

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

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

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 12-page Report and Recommendation (the “Report”) (D.I. 351)¹, dated May 11, 2017, recommending that the Court grant the portions of Defendants’ motion for summary judgment related to GSK’s claim of lost profits damages for “convoyed sales”² (D.I. 248);

WHEREAS, on May 18, 2017, GSK objected to the Report (D.I. 361) (“GSK Objections”

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

²The Report, and accordingly, this Order, solely relates to arguments in Defendants’ “Combined Motion for Summary Judgment and to Exclude Certain Expert Testimony” related to convoyed sales.

or “GSK Objs”);

WHEREAS, on May 25, 2017, Defendants responded to the GSK Objections (D.I. 381) (“Defendants Response” or “Defs 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)(1); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. GSK’s Objections (D.I. 361) are OVERRULED, Judge Burke’s Report (D.I. 351) is ADOPTED, and the portion of Defendants’ Motion for Summary Judgment related to convoyed sales (D.I. 248) is GRANTED.

2. In its Objections, GSK asserts that two factual disputes preclude summary judgment: (1) whether there is a functional relationship between all carvedilol dosages used to treat Congestive Heart Failure, and (2) whether patients would take COREG® rather than generic carvedilol during the convoyed sales period. (GSK Objs at 6-9) GSK’s contentions are unavailing.

As the Report stated, “[t]he question here is not whether sales before and after the six-month maintenance period have some relationship.” (Report at 9) There is undisputedly some functional relationship between carvedilol dosages – be they branded or generic carvedilol – administered before the six-month maintenance period and those administered after the six-month maintenance period.³ (See D.I. 335 at 145; GSK Objs at 8 (“Dr. McCullough’s testimony

³For simplicity, and without deciding any contested issue, the Court refers herein to the dosing periods as: (i) initial monitoring period, (ii) six-month maintenance period, and (iii) ongoing maintenance period.

establishes that the initial monitoring dosages and the initial maintenance dosages would not be given unless they were a part of a course of treatment designed to include maintenance dosages given after 6 months of the maintenance period.”)) But to be eligible for lost profits on convoyed sales, GSK must prove that a functional relationship exists between *branded* carvedilol (COREG®) before and after the six-month maintenance period, such that the allegedly infringing sales of COREG® during the ongoing maintenance period *require* prior initial sales of COREG® during an earlier period. (Report at 9) GSK has failed to make this showing.

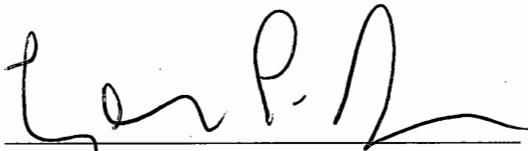
A reasonable jury would have to be able to find that the carvedilol administered during the initial monitoring period and/or during the six-month maintenance period constitutes a “functional unit” with the carvedilol administered during the ongoing maintenance period. Again, the record cannot support such a finding. To the contrary, even GSK’s expert, Dr. McCullough, has “full confidence” that the generic and branded carvedilol are “therapeutically interchangeable.” (See Report at 9-10) (citing Dr. McCullough’s deposition testimony)⁴ On this record, no reasonable factfinder could find the required functional relationship between the initial monitoring period doses or the six-month maintenance period doses, on the one hand, and the ongoing maintenance period doses, on the other.

Similarly, whether patients would take or even prefer to take COREG® rather than generic carvedilol during the convoyed sales period is irrelevant if patients are not *required* to do

⁴GSK asserts that the Report quotes Dr. McCullough’s testimony “out of context” because it fails to account for the fact that Dr. McCullough was testifying about the nature of the inquiry in the “real-world,” not in the “but for” world applicable to GSK’s lost profits claims. (GSK Objs at 5) The Court disagrees. As Defendants point out, “[n]othing in the ‘but for’ world alters the scientific reality that branded COREG is fully interchangeable with generic carvedilol.” (Defs Resp at 7)

so. Lost profits for convoyed sales are available “if both the patented and unpatented products together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.” *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (internal quotation marks omitted). Convoyed sales are not available for “items that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage.” *Id.* (quoting *Rite-Hite Corp. v. Kelley Co. Inc.*, 56 F.3d 1538, 1550 (Fed. Cir. 1998)). GSK has failed to adduce evidence from which it may reasonably be found that COREG® **must** be used during the initial monitoring period or six-month maintenance period in order to treat CHF with COREG® after the six-month maintenance period. The fact that COREG® **could** have been prescribed in all periods, and even the contested fact that doctors **preferred** the branded carvedilol be prescribed in all periods, does not provide a basis for finding that such prescriptions were **required**; and, hence, does not provide a basis for finding that the pre-ongoing maintenance period sales and ongoing maintenance period sales could together be considered a functional unit.

May 26, 2017
Wilmington, Delaware


HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE