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 an 18-page Report and Recommendation (the "Report") (D.I. 376),[1] dated May 24, 2017, recommending that the Court deny the portion of Defendants' motion for summary judgment and supplemental letter briefing related to the construction of the claim term "said maintenance period is greater than six months" and whether sales during the first six months of the maintenance period are non-infringing (D.I. 248, 326,

[1]All references to the docket index (D.I.) are to the *Teva* action, C.A. No. 14-878.

331);[2]

WHEREAS, on May 30, 2017, Defendants objected to the Report (D.I. 385) ("Defendants Objections" or "Defs Objs");

WHEREAS, on June 6, 2017, GSK responded to the Defendants Objections (D.I. 402) ("GSK Response" or "GSK Resp");

WHEREAS, the Court has considered the parties' objections and responses *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. Defendants' Objections (D.I. 385) are OVERRULED, Judge Burke's Report (D.I. 376) is ADOPTED, and the portion of Defendants' Motion for Summary Judgment related to the above-referenced issues (D.I. 248) is DENIED.

2. Defendants object that the Report improperly construes the claim term "said maintenance period is greater than six months" to mean "so long as the maintenance period reaches six months." (Defs Objs at 4) Defendants find two principal faults with this construction: (1) it allows for "retroactive springing infringement," as prescriptions of carvedilol that were not infringing at the time they were filled suddenly become infringing, retroactively, once a patient has taken the maintenance dose for six months and one day; and (2) it renders the claims indefinite and invalid. (*Id.* at 1-2) Further, Defendants contend that the plain and ordinary meaning of the term "said maintenance period is greater than six months" requires that

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[2]The Report, and accordingly, this Order, solely relates to arguments in Defendants' motion related to the above-referenced issues.

"(i) daily maintenance dosages (as opposed to the initial dosages during the monitoring period) be administered to a patient during a maintenance period, ***'and'*** (ii) the administration occur when 'said maintenance period ***is*** greater than six months.'" (*Id.* at 4) Under Defendants' construction, therefore, "the claims of [U.S. Patent No. RE40,000 (the "'000 patent")] cover administering carvedilol only during the portion of the maintenance period that is greater than six months" and any administration of carvedilol occurring before that point is non-infringing. (*Id.* at 3) Each of Defendants' contentions is unavailing.

3. The Report construed "said maintenance period is greater than six months" to encompass the entire maintenance period: the first six months in which the maintenance dose is administered, as well as any portion of the maintenance period that runs thereafter. (*See* Report at 11-12) So long as the maintenance dose is ultimately administered for at least six months, every day of the maintenance period may be found to be infringing (provided that all of the other elements of the claimed method are present).[3] As the Report correctly explained, "[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." (*Id.* at 11)

4. This construction is consistent with the Court's constructions of "maintenance period" and "maintenance dosages," which mean, respectively, "a period of time over which the maintenance dose is taken into a patient's body" and "dosages in the therapeutic amount given during the maintenance period," including "initial or early dosage[s] that turn[] out to be the

[3]As the Report observes, "[i]t 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." (Report at 9 n.4)

'maintenance dosage[s].'" (Report at 4) If, as Defendants contend, only those administrations of carvedilol "that occur when said maintenance period is greater than six months" could be infringing, the Court's construction of "maintenance dosages" – which explicitly includes early dosages that turn out to be maintenance dosages – would be rendered obsolete. Put another way, the Court's constructions of "maintenance period" and "maintenance dosages" necessarily account for the situation where pre-six-month dosages turn out to be maintenance dosages and, thus, are included as part of the "period of time over which the maintenance dose is taken," i.e., the maintenance period, such that if the administration of those maintenance dosages continues for six months, it will infringe the '000 patent. Defendants' proposal, by contrast, is inconsistent with the Court's construction of these terms.

5. Defendants have failed to adduce clear and convincing evidence that the Court's construction – "so long as the maintenance period reaches six months" – renders the claims indefinite. Defendants contend this is so because the Court's construction leaves physicians with "no idea whether or not their writing a prescription for generic carvedilol during the first six months of the maintenance period is or is not infringing." (Defs Objs at 5) This is not quite correct, and (more importantly) does not suggest a person of ordinary skill would have any difficulty in arriving at reasonable certainty as to the scope of the claims. *See generally Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). As the Report recognized, "[i]t is of course true that a doctor will not know that infringement has, in fact, occurred until she has completed all of the steps of the method . . . [b]ut 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." (Report at 13)[4]

6. The Court has considered *de novo* each of the other arguments raised by Defendants in their Objections and finds that each of them lacks merit and requires no further discussion.

June 9, 2017
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

[4](*See also* GSK Resp at 5) ("But the fact that doctors might not always successfully complete the method doesn't mean that there is any confusion that they will infringe if they do. One wouldn't say that a patent to a process of curing rubber is indefinite just because the machines used to heat and mold the rubber might break in the middle of the method, before they can complete it.")