IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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MEMORANDUM OPINION

March 28, 2018
Wilmington, DE

STARK, U.S. District Judge:

Beginning on June 12, 2017, the Court held a seven-day jury trial in this patent infringement action (D.I. 457, 458, 459, 460, 461, 462, 463 (hereinafter, "Tr.")), resulting in a verdict of: (1) willful induced infringement of claims 1, 2, and 3 of U.S. Patent No. RE40,000 ("the '000 patent") by Defendant Teva Pharmaceuticals USA, Inc. ("Teva") during the "skinny label" (also referred to as "partial label" or "carve-out") period; (2) no induced infringement of claims 6, 7, 8, and 9 of the '000 patent by Teva during the skinny/partial label period; (3) willful induced infringement of all asserted claims (claims 1-3 and claims 6-9) of the '000 patent by Teva during the "full label" (also referred to as "amended label") period; (4) no invalidity of the '000 patent; and (5) an award to Plaintiffs GlaxoSmithKline and SmithKline Beecham (Cork) Ltd. ("GSK") of $234,110,000 in lost profits and $1,400,000 in reasonable royalty damages. (D.I. 448)

Pending before the Court are the parties' post-trial motions. Teva filed a renewed motion for judgment as a matter of law ("JMOL"), or in the alternative for a new trial, on five grounds: (1) no inducement of infringement of any claims at any time – that is, during either the skinny label or full label periods – and no lost profits; (2) no inducement of any claims during the skinny label period; (3) no inducement of claims 6 and 7 during the full label period; (4) no willful infringement; and (5) invalidity. (D.I. 464)[1] GSK filed a motion for enhanced damages, attorney fees, and pre- and post-judgment interest. (D.I. 466) Finally, Teva has moved to strike multiple

[1]During oral argument on the pending motions, Teva also argued that if the Court found liability, the proper remedy was a remittitur of damages to a figure not to exceed $1.4 million for a reasonable royalty, rather than a new trial on damages which would, in Teva's view, be futile. (D.I. 484 (hereinafter, "Hr'g Tr.") at 27-28)

exhibits GSK submitted in support of its post-trial motion that Teva contends were not part of the trial record. (D.I. 474)

The Court heard oral argument on October 26, 2017. Having considered the parties' briefing (D.I. 465, 467, 471, 472, 475, 476, 477, 478, 479) and letters regarding supplemental authority (D.I. 483, 485, 486, 487), and for the reasons discussed below, the Court will grant in part and deny in part Teva's JMOL motion (D.I. 464), and deny as moot both GSK's motion (D.I. 466) and Teva's motion to strike (D.I. 474).[2]

I. BACKGROUND

Congestive heart failure ("CHF") is a chronic condition that occurs when a diseased heart is unable to deliver sufficient oxygenated blood to the rest of the body. (*See generally* '000 patent; Lukas Tr. at 359-60[3]) CHF affects over five million people in the United States, and half of those who develop CHF will die within five years of diagnosis. Prior to 1997, CHF treatment included limitation of physical activity, restriction of salt intake, and the use of a diuretic – a drug that decreases excess fluid – and digoxin – a drug that stabilizes heart rhythm. (*See* '000 patent; Lukas Tr. at 361) Angiotensin converting enzyme ("ACE") inhibitors were also prescribed in

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[2]On July 27, 2017, the Court advised the parties of its inclinations (D.I. 456) concerning the issues the parties indicated they intended to raise (D.I. 455) in their post-trial motions. The Court's ruling today in favor of Teva on the key issue of GSK's liability for induced infringement is different than the previously-announced inclinations. (*See* D.I. 456 at 2 ("I am inclined to disagree with Teva that no reasonable juror could have concluded that Teva's actions induced even a single physician to administer Teva's carvedilol to a patient for use in an infringing manner."); *but see also generally id.* at 3 ("I conclude by emphasizing that the views expressed in this letter do not constitute an order but are merely my present inclinations, based principally on my recollection of the trial and the parties' limited post-trial submissions. I will only be able to make final decisions after receiving the forthcoming briefing and conducting oral argument."))

[3]Citations to the trial transcript are in the format: "[Witness name] Tr. at [page number]."

conjunction with a diuretic, digoxin, or both. (*See* '000 patent) While ACE inhibitors caused an improvement in CHF mortality rates, doctors were still looking for other solutions. (Lukas Tr. at 362)

In the late 1980s, GSK and its research partner, Boehringer Mannheim GmbH, began researching the possibility of using carvedilol to treat CHF. (Ruffalo Tr. at 1271-72) Carvedilol belongs to a class of chemical compounds known as beta-blockers, which are drugs used to treat high blood pressure or hypertension. In the early 1990s, beta-blockers, which slow the heart rate and depress the heart's contractility – that is, its ability to pump – were clinically contraindicated for CHF, as CHF patients are critically dependent on how well their heart pumps. (*See* Lukas Tr. at 357-58) Treating high blood pressure with beta-blockers worsened a patient's heart failure due to the beta-blocker's depressive effect on the heart's pumping function. (*See id.*)

GSK's research led to unexpected results showing that "the patients who were receiving carvedilol were staying alive whereas the patients on placebo were the ones who were dying." (*Id.* at 364-67, 370-72; PTX-879) These results prompted GSK to file New Drug Application ("NDA") No. 20-297 with the U.S. Food and Drug Administration ("FDA"), seeking approval of carvedilol in combination with ACE inhibitors, diuretics, or digoxin to reduce the risk of mortality caused by heart failure, as well as an application for a patent on a method of using carvedilol to decrease the risk of mortality caused by CHF. (Lukas Tr. at 373, 379-81; PTX-229) In May 1997, the FDA approved carvedilol as the first beta-blocker for the treatment of CHF, leading to GSK's launch of Coreg®, the brand name of its carvedilol tablets. (Lukas Tr. at 377) The patent issued in June 1998 as U.S. Patent No. 5,760,069 (the "'069 patent"), entitled "Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure."

GSK ultimately received approval from the FDA to market Coreg® for three indications: (1) hypertension; (2) mild-to-severe CHF; and (3) left ventricular dysfunction ("LVD") following myocardial infarction (heart attack) in clinically stable patients ("Post-MI LVD"). (*See* Lukas Tr. at 382-83) Despite receiving FDA approval for three indications, GSK only marketed Coreg® in the United States for the CHF indication. The FDA published the '069 patent in the Orange Book[4] with use code U-233, "decreasing mortality caused by congestive heart failure." (*See* Pastore Tr. at 889)

GSK undertook further patent prosecution efforts, including to correct certain errors in the '069 patent. Consequently, on January 8, 2008, the '069 patent reissued as the '000 patent. (*See* Lukas Tr. at 373-74, 405, 409-10) Claim 1 of the '000 patent, the only independent claim, recites:

> A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,
>
> *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

(emphasis in original) After issuance of the '000 patent, the '069 patent was de-listed from the Orange Book, and the '000 patent was listed with the same use code, i.e., U-233, "decreasing

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[4]The Orange Book is the name commonly used to refer to the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*. It includes a listing of approved drug products and, among other things, information about the patents that cover each drug product. *See Intendis GmbH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1359 (Fed. Cir. 2016); *see also* 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 314. 3, 314.53.

mortality caused by congestive heart failure." (Karst Tr. at 1042)

Meanwhile, back in March 2002, Teva had filed with the FDA Abbreviated New Drug Application ("ANDA") No. 76-373, seeking permission to market generic carvedilol tablets. (*See* Pastore Tr. at 442-43) Teva initially submitted a paragraph IV certification asserting that the '069 patent was invalid and requesting that its ANDA not be given final approval until a second Orange Book listed patent (one which covered the carvedilol compound) expired in March 2007.[5] Then, however, in August 2007, Teva sought FDA approval of its ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) – a "section viii carve out" – so that it could label its generic carvedilol tablets as indicated only for uses not covered by GSK's '000 patent: that is, for treatment of hypertension and post-MI LVD. (*See* Pastore Tr. at 456-57; Lietzan Tr. at 534-37) At this point, since the '000 patent only claimed a method of using carvedilol for treatment of mild to severe CHF, Teva's position was that its "skinny label" generic product would not run afoul of the '000 patent because Teva's product would not be approved – or labeled as being approved – for the infringing use of treatment of CHF.

In 2007, with the expiration of the '067 patent, GSK's period of exclusivity with respect to carvedilol ended and generic carvedilol entered the market. Fourteen companies marketed generic carvedilol, including Teva. (*See* Zusman Tr. at 1164; *see also* Pastore Tr. at 897-98; Hofmann Tr. at 1533) Specifically, on September 5, 2007, Teva received FDA approval of its generic tablets and launched its drug product with the carved out/skinny label – that is, excluding the CHF indication. (*See* Pastore Tr. at 461)

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[5]U.S. Patent No. 4,503,067 (the "'067 patent"), not at issue here, covers the carvedilol compound.

In April 2011, the FDA sent Teva a letter in response to the de-listing of certain GSK patents from the Orange Book, instructing Teva to "revise [its] labeling to include the information associated with [the de-listed] patent." (*Id.* at 461-63; PTX-15) One of the patents that had been de-listed was GSK's '069 patent, which had been reissued in 2008 as the '000 patent. (*See* PTX-15; Lukas Tr. at 352-53) Teva, therefore, amended its label in 2011 to be essentially a copy of GSK's full label, thereby covering all three indications: hypertension, CHF, and post-MI LVD. (Pastore Tr. at 461-65) The '000 patent expired on June 7, 2015, the date the '069 patent was originally set to expire.

The following table is helpful for understanding the principal issues that were in dispute at trial and are again presented by the pending motions.

Indications Implicated at Various Points

Indication	**GSK's '000 patent**	**GSK's FDA Approval**	**GSK's Marketing of Coreg®**	**GSK's Orange Book Listing**	**Teva's Skinny a.k.a. Partial a.k.a. Carve-Out Label (Jan. 2008 - April 2011)**	**Teva's Full a.k.a. Amended Label (May 2011-June 2015)**
hypertension	No	Yes	No	No	Yes	Yes
mild/severe CHF	Yes	Yes	Yes	Yes (U-233)	No	Yes
post-MI LVD	No	Yes	No	No	Yes	Yes

As shown, GSK's patent-in-suit only claims a method of using carvedilol for the treatment of mild to severe CHF. (PTX-1; *see* Lukas Tr. at 352-54) Although GSK obtained FDA approval to market carvedilol as safe and effective also for the treatment of hypertension and post-MI LVD, it did not have patent protection on such uses, and it has never marketed its

branded drug, Coreg®, to be used to treat anything other than CHF. (*See* Lukas Tr. at 350-52) The Orange Book listing for the '000 patent refers only to CHF, and not also to hypertension or post-MI LVD. (*See* Karst Tr. at 1040-44; Pastore Tr. at 888-90; Lietzan Tr. at 527-29, 566-67) When Teva initially launched and sold its generic carvedilol, during the skinny label period of January 2008 through April 2011, its label identified as approved indications only hypertension and post-MI LVD. (*See* Karst Tr. at 1027-28) It was not until the full label period, May 2011 through the expiration of the '000 patent in June 2015, that Teva's label also included the previously-patented method of use – treatment of CHF – as an approved indication for Teva's generic product. (*See* Pastore Tr. at 461-62; Zusman Tr. at 1229)

II. LEGAL STANDARDS

A. Judgment as a Matter of Law

Judgment as a matter of law is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. Fed. R. Civ. P. 50(a)(1). "Entry of judgment as a matter of law is a sparingly invoked remedy," one "granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (internal quotation marks omitted).

To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed.

Cir. 1998) (internal quotation marks omitted). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984).

In assessing the sufficiency of the evidence, the Court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991); *see also Perkin-Elmer Corp.*, 732 F.2d at 893. The Court may not assess the credibility of witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.*, 732 F.2d at 893. Rather, the Court must determine whether the evidence reasonably supports the jury's verdict. *See Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998); *Gomez v. Allegheny Health Servs. Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995) (describing standard as "whether there is evidence upon which a reasonable jury could properly have found its verdict"); 9B Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure § 2524 (3d ed. 2008) ("The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury properly could find a verdict for that party.").

B. New Trial

Federal Rule of Civil Procedure 59(a) provides in pertinent part, "[t]he court may, on motion, grant a new trial on all or some of the issues – and to any party – as follows: . . . after a

jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." New trials are commonly granted where "the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice," where "newly-discovered evidence exists that would likely alter the outcome of the trial," where "improper conduct by an attorney or the court unfairly influenced the verdict," or where the jury's verdict was "facially inconsistent." *Zarow-Smith v. N.J. Transit Rail Operations*, 953 F. Supp. 581, 584-85 (D. N.J. 1997) (internal citations omitted).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. *See Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem Corp.*, 9 F.3d 282, 289 (3d Cir. 1993) (reviewing "district court's grant or denial of a new trial motion" under "abuse of discretion" standard). Although the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law, in that the Court need not view the evidence in the light most favorable to the verdict winner, ordinarily a new trial should only be granted "where a miscarriage of justice would result if the verdict were to stand," the verdict "cries out to be overturned," or the verdict "shocks [the] conscience." *Williamson*, 926 F.2d at 1352-53.

III. DISCUSSION

A. The Jury Could Not Reasonably Find that Teva Caused Doctors to Infringe

The jury found that Teva induced infringement of claims 1, 2, and 3 of the '000 patent during the skinny label period and of claims 1-3 and 6-9 during the full label period. (D.I. 448 at 2-3) Teva moves for JMOL of no inducement or no lost profits damages on the basis that the jury could not reasonably have found that Teva caused doctors to infringe these claims of GSK's

patent during the respective periods.[6] (D.I. 465 at 4) Having reviewed the record under the appropriate standard, including by drawing all reasonable inferences in favor of GSK as the verdict winner, the Court concludes that substantial evidence does not support the jury's findings on inducement in either the skinny or full label period. Therefore, the Court will grant this portion of Teva's JMOL motion.

To prove inducement, GSK was required to prove by a preponderance of the evidence that, among other things, "Teva's alleged inducement, ***as opposed to other factors***, actually ***caused*** the physicians to directly infringe." (D.I. 440 at 26) (emphasis added) The jury was instructed that "Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer ***and that the communication was the cause of the direct infringement by the third-party infringer***." (*Id.* at 31) (emphasis added) Thus, the Court must now evaluate whether substantial evidence supports the jury's finding that Teva did cause the alleged infringement.[7]

Teva contends that the substantial uncontroverted evidence presented at trial showed that alternative factors caused doctors to infringe GSK's patent. Teva thus asserts that a reasonable

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[6]Teva requested a new trial as an alternative to JMOL, but explained that if the Court agreed there is a lack of evidence of inducement, a new trial would be futile. (*See* D.I. 465 at 10 n.3 ("[W]hile Teva requests a new trial under Rule 59 as an alternative remedy, that trial would inevitably result in a similar failure of proof."); *see also* Hr'g Tr. at 28) The Court agrees with Teva that, given the conclusions announced here, a new trial would be futile.

[7]As an alternative basis for JMOL of no inducement, Teva contends that GSK failed to "offer any evidence that any doctor – let alone ***all*** doctors – administer carvedilol with the specific intent to decrease mortality instead of to treat symptoms or for other purposes." (D.I. 465 at 9) Without proving such intent, Teva argues, there can be no direct infringement, and accordingly, no inducement. (*Id.* at 8-9) Because the Court finds GSK failed to prove the causation element, it need not address this argument.

jury could not conclude that even a single doctor – let alone the entire class of infringing doctors – was induced to infringe based on ***Teva's*** actions. Moreover, because GSK only asserted a "class" theory of liability – that is, that Teva induced doctors as a class to infringe – and failed to prove that theory, Teva's view is that GSK cannot now have the verdict upheld on an alternative theory of liability (i.e., the theory that "at least one" doctor was induced to infringe by Teva's actions). (*See* D.I. 465 at 1-2)

GSK responds that the jury's verdict should be sustained because GSK presented "ample evidence," including Teva's label and marketing materials, "from which [the jury] could infer Teva actually caused physicians to directly infringe." (D.I. 472 at 6) (internal quotation marks omitted) GSK argues that "JMOL of no inducement is only appropriate where the plaintiff fails to present sufficient evidence of even one act of direct infringement." (*Id.* at 9; *see also* Hr'g Tr. at 52 ("[T]he law doesn't require us to prove [inducement of the entire class]. What the law requires us to prove is just one of the class."); *id.* at 57 ("All we needed was circumstantial evidence of one doctor . . . ."); *see generally* D.I. 440 at 4.2.1 (instructing jury: "Proof of direct infringement may be based on circumstantial evidence.")) GSK contends that it provided substantial evidence through the testimony of its expert, Dr. Peter McCullough, permitting a reasonable factfinder to find that at least one doctor was induced to prescribe generic carvedilol by Teva's actions. (*Id.* at 71-72)

The Court agrees with Teva that neither sufficient nor substantial evidence supports the jury's finding of inducement. GSK failed to prove by a preponderance of the evidence that "***Teva's*** alleged inducement, as opposed to other factors, actually ***caused*** the physicians [i.e., as a class or even at least one of them] to directly infringe," by prescribing generic carvedilol and to

do so for the treatment of mild to severe CHF. (D.I. 440 at 26, 31) (jury instruction; emphasis added) Without proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand.[8]

GSK insists that Dr. McCullough identified himself as at least one doctor who was induced to prescribe generic carvedilol to a patient for the treatment of mild to severe CHF due to Teva's actions (or inactions), including Teva's label. (*See* Hr'g. Tr. at 52-53 (discussing GSK slide 4); *id.* at 69-72 (discussing GSK slides 32-33)) But the portion of Dr. McCullough's testimony to which GSK points (*see* McCullough Tr. at 631, 1659-63) does not show Dr. McCullough stating what GSK seems to think he said. Dr. McCullough merely said, in a conclusory manner, that Teva's labels (partial and full) "meet each and every limitation of claim 1" and a doctor performing the method of the claim would be the direct infringer. (*See id.* at 631) But even if the label were enough in a post-launch world, Dr. McCullough specifically stated that he did not read Teva's label prior to administering generic carvedilol, but "just

[8]The parties dispute whether the "class" theory and the "at least one" theory are really two separate theories and, if so, which theory GSK was required to prove. (Hr'g Tr. at 14-15, 24-26, 52) While Teva argues that the Federal Circuit clearly outlined two separate theories for proving induced infringement, *see Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004); *see also* Hr'g Tr. at 14-15, GSK maintains that the two theories "are actually one and the same" (Hr'g Tr. at 78, 52). The Court agrees with Teva that the two theories are distinct from one another. *See Dynacore*, 363 F.3d at 1274-75 ("Plaintiffs who identify ***individual*** acts of direct infringement must restrict their theories of vicarious liability – and tie their claims for damages or injunctive relief – to the ***identified*** act. Plaintiffs who identify an entire category of infringers (e.g., the defendant's customers) may cast their theories of vicarious liability more broadly, and may consequently seek damages or injunctions across the entire category.") (internal citations omitted); *see also Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 2004 WL 2898061, at *3 (D. Del. Dec. 14, 2004) (requiring plaintiffs to "adduce evidence that 100% of the defendants' . . . units [infringed]" after plaintiffs' position at trial was that "all" of defendants' units infringed). The Court need not decide which theory GSK was required to prove as, under either theory, GSK failed to prove causation.

assume[d] they were the same" based on the information the generic company provided. (*See id.* at 1659-63) As Dr. McCullough concedes that he did not read Teva's label, he cannot state, for instance, that he noticed or otherwise knew what (if anything) that label said about using carvedilol to treat CHF. Moreover, Dr. McCullough testified that he relied on various other sources, none of which are attributable to Teva, in deciding to prescribe carvedilol, both before and after generics entered the market. (*See* McCullough Tr. at 666-69, 676-78) GSK, therefore, has not met its burden to show inducement.

Below, the Court describes with more particularity its conclusion with respect to first the skinny label period and then the full label period.

1. The Skinny Label Period

The skinny label period, January 8, 2008 through April 30, 2011, is the period during which Teva's label carved out the CHF indication pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"). The Court agrees with Teva that the record lacks substantial evidence that Teva's skinny label, in combination with other acts Teva took (or refrained from taking) during this period, caused of any physician's direct infringement. (*See* D.I. 465 at 13-25) Instead, as Teva argues, the record conclusively demonstrated – and a reasonable jury could only have found – that any infringing use by any physician during the skinny label period was caused by factors unrelated to Teva.

The unrebutted evidence presented at trial showed that Teva's skinny label omitted from its label the language contained on GSK's Coreg® label concerning the use of carvedilol to treat CHF. (*See* Lietzan Tr. at 539, 541; Zusman Tr. at 1190-91) It is further undisputed that Teva's generic carvedilol, during the skinny label period, was not approved for treatment of CHF,

making such use an "off-label" use. Moreover, GSK's expert, Dr. McCullough, conceded that he would not prescribe generic carvedilol for CHF if it was not an approved use on the label. (*See* McCullough Tr. at 1660-61) The Court may, indeed must, consider unrebutted evidence presented at trial that supports the moving party on JMOL, in evaluating whether the jury had substantial evidence to support a reasonable finding against the moving party. *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1345 (Fed. Cir. 2007) ("The rule that a jury verdict is reviewed for support by 'substantial evidence' does not mean that the reviewing court must ignore the evidence that does not support the verdict. . . . [T]he court should give credence to the evidence favoring the nonmovant as well as that evidence supporting the moving party that is uncontradicted and unimpeached.") (internal quotation marks omitted).

Teva's skinny label did not instruct doctors to prescribe generic carvedilol for an off-label use, i.e., treatment of CHF. *See Warner-Lambert v. Apotex Corp.*, 316 F.3d 1348, 1364-65 (Fed. Cir. 2003) ("[T]he request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe."). Similarly, Teva's skinny label identified the approved indications as being hypertension and post-MI LVD, which were not covered by GSK's patent, and which cannot be considered infringing uses. *See id.*[9]

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[9]GSK contends that certain post-MI LVD language in Teva's skinny label provides instructions for "treating heart failure patients" and that "patients with post-MI LVD . . . suffer from an early stage of heart failure." (D.I. 472 at 14; *see also* PTX-1080.0003 (Teva skinny label: "Carvedilol 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) . . . .")) To GSK, this language on Teva's label "encourages doctors to use carvedilol to reduce the risk of death from symptomatic

While GSK's evidence of inducement during the skinny label period consisted principally of Teva's label (and testimony about it), GSK did present other evidence. In seeking to prove inducement, GSK relied on Teva's "AB rating" as well as Teva's 2008 and 2009 product catalogs and Teva's October 2009 Generic Product Reference Guide. (PTX-1208; PTX-1212; PTX-1226) These marketing materials trumpeted Teva's AB rating, without expressly stating that Teva's generic carvedilol was not approved for treatment of CHF. In the Court's view, even the totality of this evidence, taken in the light most favorable to GSK, and drawing all reasonable inferences in favor of GSK, cannot support a reasonable finding that Teva caused any infringement of GSK's '000 patent.

The jury was instructed that "[t]he fact that Teva obtained an AB rating for its generic product is not by itself a sufficient basis to find that Teva had an intent to infringe." (D.I. 440 at 29) GSK argues that Teva did something more than "obtain[] an AB rating;" Teva also listed and marketed Teva's generic carvedilol as AB rated ***to Coreg®***, without specifying that Teva's generic carvedilol – unlike GSK's Coreg® – was ***not*** approved for the CHF indication. (*See* D.I.

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congestive heart failure, as required by the claims." (D.I. 472 at 14) The Court disagrees. While there may be some overlap between populations of patients suffering from CHF – the treatment of which is within the scope of the '000 patent's claims – and those suffering from post-MI LVD – whose treatment is outside the scope of the claims – the two indications are distinct and require different clinical testing and different FDA approvals to treat. (*See* Zusman Tr. at 1183-84 (explaining difference between post-MI LVD patients and CHF patients); *see also* Shusterman Tr. at 1522-23 (explaining that studies for each indication involved "[f]undamentally different patient group[s]" and "[f]undamentally different physiology going on in those two periods of time"); McCullough Tr. at 605-06 (differentiating post-MI LVD patients from CHF patients); *id.* at 682 (admitting that post-MI LVD is broader than CHF, as not all post-MI LVD patients suffer from CHF)) To infringe the '000 patent, carvedilol must have been prescribed to treat the risk of mortality ***caused by CHF***. Accordingly, a reasonable juror could not have found that Teva's inclusion of post-MI LVD language in its skinny label caused or even encouraged direct infringement of the '000 patent's claimed method of use of treating CHF.

472 at 5, 15) But this fact does not support a reasonable finding that Teva caused infringement. As both parties showed at trial, being AB rated signifies that a generic drug is therapeutically equivalent to a branded drug. (*See* Lietzan Tr. at 542; Karst Tr. at 1031-32) The undisputed evidence demonstrates that a generic drug cannot be listed as "AB rated" generally, as "AB rated" is a relative term; it necessarily requires a comparison between the generic drug and some branded reference drug. (*See* Lietzan Tr. at 534; *see also* Karst Tr. at 1031-32)

In addition, as GSK conceded, there is no FDA requirement that a generic drug company specify for which uses it is (or is not) AB rated. (*See* Lietzan at 577-78) Nor had either party's experts ever seen such a clarifying statement in any press release or product catalog. (*See* Lietzan Tr. at 548-49, 577-78; Karst Tr. at 1030)[10] The Orange Book states that therapeutic equivalent determinations are not made for unapproved off-label indications. (*See* DTX-2171; Karst Tr. at 1035) GSK's expert, Professor Erika Lietzan, acknowledged that "the meaning of therapeutically equivalent of AB rating is if the generic drug is used ***in accordance with its label***, you would expect it to have the same clinical effect in a person as if that person had taken the brand drug." (Lietzan Tr. at 534 (emphasis added); *see also id.* at 542 ("AB rating means . . . if a

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[10]Teva contends that "GSK seeks to impose on Teva (and the entire industry) an affirmative duty to correct the incorrect ***assumption*** that doctors purportedly make by misunderstanding the FDA's AB-rating designation, or risk being held liable for ***all*** conduct of the doctors." (D.I. 465 at 2-3) This is not the only unprecedented "duty" GSK seeks to impose. GSK also asks that this case make clear that when a generic adds an indication to its label by eliminating a previous carve-out it must send the branded company a new paragraph IV notice (*see* Hr'g Tr. at 120; Tr. at 1840-41 (GSK closing argument)), and provide "disclaimers clarifying its product was not approved for heart failure" (*see, e.g.*, D.I. 472 at 15). GSK points to no authority to support the obligations it would have the Court create, duties which appear to be inconsistent with governing law. *See generally Warner-Lambert*, 316 F.3d at 1365 ("[I]ntent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent.").

patient took the generic carvedilol for one of the uses in its label, you would expect it to have the same clinical effect as if the patient is taking Coreg.")) Teva's skinny label, as addressed above, omitted substantial information regarding the CHF indication and, instead, stated that the product was approved for hypertension and post-MI LVD indications. Accordingly, there is not legally sufficient evidence to support a finding that Teva, by listing its carvedilol as AB rated to Coreg® in product catalogs and reference guides, encouraged infringement.

Additionally, a reasonable juror would had to have found, based on the record presented at trial, that in July 2007, prior to the launch of generic carvedilol (including by Teva), doctors deciding to write a prescription for carvedilol relied on various sources ***other than Teva's label and marketing materials***. In addition to the knowledge and experience that ordinarily skilled cardiologists had acquired by July 2007 about the benefits of treatment with carvedilol, such doctors had access to American Heart Association and American College of Cardiology guidelines, carvedilol research studies published in the *New England Journal of Medicine*, *The Lancet*, and the *British Heart Journal*, GSK's own Coreg® label and product insert, and GSK's extensive promotional activity – totaling nearly $1 billion (*See* Vojir Tr. at 508-09) – which included sending doctors to hospitals, giving seminars, and detailing, marketing, and advertising Coreg®. (*See* D.I. 465 at 7-8; Vojir Tr. at 497-511; McCullough Tr. at 666-69, 676-77; Zusman Tr. at 1151, 1164-65; PTX-78; DTX-2655.4; PTX-534)

Further, Teva showed that once generic carvedilol entered the market in September 2007, and continuing beyond 2007, doctors continued prescribing carvedilol (be it Coreg® or a generic) in the same manner as they had prior to the generics' entrance, as they based their prescription decisions on the various factors addressed above without relying on Teva's – or any

other generic manufacturers' – label. (*See* McCullough Tr. at 677-78) GSK's expert, Dr. McCullough, testified that he had not read Teva's generic label before he started writing prescriptions for carvedilol. (*See id.* at 1662-63)[11] As GSK concedes, prior to the generics' entrance into the market in 2007, physicians already knew how to use carvedilol for treating CHF. (Hr'g Tr. at 85-86) Three cardiologists testified at trial – GSK's expert, Dr. McCullough, and Teva's experts, Drs. Zusman and Rosendorff – and all three agreed that even in September 2007, when generic companies (including Teva) began selling carvedilol, doctors relied on guidelines and research, as well as their own experience, in addition to GSK marketing. (*See* McCullough Tr. at 676-79; Zusman Tr. at 1164-72, 1176-77; Rosendorff Tr. at 1296-97) None viewed generic labeling, including Teva's label, as impacting prescribing behavior. (*See id.*)[12] In

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[11]The specific testimony was as follows:

Q. Now, before you started administering generic carvedilol to your patients, whether you wrote it as Coreg or not, did you read Teva's generic label?

A. No, I didn't.

Q. Why not?

A. I just assume they were the same.

The Court also agrees with Teva that Dr. McCullough failed to acknowledge the causation requirement of an inducement claim. (*See, e.g.*, D.I. 477 at 3) (citing, e.g., McCullough Tr. at 614-17)

[12]The only "exception" to this is Dr. Randall Zusman's testimony regarding the hypothetical scenario of what might be called an "unfrozen caveman cardiologist" (*see also Saturday Night Live: Unfrozen Caveman Lawyer* (NBC television broadcast 1991-96)) – that is, "someone who is inexperienced, somehow has missed all of this education during the course of the their training, now they are going to treat a patient with heart failure, and they somehow came upon Teva's skinny label." (Zusman Tr. at 1153-54) Even such a doctor (who would not have been a person of ordinary skill in the art at any pertinent date) "would immediately see that the [CHF] indication is not included" on Teva's skinny label and would then have turned to various

this context, there was no reasonable basis for the jury to have found that anything Teva did – including selling generic carvedilol, giving it a "skinny label," and all aspects of how Teva marketed its carvedilol – caused even a single doctor to prescribe carvedilol for the treatment of CHF.

Teva's uncontroverted evidence of alternative factors that caused physicians to prescribe carvedilol in an infringing manner cannot be ignored. *See Integra*, 496 F.3d at 1345 ("The rule that a jury verdict is reviewed for support by 'substantial evidence' does not mean that the reviewing court must ignore the evidence that does not support the verdict. . . . [T]he court should give credence to the evidence favoring the nonmovant as well as that evidence supporting the moving party that is uncontradicted and unimpeached.") (internal quotation marks omitted).

As Teva correctly notes, no direct evidence was presented at trial that any doctor was ever induced to infringe the '000 patent by Teva's label (either skinny or full). There was no direct evidence that Teva's label caused even a single doctor to prescribe generic carvedilol to a patient to treat mild to severe CHF. Hence, in order to uphold the verdict, the Court must find in the record substantial evidence to render it reasonable for the jury to have inferred that at least one doctor was so induced. GSK, as the verdict winner, is entitled to the benefit of all reasonable inferences that may be drawn from the evidence presented to the jury. The Court's determination, however, is that – given the dearth of evidence that doctors read and understand and are affected by labels, and given the vast amount of evidence that doctors' decisions to prescribe carvedilol during the relevant periods were influenced by multiple non-Teva factors –

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non-Teva guidelines, textbooks, and research to gather information necessary to making a prescribing decision. (*See id.*)

such an inference was an unreasonable one for the jury to have drawn. *See McAnally v. Gildersleeve*, 16 F.3d 1394, 1500 (8th Cir. 1994) ("[Courts] cannot accord the jury with the benefit of unreasonable inferences, or those at war with the undisputed facts.") (internal quotation marks omitted).[13]

GSK suggests that the Court cannot (or at least should not) grant Teva's JMOL because it

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[13]In reaching this conclusion, the Court is applying the same legal standards on which it instructed the jury, including its instructions on "Induced Infringement" and "Inducement Must Cause Direct Infringement." (D.I. 440 at 4.2 (listing each element GSK must prove to show inducement, including "that Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe"); *id.* at 4.2.4 ("Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer and that the communication was the cause of the direct infringement by the third-party infringer. . . . GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial – as opposed to direct – evidence."))

The Court recognizes that these are not the instructions GSK proposed. (*See generally* D.I. 431 at 27-29) GSK, while not waiving any objections, has not renewed its objections nor raised any argument that the Court should, in evaluating Teva's JMOL motion, apply a standard different than the one on which it instructed the jury. (*See generally* Tr. at 1414-15, 1430-32) Teva contends that the jury instructions were correct and emphasizes that GSK has not contended the Court should not apply them to the motion. (*See* Hr'g Tr. at 6 ("The jury instructions correctly set out the law. . . . And we, we think, to be clear, that the instructions are correct. But we think that GSK hadn't argued specifically that you should apply a different standard."))

Therefore, the Court perceives no basis to conclude that its instructions were incorrect and, for purposes of Teva's JMOL motion, the Court has applied the standards it provided in its jury instructions. (*See also* D.I. 411 at 3-5 (holding that in post-launch context, patentee must prove actual inducement); Tr. at 1414 (GSK counsel conceding, in context of post-launch inducement, "the law is and . . . the [C]ourt's rulings have shown there [are] causation requirements"); *see generally Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 (Fed. Cir. 1995) ("While the jury's factual findings receive substantial deference on motion for JMOL, the legal standards that the jury applies, expressly or implicitly, in reaching its verdict are considered by the district court and by the appellate court de novo to determine whether those standards are correct as a matter of law."))

denied Teva's motion for summary judgment. (*See, e.g.*, D.I. 472 at 2) ("Teva's JMOL request should be denied because it repeats the same arguments the Court has rejected before trial, wrongly argues that GSK's evidence is insufficient even though the Court already concluded it could support a jury verdict, asks the Court to substitute its judgment for the jury's on disputed facts, and ignores the jury charge.") The Court disagrees. In connection with adopting Magistrate Judge Burke's recommendation to deny Teva's motion for summary judgment of non-infringement, the Court wrote:

> Defendants may prevail at trial based on their view that GSK's "long chain of inferences" does not establish causation. But that is a matter for the jury to decide after hearing the conflicting evidence (e.g., what the label instructs versus whether anyone read it, how Teva marketed its generic product versus whether cardiologists already knew to use carvedilol before GSK even obtained its patent, etc.) to be presented by both sides. The Court does not find, on the record before it, that "GSK's proposed inferences [are] unreasonable."

(D.I. 411 at 5) (internal citations omitted) After reviewing the entirety of the record GSK actually created at trial, as well as the unrebutted trial evidence presented by Teva, the Court now concludes (as it is free to do, notwithstanding the assessment it made prior to trial), that the inference of causation that GSK asks be drawn is not reasonable, as it is not supported by substantial evidence in the trial record.

Considering the record as a whole, substantial evidence does not support a finding by a reasonable factfinder that even at least one doctor was induced to prescribe generic carvedilol to be used in an infringing manner due to ***Teva's*** actions, as opposed to the various other factors

supported in the record, during the skinny label period.[14] Therefore, the Court cannot uphold the verdict of infringement with respect to the skinny label period.

2. The Full Label Period

The full label period, May 1, 2011 through June 7, 2015, runs from when Teva amended its label to include the CHF indication until the '000 patent expired. In attempting to prove inducement during the full label period, GSK presented evidence of Teva's full label along with various other materials, including Teva's 2004 and 2007 press releases, Teva's 2011 product catalog, the 2012 and 2013 editions of Teva's Monthly Prescribing Reference ("MPR"), and Teva's AB rating (including as it was listed on Teva's website). (*See* PTX-1297; PTX-1301;

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[14]Following oral argument, the parties notified the Court on several occasions of subsequent authority they believe is pertinent to the issues pending before the Court. (*See* D.I. 483, 485, 486, 487) The Court has considered these new cases, and they do not alter the outcome announced in this opinion.

For instance, GSK directs the Court to *Sanofi v. Watson Laboratories Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017), for the proposition that the marketing of a generic drug with labeling that encourages infringement can be viewed as causing infringement despite the fact that the innovator company published the results of clinical studies and promoted the patented use. (*See* D.I. 485 at 2) That case does not persuade the Court to reach a different conclusion than described above. *Sanofi* involved the ordinary Hatch-Waxman framework, "where a claim of induced infringement is filed ***before*** the generic has launched its product, and necessarily, before the generic has even attempted to communicate with any direct infringer." (D.I. 411 at 3) (emphasis added) In those cases, as this Court held during earlier portions of this case, "the focus must be on intent, rather than actual inducement." (*Id.*) Here, by contrast, "GSK filed its case almost seven years after Defendants launched their generic carvedilol products into the market. Hence, GSK's inducement claims are not premised on a hypothetical, but instead must be supported by sufficient evidence as to what actually happened during the relevant time period." (*Id.* at 3-4) (internal citations and quotation marks omitted) This Court has decided that reliance on a label and speculation about what may occur in the future cannot substitute for actual evidence about what has actually occurred in the past when, as in this case, there has been a period of actual, past conduct that is pertinent to infringement. Additionally, unlike the label involved in *Sanofi*, Teva's skinny label expressly carved out the patented use from its label. Therefore, the skinny label here does not support the same sort of inducement inferences the court found present in *Sanofi*.

PTX-1165; PTX-1203; PTX-1205; PTX-0860; McCullough Tr. at 635-36)

As addressed above, however, Teva presented substantial, unrebutted evidence of multiple factors unrelated to Teva that actually caused doctors to infringe the '000 patent. A reasonable factfinder could only have found that these alternative, non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use. Regardless of Teva's actions after it amended its label in May of 2011, including its elimination of the carve-out from its label, physicians were already prescribing generic carvedilol to treat CHF at that time. No substantial evidence was presented at trial to support a finding that anything about doctors' behavior – either as a class, or even a single doctor – was induced to change by Teva's label, or by anything else Teva did (or failed to do).[15] GSK conceded that physicians' reasons for and methods of prescribing carvedilol did not change when generics entered the market. (*See* McCullough Tr. at 677-78) For all these reasons, a reasonable jury could not find that Teva caused any direct infringement and, therefore, Teva cannot be held liable for inducement of infringement.

In sum, substantial evidence does not support the jury's finding on causation, and therefore does not support its verdict that Teva is liable for induced infringement, during both the skinny and full label periods. The Court will grant Teva's JMOL. Without a finding of infringement, there is no liability, so Teva cannot be found to be a willful infringer and cannot be ordered to pay GSK any damages. Accordingly, the Court will grant Teva's JMOL motion on

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[15]In coming to this conclusion, the Court is not holding that a full label will never be sufficient to prove causation, only that, in the context of this specific case, confronting Teva's specific motion, Teva's full label (along with the other evidence presented at trial) is insufficient. (*See* Hr'g Tr. at 87) (GSK's counsel acknowledging that "this is such a fact specific case")

each of these grounds.[16]

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[16]Both sides of this case identify important policy questions they see as being implicated by their disputes. GSK contends that a finding in favor of Teva, absolving the generic from liability for a method of treatment claim, will cause "the entire Hatch-Waxman framework [to] come[] crashing down" because it will result in "every generic dragging their feet so as not to go to trial during the 30-month stay in the Hatch-Waxman cases and then launch at risk and they're home free," because the innovator branded company will necessarily already have educated the market to use the drug. (Hr'g Tr. at 86-87) This reality, it is argued, combined with the Court's determination that the branded company cannot rely exclusively on the generic's label when the generic has already begun marketing its product, create a formula for generics to insulate themselves from any possible liability for induced infringement. (*See id.*; *see also* D.I. 472 at 11 (warning that acceptance of Teva's view "creates an incentive for generic manufacturers to launch at risk, destroy the innovator's market, and then argue it was not liable because its label was not the 'sole cause' of the direct infringement"))

For its part, Teva asserts that "GSK is fundamentally trying to use this case to put the [Hatch-Waxman] system on trial." (Hr'g Tr. at 30) In particular, in Teva's view, upholding the jury's verdict and allowing GSK to collect enormous damages (well beyond Teva's carvedilol revenues, and orders of magnitude above its profits on the product (*see id.* at 47-48, 117)) would eviscerate the section viii carve-out, as there would be no way a generic could avoid inducing infringement even if all the infringement is based on an off-label use. (*See id.* at 31 (arguing carve-outs are "part of the statute," which was "designed to enable the sale of drugs for non-patented uses [that are addressed on the skinny label] even though this would result in some off-label infringing uses"); *see also* D.I. 477 at 10-11 ("The implications of GSK's position cannot be understated: GSK seeks to place an affirmative obligation on generic pharmaceutical companies to police and affirmatively correct doctors' misunderstanding of AB-ratings. This is not the law."); D.I. 465 at 23 n.11 ("By endorsing [GSK's] legal theory, the Court would create a new rule that would dramatically upset the delicate balance struck by the Hatch-Waxman Act."). Since section viii is in the statute, it would be wrong and problematic, in Teva's view, to effectively read it out of the Hatch-Waxman Act. *See Caraco Pharma. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012) ("[S]ection viii provides the mechanism for a generic company to identify those [unpatented] uses, so that a product with a label matching them can quickly come to market."); *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) ("[A] generic manufacturer may avoid infringement by proposing a label that does not claim a patented method of use, ensuring that one patented use will not foreclose marketing a generic drug for other unpatented ones.") (internal quotation marks omitted); *id.* at 631 ("[Hatch-Waxman] was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses.").

The Court notes the parties' concerns and hopes neither side is correct in its predictions as to the dire consequences of the Court's ruling. Beyond prompting these observations, however, the parties' policy arguments have not impacted the Court's ruling on the pending

B. Substantial Evidence Supports the Jury's Finding of No Invalidity

Teva additionally seeks JMOL of invalidity, or a new trial, on two grounds: (1) the Kelly reference anticipates the asserted claims; and (2) the asserted claims are obvious in light of Kelly and Garg. (*See* D.I. 465 at 27-29) The Court is not persuaded by Teva and will deny this aspect of Teva's JMOL motion.

Regarding anticipation, before trial, the Court identified three genuine disputes of material fact: (1) whether Kelly disclosed a maintenance period greater than six months; (2) whether Kelly's patient population was the same as that covered by the claims; and (3) whether Kelly was "too theoretical" to be considered enabling. (*See* D.I. 380 at 2-3, 5-6; D.I. 417 at 1-2 & n.1) On each of these factual questions, Teva contends that the jury's findings for GSK were unreasonable. (*See* D.I. 465 at 27-29) The Court disagrees.

GSK presented sufficient evidence to support a reasonable inference that the Kelly reference only taught treatment follow-up ***after*** six months, rather than ***continuing*** treatment for six months (*see, e.g.*, McCullough Tr. at 1673, 1677-78, 1731-32) and that the study may have dealt with a different patient population, as more than one type of heart failure exists and Kelly did not specify which type of heart failure patients it was treating (*see, e.g.*, *id.* at 1672-73, 1681-82). GSK also presented sufficient evidence to support the inference that Kelly was too theoretical, as the study had not yet begun and could require undue experimentation. (*See, e.g.*, *id.* at 1678-79) Each of these factual disputes was for the jury to resolve, and its finding that Teva did not prove the contrary by clear and convincing evidence was reasonable based on the record.

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motions.

Regarding obviousness, Teva contends that the questions left open by Kelly (as addressed above) were all answered by Garg. (*See* D.I. 465 at 29) Thus, Teva asserts that the claims are obvious and the jury's conclusion, even in light of GSK's evidence of secondary considerations of non-obviousness, was unreasonable. (*See id.* at 29-30) However, as GSK notes (and as the Court finds above), the jury's finding that Kelly did not disclose the three disputed claim elements was reasonable based on the record. Moreover, contrary to Teva's contention, GSK provided evidence through Dr. McCullough that Garg does not supply the duration element lacking in Kelly. (*See* McCullough Tr. at 1682) This evidence, in addition to GSK's evidence that the prior art taught away from and discouraged beta-blockers in heart failure, was sufficient to render the jury's finding that the patent was non-obvious reasonable. Therefore, the Court will deny Teva's motion for JMOL or a new trial on invalidity.

IV. CONCLUSION

For the reasons stated above, the Court will grant in part and deny in part Teva's motion for judgment as a matter of law. (D.I. 464) Because substantial evidence does not support a finding of induced infringement, there is no basis for enhanced damages, attorney fees, and interest. Accordingly, GSK's motion (D.I. 466) and Teva's motion to strike multiple exhibits GSK submitted in support of its motion (D.I. 474) will be denied as moot. An appropriate Order follows.