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 patent infringement actions filed by Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited (collectively, "GSK" or "Plaintiffs") against Defendants Glenmark Pharmaceuticals Inc., USA ("Glenmark") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Defendants"), presently before the Court is the portion of Defendants' motion for summary judgment that asks the Court to (1) "adopt Defendants' proposed construction" with regard to the claim term "said maintenance period is greater than six months" and (2) "hold that sales [of carvedilol, the drug at issue in the case, by Defendants] during the first six months of the maintenance period are non-infringing" (the "Motion"). (Civil Action No.

14-877-LPS-CJB (hereinafter "*Glenmark* Action"), D.I. 215 at 46-47; Civil Action No. 14-878-LPS-CJB (hereinafter "*Teva* Action"), D.I. 249 at 46-47; *see also Glenmark* Action, D.I. 214 at 1 (motion seeking summary judgment on the ground that "administering carvedilol during the first six months of the maintenance period is not an act of direct infringement'); *Teva* Action, D.I. 248 at 1 (same))[1] The Court recommends that Defendants' Motion be DENIED.[2]

I. BACKGROUND

A. Procedural History

On July 3, 2014, GSK commenced these actions. (D.I. 1) GSK alleges that Defendants induce infringement of United States Patent No. RE40,000 (the "'000 patent") by making, offering to sell, selling, importing, and otherwise promoting and distributing generic carvedilol tablets. (*See, e.g.*, D.I. 59, 175) 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. (D.I. 16; *Teva* Action, D.I. 18)

Briefing on the instant Motion was completed on March 3, 2017. (D.I. 274) The parties thereafter submitted supplemental letter briefs with respect to the issues raised in the instant Motion in light of Chief Judge Stark's February 17, 2017 claim construction order. (D.I. 288, 292) The Court held oral argument on the Motion (and various other summary judgment and

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[1] The Court notes that the Motion is included in Defendants' "Combined Motion for Summary Judgment and to Exclude Certain Expert Testimony" in which they, *inter alia*, move for summary judgment with respect to other issues. (*Glenmark* Action, D.I. 214; *Teva* Action, D.I. 248) This Report and Recommendation solely addresses Defendants' arguments as to the above-referenced issues.

[2] The Court will cite to docket index (or "D.I.") numbers from the *Glenmark* Action (Civil Action No. 14-877-LPS-CJB) herein, unless otherwise noted.

Daubert motions filed in the case) on March 24, 2017. (D.I. 296 (hereinafter, "Tr.")) Thereafter, Defendants filed a Notice of Supplemental Authority on April 10, 2017, (D.I. 298), to which Plaintiffs filed a response on April 13, 2017, (*Teva* Action, D.I. 340).

A 5-day trial is set to begin in the *Teva* Action (Civil Action No. 14-878-LPS-CJB) on June 12, 2017. (*Teva* Action, D.I. 38, 329, 350)

B. Factual Background

The Court hereby incorporates the discussion of certain factual background relating to this matter contained in its Report and Recommendation on Defendants' motion for summary judgment of invalidity, issued on May 2, 2017. (D.I. 299)

The '000 patent, at issue in this case, contains 9 method claims directed to methods of decreasing mortality caused by congestive heart failure (or "CHF") in a patient in need thereof by administering carvedilol in a manner recited in the claims. ('000 patent)[3] GSK asserts all but claim 5 against Defendants in these actions. (D.I. 215 at 3) Claim 1 is the only independent claim of the '000 patent, and it reads:

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

[3] 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."

six months.

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

After holding a *Markman* hearing, the Court construed the term "maintenance period" as used in the claims to mean a "period of time over which the maintenance dose is taken into a patient's body." (D.I. 133 at 44 (internal quotation marks omitted)) "Maintenance dosages," in turn, were construed to mean "dosages to maintain the therapeutic effect following a period in which the patient's tolerance of the drug is monitored." (*Id.* (internal quotation marks omitted))

Chief Judge Stark later sustained Plaintiffs' objection to the Court's construction of "maintenance dosages," finding that the term should instead be construed to mean "dosages in the therapeutic amount given during the maintenance period[.]" (D.I. 251 at 2-4 (internal quotation marks omitted)) In doing so, Chief Judge Stark noted that the patent contrasts a "maintenance dosage" of carvedilol (dosages used to maintain a therapeutic effect) with low "'starting' dosages administered to check a patient's tolerance before 'up-titrating' to the maintenance dose." (*Id.* at 3) The District Court concluded that "the record does not support viewing an initial or early dosage in an amount that turns out to be the 'maintenance dosage' as excluded from the meaning of 'maintenance dosage' (even if the physician is closely monitoring the patient's tolerance of this amount)" and that the term "maintenance dosage" should be understood to be contrasting only with initial "dosages of less than the final, therapeutic amount." (*Id.* at 3-4)

The instant dispute implicates the question of whether administration of the accused products (Defendants' generic carvedilol) during the initial six months of the maintenance period

(assuming a patient ends up taking maintenance dosages for more than six months) falls within the scope of the claims. The Court will herein refer to dosages of carvedilol provided in this period as those provided in "the initial six months of the maintenance period."

II. DISCUSSION

A. Legal Standards

1. Claim Construction

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 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; *see also Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).

In proceeding with claim construction, 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." *Phillips*, 415 F.3d 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 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.

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 though, 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, 980-81 (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).

2. Summary Judgement

A grant of summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 & n.10 (1986). If the moving party meets this burden, the nonmovant must then "come forward with specific facts showing that there is a *genuine issue for trial*." *Id.* at 587 (emphasis in original) (internal quotation marks and citation omitted). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal

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

B. Analysis

With their Motion, Defendants seek to resolve the parties' dispute about whether, so long as a patient takes a maintenance dosage of carvedilol for more than six months, administration of the drug during the initial six months of the maintenance period falls within the scope of the claims. As an initial matter, the Court addresses how to properly categorize that dispute.

On this score, the Court questioned the parties during oral argument as to whether the dispute: (1) implicates an issue of claim construction, or (2) is better categorized, *inter alia*, as a

dispute concerning the proper measure of damages to be awarded when a doctor has administered daily maintenance dosages of carvedilol to a patient (in conjunction with the patented method) for a maintenance period that is greater than six months. (Tr. at 125-26, 137-38) After reflection, the Court views the Motion, as do Defendants, (*see, e.g.*, *id.* at 125-26, 163), as hinging on the proper construction of the claim term "said maintenance period is greater than six months."

Plaintiffs, to the contrary, had suggested that the dispute was probably not a "claim construction [issue] because [they] don't think there's a disagreement about what the words [of the claim term] mean"—rather, "[i]t's more about how you apply those words in [the] infringement [analysis] and then how that relates to damages." (*Id.* at 139) However, the crux of this dispute is about (1) whether the entire span of a maintenance period lasting for more than six months "falls within the scope of the claims[,]" (D.I. 215 at 46), or (2) whether the initial six months of such a period does not fall within the scope of the claims, such that the administration of daily maintenance dosages during those initial six months "does not infringe since it *does not occur during* a 'maintenance period [that] is greater than six months[,]'" (D.I. 274 at 15-16 (emphasis added); *see also* D.I. 187 at 2).[4] The United States Court of Appeals for the Federal Circuit has explained that "[c]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." *O2 Micro Int'l Ltd. v. Beyond Innovation*

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[4] It is undisputed that if a doctor administers carvedilol to a patient for less than six months (because the patient died, or could not tolerate the drug, or stopped taking it for some other reason), there has been no infringement. (Tr. at 127, 134, 136) It is also undisputed that the "maintenance period" starts when the first maintenance dose is given. (*Id.* at 126, 128, 133) Thus, it is the "is greater than six months" language that really triggers the parties' dispute here.

Tech. Co., Ltd., 521 F.3d 1351, 1362 (Fed. Cir. 2008) (internal quotation marks and citation omitted). Thus, "[w]hen the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *Id.* The Court will now do so with respect to the claim term "said maintenance period is greater than six months."

Defendants make two primary arguments in support of their view that the claims' reference to a "maintenance period [that] is greater than six months" refers to a period of time commencing when the physician has already administered the carvedilol as claimed by the '000 patent for six months. The Court will address both in turn.

First, Defendants assert that the plain language of the claims compels a conclusion that "the infringement only begins when the maintenance period is greater than six months." (Tr. at 125; *see also* D.I. 215 at 47; D.I. 274 at 15-16) In support of their "plain language" argument, Defendants note that the claim language here is that the said "maintenance period *is* greater than six months," not that it "turns out to be greater than six months" or "becomes greater than six months." (Tr. at 128; Defendants' Claim Construction Dispute Presentation at Slide 4 (certain emphasis in original, certain emphasis added)) And Defendants argue that their position is also correct because the infringing act is the act of "administering daily maintenance dosages," and administering any of those daily maintenance dosages during the initial six months of the maintenance period cannot amount to infringement, since all such dosages are not administered during a maintenance period that "'is greater than six months.'" (D.I. 274 at 15-16)

For their part, Plaintiffs respond by arguing that the claim term "said maintenance period is greater than six months" defines the *length* of the maintenance period, not when it begins—meaning the administration of maintenance dosages start when a "final, therapeutic

amount" is reached, and the "maintenance period" starts when the maintenance dosage is first administered. (D.I. 258 at 47; Tr. at 133; GSK's Claim Construction Dispute Presentation at Slide PDX-103; D.I. 288 at 2) As for the import of the "is greater than six months" language in the term, Plaintiffs argue that "[d]octors' administration of the claimed method for the entire maintenance period, induced by Defendants[']actions, infringes so long as the maintenance period reaches six months." (D.I. 258 at 47; *see also* Tr. at 134 ("[T]he physician needs to administer the treatment protocol for greater than six months. If he does that, there's infringement. All the steps have been performed."))

The Court believes that the plain language of the claims supports Plaintiffs' position. The term "maintenance period is greater than six months" does not indicate that said maintenance period *starts* at six months. Nor does the plain language of the claims state that they cover administering maintenance dosages "*after* a maintenance period *has reached* six months," or administering maintenance dosages "in the post-six month period." Instead, the claims plainly recite administering maintenance dosages "*for* a maintenance period . . . and said maintenance period is greater than six months." ('000 patent, col. 8:37-40 (emphasis added)) A maintenance period greater than six months, that undisputably started when the first maintenance dosage was given at least six months prior, necessarily includes all of the days after that six-month mark, and also all of the days that came before it. It encompasses the entire period, as the language "unambiguously requires that the maintenance period . . . *must last for at least six months*." (D.I. 251 at 6 (emphasis added)); *cf. Gen. Foods. Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1274 (Fed. Cir. 1992) ("[E]ach claim [of a patent] is an *entity* which must be considered *as a whole*.") (emphasis in original). So, while a physician would not be infringing the asserted

claims until she administered carvedilol in the manner otherwise set out in the claims for six months and a day, the scope of the infringement at that point would implicate the entire time period (six months and a day) that carvedilol has been administered.

Second, Defendants argue that Plaintiffs' interpretation of the term "said maintenance period is greater than six months" would "render the claims hopelessly indefinite" because a doctor "would have no way of knowing if an 'administration' of carvedilol during the first six months is infringing or not at the time of the claimed administration." (D.I. 215 at 47; *see also* Tr. at 126-29 ("GSK's construction means that you don't know when you're infringing until you get to the six-month period")) Adoption of Plaintiffs' position, Defendants assert, would allow for "retroactive infringement[,]" (D.I. 292 at 1)—that is, if a doctor administers the claimed method for greater than six months, "all of the sudden under [Plaintiffs'] theory all of these [carvedilol tablets the doctor] gave for the last six months retroactively spring[] up and become[] infringing." (Tr. at 127) And so Defendants assert that their view regarding the proper scope of the claim term is the correct one, because it provides certainty to the issue of when infringement begins. (Defendants' Claim Construction Dispute Presentation at Slide 4)

The Court is not persuaded that adoption of Plaintiffs' proposal would render the claims indefinite ("hopelessly" or otherwise). Even applying Plaintiffs' proposed construction, the claims inform the person of skill in the art about the scope of the invention with reasonable certainty. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). As Plaintiffs point out, "there can be no dispute that doctors reading the claims would know that if they administer maintenance dosages with the intent to reduce mortality for a period greater than six months, they infringe, and if it is less, they don't." (D.I. 258 at 48; *see also Teva* Action, D.I.

340 ("Determining infringement of the methods claimed in the '000 patent does not present any uncertainty. The claim limitation is satisfied for an individual patient when the patient has been on daily maintenance dosages of the claimed drugs for a maintenance period greater than six months."))

It is of course true that a doctor will not know that infringement has, in fact, occurred until she knows that she has completed all of the steps of the method (i.e., administration of daily maintenance dosages of carvedilol concomitantly with an ACE inhibitor, diuretic, or digoxin to decrease a CHF patient's risk of mortality for a maintenance period that is greater than six months). For instance, a doctor who has been administering daily maintenance dosages of carvedilol as claimed in the patent to a patient for two months does not know then whether or not that particular patient will survive longer than six months. But that does not mean that there is uncertainty about the *scope of the claimed method* at issue. A doctor will always know what needs to happen in order for infringement to occur—there is no uncertainty about that. The only uncertainty lies in whether the doctor will actually complete all of the steps of the method (i.e., treating a patient otherwise in accordance with the method for six months and a day). Accordingly, on this record, the Court is not convinced that adopting Plaintiffs' construction would render the claims indefinite. *Cf. Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1372-73 (Fed. Cir. 2008) (reversing the district court's grant of summary judgment of indefiniteness where it was "based on [the court's] misunderstanding that claim definiteness requires that a potential infringer be able to determine if a process infringes before practicing the claimed process" and the test for indefiniteness instead depends "on whether the claim delineates to a skilled artisan the bounds of the invention") (internal quotation marks and citations omitted);

Homeland Housewares, LLC v. Sorensen Research & Dev. Trust, Case No. CV 11-3720-GW(JEMx), 2013 WL 12134266, at *5 (C.D. Cal. Feb. 28, 2013) (noting that "definiteness only requires that the bounds [of the claims] can be determined at any time, whether before, during, or after practicing the claimed method").

The cases that Defendants cite, (D.I. 215 at 47; D.I. 298), do not convince the Court otherwise. This is because they involved circumstances where a party's proposal would render uncertain the scope of the invention.

In *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), for example, the Federal Court rejected a proposed construction for the term "synergistically effective amount" as the "epitome of indefiniteness." 349 F.3d at 1384. But there the patent claim, directed to a pharmaceutical composition useful for treating bacterial infections, did not identify the specific bacteria, and the proposed construction (i.e., "[a] formulation falls outside the scope of the claims if a given antibiotic, bacteria, and disease combination provides no synergy") allowed for a given embodiment to *simultaneously* infringe and not infringe the claims, depending upon the specific bacteria chosen for analysis. *Id.* The Federal Circuit considered a similar situation in *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008), where it rejected the plaintiff's proposed construction for the term "fragile gel" as "likely to be indefinite" because the proposal did not resolve ambiguity as to the term's scope. 514 F.3d at 1251-55. The patentee's proposed construction merely meant "adequate for the circumstances." *Id.* at 1254. But the *Halliburton* Court explained that a wide variety of factors (such as formation geology, wellbore size, depth and angle) could affect adequacy, thus requiring that "an artisan make a separate infringement determination for every set of circumstances in which the

composition may be used"—determinations that were "likely to result in differing outcomes (sometimes infringing and sometimes not)." *Id.* at 1254-55 ("In other words, a given fluid might be adequate to suspend drill cuttings in some formations and/or well configurations, whereas in others it would not be."). Here, in contrast, the claims of the '000 patent "provide a clear line[] to determine when infringement occurs[,]" (*Teva* Action, D.I. 340 at 1), as the person of skill in the art knows with clarity (at every point in time) exactly how long and exactly in what ways carvedilol must be administered so as to infringe the patent-in-suit.

Defendants recently directed the Court's attention to the Federal Circuit's decision in *The Meds. Co. v. Mylan, Inc.*, 853 F.3d 1296 (Fed. Cir. 2017), in which that Court purportedly considered, and rejected, "a similar argument" to that Plaintiffs make here. (D.I. 298) In that case, the patent at issue was directed to pharmaceutical formulations ("batches") of a particular drug, produced through a compounding process that consistently minimizes impurities in the batches. 853 F.3d at 1298, 1300. The Federal Circuit construed the claims to require the use of an "efficient mixing" process to achieve batch consistency (i.e., batches with an impurity level that does not exceed about 0.6%). *Id.* at 1302-04. In doing so, the Court rejected the patentee's position that the "batches" limitation was not limited to a *particular compounding process* that achieves batch consistency and that instead the batches limitation was satisfied *whenever* an accused infringer consistently produces batches with impurity levels that did not exceed 0.6%, no matter what process achieved that outcome. *Id.* at 1303. The Court explained that with respect to the "ongoing commercial compounding process" required by the claims, the patentee's proposal was unworkable and could not provide reasonable certainty regarding the scope of the claims. *Id.* This was so because in the absence of requiring the use of a particular compounding

process that utilized efficient mixing, then "proof of infringement would [simply be dependent on] forward-looking assessments" of whether an accused infringer's production of future batches would be likely to generate the requisite impurity levels. *Id.* at 1303. Here, in contrast, there are clear markers in the claims that provide the requisite reasonable certainty as to what is infringing conduct. Again, even if one does not infringe the claims until administrating carvedilol for the time period set out therein, the claims make very clear the particular, multi-faceted process that must be followed in order to get to infringement.

In sum, if there is a case that stands for the proposition that a claim is rendered indefinite if an actor knows precisely what the claim requires for infringement, but will not know that he has completed all of the claimed steps until a particular duration of time has passed, Defendants have not cited it here.

III. CONCLUSION

For the reasons set out above, the Court recommends that Plaintiffs' construction of "said maintenance period is greater than six months" be adopted, and that therefore, so long as a patient takes a maintenance dose for more than six months, the entire period in which he takes the maintenance dose (including the first six months) falls within the scope of the claims. In light of this recommendation, the Court further recommends that Defendants' motion seeking summary judgment on the ground that "administering carvedilol during the first six months of the maintenance period is not an act of direct infringement" be DENIED. It does so because if the administration of carvedilol ultimately goes on to exceed six months in such a case, then the administration of the drug during the first six months of the maintenance period is a part of the

full scope of the infringement of the claims.[5]

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1) and D. Del. LR 72.1. The parties may serve and file specific written objections by no later than **May 30, 2017**; responses are due by no later than **June 6, 2017.** The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

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

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **May 31, 2017** for review by the Court, along with a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough*

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[5] In a footnote in their opening brief, Defendants argued that if the Court adopts Plaintiffs' position, "it would need to grant summary judgment of non-infringement to Defendants for the first six month period of maintenance therapy" because "no one would know whether the use was infringing at the time of the use" and so GSK would be unable to "prove that Defendants intended to cause infringement when those sales were made." (D.I. 215 at 46 n.19) Plaintiffs did not respond to this particular argument, and Defendants devoted only a few sentences to the argument again in their reply brief. (D.I. 274 at 16) Since the argument was initially raised only in a footnote and was not fully taken up by the parties, the Court will not further address it here and will not consider it to be a basis on which summary judgment could be granted.

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

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

Dated: May 24, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE