IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. GLENMARK GENERICS 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

Presently pending in these two related patent infringement cases are Defendant Glenmark Generics Inc., USA's ("Glenmark") and Teva Pharmaceuticals USA, Inc.'s ("Teva") (collectively, "Defendants") motions to dismiss Plaintiffs GlaxoSmithKline LLC ("GSK") and SmithKline Beecham (Cork) Limited's (collectively, "Plaintiffs") First Amended Complaints ("FAC"), pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motions"). (Civil Action No. 14-877-LPS-CJB, D.I. 18; Civil Action No. 14-878-LPS-CJB, D.I. 20)[1] For the reasons set

[1] The allegations in the respective FACs are very similar; as to the key issues at play in the Motions, the FACs are at times nearly identical. The parties' respective briefs are, in turn, very similar across the two cases. For this reason, the Court resolves both Motions together

forth below, the Court recommends that Defendants' Motions each be GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

A. Factual Background

The patent-in-suit, U.S. Patent No. RE40,000 (the "Asserted Patent" or the "'000 Patent") relates to the chemical compound carvedilol. Carvedilol belongs to a class of chemical compounds known as beta-blockers, which are drugs that, among other things, may be used to treat patients with high blood pressure, or hypertension. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 8; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 8) Approximately two decades ago, GSK filed New Drug Application ("NDA") No. 20-297 with the United States Food and Drug Administration ("FDA") on carvedilol tablets for management of hypertension, and in September 1995, it received approval to market the drug for that purpose. (*Id.*) However, GSK did not launch carvedilol then, in part due to the "crowded hypertensive treatment market[.]" (*Id.*) Instead, GSK pursued promising research suggesting that carvedilol could be used to successfully treat chronic heart failure ("CHF"); eventually, this led to the FDA's May 1997 approval of carvedilol for the treatment of CHF. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 8-17; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 8-17) Thereafter, GSK began marketing and selling carvedilol 3.125 mg, 6.25 mg, 12.5 mg and 25 mg tablets (referred to herein as "carvedilol tablets") under the brand name COREG® ("COREG"). (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 18; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 18)

By the year 2003, COREG had received FDA approval for multiple indications: for

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in this single Report and Recommendation.

management of hypertension, for treatment of mild-to-severe CHF and for a third use—treatment of left ventricular dysfunction following myocardial infarction in clinically stable patients ("left ventricular dysfunction"). (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 8, 17, 22-24; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 8, 17, 22-24) Despite this, GSK has only ever marketed COREG in the United States for the CHF indication (and has never marketed it for any other indication). (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 18, 25; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 18, 25)

GSK also obtained United States Patent No. 5,760,069 ("'069 Patent"), issued in June 1998, on a method of treatment using carvedilol to decrease the risk of mortality caused by CHF. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 28; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 28) In January 2008, that patent reissued as the Asserted Patent, which is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering COREG. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 28-33; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 28-33) The key claim of the Asserted Patent (and its only independent claim) is claim 1, which 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.*

(Civil Action No. 14-877-LPS-CJB, D.I. 14, ex. E ("'000 Patent"), col. 8:30-40 (emphasis in

original)) The italicized portion of the claim above is the portion that was added to the claim during the reissue proceeding.

Teva holds Abbreviated New Drug Application ("ANDA") No. 76-373 for generic carvedilol tablets. (Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 44) Although Teva had originally submitted a Paragraph IV certification asserting that the '069 Patent was invalid, eventually Teva sought FDA approval under 21 U.S.C. § 355(j)(2)(A)(viii) (a "Section viii carve out") to label its generic carvedilol tablets only for uses not covered by the patent—i.e., treating hypertension and left ventricular dysfunction. (*Id.* at ¶¶ 38-44; D.I. 22, ex. C)[2] Teva received this FDA approval on or about September 5, 2007 and launched its generic COREG tablets in the United States immediately thereafter. (Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 44) In May 2011, however, Teva amended its label to fully conform with and be identical (for all relevant purposes) to GSK's label for COREG, such that Teva's label now expressly included the CHF indication. (*Id.* at ¶¶ 45-46 & ex. G)

Glenmark holds Abbreviated New Drug Application ("ANDA") No. 78-251 for generic carvedilol tablets. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 40) It filed its application with a Section viii carve out, i.e., without those portions of the label relating to the CHF indication. (*Id.* at ¶ 42) On or about September 5, 2007, the FDA granted approval for Glenmark's ANDA, and Glenmark immediately launched its generic COREG tablets in the United States. (*Id.*) Thus, at the time of this launch, Glenmark's label promoted use for two

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[2] In resolving a Rule 12(b)(6) motion, the Court can consider the content of Teva's label from this time period, (Civil Action No. 14-878-LPS-CJB, D.I. 22, ex. C), although it is not attached to the FAC, since the document is integral to the FAC, (*id.*, D.I. 16 at ¶¶ 44-45). *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

indications—treating hypertension and left ventricular dysfunction. (*Id.*) However, it is alleged that at least between about August 2009 and about August 2010, Glenmark revised its label for generic carvedilol tablets to fully conform with and be identical (for all relevant purposes) to GSK's label for COREG, such that the label now expressly included the CHF indication. (*Id.* at ¶¶ 43-44 & ex. G) Thereafter, it appears that Glenmark switched back to the version of the label that it had utilized prior to about August 2009. (*Id.*; *see also* D.I. 21 at 5)

B. Procedural Background

Plaintiffs commenced these actions on July 3, 2014, alleging indirect infringement claims against the Defendants concerning the Asserted Patent. (Civil Action No. 14-877-LPS-CJB, D.I. 1; Civil Action No. 14-878-LPS-CJB, D.I. 1) Soon after, Defendants moved to dismiss the Complaints for failure to state a claim, pursuant to Rule 12(b)(6). (Civil Action No. 14-877-LPS-CJB, D.I. 10; Civil Action No. 14-878-LPS-CJB, D.I. 10) In response, on September 22, 2014, Plaintiffs filed the FACs. (Civil Action No. 14-877-LPS-CJB, D.I. 14; Civil Action No. 14-878-LPS-CJB, D.I. 16) On October 16, 2014, Chief Judge Leonard P. Stark referred these cases to the Court to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (Civil Action No. 14-877-LPS-CJB, D.I. 16; Civil Action No. 14-878-LPS-CJB, D.I. 18)

Defendants then filed the instant Motions, in lieu of answering the FACs, on October 23, 2014. (Civil Action No. 14-877-LPS-CJB, D.I. 18; Civil Action No. 14-878-LPS-CJB, D.I. 20) The Motions were fully briefed as of November 20, 2014. (Civil Action No. 14-877-LPS-CJB, D.I. 22; Civil Action No. 14-878-LPS-CJB, D.I. 25) On April 13, 2015, at the request of all

parties, the Court heard oral argument on the Motions.[3] (Civil Action No. 14-877-LPS-CJB, D.I. 36 ("Tr.")) On April 15, 2015 and April 17, 2015, the parties filed supplemental letter briefs, which the Court has also considered. (Civil Action No. 14-877-LPS-CJB, D.I. 33, 34; Civil Action No. 14-878-LPS-CJB, D.I. 34, 35)

II. STANDARD OF REVIEW

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

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[3] The Court heard argument in conjunction with holding a Case Management Conference.

Allegheny, 515 F.3d 224, 233 (3d Cir. 2008)).

III. DISCUSSION

The FACs allege that Defendants have indirectly infringed the Asserted Patent by inducement of infringement under 35 U.S.C. § 271(b) (Count I) and contributory infringement under 35 U.S.C. § 271(c) (Count II). The Motions seek dismissal of both Counts, and the Court will address the arguments as to each Count in turn.

A. Induced Infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." In order to prove induced infringement, the patentee "must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012) (internal quotation marks and citations omitted); *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1292-93 (Fed. Cir. 2008) ("Thus, 'inducement requires evidence of culpable conduct, *directed to encouraging* another's infringement, not merely that the inducer had knowledge of the direct infringer's activities.'") (emphasis added) (citation omitted).

Plaintiffs' claims for induced infringement are based on two general sets of allegations—that Defendants induced infringement: (1) during the time periods when their labels did not contain a CHF indication (i.e., for Teva, from approximately January 2008 through May 2011, and for Glenmark, from approximately January 2008 through August 2009 and post-August 2010) and (2) during the time periods when their labels were amended to include the CHF indication and were thus essentially identical to the COREG label (i.e., for Teva, after

approximately May 2011, and for Glenmark, from approximately August 2009 to August 2010). The parties have separately addressed the vitality of the claims in these two sets of time periods, and the Court will do the same below.

1. Time Periods When Defendants' Labels Did Not Include the CHF Indication

With regard to the time periods in which Defendants' labels for their generic carvedilol tablets did not include the CHF indication, Plaintiffs focus on two paragraphs in the Background section of the FACs, arguing that they provide the requisite factual specificity to withstand the Motions. (Civil Action No. 14-877-LPS-CJB, D.I. 21 at 12-13; Civil Action No. 14-878-LPS-CJB, D.I. 24 at 12-13) Those paragraphs state:

> [53. / 55.] In addition, even prior to its labeling change, [Teva/Glenmark] caused its generic carvedilol . . . tablets to be listed in the Orange Book with a therapeutic equivalence rating of "AB," which indicates that its generic copies are considered therapeutically equivalent to COREG® on all indications approved for the generic drug. *On information and belief, since the approval of its ANDA . . . [Teva/Glenmark] has actively promoted the "AB" rating of its generic carvedilol tablets and marketed them as therapeutically equivalent to and fully substitutable for GSK's COREG® tablets indicated for treatment of CHF.* Although the Orange Book states explicitly that an AB rating is limited to what is on the generic's approved label . . . [Teva/Glenmark] never informed the public that its generic carvedilol was not approved by the FDA for the CHF indication when it touted its generic copy as AB-rated and fully substitutable for COREG®.
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> [54. / 56.] On information and belief, [Teva/Glenmark] knew that when an AB-rated generic drug is available, many states and/or third party payers of prescription drugs (e.g., health insurance plans, Medicare and Medicaid programs) have adopted policies to encourage or require the substitution of the AB-rated generic drugs for the branded drugs, regardless of whether the generic drug label includes all the indications contained in the branded drug label. [Teva/Glenmark] also knew that unless informed otherwise, the

> market would assume that, like most-AB-rated generic drugs, [Teva's/Glenmark's] generic carvedilol tablets were labeled identically to COREG® and included the CHF indication. *As a result, by promoting its generic carvedilol tablets as AB-rated and fully substitutable for COREG®* without informing the market that its generic carvedilol tablets were not approved for the CHF indication, [Teva/Glenmark] knew and intended that its generic carvedilol tablets would be substituted for COREG® for patients prescribed the drug for treatment of congestive heart failure in the direct infringement of the '000 [P]atent.

(Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 53-54 (emphasis added); Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 55-56 (emphasis added))

Much of these paragraphs focus on what Defendants *knew* or what they *did not do* (or, in some cases, what those *other than Defendants* did). But, as the Federal Circuit has recognized, a claim for induced infringement requires more: "mere knowledge of possible infringement by others does not amount to inducement; specific intent *and action* to induce infringement must be proven. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (emphasis added); *see also Novartis Pharm., 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 citation omitted) (citing *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006)). The law requires the patent holder to plead facts that plausibly suggest that Defendants "promote[d] or encourage[d] doctors to infringe the . . . patent." *Warner-Lambert Co.*, 316 F.3d at 1364 (emphasis added).

When it comes to actions taken by Defendants that might be argued to amount to inducement of infringement, these key paragraphs say far less. The paragraphs do allege that Defendants "caused [their] generic carvedilol . . . tablets to be listed in the Orange Book with a

therapeutic equivalence rating of 'AB,' [indicating that their] generic copies are considered therapeutically equivalent to COREG® on all indications approved for the generic drug." But as the FACs themselves note, the "Orange Book states explicitly that an AB rating is limited to what is on the generic's approved label[.]" It is hard to conclude that Defendants' obtaining an AB rating in the Orange Book for their product, standing alone, could amount to sufficient "action" to encourage infringement of a patented use *not listed* on their label—when the Orange Book affirmatively instructs that a generic drug product is the therapeutic equivalent of a branded drug only for those uses *listed* on the Defendants' label.[4]

In the end, the claims will sink or swim based on the FACs' content regarding the sentences rendered in italics above, particularly the allegations that Defendants "actively . . . marketed" and "promot[ed]" their generic drugs as "A-B rated" and as "therapeutically equivalent to" and "fully substitutable for . . . COREG[.]" Plaintiffs seem to acknowledge this, as in their answering brief, they refer to these sentences as specifying the "actual actions by the defendants to encourage infringement" and assert that these allegations render their induced infringement claims plausible. (Civil Action No. 14-877-LPS-CJB, D.I. 21 at 13-15 (emphasis omitted); Civil Action No. 14-878-LPS-CJB, D.I. 25 at 13-15 (emphasis omitted)) Yet these key sentences suffer from a particular lack of any meaningful factual content. What type of "market[ing]" and "promoting" are Defendants alleged to have engaged in that gives rise to the claim? Is it simply the act of causing their drugs and accompanying drug labels to be sent out

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[4] *Cf. Novartis Pharm., Corp.*, 2013 WL 5770539, at *9 (dismissing, in an ANDA case, an induced infringement claim where defendants' proposed labels did not seek approval to market their generic drug to treat osteoporosis, a use protected by plaintiff's patent and approved by the FDA); *see also AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed Cir. 2012).

into the market? Or does it refer additionally to other acts, such as web-based or person-to-person marketing that is asserted to have confused the public into thinking that Defendants' drugs should be used for the patented form of treatment?[5] And if it is the latter, what is at least the general nature or scope of that alleged conduct said to be?

These key paragraphs of the FACs are silent as to these important questions, the answers to which could have an impact as to whether the claims here are plausible. As a result, they leave Defendants to guess at what the contours of these induced infringement allegations are. Without any further factual detail, Plaintiffs' "market[ing]" and "promoting" allegations are not much of a step up from a blanket statement that "Defendants have encouraged infringement"—i.e., a parroting back of the elements of the claim. Such allegations are insufficient to meet the requirements of *Twombly* and *Iqbal* that "enough facts" be pleaded to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570.

2. Time Periods When Defendants' Labels Did Include the CHF Indication

With regard to the time periods in which Defendants' labels for their generic carvedilol tablets included the CHF indication (in other words, time periods in which the generics' labels were essentially identical to GSK's COREG label), Defendants' main argument for dismissal is narrowly focused. That is, Plaintiffs have alleged (and it is not disputed) that during these time

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[5] At oral argument, counsel for Plaintiffs suggested that Plaintiffs do in fact have such evidence, and that this evidence is what motivated the inclusion of these rather generalized allegations in the FACs. (Tr. at 64, 81-82 (Plaintiffs' counsel explaining that "we go to a website and the products are listed . . . with their [AB] rating. And . . . sometimes there's a link to the branded drug's label that's utilized. So [the generic's website] will say compare [COREG], so you are encouraging people to go to the place that has the indication [for the patented use]")) Of course, no such conduct is set out in any level of detail in the FACs.

periods, Defendants' labels included, as one approved indication, treatment to decrease a risk of mortality caused by CHF. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 43; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 45) And there is no question that statements "in a package insert that encourage infringing use of a drug product are alone sufficient to establish intent to encourage direct infringement" for purposes of an induced infringement claim. *Bone Care Int'l, L.L.C. v. Roxane Labs., Inc.*, C.A. No. 09-cv-285 (GMS), 2012 WL 2126896, at *9 (D. Del. June 11, 2012) (internal quotation marks and citation omitted); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed Cir. 2010) (noting that the "pertinent question" as to whether a proposed label can provide evidence of a pharmaceutical company's specific intent to induce infringement is "whether the proposed label instructs users to perform the patented method" and "would inevitably lead some consumers to practice the claimed method"). Defendants' challenge here, however, is that the FACs do not sufficiently allege induced infringement because their labels could not be plausibly read to encourage administration of carvedilol to treat CHF for (as the Asserted Patent requires) a "maintenance period [of] *greater than six months*." ('000 Patent, col. 8:39-40 (emphasis added)) For the reasons set forth below, the Court disagrees with Defendants.

First, as Plaintiffs allege, Defendants' labels stated that Defendants' tablets were "'indicated for the treatment of mild-to-severe *chronic* heart failure'"—i.e., a malady that by definition persists for a lengthy period of time or is constantly recurring. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 44 (quoting ex. G at § 1.1) (emphasis added); Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 46 (quoting ex. G at § 1.1) (emphasis added)) And in advising patients as to use of carvedilol, the labels at issue caution that "'[p]atients should not interrupt or

discontinue using carvedilol tablets without a physician's advice'" and warn that "'[i]f you stop taking carvedilol tablets suddenly, you could have chest pain and/or a heart attack.'" (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 46 (quoting ex. G at §§ 17.1, 17.2); Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 48 (quoting ex. G at §§ 17.1, 17.2); *see also* Civil Action No. 14-877-LPS-CJB, D.I. 14, ex. G at "Dosage and Administration" section (instructing patients taking carvedilol for heart failure to start at 3.125 mg and increase to 6.25, 12.5, and then 25 mg over two-week intervals, and to "*[m]aintain* lower doses if higher doses are not tolerated" (emphasis added); Civil Action No. 14-878-CJB, D.I. 16, ex. G at "Dosage and Administration" section (same)) If one encourages a drug's use for a chronic disease, and one strongly encourages those taking the drug to continue to take it for an open-ended period (absent a doctor's advice otherwise), it is at least a plausible conclusion that one is encouraging the drug's administration for more than six months. These pleaded facts are probably enough, on their own, to support a claim of induced infringement.[6] But more is alleged.

Plaintiffs further note that portions of Defendants' labels promote data from many clinical studies in which carvedilol was taken by patients with mild to severe heart failure. Plaintiffs explain that "[a]ll the treatment durations mentioned in this section [of the labels] are greater than 6 months." (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 47-48; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 49-50) Indeed, these sections tout the beneficial results patients

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[6] Plaintiffs also plead that FDA regulations (21 C.F.R. § 201.57(c)(3)(i)(F)) establish that the "Dosage and Administration" section of Defendants' labels were required to state "'[t]he usual duration of treatment *when treatment duration should be limited*'"; they note that in that section, the labels do "not identify a limitation on treatment duration for the CHF indication." (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 45 (emphasis added); Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 47 (emphasis added))

obtained when taking carvedilol for CHF "during an average follow-up of 7 months" or "over 18 to 24 months" or where "[t]he mean duration of follow-up was 4.8 years" or where "[t]he trial was stopped after a median follow-up of 10 months [due to a large reduction in mortality.]" (Civil Action No. 14-877-LPS-CJB, D.I. 14, ex. G at § 14.1; Civil Action No. 14-878-LPS-CJB, D.I. 16, ex. G at § 14.1) The labels also indicate that "[a]pproximately 60% of the total treated population in placebo–controlled clinical trials received carvedilol for at least 6 months and 30% received carvedilol for at least 12 months"—and it is further alleged that much of the remainder of the population (i.e., the other 40%) stopped participating in the studies before six months not because they (or their physician) independently determined to stop the therapy, but instead due to the trials' early termination or the patients' death. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 48 (quoting ex. G at § 6.1); Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 50 (quoting ex. G at § 6.1)) Thus, the inclusion of this data, describing many examples of the drugs' administration for more than six months to treat CHF (and the beneficial effects thereof), could be seen to encourage just that same type of administration in the future.

And lastly, the allegations here are not that Defendants' labels were created and existed in a vacuum. Instead, Plaintiffs assert that Defendants distributed the labels (and their generic drug products) at the same time that GSK was simultaneously actively using the identical label in a widespread fashion to promote the approved use of COREG in a manner that would meet the claim's limitations. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 43-48; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 45-50)

In the end, while the labels at issue during these time periods did not flatly state "carvedilol should be administered for a maintenance period of greater than six months," there is

no requirement that Defendants need to have mimicked the precise wording of claim 1. Instead, the question is whether the allegations, when considered in their entirety and in context, *plausibly* suggest an intent and actions to encourage administration of carvedilol in a manner that would meet the claim limitations. *See In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1342-43 (Fed. Cir. 2012). For the reasons set out above, the Court finds that they do. *Cf. IGI Labs., Inc. v. Mallinckrodt LLC*, Civil Action No. 13-2044-RGA, 2014 WL 1652790, at *1-2 (D. Del. Apr. 22, 2014) (denying a motion to dismiss induced infringement counterclaims, where the patents at issue covered "using diclofenac for treating osteoarthritis of the knee via applying the diclofenac, waiting for it to dry, and applying either a second medication, sunscreen or insect repellant" and the plaintiff's label "instructs the reader to '[w]ait until the treated area is dry before applying sunscreen, insect repell[e]nt, lotion, moisturizer, cosmetics, or other topical medication'"); *Bone Care Int'l*, 2012 WL 2126896, at *11 (finding that a labeling instruction to administer a drug "for the treatment of secondary hyperparathyroidism ['SHPT'] in patients with chronic kidney disease on dialysis" would induce infringement of a patent claiming use of the drug for both treatment of SHPT and end stage renal disease, because a majority of patients with end stage renal disease have SHPT).[7]

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[7] Glenmark additionally argues that Plaintiffs' induced infringement claims fail due to the absence of facts pled to support a claim of direct infringement of the Asserted Patent, a required element of inducement of infringement. (Civil Action No. 14-877-LPS-CJB, D.I. 19 at 2, 14, 19; D.I. 22 at 2-3, 10) As set out above, claim 1 of the '000 Patent requires the administration of carvedilol "in conjunction with one or more therapeutic agents . . . selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and a digoxin." ('000 Patent, col. 8:32-36) Glenmark asserts that "the patent claims a combination of two drugs and there are *zero* allegations of any combination use." (Civil Action No. 14-877-LPS-CJB, D.I. 22 at 10 (emphasis in original); *see also id.* at 2-3; D.I. 19 at 2, 14, 19) With respect to the time period when Glenmark's label included the CHF indication, portions of that label make it clear that carvedilol is "usually" taken with one of these other three possible drugs,

B. Contributory Infringement

Under 35 U.S.C. § 271(c), a patentee must demonstrate that an alleged contributory infringer has sold, offered to sell or imported into the United States a component of a material or apparatus for use in practicing a patented process "knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." *See also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009); *Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 566 (D. Del. 2012). Here, Defendants' challenge to Count II is that the FAC does not sufficiently allege facts indicating that the carvedilol tablets at issue have no "substantial noninfringing uses." (Civil Action No. 14-877-LPS-CJB, D.I. 19 at 9-10; Civil Action No. 14-878-LPS-CJB, D.I. 21 at 10-11) A noninfringing use is "substantial" if it is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009).

It is not disputed that there are non-infringing uses for Defendants' carvedilol, including its use to treat hypertension, its use to treat left ventricular dysfunction, and its administration to

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(*see, e.g.*, *id.*, D.I. 14, ex. G at §§ 1.1, 1.3, 5.4, 14.1), and Plaintiffs note this in the FAC, (*id.* at ¶ 44). Thus, it is plausible that Glenmark's label specifically encourages the use of carvedilol together with one of these other medications (for a period of more than six months). The issue is less clear with respect to the time periods when Glenmark's label did not include the CHF indication. Even so, during that time frame, portions of GSK's label and the Asserted Patent establish that carvedilol was often taken with one of these add-on drugs, (*see, e.g.*, Civil Action No. 14-877-LPS-CJB, D.I. 14, ex. F at §§ 1.1, 1.3, 5.4, 14.1; '000 Patent, col. 1:31-41)—leading to the fair inference that if Glenmark was inducing the administration of carvedilol for CHF in these periods, it was encouraging individuals to do so in the way that drug is often administered (i.e., in conjunction with one of these other drugs). If Plaintiffs amend their claims with respect to these time periods (as the Court recommends they be given the opportunity to do at the conclusion of this Report and Recommendation), they can make this allegation relating to direct infringement even clearer in the amended complaint.

CHF patients for a maintenance period of six months or less.[8] Indeed, the FACs make repeated reference to these non-infringing uses, (*see, e.g.*, Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 8, 23, 24, 48; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 8, 23, 24, 50), some of which were the only FDA-approved indications on Defendants' labels for certain time periods relevant to this case.

Instead, the question is whether the carvedilol tablets at issue were used in a more than "occasional" manner for these three purposes. And in the key portions of the FACs, Plaintiffs plead facts suggesting that they were not.[9]

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[8] Defendants suggest a fourth non-infringing use in their reply briefs: use of carvedilol during periods of up-titration. (Civil Action No. 14-877-LPS-CJB, D.I. 22 at 3-4; Civil Action No. 14-878-LPS-CJB, D.I. 25 at 3) Up-titration is an initial period, lasting a few weeks, in which the drug is given to patients for the purpose of calibrating the size of the appropriate maintenance dosage, before thereafter being administered to the patient at that now-identified appropriate dosage level. (Civil Action No. 14-877-LPS-CJB, D.I. 14, ex. G at § 2.1; Civil Action No. 14-878-LPS-CJB, D.I. 16, ex. G at § 2.1) The Court is not convinced that administration of carvedilol to treat CHF during this time period is necessarily a separate "use" of the drug that is different from its use to treat CHF during the maintenance period referred to in claim 1. Indeed, it appears this is a legal issue that may be further debated later in the case during the claim construction stage. (*See* Tr. at 19-20 (Teva's counsel acknowledging that "once we start talking about an up-titration period versus maintenance period, we start to push into an issue of claim construction"); *id.* at 72-73 (Plaintiffs' counsel noting that whether the up-titration period is a separate period that cannot be combined with the maintenance period is "a claim construction issue at some level"))

[9] As a result, the allegations here are unlike those ordered dismissed in *Palmetto Pharm. LLC v. AstraZeneca Pharm. LP*, No. 2:11-cv-00807-SB-JDA, 2012 WL 484907 (D.S.C. Jan. 4, 2012), *report and recommendation adopted by* 2012 WL 484848 (D.S.C. Feb. 14, 2012). In *Palmetto*, the patent claimed only a method for treating non-hyperlipidemic persons, and the plaintiff did not dispute (and pleaded facts in its Amended Complaint that affirmatively established) that for a period of seven years, the defendant's accused drug product (CRESTOR) had been "widely prescribed" for the treatment of hyperlipidemic persons. *Id.* at *2, *7 (citing D.I. 27 at ¶¶ 13-14, 25)). In contrast, here the FACs do *not* admit that Defendants' carvedilol tablets (or those manufactured by any other entity) were "widely prescribed" for any of the non-infringing uses discussed above. Indeed, Plaintiffs hotly dispute that fact, and pleaded facts in the FACs that set out at least a plausible basis to believe that no such widespread prescription

For example, as to carvedilol's use to treat hypertension, Plaintiffs assert that "[h]ypertensive treatment is a crowded market in which many treatment options are available." (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 25; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 25) As a way to suggest that carvedilol was not actually used often in the relevant time periods to treat hypertension, Plaintiffs cite to a 2014 report (or "guideline") commissioned by the United States Department of Health and Human Services that: (1) recommended four classes of other drugs for initial treatment of hypertension and (2) specifically stated that beta-blockers (like carvedilol) were not recommended for the initial treatment of hypertension, due to poor study results and the lack of credible clinical trial data suggesting beta-blockers' effectiveness for this purpose. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 25 & ex. D; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 25 & ex. D) As to carvedilol's treatment for left ventricular dysfunction, Plaintiffs allege that "a much smaller population of patients suffer from" that malady than do the 5.1 million persons in the United States who suffer from CHF. (Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶¶ 9, 26; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶¶ 9, 26) Lastly, as noted in the subsection above, much of the thrust of the FACs explains why the "vast majority" of those who have used carvedilol to treat CHF have done so for a period of "more than six months." (*See, e.g.*, Civil Action No. 14-877-LPS-CJB, D.I. 14 at ¶ 27; Civil Action No. 14-878-LPS-CJB, D.I. 16 at ¶ 27)

As was noted by at least one Defendant, Plaintiffs' allegations in this regard could be seen to "raise more questions than they answer[.]" (Civil Action No. 14-878-LPS-CJB, D.I. 25 at 1) The facts alleged certainly could be more full, for example, and they contain no actual data as to

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occurred.

how many Americans were taking carvedilol in the time periods at issue here for any of these non-infringing uses. (*See* Tr. at 63 (Plaintiffs' counsel asserting that Plaintiffs intend to seek out such data during discovery)) Moreover, carvedilol clearly was approved to treat hypertension and left ventricular dysfunction for many years prior to and subsequent to COREG's launch.[10] And indeed, Defendants argue that certain portions of the materials that Plaintiffs attach to their FACs might even *help* Defendants rebut the claim of contributory infringement. (*See, e.g.*, Civil Action No. 14-878-LPS-CJB, D.I. 21 at 12)[11]

However, "questions" about a party's liability need not be definitively "answer[ed]" at the

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[10] However, the Court is not prepared to conclude that, as a legal matter, the sole fact that a drug is FDA-approved for a non-infringing use renders a plaintiff unable to successfully assert that the drug has no "substantial" non-infringing uses. (*See* Tr. at 12 (Teva's counsel explaining that "Teva isn't arguing and I'm not getting up here and saying that just because [uses of carvedilol for the treatment of hypertension and the treatment of left ventricular dysfunction] are FDA-approved they must be substantial[] uses")); *see also Novartis Pharm., Corp.*, 2013 WL 5770539, at *10 (rejecting defendants' argument that "'[a]n FDA approved indication is necessarily [a] substantial' [non-infringing use, where] Plaintiffs previously sought approval for [the FDA-approved indication and] conducted clinical trials for this indication[, one] for which the FDA deemed the product safe and effective") (internal citation omitted). Presumably, such FDA approval would, on average, make it more difficult to prevail on this type of contributory infringement claim. But the Court is not aware of precedent suggesting that it makes such a claim impossible to bring or renders that claim *de facto* implausible.

[11] For example, Defendant Teva notes that the 2014 guideline referenced above is attached to the FAC, and that a table within the report references at least two other guidelines issued between 2010-2014 that recommended that beta-blockers be used to treat certain adults who suffer from hypertension. (*See, e.g.*, Civil Action No. 14-877-LPS-CJB, D.I. 14, ex. D at 518; Civil Action No. 14-878-LPS-CJB, D.I. 16, ex. D at 518) And it is true that these facts might help combat Plaintiffs' claim. But it is also worth noting that even when looking at this particular table, the record is not as one-sided as Defendants suggest. The table lists seven guidelines in total, and the other five guidelines (one from 2010, one from 2011, one from 2012, one from 2013 and the 2014 guideline cited in the FACs) did not recommend use of beta-blockers to initially treat hypertension at all. (*Id.*) And even as to those two guidelines in which beta-blockers were recommended, beta-blockers as a class were recommended only for particular subsets of the general population, and even then, were recommended along with a number of other drug treatment options. (*Id.*)

pleading stage. Instead, all Plaintiffs must do at this stage is point to sufficient facts that render it plausible that their claims could succeed. Here, the allegations may fall fairly close to the plausibility line. But the key paragraphs cited above, and the entirety of the 70+ paragraph FACs, contain enough factual specificity to put Defendants on notice of the claim of contributory infringement, and to sufficiently suggest that any non-infringing use of carvedilol was occasional and non-substantial. *Cf. Novartis Pharm., Corp.*, 2013 WL 5770539, at *10 (denying a motion to dismiss a contributory infringement claim where the FDA-approved uses for the drug at issue included a non-infringing use (the treatment of Paget's disease), since it was plausible that any such use was occasional, where 0.3% of the drug's use was to treat Paget's disease, amounting to treatment of "'at least hundreds and hundreds of cases of Paget's with [the drug] every year'") (internal citation omitted); *Braintree Labs., Inc. v. Nephro-Tech., Inc.*, 31 F. Supp. 2d 921, 924-25 (D. Kan. 1998) (denying the defendant's motion to dismiss a contributory infringement claim and explaining that the issue of whether the defendant's product is capable of being sold for a substantial noninfringing use is a question of fact more appropriately resolved at a later stage in the case, such as summary judgment or trial).

C. Nature of Dismissal

With regard to the claims for induced infringement during the time periods where the CHF indication was not on Defendants' labels, the Court recommends that the dismissal be without prejudice. Defendants argue that because Plaintiffs have already amended their initial Complaint once, the dismissal should be with prejudice, because further amendments would be "futile." (Civil Action No. 14-877-LPS-CJB, D.I. 19 at 20; Civil Action No. 14-878-LPS-CJB, D.I. 21 at 20) Yet this is the first instance in which a court has found Plaintiffs' allegations

wanting and where Plaintiffs would now be attempting to overcome those identified deficiencies (if it is possible to do so). And, as noted above, it appears that there is additional factual content that Plaintiffs could add to these induced infringement allegations that would, at a minimum, make their argument against dismissal far stronger.

It is within the Court's discretion to grant leave to amend, *see Foman v. Davis*, 371 U.S. 178, 182 (1962), and amendment should be allowed "when justice so requires[,]" Fed. R. Civ. P. 15(a)(2). In light of that, and because it is not clear to the Court that amendment would be futile, the Court recommends that Plaintiffs be given leave to file further amended complaints addressing the identified deficiencies regarding the claims recommended for dismissal. *See, e.g.*, *Abrams v. Wainscott*, Civil Action No. 11-297, 2012 WL 3614638, at *4 (D. Del. Aug. 21, 2012).

IV. CONCLUSION

For the foregoing reasons, the Court recommends that Defendants' Motions each be GRANTED-IN-PART and DENIED-IN-PART. More specifically, the Court recommends that the Motions be GRANTED as to Plaintiffs' claims regarding induced infringement during the time periods where the CHF indication was not on Defendants' labels, and that they be DENIED as to Plaintiffs' claims regarding induced infringement during the time periods where the CHF indication was on Defendants' labels, and as to Plaintiffs' claims for contributory infringement. The Court also recommends that if the District Court affirms this Report and Recommendation as to dismissal of the afore-mentioned induced infringement claims, that: (1) Plaintiffs be given fourteen (14) days from the date of affirmance to file further amended complaints; and (2) failure to do so shall give rise to dismissal with prejudice of those claims.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

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

Dated: April 22, 2015

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE