IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

REPORT AND RECOMMENDATION

In these two related actions filed by Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited (collectively, "GSK") against Defendants Glenmark Pharmaceuticals Inc., USA ("Glenmark") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Defendants"), GSK alleges that Defendants indirectly infringe U.S. Patent No. RE40,000 (the "'000 patent"). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions as set forth below.

I. BACKGROUND[1]

A. The Parties

GSK manufactures and sells the drug carvedilol under the trade name COREG®. (D.I. 59 at ¶¶ 8, 22)[2] SmithKline Beecham (Cork) Limited is the owner, by assignment, of the '000 patent, and GlaxoSmithKline LLC is the patent's exclusive licensee. (*Id.* at ¶¶ 37-38)

Defendants are engaged in the business of developing, manufacturing, and distributing generic versions of branded drug products throughout the United States. (Civil Action No. 14-877-LPS-CJB, D.I. 61 at ¶ 47; Civil Action No. 14-878-LPS-CJB, D.I. 60 at ¶ 47)

B. Carvedilol

Carvedilol has been a known beta blocker since at least 1978. (U.S. Patent No. 4,503,067) In 1979, researchers investigated and published results describing the use of beta-blockers to treat congestive cardiomyopathy, (D.I. 75, Expert Declaration of Clive Rosendorff, M.D., Ph.D. ("Rosendorff Decl."), ex. 7), and by 1989 researchers published the results of a study in which sixteen patients with congestive heart failure ("CHF") were given carvedilol, (D.I. 76, Declaration of Jennifer L. Ford, ex. 1).

But GSK cites to evidence indicating that before the approval of COREG for the treatment of CHF in 1997, physicians treating CHF patients generally avoided beta blockers,

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

[2] For simplicity's sake, the Court will refer to the "D.I." number in Civil Action No. 14-877-LPS-CJB, unless otherwise indicated.

instead traditionally prescribing agents that increased the strength of muscular contraction or had peripheral vasodilatory effects. (D.I. 70 at 4 (citing D.I. 72, Declaration of Bernard R. Chaitman, M.D. ("Chaitman Decl.") at ¶¶ 22-23)) Indeed, according to GSK, beta blockers were contraindicated in the treatment of CHF because such compounds weaken the force of muscular contractions, and CHF was viewed primarily as a blood disorder.[3] (*Id.* at ¶ 22; *see also* '000 patent, col. 3:56-60)[4]

GSK pursued promising research suggesting that carvedilol could be used to successfully treat CHF, initiating a clinical trial in 1992. (D.I. 71, Declaration of Michael A. Amon ("First Amon Decl."), ex. 1 at 1349) The clinical trial was terminated early based on the finding of a significant effect of carvedilol on survival. (*Id.* at 1350) The results of the clinical trial were published in *The New England Journal of Medicine*. (*Id.*, ex. 1) In May 1997, carvedilol became the first beta-blocker approved by the Food and Drug Administration ("FDA") for the treatment of mild to moderate CHF of ischemic or cardiomyopathic origin, in conjunction with digitalis, diuretics, and ACE inhibitor, to reduce the progression of disease as evidenced by cardiovascular death, cardiovascular hospitalization, or the need to adjust other CHF indications. (D.I. 59 at ¶ 21) GSK then initiated a clinical trial for severe CHF patients which showed that carvedilol reduced the risk of mortality in these patients. (First Amon Decl., ex. 2) The clinical trial was stopped early due to the finding of a significant beneficial effect of carvedilol. (*Id.* at

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[3] Defendants assert that these statements are "factually incorrect" and that "[b]y 1995, there were many published reports of the beneficial effects of [beta] blockers, including carvedilol, in CHF patients." (D.I. 87 at 2-3)

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

1653) In November 2001, the FDA approved COREG for the treatment of mild-to-severe CHF of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and also to reduce the risk of hospitalization. (D.I. 59 at ¶ 27)[5]

C. '000 Patent

In June 1995, GSK and its research partner filed a patent application directed to a method of using carvedilol to decrease the risk of mortality caused by CHF, which issued as U.S. Patent No. 5,760,069 (the "'069 patent") entitled "Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure." (*Id.* at ¶ 35) In January 2008, that patent reissued as the '000 patent, which is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book") as covering COREG. (*Id.* at ¶¶ 39-40)

The '000 patent contains 9 method claims directed to methods of decreasing mortality caused by CHF in a patient in need thereof by administering carvedilol in a manner recited in the claims, ('000 patent), all of which are asserted against Defendants in these actions, (D.I. 70 at 6). Claim 1 is the only independent claim of the '000 patent, and it reads:

> **1.** A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,

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[5] GSK thereafter conducted two additional studies to test whether carvedilol could be used to treat patients with CHF, or that were likely to develop CHF, who had recently experienced a myocardial infarction (a heart attack). (D.I. 59 at ¶¶ 28-29) In March 2003, COREG received approval for the treatment of these patients. (*Id.* at ¶ 31) COREG has also been FDA-approved to treat hypertension since 1995. (*Id.* at ¶ 8)

> *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

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

D. Procedural History

On July 3, 2014, GSK commenced these actions. (Civil Action No. 14-877-LPS-CJB, D.I. 1; Civil Action No. 14-878-LPS-CJB, D.I. 1) GSK alleges that Defendants indirectly infringe the '000 patent by making, offering to sell, selling, importing and promoting and distributing generic carvedilol tablets. (*Id.*) 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)

The parties filed simultaneous opening claim construction briefs on November 5, 2015, and simultaneous responsive briefs on December 22, 2015. (Civil Action No. 14-877-LPS-CJB, D.I. 70, 74, 83, 84; Civil Action No. 14-878-LPS-CJB, D.I. 76, 80, 90, 92)[6] The Court held a *Markman* hearing on April 4, 2016. (Civil Action No. 14-877-LPS-CJB, D.I. 118; Civil Action No. 14-878-LPS-CJB, D.I. 147 (hereinafter "Tr."))

II. STANDARD OF REVIEW

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the

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[6] Glenmark and Teva filed joint opening and responsive briefs.

protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015).

The Court should typically assign claim terms their "'ordinary and customary meaning[,]'" which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent, but rather should endeavor to reflect their "meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321.

To that end, the Court should look first and foremost to the language of the claims themselves, because "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id.* at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable" in discerning the meaning of a particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* Moreover, "[d]ifferences among claims can also be a useful guide[,]" as when "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent

claim." *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which "may reveal a special definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess." *Id.* at 1316. In that case, "the inventor's lexicography governs." *Id.* Even if the specification does not contain a special definition of the term at issue, it "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). In addition to the specification, a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317 (citations omitted).

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises[,]" can also "shed useful light on the relevant art[.]" *Id.* (internal quotation marks and citations omitted). Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* (internal quotation marks and citations omitted); *accord Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995).

In utilizing these resources during claim construction, courts should keep in mind that "[t]he construction that stays true to the claim language and most naturally aligns with the

patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

The parties have put forward six terms or sets of terms for the Court's review. The Court takes up the disputes in the order in which they were argued.

A. Disputed Terms

1. "decreasing mortality caused by congestive heart failure" / "to decrease a risk of mortality caused by congestive heart failure"

The term "decreasing mortality caused by congestive heart failure" is found in the preamble of claim 1, and the term "to decrease a risk of mortality caused by congestive heart failure" is found in the claim's body. ('000 patent, col. 8:30-40) All of the parties agree that both terms mean the same thing. (D.I. 70 at 16; GSK's Markman Presentation, Slide 12; Tr. at 9, 30-31, 39) There are two disputes with respect to these terms: whether they constitute a claim limitation, and to the extent they do, how they should be construed.

a. Whether language is a claim limitation

The Court first takes up the issue of whether this claim language is a claim limitation—an issue that presents a few different (and at times, difficult) questions in light of these particular claims, the caselaw, and the record presently before the Court. GSK asserts that this claim language is a claim limitation, (D.I. 70 at 15), while Teva argues that this language is a non-limiting statement of intended result, (D.I. 74 at 3). Glenmark does not contest that the terms amount to claim limitations. (*Id.* at 4 n.3)

Teva's position is premised on its view that "the Examiner missed [the] underlying legal

question of whether or not" GSK could even claim what it did here, and that "these claims should have never issued." (Tr. at 56-57) Teva cites to the decision by the United States Court of Appeals for the Federal Circuit in *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) as controlling. (D.I. 74 at 4; D.I. 84 at 2-3) The *Bristol-Myers* Court explained that while an inventor may patent a "new use of a known process," 35 U.S.C. § 100(b), he may not patent a "new *result* of [an old] use," *Bristol-Myers Squibb*, 246 F.3d at 1375 (emphasis added). Teva asserts that in order to determine which side of the line a particular method of treatment falls on, courts ask whether the term at issue (here, e.g., "decreasing mortality caused by congestive heart failure") "involves a manipulative difference in the use of the drug" from that known in the prior art—that is, does it "change any aspect of the treatment"? (D.I. 74 at 5-6 (citing *Bristol-Myers Squibb*, 246 F.3d at 1376)). If the answer is no, then the method of treatment is not patentable because the claimed result is "simply an additional benefit of the old use of the drug." (*Id.* at 5) Teva asserts that GSK's claims impermissibly recite merely a particular result of a known use—that there is no "manipulative difference in the use of carvedilol in CHF patients 'to decrease mortality' from the admitted prior art uses of carvedilol in CHF patients—*i.e.*, to treat symptoms or improve quality of life"—and that the "decreasing mortality" language is therefore a non-limiting statement of intended result. (D.I. 84 at 2)

For the reasons discussed below, the Court concludes that the issue of whether the claims of the '000 patent are impermissibly directed to a new result of a known process is not properly resolved at this stage of the case. In putting that issue to the side, the Court otherwise concludes that, after applying principles of claim construction to the claim language at issue, the terms constitute a claim limitation.

As to the first of these two conclusions, the Court notes the differing procedural stage at which this issue was confronted in *Bristol-Myers*. On review before the *Bristol-Myers* Court were two decisions by the district court: a claim construction opinion, and an opinion that granted the defendants' motion for summary judgment that certain claims of the asserted patents were anticipated by a prior art reference ("Kris"). *Bristol-Myers*, 246 F.3d at 1372-73. The claims at issue covered, *inter alia*, a method for "reducing hematologic toxicity" by administering an "antineoplastically effective amount" of the anticancer drug paclitaxel over a period of about three hours, and a method of treating a patient in order "to effect regression of a taxol-sensitive tumor" by administering that drug over the same time period. *Id.* at 1371-72 & n.1.[7] Prior to the patentee's development of this method, the standard infusion time for paclitaxel was 24 hours. *Id.* at 1373. Kris disclosed treatment of patients with three-hour infusions of paclitaxel within the claimed dosage ranges, but with no observation of antitumor response. *Id.* at 1372. Taking up claim construction first, the Federal Circuit (for a number of different reasons) affirmed the district court's conclusions that the above-referenced claim terms directed at efficacy were not claim limitations. *Id.* at 1372-73, 1375-77. The Court then proceeded to the anticipation issue, largely affirming the district court's decision that several claims were anticipated by Kris. *Id.* at 1377-81.

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[7] More specifically, for example, claim 1 recited "a method for *reducing hematologic toxicity* in a cancer patient undergoing [t]axol treatment comprising parenterally administering to said patient an *antineoplastically effective amount* of . . . taxol over a period of about three hours." *Bristol-Myers*, 246 F.3d at 1371 (emphasis in original) (internal citation omitted). Claim 5 recited "[a] method for treating a cancer patient *to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity*, said method comprising . . . parenterally administering to said patient [a certain amount of] taxol over about 3 hours." *Id.* at 1372 (emphasis in original) (internal citation omitted).

In finding that the claims' expressions of efficacy were non-limiting, the *Bristol-Myers* Court was unpersuaded by the patentee's contention that they be treated as limitations because they distinguished a new use of the process (i.e., that it is useful in treating cancer) over the prior art. *Id.* at 1376. Instead, the Court concluded that "the claimed process here is not directed to a new use; it is the same use [treating cancer], and it consists of the same steps as described by Kris. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Id.*

But it is important to again reflect on the procedural posture of *Bristol-Myers*. There, the Court's determination that the claimed process was directed to the same use as Kris, and that it consisted of the same steps described by Kris, all flowed from a fully-informed record as to that issue. The Kris reference was front and center before the *Bristol-Myers* Court, with arguments specific to that reference also before the Court. Notably, the lower court's claim construction decision (that the relevant terms were not limiting) was premised on the claim language and the patents' file histories—not on a comparison of the claims to Kris. *Bristol-Myers Squibb Co. v. Immunex Corp.*, 86 F. Supp. 2d 447 (D.N.J. 2000). It was only in the district court's *separate* decision relating to anticipation that the court determined that the asserted claims were directed to necessary results of practicing the steps disclosed by Kris, and that "where the prior art discloses the steps of a process, and experiments conducted by the patentholder did not manipulate or otherwise alter the basic application and experimentation disclosed in the prior art, the patent is invalid as anticipated." *Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp.*, 86 F. Supp. 2d 433, 442-43 (D.N.J. 2000) (internal quotation marks and citation omitted). And significantly, the Federal Circuit had the benefit of both of these decisions, and the full record

associated therewith, in reaching its above-stated conclusions.[8]

Here, in contrast, the matter of claim construction is the sole issue before the Court. And accordingly, Teva's argument that GSK's claims are not patentable "in view of the prior art" because they are directed to a result of a known process, (Tr. at 36), is one for a different day. Indeed, both GSK and Glenmark are in agreement that the issue of whether the claims are improperly directed towards a particular result of a known use is "not an argument for this proceeding." (*Id.* at 62; *see also id.* at 91)

To be sure, Teva does point to certain statements in the prosecution history that certainly provide information as to prior art disclosures. But in order for the Court to properly determine whether the claims reflect the same steps as those recited in the prior art, it will be necessary and beneficial to consider the full span of that art, accompanied by specific arguments with respect thereto. Put another way, it is clear in this case that (as did the district court in *Bristol-Myers*) the Court will need to resolve a dispute between the parties as to whether GSK "did not 'manipulate or otherwise alter the basic application and experimentation' disclosed in the prior art" in identifying the claimed method. *Bristol-Myers*, 86 F. Supp. 2d at 443 (citation omitted). And if, as Teva asserts, the issue for the Court will then be "is there a difference between administering a

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[8] Teva also relies upon *In re May*, 574 F.2d 1082 (C.C.P.A. 1978) and in *In re Omeprazole Patent Litig.*, 258 F. Supp. 2d 221 (S.D.N.Y. 2001) in arguing that a statement of intended result is non-limiting when it does not result in manipulative changes in the process claimed. (D.I. 74 at 4, 6; Tr. at 41-42; Defendants' Markman Presentation, Slides 19-20) Again, neither of the two cases were at the procedural stage of the instant matter when the relevant decisions were rendered. *In re May* involved the review of an examiner's rejection of a patent application because, *inter alia*, certain claims were deemed anticipated by a prior art reference. *In re May*, 574 F.2d at 1084, 1090. The *In re Omeprazole Patent Litig.* decision involved resolution of a motion for summary judgment of anticipation. *In re Omeprazole Patent Litig.*, 258 F. Supp. 2d at 225-32.

drug to [CHF] patients for the purposes of decreasing mortality . . . versus for the purposes of achieving the symptomatic benefit that was in the prior art[,]" (Tr. at 50-51), the answer to that question may turn on, *inter alia*, (1) the scope of relevant prior art; (2) whether that prior art is properly described as relating to use of carvedilol to treat a "different condition" from CHF, or to treat a "symptom" of CHF; and/or (3) how the prior art describes dosing amounts/schedules regarding the use of carvedilol as described in that art. There will be significant disputes between the parties on these fronts, (D.I. 83 at 11 (citing D.I. 68, ex. K at 3); Tr. at 43-53, 86-90; Defendants' Markman Presentation, Slide 26), and those disputes should be resolved after discovery is complete, at the summary judgment stage.[9]

Turning then to more traditional issues of claim construction, it is clear that the terms at issue are claim limitations. One way to see this is to compare these terms in claim 1 with the claims/terms at issue in *Bristol-Myers*. In *Bristol-Myers*, before the Federal Circuit conveyed its finding that the claims were drawn to a particular result of known steps recited in Kris, it set out a number of reasons supporting its decision that the claims' statements of intended results were non-limiting. But as to many of those cited reasons, *Bristol-Myers* is distinguishable from the

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[9] As the Court will explain next, principles of claim construction dictate that the "decreasing mortality" language is indeed a claim limitation. But the Court does not believe that this finding at the claim construction stage forecloses Teva's ability to argue down the line that the claims are anticipated—including by arguing that GSK could not legally claim (decreasing mortality) what Teva describes as a "particular result" of a known use of the method. (Tr. at 58); *see Bristol-Myers*, 246 F.3d at 1373 (reiterating the district court's finding that even if the claim terms at issue were limiting, the claims "would have been inherently anticipated because reducing toxicity and tumor regression were necessary consequences of practicing the method steps of Kris"); *see also In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1347-51 & n.4 (Fed. Cir. 2002) (finding that the preamble limited claim scope based on the content of both the patent specification and the prosecution history, but going on to find that the claim was anticipated because that claim limitation was inherent in the prior art) (citing *Bristol-Myers*, 246 F.3d at 1376).

instant case.

First, with respect to the preamble language "for reducing hematologic toxicity," the *Bristol-Myers* Court found, *inter alia*, that "the language of the claim itself strongly suggests the independence of the preamble from the body of the claim." 246 F.3d at 1375. That is not the case here.

The Federal Circuit has held that language in the preamble of a claim constitutes a limitation if the preamble "sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need.'" *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003). In *Jansen*, the claim at issue required that the method be performed on a "'human in need thereof'" and that the method be used "'for treating or preventing macrocytic-megaloblastic anemia.'" *Id.* at 1332. The Court explained that in such circumstances, "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose"; therefore, the preamble was not merely a statement of effect that may or may not be desired, but instead "a statement of the intentional purpose for which the method must be performed." *Id.* at 1333; *see also Sanofi v. Glenmark Pharms. Inc.*, Civil Action No. 14-264-RGA, 2015 WL 5092631, at *4-5 (D. Del. Aug. 28, 2015) (construing "'a method of decreasing a risk of cardiovascular hospitalization in a patient'" in a preamble as a limitation where the claim also recited that the drug at issue would be provided to "to a patient in need thereof"). In contrast to *Jansen*, the claims before the *Bristol-Myers* Court did not state that the methods at issue were to be performed on a patient "in need thereof." And here, the preamble language at issue is like that in *Jansen* (and not like that in *Bristol-Myers*): it recites the objective of the method—"decreasing mortality caused by congestive heart failure"—and

instructs that the method be performed on a "patient in need thereof" (i.e., a patient in need of a reduction in the risk of mortality caused by CHF, with that patient being further referred to later in the body of the claim). (D.I. 70 at 7-8; D.I. 83 at 7-8) Pursuant to the rationale of *Jansen*, then, the claim language at issue here breathes life into the "decreasing mortality" term of the preamble and should therefore be construed as a limitation.[10]

Second (and relatedly), while the language at issue before the *Bristol-Myers* Court "strongly suggest[ed]" independence between the preamble and body of the claim, here the term "said patient" in the claim body relies on and derives antecedent basis from "a patient in need [of having their risk of mortality decreased]" in the preamble. (D.I. 70 at 8; D.I. 83 at 10; Tr. at 31) This is further evidence that the language of the preamble constitutes a necessary component of the claimed invention. *See, e.g.*, *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003).

Third, the prosecution history in *Bristol-Myers* made an exceedingly poor case that the language "an antineoplastically effective amount" was a claim limitation. Although the patentee had argued that the term was limiting because it was added by amendment to distinguish over Kris's lack of observation of antitumor efficacy, the *Bristol-Myers* Court found instead that the language was added voluntarily, after the examiner had already deemed the claims to be allowable. 246 F.3d at 1374-75. The Court therefore concluded that such "unsolicited assertions of patentability made during prosecution do not create a material claim limitation where we have

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[10] While Teva attempts to argue that *Jansen* is inapplicable here, (D.I. 74 at 5; D.I. 84 at 4), it is telling that even Glenmark agrees with GSK that (1) *Jansen* is the "correct case law" to consider in determining whether the preamble "breathes life into the claims"; (2) the Court and the parties cannot "just run away from [that] case law"; and (3) GSK "makes a good point about [that] law." (Tr. at 62-64)

determined that the language does not create one." *Id.* at 1375.

Here, unlike in *Bristol-Myers*, the prosecution history does not clearly weigh against GSK's position. It cannot be seriously disputed that, at a minimum, a significant portion of the applicant's arguments for patentability was that the drug's usefulness in decreasing mortality of CHF patients was something distinct from its usefulness in treating symptoms of CHF. (D.I. 83 at 8 (citing D.I. 68, Ex. F at GSK00000109-16 ('000 patent reissue proceedings),[11] Ex. N at GSK00009493-95 ('069 patent prosecution)); Tr. at 91; *see also* Tr. at 56-57 (Teva not disputing that "much of the fight and discussion [] before the Examiner and leading to [] the issuance of the patent ultimately" was over the impact of the "decreasing mortality" language, and instead asserting that the Examiner missed the issue of whether GSK could patent such an alleged new use), *id.* at 62 (Glenmark acknowledging with respect to this dispute that "GSK points out some very good case law and says, if that's the purpose of the claim, *that is why it issued, then it's a limitation*") (emphasis added)) It is hard to know for certain what aspects of claim 1 ultimately prompted the United States Patent and Trademark Office ("PTO") to allow the '000 patent to issue over any concern regarding invalidity, as the PTO's ultimate rationale for allowance is not spelled out in the prosecution history.[12] But at a minimum, the case is distinguishable from

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[11] For instance, in responding to the Examiner's rejection of certain claims in the reissue application as obvious over Ohlstein, the applicants asserted that "even if Ohlstein is considered to teach or suggest the use of carvedilol to treat symptoms associated with or in the presence of CHF, since Ohlstein (even in view of the secondary references) does not teach or suggest an intended 'method of decreasing mortality caused by congestive heart failure in a patient in need thereof,' as more specifically set forth in the pending claims, Ohlstein (in view of the secondary references) does not render obvious the claimed subject matter." (D.I. 68, ex. F at GSK00000115) (emphasis in original))

[12] For example, it is true, as Teva notes, (D.I. 84 at 3-4) that the "decreasing mortality" language was in the claims in some form from the date of their inception, and that

Bristol-Myers in that here: (1) the patentees clearly relied on the "decreasing mortality" limitations to persuade the PTO that the claimed invention was patentable; and (2) the prosecution history does not definitively demonstrate that the limitations were immaterial to patentability. *Compare Jansen*, 342 F.3d at 1333 (noting that its conclusion that the preamble constituted a limitation was bolstered by the fact that "the patentability of the claims hinged upon" the presence of the terms at issue in the claim language), *and In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1348 (Fed. Cir. 2002) (concluding that the preamble is a claim limitation where the prosecution history demonstrated "a clear reliance by the patentee on the preamble to persuade the Patent Office that the claimed invention is not anticipated by the prior art"), *with In re Copaxone 40 Mg*, Civil Action No. 14-1171-GMS, 2016 WL 873062, at *1 n.2 (D. Del. Mar. 7, 2016) (finding certain claim language to be non-limiting where, just as in *Bristol-Myers*, "there is also no evidence that these terms are central to patentability or were used to meaningfully distinguish the claims from the prior art").

For these reasons, the principles of claim construction dictate that the "decreasing mortality" terms should be construed as a claim limitation. Teva's argument that the claims improperly recite a particular result of a known use of carvedilol is more amenable to resolution on a motion for summary judgment of invalidity.

b. Proper Construction

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during reissue, GSK added other claim language indicating that the drug would be administered in daily maintenance dosages for a maintenance period greater than six months. The patentee relied on, *inter alia*, both the "decreasing mortality" limitations and the limitations regarding the maintenance treatment in attempting to overcome invalidity concerns during the reissue proceeding. (D.I. 68, ex. F at GSK00000109-10, 19) It could be that it was the "maintenance treatment" claim language—not the "decreasing mortality" limitations—that was material to traversing the Examiner's obviousness concerns. But it is hard to say for sure.

That leaves the issue of the proper construction of the "decreasing mortality" terms. GSK asserts that "decreasing mortality caused by [CHF]" and "to decrease a risk of mortality caused by [CHF]" should be construed as "'attempt to reduce the probability that a patient will die as a result of congestive heart failure[.]'" (D.I. 70 at 15) Glenmark contends that the "decreasing mortality" terms should be construed to mean "'a reduction in the number of deaths of patients with CHF from the use of carvedilol with an ACE inhibitor, a diuretic, or digoxin. This does not include the reduction or treatment of any symptoms, signs, or causes of CHF, including the reduction or treatment of hypertension or high blood pressure, or any improvement in the quality of life of a patient with CHF.'" (D.I. 74 at 4) Teva is in agreement with Glenmark's proposal. (*Id.* at 4 n.3) The primary dispute between the parties here is whether the claims somehow require an actual reduction in deaths resulting from CHF (Glenmark's position), or instead require an attempt to prolong life by reducing the risk of mortality from CHF (GSK's position). (D.I. 83 at 3; Tr. at 9, 67) For the following reasons, the Court concludes that GSK's proposed construction should be adopted.

First, considering the claim language itself, the Court agrees with GSK that Glenmark's proposal improperly excludes the concept of risk that is present in the claims. (D.I. 83 at 3; Tr. at 10, 16) The claims require administration of the drugs to the CHF patient "to decrease a *risk* of mortality" caused by CHF, ('000 patent, col. 8:38), and the plain meaning of "risk" here is the "possibility of loss or injury" or the "degree of probability of such loss[,]" (D.I. 70 at 15 (citing First Amon Decl., ex. 5 (*Webster's Ninth New Collegiate Dictionary*) at 1018); *see also* Tr. at 13). Thus, GSK's inclusion of "probability" in its construction is rightly meant to capture the "explicit use of the word 'risk' in the claims." (D.I. 83 at 3; *see also* Tr. at 13)

Other intrinsic evidence also reiterates why the concept of risk should be captured in any construction. The specification of the '000 patent explains that the clinical studies conducted by the patentees showed a "reduction in the risk of death" of 67% in CHF patients given carvedilol. ('000 patent, col. 6:22-23; *see also id.*, cols. 7:62-65) And the prosecution history confirms that the claimed method is meant to decrease the "risk" of death. (*See, e.g.*, D.I. 68, ex. F at GSK00000117-18 ("[T]he GSK Carvedilol Study . . . showed a dramatic decrease in the *risk of mortality* by about 65%." and "[T]he COPERNICUS study showed that for patients with severe heart failure there was a 35% decrease in the *risk of death* using carvedilol as compared with placebo.") (emphasis added))

Next, another point of contention between the parties is whether the construction should include the concept of an "attempt." The Court agrees with GSK that the concepts of both "risk" and "attempt" present in its proposal (but absent from Glenmark's proposal) accurately reflect the nature of the patentee's discovery in that "the doctor gives [a patient in need thereof] a treatment that has been found to reduce the risk of death in a group of similar patients and hopes that it will reduce the risk that the particular CHF patient will die" from CHF. (D.I. 70 at 17 (citing Chaitman Decl. at ¶ 42); *see also* D.I. 83 at 3; Tr. at 13 (GSK's counsel explaining that the words "risk" and "attempt" in their proposed construction reflect the realities of the invention)) In describing the clinical studies carried out by the patentees, the specification demonstrates that the reduction in risk of mortality resulting from the administration of the claimed drugs in CHF patients is a population-based statistic; that is, as GSK's counsel explained:

> [W]hen you look at how these clinical studies are done, you can't

> look at individual patients. You look at a patient population. You perform a clinical study on that patient population, the relevant parameters, and then you have a controlled group on placebo, and then you look at the relative reduction in risk for those populations as a whole. Not one particular patient, whether that patient lives or dies, because, in fact, some of the patients that are getting the drug are going to die at the same time or maybe earlier than some of the patients that aren't getting the drug.

(Tr. at 10; *see also* D.I. 83 at 3-4 ("[A]s a population, the lives of CHF patients on the therapy are prolonged as compared to those patients not receiving the therapy."); Chaitman Decl. at ¶ 42; D.I. 86, Declaration of Michael A. Amon ("Second Amon Decl."), ex. A at 179-80 (GSK's expert Dr. Bernard Chaitman testifying that a physician treating a group of patients does not know "for the individual patient if they are the one[that is] going to survive" but that the physician knows "that if you treat them all, you are going to get a reduction in mortality and that more patients are going to live than die" as compared to patients who do not receive the drug))

In other words, physicians prescribe carvedilol to their CHF patients in an effort to prolong their patients' lives by reducing their risk of mortality caused by CHF—but they cannot know beforehand which individual patients will benefit from the drug, as some patients will still die from CHF. (D.I. 83 at 3-4; Tr. at 11-12) Thus, as GSK's proposal reflects, the claims require *an attempt* to prolong life by reducing the probability that a patient will die due to CHF. (*See* Chaitman Decl. at ¶ 42 ("What the doctor does in the course of [] treating a single patient, as required by the claims, is use a method that has been shown to decrease the risk of mortality from CHF for a population of similar individuals with the hope that it will reduce the risk of death for that individual CHF patient."); Tr. at 12 ("The doctor starting this regimen of therapy is

attempting to extend the patient's life with the therapy."))[13]

Lastly, in addition to improperly excluding the concepts of "risk" and "attempt," Glenmark's proposal includes a negative limitation which (at least on its face) appears to suggest that the claimed methods are not practiced if, in addition to being administered to reduce the risk of death caused by CHF, they are administered to (or happen to) reduce or treat "any symptoms, signs, or causes of CHF" or otherwise improve the quality of life of CHF patients. (Tr. at 16-18) The Court agrees with GSK that nothing in the claim language or intrinsic record supports such a limitation. (D.I. 83 at 5) Indeed, claim 1 states that administration of the drug "*comprises* administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by [CHF,]" ('000 patent, col. 8:36-39) (emphasis added), and "comprises" is an open-ended term that is typically read to allow for additional steps, *see Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003).

During oral argument, Glenmark appeared to concede that this portion of its proposal is unnecessary. Both parties now agree that if the claimed drugs are administered to the patient solely to treat symptoms, signs or causes of CHF, and *not* to reduce a risk of mortality, then such treatment would not amount to infringement of the '000 patent. (D.I. 83 at 11; Tr. at 81-82, 95-96) And Glenmark acknowledged that if the claimed drugs are administered to reduce a risk of mortality *and* to reduce symptoms, signs or causes of CHF, "it's within the scope of the claim."

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[13] Additionally, it was unclear to the Court (and remained unclear after the *Markman* hearing), what conduct Glenmark was suggesting would, in fact, infringe claim 1 were Glenmark's position adopted and were these terms to require "a reduction in the number of deaths of patients with CHF . . . ." (Tr. 72-74, 79-82, 92-93, 98) If a party cannot clearly articulate what its proposed construction means, it is hard for the Court to conclude that such a construction is consistent with the intrinsic or extrinsic record.

(Tr. at 81) Accordingly, the Court finds that the negative limitation in Glenmark's proposal is improper.

For the foregoing reasons, the Court recommends that "decreasing mortality caused by [CHF]" and "to decrease a risk of mortality caused by [CHF]" should be construed as "attempt[ing] to reduce the probability that a patient will die as a result of congestive heart failure."

2. "said maintenance period is greater than six months" / "maintenance period"

Defendants contend that the term "maintenance period" should be construed as "[p]eriod of time over which the maintenance dose is administered." (D.I. 70 at 13) GSK, however, argues that the Court should instead construe the term "'said maintenance period is greater than six months'" and that it do so as follows: "[w]ith the intent that the patient be on the maintenance dosage for more than six months." (*Id.*) Defendants respond that if GSK's proposed term is construed, it should be construed to mean "[t]he patient is on the maintenance dosage for more than six months." (*Id.*) The core dispute here boils down to whether the "maintenance period" refers to an *intended* amount of time (GSK's position), or to the actual amount of time that the patient must be on the maintenance dosages (Defendants' position). (*Id.*; *see also* D.I. 74 at 13; D.I. 83 at 16)

The Court looks first to the claim language itself. The Court agrees with Defendants that "the plain language of the claim requires that in all instances the maintenance period *must be* greater than six months." (D.I. 84 at 12 (emphasis in original); *see also id.* at 14) The claim language does not speak to aspirations—instead, it could not be more precise in stating that the

maintenance period "*is greater* than six months." ('000 patent, col. 8:40 (emphasis added); *see also* D.I. 84 at 12; Tr. at 107-08) The concept of a physician's intent is not reflected therein.[14]

GSK's initial hook for its position (that the claims require only a physician's *intent* that the patient be on the maintenance dosage for more than six months) is the clinical studies described in the patent's specification. (D.I. 70 at 13) GSK argues that because the clinical trial results reported therein are based on an "*intent-to-treat* analysis," ('000 patent, col. 7:25 (emphasis added); *see also id.*, cols. 6:20, 7:50-51, Table 2), and thereby include patients who died during the intent-to-treat period (such that they were not on the maintenance dosage for greater than six months), then the claimed maintenance period must only refer to an intended amount of time, (D.I. 70 at 13-14).

The Court disagrees. For one thing, both sides' experts agreed that "intent-to-treat" is a term of art that relates to the way in which data from clinical trials are analyzed. (D.I. 84 at 9 (citing D.I. 85, Declaration of Timothy J. Doyle ("Doyle Decl."), ex. 1 at 100-102, ex. 2 at 67); *see also id.* at 13; Tr. at 75-76)[15] And importantly, both experts agreed that this distinct "intent-

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[14] Defendants' proposal—that the maintenance period reflects the actual amount of time that the patient must be taking the maintenance dosages, and that this period is greater than six months—also makes sense in light of the specification. The specification describes studies in which the maintenance phase of each study described therein "ranged from six to twelve months[,]" after which patients could choose to receive open-label carvedilol in an extension study. ('000 patent, col. 7:18-21) The studies were successful, with the independent Data and Safety Monitoring Board recommending that the trials be terminated early due to the beneficial results (a 67% reduction in the risk of mortality). (*Id.*, cols. 7:23-8:23) Thus, it makes sense that the claims would require someone to take the drug for at least as long as the minimum maintenance phase (six months) for patients who participated in these studies.

[15] More specifically, Defendants' expert Dr. Clive Rosendorff explained that in an intent-to-treat clinical trial design, once a particular patient is randomly placed into either the drug-receiving group or the placebo group, even if that patient thereafter stops taking the drug or is switched to the other group, the patient's trial results are analyzed as if the patient followed the

to-treat" concept does *not* have any relationship to a physician's intent when he is treating a particular patient. (D.I. 84 at 10 (citing Doyle Decl., ex. 1 at 100-102 (GSK's expert Dr. Chaitman acknowledging that "[t]he intent of a person to do a particular treatment . . . might not have anything to do with an intent to treat analysis of a randomized controlled trial."); ex. 2 at 172-173) During oral argument, GSK acknowledged that "intent-to-treat" is a term of art, but still argued that the patent's reference to the clinical studies was relevant here, because the studies demonstrate that "once the patient is on the drug in the study, they're treated . . . whether they die the next day or whether they die five years later, they're in the study." (Tr. at 104) But how patients are "treated" (or counted) in a study is not necessarily the same thing as what type of maintenance period the patentee claimed. And it certainly cannot trump claim language that clearly dictates that this maintenance period *is greater than* six months. (*Id.* at 107-08)

GSK's next argument, which also hinges on the patent specification, fails almost as easily. Here GSK asserts that were the "maintenance period" term construed in the manner Defendants propose, such a construction would "improperly exclude[] embodiments described in the '000 patent wherein patients received the claimed method of treatment, but did not survive six months on the maintenance dosage." (D.I. 70 at 14; *see also* D.I. 83 at 17; Tr. at 101) In support of this argument, GSK cites to *Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1326 (Fed. Cir. 2013) for the proposition that "'a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.'" (D.I. 70 at 14; D.I. 83 at 17)

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trial protocol for the initially assigned treatment group for the entire trial period. (Doyle Decl., ex. 2 at 67, 172-173) A patient who dies during a study is still included in the data in an intent-to-treat analysis. (*Id.* at 67-68; Tr. at 103)

Yet even assuming that the patent's reference to patient deaths occurring prior to the six-month time frame could be said to amount to a part of an "embodiment" of the invention (and the Court has real doubt that it can), (D.I. 84 at 12-13), the patent certainly does not label such a scenario as a *preferred* embodiment. (Nor does GSK's brief refer to these patients or their outcomes as a "preferred" embodiment.). Indeed, it would seem wrong to view the outcomes of this subset of patients as part of a *preferred embodiment* of the invention—an invention that is all about decreasing mortality caused by CHF pursuant the administration of the claimed drugs for a maintenance period that "is greater than six months."

Moreover, "read in the context of the specification, the claims of the patent need not encompass all disclosed embodiments." *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) ("[T]he mere fact that there is an alternative embodiment disclosed in the [] patent that is not encompassed by [the] district court's claim construction does not outweigh the language of the claim, especially when the court's construction is supported by the intrinsic evidence."); *see also Apeldyn Corp. v. Sony Corp.*, 87 F. Supp. 3d 681, 696 n.8 (D. Del. 2015). Given the plain language of the claims here, circumstances in which patients die before six months need not be included in the scope of the Court's construction of "maintenance period."

GSK also argues that the file history supports its construction, but once again, the Court is not persuaded. GSK explains that when distinguishing prior art that purportedly disclosed the use of carvedilol to treat symptoms of CHF, the patentees stated that pursuant to the claimed invention, "carvedilol is administered to CHF patients with an *intent* to treat CHF mortality." (D.I. 70 at 14 (quoting D.I. 68, ex. F at GSK00000116) (emphasis in GSK's brief)) And indeed,

the Court agrees that this statement is reflective of the claims' content—in that the drugs at issue are administered with the intent to treat a CHF patient's risk of mortality. But to the extent GSK wants the Court to infer from this statement that the claimed maintenance period only refers to an *intended amount of time*, GSK asks too much. Carvedilol may be administered to a CHF patient with the intent to decrease that patient's risk of mortality from CHF, but pursuant to the plain language of the claims, the invention still requires that patient to actually take the daily maintenance dosages for a maintenance period that "is greater than six months."

For all the foregoing reasons, the Court declines to adopt GSK's proposal. Instead, the Court agrees with Defendants that "maintenance period" is the proper term to be construed, and recommends that the term be construed as "period of time over which the maintenance dose is taken into a patient's body." No further construction relating to these terms is necessary, as the plain language of the claims provides for the length of the maintenance period (greater than six months). (*See* Tr. at 108)

3. "maintenance dosages"

Defendants propose that the term "maintenance dosages" be construed to mean "[m]aximum tolerated therapeutic dosage administered each day following the up-titration period[.]" (D.I. 70 at 11) GSK argues that the term be construed as "[d]osages intended to achieve and maintain the therapeutic effect[.]" (*Id.*) The Court finds both proposals to be problematic.

Taking up Defendants' proposed construction first, as an initial matter, the Court agrees with GSK that the words "administered each day" therein are redundant. (D.I. 70 at 12; D.I. 83 at 15; Tr. at 119, 127-28) The word "daily" is already used in the claim to describe the

"maintenance dosages" that are taken by the patient. ('000 patent, col. 8:36-37)

That leaves two limitations remaining in Defendants' proposed construction—that the maintenance dosage is a (1) maximum tolerated therapeutic dosage that (2) necessarily follows an "up-titration" period. In support of these two limitations, Defendants point to the following portion of the specification:

> As one of ordinary skill in the art will readily comprehend, the patient should be started on a low dosage regimen of the desired compound of Formula I, particularly carvedilol, and monitored for well-known symptoms of intolerance, e.g., fainting, to such compound. Once the patient is found to tolerate such compound, the patient should be brought slowly and incrementally up to the maintenance dose. The preferred course of treatment is to start the patient on a dosage regimen of either 3.125 or 6.25 mg, preferably given twice daily, for two weeks. The choice of initial dosage most appropriate for the particular patient is determined by the practitioner using well-known medical principles, including, but not limited to, body weight. In the event that the patient exhibits medically acceptable tolerance of the compound for two weeks, the dosage is doubled at the end of the two weeks and the patient is maintained at the new, higher dosage for two more weeks, and observed for signs of intolerance. This course is continued until the patient is brought to a maintenance dose. The preferred maintenance dose is 25 mg, preferably given twice daily, for patients having a body weight of up to 85 kg. For patients having a body weight of over 85 kg, the maintenance dose is between about 25 mg and about 50 mg, preferably given twice daily; preferably about 50 mg, preferably given twice daily.

('000 patent, col. 5:20-44; *see also* D.I. 74 at 11-12; D.I. 84 at 8; Tr. at 111-12) After reviewing this portion of the specification and the rest of the record, the Court concludes that while the limitations Defendants seek may be reflected in certain embodiments described in the specification, they are not required by the claims.

As for the first limitation at issue, contrary to Defendants' assertion that the specification

(and the above paragraph in particular) "is clear that the maintenance dose is the maximum tolerable therapeutic dose," (D.I. 84 at 8), the patent nowhere states that the maintenance dosage must be the maximum tolerated dosage. It is undisputed that the above excerpt from the specification makes clear that the "preferred" dosing regimen involves an initial period in which a patient receives lower dosages while being monitored for side-effects, and then is "brought slowly and incrementally up to the maintenance dosage." ('000 patent, col. 5:26-27; *see also* Doyle Decl., ex. 1 at 73) But the patent simply does not mandate that this maintenance dosage must be the *maximum* or *highest possible* tolerated dosage—indeed, it does not even use these words. Therefore, its claims do not foreclose scenarios in which a patient might be up-titrated to a new higher dosage with no side effects, but then a physician decides to stop there, and not further up-titrate for two more weeks to a new, even higher dosage. They allow the physician to stop at a level that maintains the therapeutic effect, but that is not necessarily the *maximum* tolerated dosage. (Tr. at 129-30)

In further support of the "maximum tolerated" limitation of their proposal, Defendants rely heavily on a portion of the prosecution history for the '069 patent. (D.I. 74 at 11; D.I. 84 at 11) In a Response to an Office Action in which the applicants were asserting that the invention was not obvious over certain prior art references, applicants stated that "[b]ecause carvedilol has beta-blocking properties, its dosing must be individualized and up-titrated from a sub-therapeutic dose to the maximum tolerated therapeutic dose." (D.I. 68, ex. O at GSK00009593) But the Court cannot graft a "maximum tolerated" limitation onto the construction of "maintenance dosages" based on this single sentence. Indeed, in the very next sentence of this portion of the prosecution history, as GSK points out, (D.I. 83 at 16; Tr. at 128), applicants explained that "the

dosing schedule is used *not to find the optimum individual effective dose*, but to start with sub-therapeutic doses in order to avoid side effects," (D.I. 68, ex. O at GSK00009593 (emphasis added)). And in the prior paragraph, the applicants had described a *preferred* course of treatment: "[T]he *recommended* starting dose of carvedilol for CHF is 3.125 mg twice daily for two weeks. If this dose is tolerated, the dosage is increased to 6.25 mg twice daily. Dosing *should* then be doubled every two weeks to the highest level tolerated by the patient." (*Id.* (emphasis added)) While it is certainly within the scope of the claims (and indeed, a preferred dosing regimen) to have maintenance dosages that are a patient's maximum tolerated dosages, there is nothing in the claims, the specification or the prosecution history that absolutely requires that the "optimum individual dose"—or the "maximum tolerated" therapeutic dose—be determined for every patient. (D.I. 83 at 16)

The final limitation in Defendants' proposal—that the maintenance dosage follow an up-titration period—presents a tougher question. Looking first to the plain language of the claims, the fact that certain claims recite that "maintenance" dosages are to be administered has to mean *something*. That is, the term is not simply described as "dosages" but as "maintenance dosages"; it stands to reason that a "maintenance dosage[]" is in contrast to some other kind of dosage. The Court agrees with Defendants that, were this not so, "there would be no reason to use the [term] 'maintenance period' and no reason to use the term 'maintenance dosage'" if all the claims require is to "just give the drug to that person and keep them on that same dosage." (Tr. at 132)

The patent's specification and prosecution history help explain what this other kind of dosage is: they support the idea that a "maintenance" dosage is something that is taken following an initial dosing period. The above-referenced passage of the specification indicates that a

skilled artisan will know that "the patient should be started on a low dosage regimen" of carvedilol "and monitored for well-known symptoms of intolerance[.]" ('000 patent, col. 5:20-24) This is an "initial dos[e]" and "[o]nce the patient is found to tolerate" the drug, the preferred course of treatment is to double the dose after two weeks, observe the patient for tolerance, and to continue that until "the patient is brought to a maintenance dose." (*Id.* at col. 5:24-38) The prosecution history similarly describes a dosing regimen in which the patient is given a "starting dose" that, if tolerated, is thereafter incrementally increased. (D.I. 68, ex. O at GSK00009593) This is done because "carvedilol has beta blocking properties" and therefore the dosing regimen must be "start[ed] with sub-therapeutic doses in order to avoid side effects." (*Id.*)[16]

Importantly, GSK does not appear to dispute that there is an initial dosing period of carvedilol during which the patient is monitored for tolerance to the drug. Rather, GSK's problem with Defendants' proposal seems to be that the proposal conflicts with the notion that there can be situations where there is no subsequent up-titration (or moving to a higher dose). (*See* Doyle Decl., ex. 1 at 72 (Dr. Chaitman describing up-titration as "start[ing] at a lower dose and [] increas[ing] the dose")) That is, GSK asserts that the "up-titration" limitation in Defendants' proposal is problematic because "there are patients for whom doctors never up-titrate the dose of carvedilol because they cannot tolerate a dose higher than [for instance] an initial dose of 6.25 mg twice daily." (D.I. 83 at 15) In support, GSK cites to deposition testimony from Dr. Chaitman, in which he describes a hypothetical: a physician administers carvedilol to a frail 82-year-old woman who suffered from two previous heart attacks in order to

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[16] Defendants' expert Dr. Rosendorff corroborates that there is an initial dosing phase followed by a "maintenance phase" that is "necessitated by the mechanism of action of β-blockers and the pathology of CHF[.]" (Rosendorff Decl. at ¶¶ 36-39)

reduce her risk of dying, and starts the patient on a dose of 6.25 mg of carvedilol twice a day—but then never up-titrates to a higher dosage because "she is barely tolerating the 6.25 twice a day." (Second Amon Decl., ex. A at 77-81) Yet importantly, while it may be true that in some circumstances like this one, a patient is never moved up to a higher dosage, even then, there still would have been an "initial" dosing period in which the patient was monitored for tolerance. (*Id.* at 79-80 (Dr. Chaitman explaining that in initiating carvedilol treatment for a patient, "I'm going to try the strategy . . . even though I know that this patient *may not tolerate it*. But I'm going to go slow. *I'm going to see*, but I'm not going to go higher.") (emphasis added); *see also id.* at 81; Tr. at 125 (GSK's counsel, in reference to Dr. Chaitman's hypothetical, explaining that the physician "would be thrilled if he could just get her on anything and *she can tolerate it* and *he's not going to then* try to up-titrate" her) (emphasis added))[17]

During oral argument, when pressed about whether their proposed "up-titration" limitation would encompass scenarios where the patient was never moved to a higher dosage, Defendants indicated that it would—that "the up-titration period that is contemplated in

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[17] As further evidence that there are situations in which there is no up-titration, during oral argument GSK's counsel pointed to the specification's discussion of the design of the studies, in which patients were divided into four trials. (Tr. at 125-26 (citing '000 patent, col. 6:50-62)) One of these trials was a "dose response study" and the remaining three trials were "dose titration" studies. (*Id.* at 126 (citing '000 patent, col. 6:55-61)) According to Dr. Chaitman, in the dose response study, the patients were qualified "and then they were randomly assigned a dosage, 6.25, 12.5, or 25 milligrams . . . and that's what they started on on day one *and that's what they stayed at.*" (*Id.* (emphasis added) (citing Second Amon Decl., ex. A at 81-82)) But even so, the specification goes on to explain that before patients were placed into all four trials, including the dose response trial, there was a "challenge period common to the four protocols" in which "patients received low-dose [] carvedilol (6.25 mg b.i.d.) for two weeks. . . . Patients tolerating low-dose carvedilol were then randomized to blinded medication[.]" ('000 patent, col. 7:6-18) So even for the dose response study in which there was no subsequent up-titration, there was still an initial dosing period in which the patient was monitored for tolerance.

[D]efendants' construction necessarily would include the instance where a patient could not . . . have their dosage increased because of intolerance." (Tr. at 116-18) Even so, and while the Court believes that all of the evidence supports a construction for "maintenance dosages" that makes clear that such a dosage follows a period in which the patient is monitored for tolerance, the Court will not adopt Defendants' "up-titration" language. Taking this course will help prevent a construction that implies that a patient *must* move from a lower to a higher dosage before settling at the "maintenance dosage[]."

Turning to the language in GSK's proposal, the Court agrees with Defendants, (D.I. 84 at 7), that the evidence does not support GSK's attempt to read an intent limitation into this term. Nor is there support for the idea that a maintenance dosage is one intended to "achieve" the therapeutic effect. As Defendants point out, this concept in GSK's proposal appears to improperly cover even the initial dose given before the maintenance dosage (i.e., the dosage intended to "maintain" the therapeutic effect) is taken. (D.I. 74 at 12-13 (explaining that GSK's proposed construction "conflat[es] the dosage necessary to achieve a 'therapeutic effect' with the maintenance dosage"); *see also* D.I. 84 at 7 ("GSK's construction to include doses designed to both *achieve* and *maintain* is inconsistent with the claim language that is directed only to the dose to maintain.") (certain emphasis added))

But the Court agrees with GSK that the claimed "maintenance dosages" are given to "maintain the therapeutic effect" of the drug. The claim, after all, recites a method of "administering a *therapeutically acceptable* amount of carvedilol"—via "daily *maintenance* dosages for a *maintenance* period to decrease a risk of mortality caused by [CHF.]" ('000 patent, col. 8:30-40 (emphasis added); *see also* GSK's Markman Presentation, Slide 39) The words of

the claim underscore that "maintaining" the "therapeutic effect" of carvedilol in this context is what the claims are all about.

Therefore, the Court recommends a construction for the term "maintenance dosages" that pulls in part from the persuasive portions of both sides' constructions: that "maintenance dosages" be construed as "dosages to maintain the therapeutic effect following a period in which the patient's tolerance of the drug is monitored." *Cf. Hospira, Inc. v. Eurohealth Int'l Sarl*, Civil Action No. 14-487-GMS, Civil Action No. 14-1008-GMS, 2015 WL 6697257, at *1 & n.3 (D. Del. Nov. 3, 2015) (construing "'maintenance dose'" to mean "'dose given as a continuous infusion to maintain a target concentration or desired effect'") (emphasis omitted).

4. "administering"

Defendants assert that the term "administering" should be construed as "'[d]elivering into a patient's body.'" (D.I. 74 at 15) GSK argues that "administering" should be construed to mean "'prescribing, dispensing, giving, or taking.'" (D.I. 70 at 8) The quarrel here is whether the term broadly encompasses more than the physical act of the drug being placed into a patient's body—such as a pharmacist dispensing the drug to a patient or the doctor writing a prescription for the drug. (D.I. 74 at 15 & n.8; D.I. 83 at 11-12; Tr. at 136) For the reasons discussed below, the Court finds areas of agreement and disagreement with portions of Plaintiffs' and Defendants' positions.

As to the question of whether the broader definition of "administering" put forward by Plaintiffs is warranted, the Court looks to the claim language.[18] There, the Court notes that the

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[18] The Court will focus herein on the intrinsic evidence, because other evidence provided by the parties suggests that "administering" can have "multiple potential meanings[,]" (D.I. 84 at 15), depending on the context in which the term is used. GSK, for example, points to

phrase "administering to said patient[,]" ('000 patent, col. 8:36-37), is broadly written, and seems to allow for "administering" to include a drug being in some way provided to a patient so that it may be taken, or a drug being taken by a patient.

Next, the Court looks to the specification for help. In doing so, the Court agrees with GSK that the way that the term "administering" is used in the written description leaves room for a broader interpretation than that provided by Defendants. Two portions of the specification that use variations of the term "administering" help demonstrate this:

> Pharmaceutical compositions of . . . carvedilol, alone or in combination with ACE inhibitors, or diuretics, or digoxin may be *administered* to patients according to the present invention in any medically acceptable manner, preferably orally. For parenteral *administration*, the pharmaceutical composition will be in the form of a sterile injectable liquid . . . . The nature and composition of the pharmaceutical carrier, diluent or excipient will, of course, depend on the intended route of *administration*, for example whether by

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multiple definitions for the term in a standard dictionary, including "'1: to manage or supervise the execution, use, or conduct of . . . 2 a: to mete out: dispense . . . b: to give ritually . . . c: to give remedially <~ a dose of medicine . . .'" (D.I. 70 at 8 (quoting First Amon Decl., ex. 4 (*Webster's Ninth New Collegiate Dictionary*)); *see also* D.I. 83 at 11) The Court's job, however, is to construe the term in a manner that reflects its "meaning to the ordinary artisan after reading the entire patent." *Phillips*, 415 F.3d at 1321. In other words, in construing the claim term, "the general meanings gleaned from . . . dictionaries[] must always be compared against the use of the terms *in context*, and the intrinsic evidence must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor." *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1300 (Fed. Cir. 2003) (emphasis added); *see also Renishaw PLC*, 158 F.3d at 1250 ("[W]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning."); *Fisher-Rosemount Sys., Inc. v. Invensys Sys., Inc.*, No. A-13-CA-587-SS, 2015 WL 1275910, at *14 (W.D. Tex. Mar. 19, 2015) (explaining that where a term "has multiple potential meanings, [] the context is key to determining the applicable meaning"). Similarly, both sides were able to point to decisions where a court has construed "administering" in a manner consistent with their proposals. (*See* D.I. 70 at 9-10; D.I. 74 at 17 & n.9; D.I. 83 at 12) Again, that each side can point to supportive caselaw as to the possible meaning of "administering" merely underscores "that the context of how the term is used in the patent is important." (D.I. 84 at 17)

intravenous or intramuscular injection[.]

(*Id.*, col. 4:32-44 (emphasis added))

> When a liquid carrier is used, the preparation will be in the form of a syrup, elixir, emulsion or an aqueous or non-aqueous suspension. Such a liquid formulation may be *administered* directly p.o. [by mouth] or filled into a soft gelatin capsule.

(*Id.*, col. 5:11-15 (emphasis added))[19]

The examples of "administ[ering]" referred to in these passages allow for many types of acts that result in the drug entering a patient's body. For example, some invoke the idea of a physician taking direct action to deliver the drug into a person's body (e.g., where the administration is "by intravenous or intramuscular injection" and where a physician is the one who performs the injection). But the references to the medication being taken orally (whether in a liquid or capsule form), for example, suggest that the actor who is personally responsible for putting the medicine into the patient's body is the patient him or herself, after a physician has *directed* that the dosage be taken and/or *facilitated* the taking of the dosage. (Tr. at 140 (GSK's counsel noting that "the context of the specification as a whole . . . is broad enough [such that "administering" is] not just limited to putting the drug in the mouth")) And if that is so, there is no reason why the term "administering," on its face, could not encompass circumstances wherein the physician is "giving" the dosage to a patient, where the patient is "taking" the dosage, *and* also where a medical professional is "prescribing"[20] or "dispensing" the dosage to a patient (and

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[19] "[P].o." in this latter citation means "by mouth." (D.I. 70 at 9 n.12 (citing Chaitman Decl. at ¶ 31))

[20] There is one reference to the word "prescribing" in the patent, but it is not particularly helpful to the Court in determining whether "administering" captures the concept of "prescribing." In the "Background of the Invention" section of the specification, the patentee

leaving it to the patient to take the drug on her own).

The Court does agree with Defendants that the patent requires that what is administered (the dosage) *is actually taken into the patient's body.* The claim language itself supports this idea, as the claims of the patent are directed to "[a] method of decreasing mortality caused by congestive heart failure"—and one cannot accomplish this goal for a patient if the patient does not actually take the drugs at issue into her body. (Defendants' Markman Presentation, Slide 48) Similarly, every reference to the term "administering" (or variances thereof) in the portions of the specification quoted above (and in other portions of the specification), couples the term with language strongly indicating that the drug has or will actually be taken by a patient in some particular way. (*See also* '000 patent, col. 4:54-57 ("Such formulation is especially suitable for parenteral *administration*, but may also be used for oral *administration* or contained in a metered dose inhaler or nebulizer for insufflation.") (emphasis added); col. 4:61-63 ("Alternatively, these compounds may be encapsulated, tableted or prepared in a [sic] emulsion or syrup *for oral administration.*") (emphasis added); col. 5:56-60 ("[T]he actual preferred dosages of the

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discusses traditional treatment of CHF (i.e., prior to the discovery of carvedilol as a form of treatment). ('000 patent, col. 1:29-41) The specification explains that initially, physicians would limit the patient's physical activity, restrict his salt intake, and recommend use of a diuretic. (*Id.*, col. 1:31-34) If such measures are not successful, digoxin, an agent that increases the force of mycardial contraction, would be added to the treatment plan. (*Id.*, col. 1:34-36) Next, the specification states that "angiotensin converting enzyme inhibitors . . . *are prescribed* for chronic treatment of [CHF], in conjunction with a diuretic, digoxin, or both." (*Id.*, col. 1:36-41 (emphasis added)) The passage thus does not pertain to the claimed carvedilol, nor does it explicitly link "administering" to "prescribing." Its presence could just as easily be used by GSK in support of its construction (in that just as this passage discusses "prescribing" certain drugs, so too are the claims about "prescribing" those drugs along with carvedilol), (D.I. 83 at 12-13), as it could be used by Defendants to support their construction (in that the patentees knew how to use the term "prescribing" when they wanted to, and they did not use the term in the claims), (D.I. 74 at 16). Neither argument moves the Court one way or the other.

compounds being used in the compositions of this invention will vary according to the particular composition formulated, the mode of *administration*, the particular site of *administration*, and the host being treated.") (emphasis added)) Therefore, the Court does not believe that "administering" could encompass a situation where "the patient never even filled the prescription or took the drug[.]" (D.I. 74 at 16)

Taking these factors into account, the Court concludes that it is appropriate to adopt a modified version of Plaintiffs' proposal. Therefore, the Court recommends that "administering" be construed to mean "prescribing, dispensing, giving or taking (such that what is prescribed, dispensed, given or taken is actually taken into a patient's body)."

5. "have been shown to statistically decrease"

The next disputed term, "have been shown to statistically decrease," appears in claim 8 of the '000 patent, reproduced below:

> 8. A method according to claim 1, wherein the daily maintenance dosages and the maintenance period *have been shown to statistically decrease* the risk of mortality caused by congestive heart failure.

('000 patent, col. 8:60-63 (certain emphasis added and omitted)) This claim was added during reissue proceedings. Defendants contend that the term is indefinite under 35 U.S.C. § 112. (D.I. 74 at 18-20) GSK asserts that the term is not indefinite and should be construed to mean "'have been shown to reduce by a statistically significant amount.'" (D.I. 70 at 19-20)

Section 112 requires that patent claim "particularly point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention." 35 U.S.C. § 112. If it does not, the claim is indefinite and therefore invalid. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2125 (2014). In *Nautilus*, the Supreme Court of the United States set out the test to be

applied in the indefiniteness inquiry: "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124.

The primary purpose of the definiteness requirement is to ensure that patent claims are written in such a way that they give notice to the public of what is claimed, thus enabling interested members of the public (e.g., competitors of the patent owner) to determine whether they infringe. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002). Indefiniteness is to be evaluated from the perspective of someone skilled in the relevant art at the time the patent was filed. *Nautilus*, 134 S. Ct. at 2128.

Like claim construction, indefiniteness is a question of law for the court. *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1332 (Fed. Cir. 2014); *Pi-Net Int'l Inc. v. JPMorgan Chase & Co.*, 42 F. Supp. 3d 579, 585 (D. Del. 2014). The Federal Circuit has stated that "[a]ny fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).[21]

Turning to the term at issue, Defendants contend that it renders claim 8 of the '000 patent indefinite because the intrinsic record does not identify "*which* maintenance dosages and/or

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[21] In *Nautilus*, the Supreme Court left open the question of whether factual findings subsidiary to the ultimate issue of definiteness should, in fact, trigger the application of a "clear and convincing evidence" standard, noting that it would "leave th[is] question[] for another day." *Nautilus*, 134 S. Ct. at 2130 n.10. In the absence of a Supreme Court decision to the contrary, the Federal Circuit precedent regarding this issue, referenced above, controls.

maintenance periods have been shown to have the claimed statistical effect." (D.I. 74 at 19 (emphasis in original); *see also* D.I. 84 at 19-20) The patent specification explains that patients in the clinical studies received doses of carvedilol "titrated over several weeks in the range of 6.25 to 50 mg b.i.d." for maintenance periods of "six to 12 months." ('000 patent, col. 7:11-19) Beyond that, though, the specification does not identify "any specific 'maintenance dosage' or 'maintenance period' that resulted in a specific reduction in mortality." (D.I. 74 at 19) Rather, it sets forth mortality data from the studies in the aggregate, with no information breaking out more specific dosages and/or periods of time that resulted in a statistically significant decrease in the risk of mortality in CHF patients. (*Id.*; *see also* D.I. 84 at 20) But the claims themselves are directed to the treatment of a singular patient. Therefore, according to Defendants, the physician would be left wondering "how much I give and how long I give it to reduce the probability that Jane or John is going to die as a result of [CHF]?" (Tr. at 146)

For its part, GSK responds that the specification explains that patients participating in the clinical studies described in the previous paragraph saw a 67% reduction in the risk of mortality with a p value of <0.0001, which is "universally understood . . . to be statistically significant[.]" (D.I. 83 at 18-19) And therefore, according to GSK, the person of skill in the art would understand that: (1) maintenance dosages of carvedilol "'titrated over several weeks in the range of 6.25 to 50 mg b.i.d.'" with an ACE inhibitor, diuretic, and/or digoxin had been shown to statistically decrease the risk of mortality caused by CHF; and (2) a "maintenance period of greater than six months had been shown to statistically decrease the risk of mortality caused by CHF in patients with moderate and severe CHF[,] and that a maintenance period greater than 12 months had been shown to statistically decrease the risk of mortality caused by CHF in patients

with mild CHF." (*Id.* at 19)

The Court believes that the issue of whether the disputed term renders claim 8 indefinite is one best resolved during the summary judgment stage of the case. While standard claim construction issues revolve around the proper meaning of claim terms, a finding of indefiniteness invalidates a claim entirely, and therefore a party asserting indefiniteness bears a heavy burden. *See Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, C.A. No. 14-028-LPS, 2016 WL 873435, at *6 (D. Del. Mar. 7, 2016); *CSB-Sys. Int'l Inc. v. SAP Am., Inc.*, Civil Action No. 10-2156, 2011 WL 3240838, at *18 (E.D. PA. July 28, 2011). Though the claim term is not a model of specificity, the Court would certainly benefit from fuller briefing regarding the issue. The Court would also benefit from meaningful oral argument, as the 3.5 hour *Markman* hearing unfortunately did not leave adequate time for discussion of the term. (Tr. at 144-146); *see, e.g.*, *Indus. Tech. Research Inst. v. LG Elecs. Inc.*, No. 3:13-CV-02016-GPC-WVG, 2014 WL 6907449, at *3 (S.D. Cal. Dec. 8, 2014) (noting that the parties would not have adequate time to "fully address the indefiniteness of the [disputed] claim term [] at the [Markman] hearing" and that because a "federal district court's 'duty' when determining indefiniteness demands more than a mere perfunctory inspection. . . . the Court defers the determination of indefiniteness to a later stage of the proceedings so the parties may thoroughly brief the Court on the matter") (citation omitted).

In the meantime, the Court determines that the term "have been shown to statistically decrease" is amenable to construction. Defendants have not argued otherwise. Nor have Defendants raised any dispute specific to GSK's proposed construction of the term. Therefore, the Court recommends that "have been shown to statistically decrease" be construed to mean

"have been shown to reduce mortality by a statistically significant amount." ('000 patent, col. 7:23-8:23 (describing clinical trial results relevant to the patent claims wherein the p-value was less than 0.05% and where the trials were recommended to be terminated due to a 67% of all-cause mortality); Chaitman Decl. at ¶¶ 51-52 (GSK's expert opining that these factors would have led a person of skill in the art to understand that the results of these trials were statistically significant)) The Court makes this recommendation without prejudice to Defendants' ability to raise a definiteness challenge at summary judgment—that is, to later argue that the now construed claim fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. *See Research Frontiers, Inc. v. E Ink Corp.*, Civil Action No. 13-1231-LPS, 2016 WL 1169580, at *21 (D. Del. Mar. 24, 2016) (citing cases).

6. "congestive heart failure"

Defendants suggest that this term be construed as "[a] clinical diagnosis of impaired pumping capability of the heart associated with abnormal retention of water and sodium[.]" (D.I. 70 at 18) GSK proposes that the Court construe the term as "[a] condition that occurs as a result of impaired pumping capability of the heart and is associated with abnormal retention of water and sodium[.]" (*Id.*) The crux of the dispute here centers on the initial language of each side's proposal—i.e., whether the construction must make clear that there has been a physician's "clinical diagnosis" of CHF in the patient. (D.I. 74 at 17) The latter portions of each side's proposal are identical, and come from the "Background of the Invention" section of the specification, which explains that "[c]ongestive heart failure occurs as a result of impaired pumping capability of the heart and is associated with abnormal retention of water and sodium." ('000 patent, col. 1:29-31)

The Court finds that GSK's proposed construction stays truest to the intrinsic record. Indeed, in the paragraph following the patentee's above description of CHF, the patentee explicitly states that "[c]ongestive heart failure *is a condition* . . . ." ('000 patent, col. 1:42 (emphasis added)) In this same portion of the specification, the patentee also explains that "congestive heart failure is a well-known cardiac *disorder*[,]" (*id.*, col. 1:55-56 (emphasis added)), a description of CHF that sounds more like GSK's proposed "condition" than Defendants' proposed "clinical diagnosis."

The Court also agrees with GSK that its proposal is the one that best comports with "the common understanding of the term[.]" (D.I. 83 at 19) Indeed, both parties' experts referred to CHF as a "condition," (*see* Chaitman Decl. at ¶ 46; Rosendorff Decl. at ¶¶ 30, 33), and the medical dictionary to which GSK cites does so as well, (First Amon Decl., ex. 7 ("congestive heart failure (CHF), an abnormal *condition* that reflects impaired cardiac pumping . . . .") (certain emphasis added, certain emphasis omitted)).

For their part, Defendants do not really seem to dispute that CHF is appropriately described as a medical "condition"—they even call it such—but instead assert that it is a condition that requires a clinical diagnosis by a doctor in order for the invention to be practiced. (D.I. 84 at 18) That is, their proposed construction is motivated by their position that:

> [I]n order to practice a claim that is directed towards the treatment of congestive heart failure, the alleged direct infringer must *know* that the patient has congestive heart failure. In 1995, a person of ordinary skill in the art would make that determination by arriving at a "clinical diagnosis" *of the condition.*

(*Id.* (certain emphasis added, certain emphasis omitted); *see also* Tr. at 142) Defendants are fighting for the inclusion of "clinical diagnosis" in the construction of "congestive heart failure"

to avoid an argument from GSK down the line that "the '000 patent can be infringed even if the doctor (the alleged direct infringer in GSK's view) has not determined that the patient has [CHF.]" (D.I. 84 at 19)

GSK's responsive claim construction brief addresses this concern. Their response makes clear that there is no need to improperly insert a "clinical diagnosis" limitation into the construction for "congestive heart failure," because the term "patient in need thereof" in the preamble of the asserted claims does the same work. (D.I. 83 at 19-20) GSK thus stated:

> Indeed, there is no dispute that the claimed patient who (1) needs to have their risk of mor[t]ality caused by CHF reduced, and (2) receives the claimed method of decreasing a risk of mortality caused by CHF, is a patient under the treatment of a doctor *and has been diagnosed with CHF.*

(*Id.* at 20 (emphasis added))[22]

Given the inclusion of the term "patient in need thereof" in the claims then, there is no need to construe "congestive heart failure" in a manner that deviates from the intrinsic record. For these reasons, the Court recommends that "congestive heart failure" be construed to mean "a condition that occurs as a result of impaired pumping capability of the heart and is associated with abnormal retention of water and sodium."

B. Conclusion

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "decreasing mortality caused by congestive heart failure" / "to decrease a risk of

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[22] Indeed, Defendants too appear to acknowledge the relevance of the term "patient in need thereof" to this particular dispute, explaining that the doctor would not "know that a patient is 'in need' of carvedilol without having made a diagnosis." (D.I. 84 at 19)

mortality caused by congestive heart failure" should be construed as a claim limitation that means "attempt[ing] to reduce the probability that a patient will die as a result of congestive heart failure"

2. "maintenance period" should be construed to mean "period of time over which the maintenance dose is taken into a patient's body"

3. "maintenance dosages" should be construed to mean "dosages to maintain the therapeutic effect following a period in which the patient's tolerance of the drug is monitored"

4. "administering" should be construed to mean "prescribing, dispensing, giving or taking (such that what is prescribed, dispensed, given or taken is actually taken into a patient's body)"

5. "have been shown to statistically decrease" should be construed to mean "have been shown to reduce mortality by a statistically significant amount"

6. "congestive heart failure" should be construed to mean "a condition that occurs as a result of impaired pumping capability of the heart and is associated with abnormal retention of water and sodium"

IV. CONCLUSION

The Court recommends that the District Court adopt the constructions set out in Section III.B above, for the reasons discussed in Section III.A above.

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)(2). 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: June 3, 2016

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE