 25-26 (citing McCann Decl. Vol. I, exs. 31-34; McCann Decl. Vol. II, exs. 63 at 654 & 64-67)) Dr. McCullough explains in his expert report that Defendants' product catalogs and websites publicized their generic products' AB rating and equivalence to COREG (with both of Defendants' websites also appearing to provide a link to Defendants' labels). (McCann Decl., ex. 2 at ¶¶ 158-60; *id.*, ex. 35 at ¶¶ 148-50) And Teva published complimentary copies of the MPR "targeted at healthcare professionals including physicians" which listed COREG and carvedilol as indicated for treatment of heart failure. (McCann Decl. Vol. I, ex. 2 at ¶ 161) Dr. McCullough opined that such materials "encouraged physicians to administer [Defendants' generic carvedilol] to attempt to reduce [] the risk of death in patients with heart failure"—he and "physicians practicing as [his] colleagues[] would look at

[Defendants' marketing of their generics] and have confidence and have the understanding that, in fact, when they prescribe carvedilol, that patients are indeed getting . . . equivalent products. . . . [I]f the information says here, Branded equivalent, I think doctors would trust Teva at their advertising word that, in fact, it's a brand equivalent." (McCann Decl. Vol. I, ex. 48 at 65-67; *see also id.*, ex. 2 at ¶ 149; *id.*, ex. 35 at ¶ 150; Riley Decl. Vol. I, ex. 10 at 266-67 (Dr. McCullough testifying that Glenmark's product catalog would convey the message to physicians that when they prescribe Glenmark's carvedilol, "that they indeed would be reducing the risk of mortality due to heart failure")) Although Defendants state in one breath that "[t]here is no evidence that . . . [these] other communications [of Defendants] were read by doctors, let alone influenced their prescriptions[,]" (D.I. 313 at 11), they had previously acknowledged an explicit dispute of fact in this regard, when they wrote in their opening brief that "[t]he parties' experts dispute whether physicians read generic company releases, product catalogues and websites[,]" (D.I. 249 at 17 n.8; *see also* GSK's Induced Infringement Presentation, Slide PDX-115; Tr. at 25).

In sum, the Court finds that Plaintiffs have proffered sufficient evidence to raise a genuine dispute of material fact as to whether Defendants' conduct actually caused doctors to infringe the '000 patent. While they may not have offered "hard proof" as to any one specific doctor, Plaintiffs are entitled to present the jury with their circumstantial evidence that Defendants' "internal thought process is we want people to infringe, [and] they're putting out messages, the label, their product catalog with the AB rating and saying go ahead and infringe. And then we know that doctors are infringing. The jury can make the inference that is caused by Defendants' materials." (Tr. at 25-26); *see also Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d

1201, 1222 (Fed. Cir. 2014) ("Making findings of fact by weighing evidence—such as the evidence presented by the parties regarding induced infringement—is the role of the jury.").

B. Whether GSK Has Demonstrated that a Genuine Issue of Material Fact Exists Regarding Whether Defendants Actively Encouraged Infringement During the Skinny Label Period

Defendants also argue that Plaintiffs have not put forward sufficient evidence that Defendants actively encouraged infringement of the '000 patent during the Skinny Label Period. (D.I. 249 at 17-23) The Court previously rejected a challenge by Teva regarding the sufficiency of Plaintiffs' allegations with respect to this time period at the pleadings stage, and held that, *inter alia*:

> (1) "[I]t 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 part of a winning induced infringement argument for GSK. [But] if GSK's allegations regarding the 'AB rating'] were all that it had, that could not be enough to withstand a motion to dismiss." MTD R&R, 2016 WL 3946770, at *10 n.13 (emphasis in original).
>
> (2) Teva's press releases that were published before the '000 patent issued could be relevant to Teva's intent to capture the CHF market. *Id.* at *10-11.
>
> (3) "[I]t is plausible that certain language in Teva's [skinny] label could instruct the administration of carvedilol in order to decrease a risk of mortality in patients surviving a heart attack with CHF." *Id.* at *11-16.
>
> (4) GSK pled facts in its SAC suggesting a lack of alleged substantial non-infringing uses for carvedilol, and such allegations could further suggest Teva's intent to induce use of its generic drug for the patented treatment of CHF during the Skinny Label Period. *Id.* at *16-17.

With respect to the last of the factors set out above, it is true that since the pleadings stage, the

facts have crystalized to show that over 80% of uses of Defendants' generic carvedilol are non-infringing uses. (D.I. 249 at 18 (citing Riley Decl. Vol. III, ex. 27 at ¶¶ 64-65)) In light of these substantial non-infringing uses of Defendants' products, the Court will not consider the *magnitude of the non-infringing uses* to be evidence that Defendants specifically intended to induce infringement by selling generic carvedilol. (*Id.*; *see also* D.I. 313 at 12 n.6); *Warner-Lambert*, 316 F.3d at 1365 ("[W]here a product has substantial non-infringing uses, intent to induce infringement cannot be inferred even when [the accused infringer] has actual knowledge that some users of its product may be infringing the patent."); *Acorda Therapeutics Inc. v. Apotex Inc.*, Civil Action No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *14 (D.N.J. Sept. 6, 2011) (finding that intent to infringe could not be inferred on the part of defendant where approximately 75% of the drug's uses were non-infringing), *aff'd*, 476 F. App'x 746 (Fed. Cir. 2012). The existence of a substantial non-infringing use, however, does not *preclude* a finding of induced infringement. *Vanda Pharms., Inc. v. Roxane Labs., Inc.*, 203 F. Supp. 3d 412, 434 (D. Del. 2016) (citing *Erbe Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1284 (Fed. Cir. 2010)).

As to the force of the other factors set out above, Defendants recycle some of the same underlying arguments in their Motion that they made at the pleadings stage. That is, they assert that their marketing of their generic carvedilol's AB rating, the content of the press releases at issue, and the nature of the skinny label language, even taken together, would not amount to sufficient evidence to support an induced infringement claim.

Defendants argue, for instance, that (1) the "Indications and Usage" sections of Defendants' skinny labels did not include the CHF indication, (2) that Defendants' generic

carvedilol was not FDA-approved for use in the intentional treatment of CHF during the Skinny Label Period, and therefore, (3) as a matter of law, Defendants' skinny labels could not instruct the use of carvedilol for the intentional treatment of CHF. (D.I. 249 at 19-20 (citing *Warner-Lambert*, 316 F.3d at 1354-56; *Allergan*, 324 F.3d at 1334; *Bayer*, 676 F.3d at 1324)).

In the MTD R&R, the Court explained in detail why those three cases are distinguishable from the facts here, and why it believed 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." 2016 WL 3946770, at *12-16. In its objections to the MTD R&R, Teva reiterated its position that *Warner-Lambert*, *Allergan*, and *Bayer* stand for the unequivocal law that "based on Teva's skinny label there can be no claim for inducement of a patent that requires the intentional treatment of CHF." (D.I. 194 at 4) Chief Judge Stark has now overruled Teva's objections and adopted the MTD R&R in full. *GlaxoSmithKline LLC*, 2017 WL 1050574, at *1-2. The Court remains persuaded that "the mere existence of a skinny label does not foreclose the possibility of infringement liability." (D.I. 297 at 26)[11]

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[11] *See also, e.g.*, *AstraZeneca*, 633 F.3d at 1060 ("The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [the defendant's] affirmative intent to induce infringement."); *In re Depomed Patent Litig.*, Civil Action No. 13-4507 (CCC-MF), 2016 WL 7163647, at *64 (D.N.J. Sept. 30, 2016) (noting that the MTD R&R "addressed similar facts to [the case before it]—namely, inducement by a drug label indication that was alleged to overlap with a carved out indication" and concluding that "[t]he Court agrees fully with the conclusion in *GlaxoSmithKline [LLC v. Teva Pharms. USA, Inc.*, Civil Action No. 14-878-LPS-CJB, 2016 WL 3946770 (D. Del. July 20, 2016)] that the mere fact that [the generic drug manufacturer] has carved out Indication 2 from its label does not preclude Plaintiff's claim for inducement as a matter of law."); *cf. Braintree Labs., Inc. v. Breckenridge Pharm., Inc.*, 2016-1731, 2017 WL 1829140, at *4 (Fed.

The Federal Circuit has recently suggested that when a plaintiff's induced infringement claim relies on the content of a defendant's label—whether the generic manufacturer's label copies the brand drug label or carves out particular material—the Court must assess the "link between the [] use described on the [defendant's] labeling and the patented use." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1368-69 (Fed. Cir. 2017). That is, does the defendant's label provide "vague" instructions that do not amount to "clear enough instructions for the infringing use[,]" on the one hand, or are the instructions "unambiguous on their face" in "encourag[ing] or recommend[ing] infringement[,]" on the other hand? *Id.* (internal quotation marks and citation omitted).

In light of this instruction, the Court finds that there is a genuine dispute of material fact as to whether Defendants' skinny labels instruct or encourage physicians to infringe the '000 patent. The evidence demonstrates that the conditions of CHF and Post-MI LVD are not entirely distinct and indeed can co-exist, (*see* McCann Decl. Vol. I, ex. 28 at 78), with about half of all Post-MI LVD patients suffering from CHF, (*id.*, ex. 2 at ¶ 89). The Post-MI LVD Indication in the "Indications and Usage" sections of Defendants' skinny labels state that Defendants' generic 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

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Cir. May 5, 2017) (finding that the generic manufacturer's ANDA label instructs how to engage in an infringing use and shows an affirmative intent that the product be used to infringe where it was indicated to cleanse the colon and the patented method for "inducing purgation" is "plainly within the scope of [the generic manufacturer's] proposed indication" and distinguishing *Warner-Lambert* as a case where the "ANDA applicant's labeled indication for partial seizures would not induce infringement of a 'method for treating neurodegenerative diseases" where the "two indications were *entirely distinct* because partial seizure is not a neurodegenerative disease") (emphasis added).

fraction of ≤40% (*with* or without *symptomatic heart failure*)[.]" (McCann Decl. Vol. I, exs. 25, 27 (emphasis added)) On their face, those words could be read to indicate an instruction to give the drug to patients with heart failure, in order to reduce a risk of mortality. GSK's expert Dr. McCullough agrees, opining that during the Skinny Label Period, this language did in fact "instruct[] physicians to administer carvedilol to heart failure patients to decrease their risk of dying from heart failure." (*Id.*, ex. 2 at ¶ 83 & n.87)[12] And Dr. McCullough's report then

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[12] Defendants argue that other courts have rejected arguments that language similar to the "with or without symptomatic heart failure" language in the Post-MI LVD indication could amount to an instruction to engage in an infringing use. (D.I. 249 at 20-21) Defendants then cite to two cases that concluded that generic labels' statements that the drug at issue could be taken "with or without food" did not constitute an explicit instruction to engage in the patented methods. The Court agrees with GSK, however, that these cases are distinguishable from the facts at hand. (D.I. 297 at 27)

First, in *Shire LLC v. Amneal Pharms. LLC*, Civil Action No. 11-3781 (SRC), 2014 WL 2861430 (D.N.J. June 23, 2014), a Hatch-Waxman case, the Court concluded that plaintiffs failed to raise a material factual dispute as to whether the proposed label encouraged infringement of method claims requiring administration with food where the "Dosage and Administration" section of the label indicated that the products may be taken "'with or without food.'" 2014 WL 2861430, at *5. The Court explained that this statement is "indifferent to which option is selected" and at most, "may be understood to permit an infringing use, but permission is different from encouragement." *Id.* And in *Acorda Therapeutics Inc. v. Apotex Inc.*, Civil Action No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *1 (D.N.J. Sept. 6, 2011), another Hatch-Waxman case, the asserted claims were directed to reducing somnolence by taking the drug with food, and the Court held that the plaintiff failed to show that the defendant's proposed label would induce infringement where "the label nowhere says that somnolence is reduced when capsules are given with food[,]" and instead the label only "warn[ed] patients that they might *experience* somnolence when taking tizanidine capsules (whether with or without food)." 2011 WL 4074116, at *18 (emphasis in original). The Court concluded that "[a] label devoid of any information directly explaining reduced somnolence of the capsule with food cannot be said to encourage infringement[.]" *Id.*

Here, on the other hand, as GSK points out, (D.I. 297 at 27), the "with or without" language found in the Post-MI LVD indication instructs doctors that carvedilol reduces mortality in people who have survived a myocardial infarction and who, additionally, have heart failure. In explicitly *instructing doctors to administer* carvedilol to a patient population that *includes people with heart failure* in order to reduce their risk of dying (indeed, in the CAPRICORN study

highlights how other language in additional sections of Defendants' skinny labels "provides further detail on using [Defendants'] carvedilol in heart failure patients to increase survival, or in other words, to decrease mortality." (*Id.*, ex. 2 at ¶¶ 84-90)[13] In light of the plain language of the

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described in the skinny label, nearly half of the patients had CHF), this language cannot really be characterized as being indifferent to the infringing use. And so, it is unlike language indicating that you can take a drug with or without food. A reasonable jury could conclude that the language *encourages* administration of the drug to Post-MI LVD patients who do and do not have heart failure.

[13] More specifically, the "5.1 Cessation of Therapy" sections of Defendants' skinny labels explained that patients with coronary artery disease who are being treated with carvedilol should be advised against abrupt discontinuation of therapy, and advised that since that condition is common and may be unrecognized, "it may be prudent not to discontinue carvedilol therapy abruptly even in patients treated *only for* hypertension or *heart failure*." (McCann Decl. Vol. I, exs. 25, 27 (emphasis added)) Dr. McCullough opines that his interpretation of this language "is that [Defendants] fully understood physicians were administering [their] carvedilol to patients with the sole indication of heart failure, and [Defendants were] warning those physicians not to discontinue therapy because of increased risks associated with abrupt cessation of therapy." (*See, e.g., id.*, ex. 2 at ¶ 86) A couple of sections of Defendants' skinny labels (5.4 Heart Failure/Fluid Retention and 17.1 Patient Advice) warned about "[w]orsening heart failure[,]" (*id.*, exs. 25, 27), which Dr. McCullough opines implies that carvedilol was indeed being administered for the treatment of heart failure during the Skinny Label Period and "teaches" the use of same, (*see, e.g., id.*, ex. 2 at ¶¶ 86, 90). Section 5.8, "Deterioration of Renal Function[,]" notes that on rare occasions, use of carvedilol "in patients with heart failure has resulted in deterioration of renal function" and recommends that renal function be monitored in patients with certain risk factors, including ischemic heart disease. (*Id.*, exs. 25, 27) Dr. McCullough opines that this language "teach[es] that [Defendants'] generic carvedilol is to be administered for heart failure," which Dr. McCullough found to be significant in light of the fact that before COREG, other beta-blockers were shown to be potentially beneficial in patients who had just suffered a myocardial infarction, but they were expressly contraindicated for patients having symptomatic heart failure. (*See, e.g., id.*, ex. 2 at ¶ 87) Section 8.4, "Pediatric Use[,]" "reports and teaches the use of carvedilol in pediatric patients who have heart failure." (*Id.*, ex. 2 at ¶ 88 (citing *id.*, exs. 25, 27)) Finally, Section 14.1 of Defendants' skinny labels summarized CAPRICORN and reported that 47% of the 1,959 patients in the study had symptoms of heart failure, (*id.*, exs. 25, 27), thus "confirm[ing] that carvedilol significantly decreases the risk of mortality caused by heart failure, including in those patients with Post-MI LVD[,]" (*see, e.g., id.*, ex. 2 at ¶ 89).

Although Defendants argue that language in "Warnings" sections of labels cannot encourage infringement, (D.I. 249 at 21-22), the Court is not persuaded that such language, read in conjunction with the other language throughout the label summarized above, could not

skinny labels and the undisputable "overlap" between CHF and Post-MI LVD, (D.I. 249 at 19; D.I. 313 at 13), a jury could reasonably conclude that doctors would interpret the skinny labels as instructions to administer carvedilol to reduce mortality in CHF patients. *Cf. Depomed*, 2016 WL 7163647, at *65 (explaining that the court "does not require 'magic words' in the label for a finding of inducement" but does require "a showing that [the generic manufacturer] intends its customers to use the product to treat [the patented use] because that use is readily apparent to the customer from the label").[14]

In addition to the language of Defendants' skinny labels, Plaintiffs point to other evidence that they assert demonstrates that Defendants had the intent to induce infringement of the '000

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constitute evidence of induced infringement. *Cf. Eli Lilly*, 845 F.3d at 1361, 1369 (concluding that where "the product labeling includes repeated instructions and warnings regarding the importance of and reasons for folic acid treatment" and where the patented method relates to administering a drug after pretreatment with folic acid and vitamin B12, "[t]he instructions are unambiguous on their face and encourage or recommend infringement").

[14] In his report, Dr. McCullough also opines that Defendants' skinny labels taught the administration of carvedilol for greater than six months, (McCann Decl. Vol. I, ex. 2 at ¶ 138 (noting that the "Clinical Studies" sections on the skinny labels showed that the CAPRICORN study's duration was longer than six months and set out data that would have taught the physician that "survival benefits accrue after six months of therapy, and therefore carvedilol would be administered for longer than six months")), and in maintenance dosages, (*id.* at ¶ 142 (noting that the "Dosage and Administration" sections of the skinny labels "describes in detail the process of arriving at a maintenance dosage to reduce mortality caused by heart failure")), as claimed in the '000 patent.

As for any mention of taking carvedilol in conjunction with one or more other therapeutic agents selected from the group consisting of an ACE inhibitor, a diuretic, and digoxin, ('000 patent, col. 8:33-35), Defendants' labels do make some mention of the use of such agents in conjunction with carvedilol, (*see* McCann Decl. Vol. I, exs. 25 & 27 at Sections 1.2, 2.2, 5.4, 7.4, 12.5, 14.1; *cf. id.* at Section 17.2 (noting that carvedilol tablets are "used, often with other medicines")). In light of that, and in light of the fact that Defendants' briefing barely focused on this issue, (D.I. 249 at 22), the Court finds that there is an issue of fact as to whether the label's language encourages the use of carvedilol with such agents.

patent. This evidence too helps to create a genuine issue of material fact on the intent/active encouragement question.

For example, Plaintiffs cite to evidence from the time prior to and around the launch of Defendants' generic products as being probative of an intent to induce infringement. This includes: (1) documents evidencing Teva's original plan to market and sell a product expressly labeled with the CHF indication, as well as Teva's sudden pre-launch decision to remove that indication, and (2) Defendants' press releases issued at launch that compared Defendants' generics to COREG, that referenced COREG's annual sales (amounts that included sales of the drug to be used in treating patients with heart failure), and, in Glenmark's case, that expressly stated that COREG is a medication FDA approved to treat, *inter alia*, heart failure. (D.I. 297 at 22-23 (citing *Teva* Action, D.I. 60, ex. K, L; McCann Decl. Vol. I, ex. 27; *Glenmark* Action, D.I. 59, ex. K)) The idea is that Defendants—even before the patent-in-suit issued—long had designs on encouraging physicians to administer carvedilol in a manner that would end up infringing the '000 patent, and that these documents help give away that inartfully-hidden mind set. (*Id.*)

In response, Defendants argue that this evidence "*pre-date[s]* the '000 patent and cannot constitute affirmative action on which an inducement claim is based." (D.I. 313 at 14 (citing *Nat'l Presto Indus. v. West Bend*, 76 F.3d 1185, 1196 (Fed. Cir. 1996) (emphasis in original)). But the Court already considered and rejected this argument in the MTD R&R, explaining that "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." 2016 WL 3946770, at *10-11 (citing cases) (emphasis in original).

Additionally, Plaintiffs point to Defendants' sales forecasts, which Defendants did not

adjust during the Skinny Label period to omit sales in the heart failure market, (D.I. 297 at 23 (citing McCann Decl. Vol. I, ex. 23 at 142; *id.*, ex. 24 at 76, 108-109, 217)), and to testimony from Defendants' employees indicating that they expected their generic products to be used in the same way as COREG and that they intended to capture as much of COREG's sales as possible, regardless of their products' skinny labels, (*id.* at 23, 26 (citing McCann Decl. Vol. I, ex. 24 at 76, 108-09, 216-17; *id.*, ex. 23 at 110-11; *id.*, ex. 39 at 82-83)). Plaintiffs also assert that Defendants' "promot[ion]" of their generic carvedilol tablets on their websites and in literature as AB-rated to COREG and as the "[g]eneric of Coreg[] Tablets" ensured that they would capture sales for the CHF indication, even during the Skinny Label Period. (*Id.* at 23-24; McCann Decl. Vol. I, ex. 2 at ¶¶ 158-73; *id.*, ex. 35 at ¶¶ 148-58)[15] And Plaintiffs note that

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[15] On this point, Defendants counter that (1) "GSK's argument that statements regarding an AB-rating demonstrate specific intent to induce has been rejected as a matter of law by the Federal Circuit[,]" citing *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) ("*AstraZeneca II*"), and (2) the Court has previously found that Defendants' promotion of their generic carvedilol as AB-rated is legally insufficient. (D.I. 249 at 22-23 (citing D.I. 191 at 16-34; *Glenmark* Action, D.I. 38 at 9-11)) The Court does not agree that a generic defendant's statements regarding its generics' AB rating can never be relevant to an induced infringement claim. The Court explained its conclusion in this regard in the MTD R&R. 2016 WL 3946770, at *8-10 & n.13. While the Court was not persuaded by GSK's suggestion that the mere fact that Teva promoted its drug as AB-rated to COREG should *alone* be enough to set out a plausible claim for induced infringement, it explained that "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 part of a winning induced infringement argument for GSK." *Id.* at *10 n.13 (emphasis in original). The Court is not persuaded that *AstraZeneca II* stands for a contrary proposition. Instead, *AstraZeneca II* holds that when a generic manufacturer's proposed label "explicitly and undisputably carve[s] out all patented indications for" the drug at issue, a plaintiff may not point to the fact that "pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available" to sustain an induced infringement claim, as that would "vitiate" the statute allowing section viii carve-out statements. 669 F.3d at 1380. Here, of course, Plaintiffs assert (with some force) that Defendants' skinny labels do *not* explicitly and undisputably carve out the patented indication. And they have provided some evidence that Defendants were aware that an AB rating would lead the drug to be used in the same ways as COREG could be used. (*See, e.g.*, McCann Decl. Vol. I,

during the skinny label period, Teva described carvedilol only as a "compound used in the treatment of [CHF][,]" (McCann Decl. Vol. I, ex. 37 at ¶ 14), and Glenmark agreed with that characterization, (*id.*, ex. 38 at ¶ 14).

While it is true that some of this conduct was not communicated to the alleged direct infringers, the Federal Circuit has explained that "'a defendant's acts to encourage direct infringement [can be] probative of an unlawful intent, even if customers do not learn of them or the acts don't cause the customers' direct infringement.'" *Power II*, 843 F.3d at 1331-32 (internal citation omitted). Ultimately, "[i]ntent is a factual determination particularly within the province of the trier of fact[.]" *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1378 (Fed. Cir. 2005) (internal quotation marks and citation omitted). In sum, in light of the record as a whole, a jury could reasonably conclude that Plaintiffs' evidence demonstrates Defendants' intent to induce (or actively encourage) infringement of the '000 patent during the Skinny Label Period.[16]

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ex. 23 at 111; *id.*, ex. 24 at 216-17) And so the Court disagrees with Defendants that evidence regarding Defendants' promotion of their generic carvedilol's AB rating, *coupled with* the other evidence described above that is relevant to inducement, is legally irrelevant to a showing that Defendants intended to and did actively encourage infringement. *Cf. Abraxis Biosci., Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 590 (D.N.J. 2009) (finding that defendant's act of seeking an "'A'" substitutability rating for its ANDA products, so they may be substituted for all prescriptions of [the branded drug] without any need for physician intervention or approval, is strong circumstantial evidence of [defendant's] encouragement of infringement[,]" among other pieces of evidence including "numerous encouraging statements" in the defendant's package insert labeling), *rev'd on other grounds*, 625 F.3d 1359 (Fed. Cir. 2010).

[16] Glenmark makes an additional argument that it is entitled to summary judgment of non-infringement with respect to Plaintiffs' claims relating to the full label period, because "the undisputed evidence shows that Glenmark's inclusion of the CHF indication was inadvertent as opposed to intentional conduct." (D.I. 249 at 23-24; D.I. 313 at 15) But the same evidence of intent that Plaintiffs rely upon for the Skinny Label Period with respect to their claim of induced infringement against Glenmark would also apply to this brief full-label period (in which

IV. CONCLUSION

For the reasons set forth above, the Court recommends that Defendants' Motion for Summary Judgment of No Induced Infringement 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 by no later than **May 30, 2017**; responses are due by no later than **June 6, 2017**. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **May 30, 2017** for review by the Court, along with a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough*

Glenmark's label also included the Post-MI LVD indication). In other words, if there is an issue of fact as to whether Glenmark had the requisite intent throughout the Skinny Label Period when the CHF indication *was not included*, the fact that the CHF indication *was included* for a brief time during the full label period (even if by mistake) would not *absolve Glenmark from liability* during that period. At most it might suggest that evidence of the "mistake" is not particularly probative in the intent analysis.

of Stroudsburg, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted).

The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: May 23, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE