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

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 45-page Report and Recommendation (the "Claim Construction Report") (C.A. No. 14-877 D.I. 133; C.A. No. 14-878 D.I. 165), dated June 3, 2016, recommending that the Court adopt certain claim constructions for disputed terms in U.S. Patent No. RE40,000 (the "'000 Patent");

WHEREAS, on June 20, 2016, Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited ("Plaintiffs"), objected to the Claim Construction Report ("Plaintiffs' Objections") (C.A. No. 14-877 D.I. 141; C.A. No. 14-878 D.I. 175), and specifically objected to

the Claim Construction Report's constructions of the terms "maintenance dosages," "administering," and "maintenance period;"

WHEREAS, on June 20, 2016, Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), objected to the Claim Construction Report ("Teva's Objections") (C.A. No. 14-878 D.I. 174), and specifically object to the Claim Construction Report's constructions of "administering" and "decreasing mortality;"

WHEREAS, on July 8, 2016, Defendants Glenmark Pharmaceutical Inc., USA, and Teva Pharmaceuticals USA, Inc. ("Defendants"), responded to the Plaintiffs' Objections (C.A. No. 14-877 D.I. 153; C.A. No. 14-878 D.I. 189) ("Defendants' Response to Plaintiffs' Objections");

WHEREAS, on July 8, 2016, Plaintiffs responded to the Teva's Objections (C.A. No. 14-878 D.I. 188) ("Plaintiffs' Response to Teva's Objections");

WHEREAS, the Court has considered the parties' claim construction disputes addressed by the Claim Construction Report *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Plaintiffs' Objections (C.A. No. 14-877 D.I. 141) to Judge Burke's construction of "maintenance" dosages are SUSTAINED and the Court construes the term as "dosages in the therapeutic amount."

2. Plaintiffs' Objections (C.A. No. 14-877 D.I. 141) to Judge Burke's constructions of "administering" and "maintenance period" are OVERRULED and the constructions set forth in Judge Burke's Claim Construction Report are ADOPTED.

3. Teva's Objections (C.A. No. 14-878 D.I. 174) to Judge Burke's construction of "administering" and "decreasing mortality" are OVERRULED and the constructions set forth in Judge Burke's claim construction report are ADOPTED.

4. Plaintiffs first object to Judge Burke's construction of "maintenance dosages,"[1] which Judge Burke construed as "[d]osages to maintain the therapeutic effect following a period in which the patient's tolerance of the drug is monitored." (Claim Construction Report at 33) Plaintiffs object to this construction on the grounds that the claims do not require a "monitoring period" prior to the administration of a maintenance dose. (Plaintiffs' Objections at 5) The Court agrees with Plaintiffs on this point. As Judge Burke explained, the term "maintenance dosage" refers to dosages used to maintain therapeutic effect – in contrast to, for example, low "starting" dosages administered to check a patient's tolerance before "up-titrating" to the maintenance dose. (Claim Construction Report at 29) The Court agrees with Judge Burke that the patent uses the term "maintenance dose" to draw this distinction, and also with Judge Burke's conclusion that the claim term "maintenance" does not require up-titration (i.e., it ***is*** within the scope of the claims that the initial dose used with a patient becomes the dose that patient ultimately continues to receive throughout the maintenance period). (*Id.* 29-30) Although the intrinsic and extrinsic record suggest that, as a practical matter, physicians typically monitor patients' tolerance at the beginning of their course of treatment (*id.* 31-32), the record does not support viewing an initial or early dosage in an amount that turns out to be the "maintenance dosage" amount as excluded from the meaning of "maintenance dosage" (even if the physician is closely monitoring the patient's tolerance of this amount). Rather, the patent consistently uses

[1]This term appears in all claims of the '000 patent.

the term "maintenance" dosage in contrast to dosages of less than the final, therapeutic amount. *See* '000 pat. col. 5:16-44; 7:6-21. Thus, the Court understands "maintenance dosage" to mean "dosages in the therapeutic amount given during the maintenance period," and adopts this as the construction of the disputed term.[2]

5. Plaintiffs next object to Judge Burke's construction of "administering," which was: "[p]rescribing, dispensing, giving or taking (such that what is prescribed, dispensed, given or taken is actually taken into the patient's body)." (Claim Construction Report at 37) Plaintiffs argue that the parenthetical portion of the construction is "unnecessary" and "likely to confuse the jury." (Plaintiffs' Objections at 6-7) But this language is needed to make clear that, while "administering" encompasses situations in which a physician prescribes or dispenses a dosage that the patient later takes on his or her own (as opposed to requiring the physician to take direct action to deliver the dosage into the person's body), the claims do require that the patient ultimately consume the drug. (Claim Construction Report at 35-37) In other words, this language makes clear that the method claims of the '000 patent cannot be practiced simply by "writing a prescription or filling a pill bottle at a pharmacy." (*See* Defendants' Response to Plaintiffs' Objections at 9)

6. Teva also objects to Judge Burke's construction of "administering." Teva contends that the construction should not include the terms "prescribing" and "dispensing," arguing that the specification makes clear that the term refers to the "physical delivery of the drug

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[2]Plaintiffs further objected to Judge Burke's construction of "maintenance dosages" on the ground that it "improperly imports as an additional limitation a 'monitoring' period for" the drug(s) the claims require to be administered with carvedilol (*i.e.* an ACE inhibitor, a diuretic, or digoxin). (Plaintiffs' Objections at 6) Given that the Court's construction does not require either up-titration or a monitoring period, the Court assumes this aspect of the parties' dispute is moot.

into the patient's body." (Teva's Objections at 9-10) In Teva's view, the specification communicates this limitation by using the word "administration" or "administer[ing]" solely to refer to the process of delivering drug into a patient's body. (*Id.*) While the term "administer" does include transmitting drug into the patient's body, the term does not – as used in the '000 patent – require a physician to be directly involved in that process. (*See* Claim Construction Report at 34-36) Judge Burke's use of the phrase "prescribing, dispensing, giving or taking" properly clarifies this point.[3]

7. Plaintiffs' final objection is to Judge Burke's construction of "maintenance period" as "[p]eriod of time over which the maintenance dose is taken into the patient's body."[4] (Claim Construction Report at 26) Plaintiffs argue that this term should be construed in the broader context of the phrase "said maintenance period is greater than six months," and should be given the meaning: "[w]ith the intent that the patient be on the maintenance dosage for more than six months." (Plaintiffs' Objections at 8, 10) According to Plaintiffs, their proposed construction properly includes within the scope of the claims the treatment of patients who die or

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[3]Teva objects in particular to the inclusion of the word "dispensing" in the construction, arguing that it leads to the conclusion that the claim may be practiced by the filling of a prescription by a pharmacist. (Teva's Objections at 10) The Court agrees with Teva that "administering" here does not include an individual who has "no connection to the treatment of a . . . patient" and merely fills a prescription at the direction of a physician. However, as the Claim Construction Report makes clear, that is not "dispensing;" the term instead refers to situations in which the individual responsible for a patient's treatment provides the medication to the patient. (*See* Claim Construction Report at 35-36 (explaining that "administering" could encompass circumstances "where a medical professional is 'prescribing' or 'dispensing' the dosage to a patient and leaving it to the patient to take the drug on her own") (internal citations omitted)) The key point, as Judge Burke makes clear, is that the claims encompass scenarios in which a physician directly places a drug into a patient's body, scenarios in which a physician prescribes a drug for a patient to take elsewhere, and alternatives in between. (*Id.*)

[4]This term appears in all claims of the '000 patent.

opt to switch medications before completing a six-month course of treatment. (*Id.* at 8-10) For the reasons set forth in the Claim Construction Report, the Court disagrees with Plaintiffs. (*See* Claim Construction Report at 22-26) Most importantly, the claims themselves require "administering a therapeutically acceptable amount of carvediol . . . wherein the administering comprises administering . . . maintenance dosages for a maintenance period . . . and ***said maintenance period is greater than six months***." '000 pat. at 8:30-40 (emphasis added). This language unambiguously requires that the maintenance period – which the Plaintiffs do not dispute is the period over which the maintenance dose is taken into the patient's body – must last for at least six months. Plaintiffs correctly point out that the Report's construction implies "you would not know whether the claimed method was being practiced until you saw how long the patient lives" (Plaintiffs' Objections at 10), but whether Plaintiffs like this result or not it ***is*** the result of how they drafted their claims.

8. Teva's additional objection is to Judge Burke's conclusion that "decreasing mortality" is a claim limitation.[5] (Claim Construction Report at 9, 17) The Court agrees with Judge Burke, who explained that "decreasing mortality" recites the objective of the claimed method (to treat congestive heart failure) and distinguishes it from the use of the same method to treat other illnesses (or mere symptoms of heart failure). (*Id.* at 14-15); *see Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1332-33 (Fed. Cir. 2003); *see also Sanofi v. Glenmark Pharms. Inc.*, 2015 WL 5092631, at *6 (D. Del. Aug. 28, 2015). Further, the term, as used in its broader context ("decreasing mortality caused by congestive heart failure in a patient in need thereof") provides antecedent basis for the term "said patient," and clarifies that "said patient" refers to a

[5]This term appears in all claims of the '000 patent.

patient having a risk of mortality due to congestive heart failure. (*See* Claim Construction Report at 15) Finally, as Judge Burke explained, the patentees relied on the "decreasing mortality" limitations to persuade the PTO that the claimed invention was patentable. (*See id.* at 15-16) Regardless of whether the PTO ultimately relied on these statements in its patentability determination, the Court must hold the patentee to its unambiguous statements about claim scope. *See Fenner Investments, Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1325 (Fed. Cir. 2015) ("[T]he interested public has the right to rely on the inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them, or how much weight they were given").

9. Given the detailed reasoning provided in the Claim Construction Report, and given that the parties have not raised any arguments that are not adequately addressed therein, the Court finds it unnecessary to address Plaintiffs' Objections (C.A. No. 14-877 at D.I. 141) or Teva's Objections (C.A. No. No. 14-878 D.I. 174) any further.

February 17, 2017
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE