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

MEMORANDUM ORDER

At Wilmington this **6th day of February, 2017**.

The Court has considered the parties' letter submissions, (Civil Action No. 14-877-LPS-CJB ("*Glenmark* Action"), D.I. 191, 196, 199; Civil Action No. 14-878-LPS-CJB ("*Teva* Action"), D.I. 229, 234, 237), relating to Plaintiffs GlaxoSmithKline LLC ("GSK") and SmithKline Beecham (Cork) Limited's (collectively, "Plaintiffs") pending letter motion to strike references to angiotensin receptor blockers ("ARBs") from Defendants Glenmark Pharmaceuticals Inc., USA's ("Glenmark") and Teva Pharmaceuticals USA, Inc.'s ("Teva")

(collectively, "Defendants") Expert Rebuttal Reports, (*Glenmark* Action, D.I. 201; *Teva* Action, D.I. 238), as well as the parties' arguments made during the January 27, 2017 teleconference with the Court.[1] Plaintiffs request that the Court strike a "narrow set of paragraphs" in certain of Defendants' experts' rebuttal reports that reference the use of carvedilol with ARBs. (D.I. 191 at 1)[2] Plaintiffs allege that these paragraphs assert a new, sixteenth theory of a non-infringing alternative to Plaintiffs' patented method of using carvedilol and ACE inhibitors to treat congestive heart failure: the use of carvedilol with ARBs to treat congestive heart failure. (*Id.*) And Plaintiffs assert that this theory should be stricken because it was never disclosed during fact discovery and causes surprise and prejudice to them. (*Id.*)[3]

For their part, Defendants explain that their experts will not be "expressly identify[ing] the use of ARBs as a non-infringing alternative to [COREG®] (the brand name of GSK's

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[1] Our Court has treated motions to strike as non-dispositive motions, which may be resolved by the Court pursuant to 28 U.S.C. § 636(b)(1)(A) and D. Del. LR 72.1(a)(2). *See, e.g.*, *Novartis Pharms. Corp. v. Actavis, Inc.*, Civil Action No. 12-366-RGA-CJB, 2013 WL 7045056, at *1 n.1 (D. Del. Dec. 23, 2013) (citing cases). This is in line with decisions of other courts in this Circuit, which have also treated such motions as non-dispositive, at least where the ultimate decision was not determinative of a party's claims (just as the decision is not here). *See, e.g.*, *Hawkins v. Waynesburg Coll.*, Civil Action No. 07-5, 2007 WL 2119223, at *1 n.1 (W.D. Pa. July 20, 2007); *Reedy v. CSX Transp., Inc.*, Civil Action No. 06-758, 2007 WL 1469047, at *1 n.1 (W.D. Pa. May 18, 2007).

[2] For simplicity's sake, the Court will refer to the "D.I." number in the *Glenmark* Action, unless otherwise indicated.

[3] Specifically, Plaintiffs request that the Court strike all references to ARBs in paragraphs 5, 18 and 23-26 of Teva's expert Dr. Clive Rosendorff's report; paragraphs 39, 41, 54, 55, 63, 84, 96, 121, 127 and 218 of Teva's expert Dr. Randall Zusman's report; and paragraphs 30, 42, 100, and footnote 54 of Glenmark's expert Dr. Sean Beinart's report. (D.I. 191 at 1 n.1)

carvedilol tablets)." (D.I. 196 at 2; *see also Teva* Action, D.I. 234 at 1)[4] They also assert that the references to ARBs in their experts' rebuttal reports fall into two categories that are permissible under the circumstances here: (1) background information that covers current treatment options for heart failure but that offers no affirmative opinions regarding non-infringing alternatives; and (2) opinions properly offered in response to the opinion disclosed in GSK's expert's opening report that "carvedilol is not prescribed with other therapies beyond the three drugs listed in the claims (diuretics, digoxin, and ACE inhibitors)." (*Teva* Action, D.I. 234 at 1-2; *see also Glenmark* Action, D.I. 196 at 1-3 (citing *id.*, ex. 1 at ¶ 109 (GSK's expert Dr. McCullough opining that carvedilol "'is primarily administered as part of a combination of medications that typically include at least an ACE inhibitor and/or diuretics'")))

Federal Rule of Civil Procedure 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26[](e), the party is not allowed to use that information . . .to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." In considering whether to exclude evidence relating to an untimely or otherwise improper disclosure, the United States Court of Appeals for the Third Circuit has directed district courts to weigh certain factors, known as "the *Pennypack* factors": (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded.

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[4] Three paragraphs in Teva's expert rebuttal reports had actually affirmatively opined that ARBs are a non-infringing alternative to the use of COREG itself, but Teva has agreed to withdraw the references to ARBs in those paragraphs. (*Teva* Action, D.I. 234 at 1) Those references are found in paragraphs 23 and 26 of Dr. Rosendorff's report and paragraph 84 of Dr. Zusman's report. (*Id.*)

See Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985); *see also Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997).

Plaintiffs point to Defendants' responses to the following interrogatories in claiming that Defendants failed to timely disclose ARBs as a non-infringing alternative:

> **Interrogatory No. 19:** Identify any product or method that you contend was an available, acceptable non-infringing alternative to Coreg®. . . .
>
> **Interrogatory No. 8**: For each claim of the '000 patent, describe in detail all facts and identify all evidence in support of Defendant's contention, if any, that Defendant does not infringe the claim.

(D.I. 191, ex. D at 6, 25)

With respect to Interrogatory 19, the Court agrees with Teva that the interrogatory is ambiguous, in the sense that it does *not* request Defendants to identify any method they contend is an acceptable non-infringing alternative to the *methods claimed in the '000 patent*. (*Teva* Action, D.I. 234 at 2 n.1) Accordingly, the Court further agrees that Teva's interpretation of the interrogatory—that it sought identification only of drugs that could be used in lieu of *COREG itself* (i.e., as an alternative to COREG), and that ARBs are not such drugs—is reasonable. (*Id.*)

As for Interrogatory No. 8, it was certainly not solely and explicitly focused on seeking a list of the entire universe of possible non-infringing alternatives to the claimed method. Instead, it more broadly asked for Defendants' contentions that *Defendants do not infringe* the claimed method. Defendants' responses thus disclosed facts responsive to that (broader) issue (e.g., asserting why, in Defendants' view, they did not induce infringement of the claims). (D.I. 191,

ex. D at 6-14; *id.*, ex. E at 11-14) Of course, one of the many ways that Defendants would not be guilty of inducing infringement is if they encouraged others to commit an act, but that act did not amount to an act of *direct infringement* of the claims. And on that score, Defendants' respective responses to Interrogatory No. 8 did note that carvedilol has multiple "non-infringing uses" ("including[,]" for example, using carvedilol for the FDA-approved indications of treatment of hypertension and treatment of left ventricular dysfunction following myocardial infarction). (*Id.*, ex. D at 8; *id.*, ex. E at 13) With this in mind, to the extent that the expert report paragraphs at issue (regarding the use of carvedilol with ARBs to treat heart failure) could be said to amount to Defendants *articulating a scenario under which they could not infringe the patent-in-suit* (e.g., a scenario in which they would not be inducing *direct infringement* of the patent), then the content of those paragraphs would seem to implicate Interrogatory No. 8. And a number of the paragraphs at issue do seem to fit this bill.[5]

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[5] Of those, at least some would probably be permissible anyway, even if there was a violation of the Federal Rules, because they amount to proper rebuttal testimony. Information disclosed in rebuttal expert reports can be appropriate and not untimely, even if not previously disclosed in fact discovery, so long as the intent of the content at issue is "solely to contradict or rebut evidence on the same subject matter identified by the opposing party's expert report." *Withrow v. Spears*, 967 F. Supp. 2d 982, 1001 (D. Del. 2013) (internal quotation marks and citation omitted). Here, certain of the paragraphs at issue (i.e., at least those that make specific reference to the ACCF/AHA Guidelines ("Guidelines") in stating that a patient may take carvedilol in combination with ARBs for treatment of congestive heart failure), would fall into this category of permissible disclosure. This is because GSK's expert, while relying upon the same industry Guidelines throughout his report, nevertheless "was silent on the use of ARBs in combination with carvedilol[,] even though he was undoubtedly aware of their use as a treatment option[,]" since those very same Guidelines "plainly state that ARBs may be used with carvedilol for the treatment of heart failure in certain instances." (D.I. 196 at 3) In a similar vein, Teva's counsel noted during the teleconference that one paragraph of Dr. Zusman's report at issue references ARBs, as part of a rebuttal to a question in a survey that Plaintiffs conducted (regarding the prescribing habits of physicians over time with regard to carvedilol). (D.I. 191, ex. B at ¶ 218) This reference also surely amounts to proper rebuttal.

The Court, then, assumes that at least some of the paragraphs at issue implicate content that should have been earlier disclosed as a response to Interrogatory No. 8. But even doing so, it concludes that the *Pennypack* factors would not counsel in favor of granting the motion.

The Court finds that the first *Pennypack* factor, which considers surprise or prejudice, leans in Plaintiffs' favor. References to ARBs may have caused Plaintiffs some amount of surprise, since ARBs were not a part of Defendants' disclosures during fact discovery. (Any surprise should not be too significant, however, since it is not disputed that Plaintiffs' infringement expert is familiar with the use of carvedilol and ARBs to treat congestive heart failure, and has cited to material that takes note of such treatment.). The late disclosure has caused Plaintiffs some prejudice, since they did not take discovery regarding ARBs and their expert did not address ARBs in his opening report. (D.I. 191 at 2)

But the remaining *Pennypack* factors discussed by the parties go Defendants' way. Any prejudice Plaintiffs face can be cured, and that cure can come in sufficient time so as not to unduly disrupt the order and efficiency of trial. The Court acknowledges that the timeframe is rather tight, with trial in one of these cases scheduled to begin in June. Yet the references to ARBs are circumscribed in nature, and the Court would be surprised if more than very limited additional discovery is required on this point. (D.I. 199 at 2) Finally, the Court sees no evidence of bad faith on the part of Defendants in not earlier disclosing ARBs. (D.I. 196 at 4; *see also Teva* Action, D.I. 234 at 1)

On balance, the *Pennypack* factors militate against granting the extreme sanction called for by Plaintiffs' motion. The Court thus ORDERS that the motion is DENIED. The references to ARBs in Defendants' rebuttal reports will not be stricken (with the exception of the three

paragraphs that Teva has agreed to withdraw). The Court grants Plaintiffs leave to have Dr. McCullough file a supplemental expert report with respect to ARBs. Beyond that, if any further discovery is actually needed, the Court trusts that the parties can work that out, after meeting and conferring on the issue.

Because this Memorandum Order 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 Memorandum Order. Any such redacted version shall be submitted no later than **February 13, 2017** for review by the Court, along with a motion for redaction that includes 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 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 Memorandum Order.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE