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

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 Plaintiffs' *Daubert* motion ("Motion") to exclude testimony offered by Defendants' proffered expert, Sandra Kinsey,

M.B.A., R.Ph. (D.I. 211)[1] For the following reasons, the Court DENIES the Motion.[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 by making, offering to sell, selling, importing, and otherwise promoting and distributing generic carvedilol tablets. (*See, e.g.*, D.I. 59, 175)

Briefing on the instant Motion was completed on March 3, 2017. (D.I. 270) The Court held oral argument on the Motion (and various other summary judgment and *Daubert* motions filed in the case) on March 24, 2017, (D.I. 296 (hereinafter, "Tr.")). 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)

B. Factual Background

Ms. Kinsey is a currently a registered pharmacist in Arkansas and Kansas, and she works in stores with independent pharmacists on prescription filling, operational processes and related matters. (D.I. 256, ex. B ("Kinsey Report") at ¶ 2) She is also the president of her own retail healthcare consulting firm. (*Id.* at ¶ 1) From approximately 1997 to 2014, Ms. Kinsey held several positions at Walmart Store, Inc. ("Walmart"), including the title of Vice President of

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[1] 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.

[2] Under the circumstances here, the resolution of this *Daubert* Motion is properly treated as non-dispositive, and is 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.*, *Withrow v. Spears*, 967 F. Supp. 2d 982, 987 n.1 (D. Del. 2013) (citing cases).

Pharmacy Merchandising, Health & Wellness. (*Id.* at ¶ 3) While at Walmart, she was responsible for all of the company's prescription product procurement, preferred formulary development, distribution and supply chain, pricing, and inventory management for over 5,000 stores. (*Id.*)

During her time at Walmart, Ms. Kinsey was "instrumental in building [the company's] propriety prescription management system, including the pharmacist interface and all product substitution logic." (*Id.*) In that regard, she worked to set a company-wide protocol for: (1) how drug prescriptions should be evaluated; (2) the circumstances in which generic drug substitution would occur; and (3) compliance with state-specific substitution laws. (D.I. 257, ex. 42 at 42-45)

In her expert report, Ms. Kinsey explains that she was asked to "describe how the dispensing of prescription drugs occurs at pharmacy, and to discuss the factors that influence which product ultimately is dispensed for a particular prescription." (Kinsey Report at ¶ 10) Among her overarching conclusions were the following:

> (1) For the entire period relevant to this suit, pharmacists were authorized in every state to substitute an "AB-rated" generic drug product (like Defendants' generic carvedilol products at issue in this case) when filling a prescription for the corresponding brand product (like Plaintiffs' branded drug COREG®, relevant here), without obtaining prior approval from the prescribing physician.;
>
> (2) Even if a generic drug manufacturer were to communicate to pharmacies, insurers or others that a particular AB-rated generic product was approved for fewer than all of the United States Food & Drug Administration ("FDA")-approved indications in the brand label, this information would not reduce the frequency with which that product was dispensed in place of the corresponding brand.;
>
> (3) Differences in approved indications for AB-rated generic products compared to the corresponding brand product play no role in generic substitution practices at the pharmacy.;

(4) The out-of-pocket expense that a patient incurs by filling a prescription plays an important role in determining which medicine a pharmacy will dispense.

(*Id.* at ¶ 10(a)-(d))

II. DISCUSSION

A. Legal Standard

Rule 702 governs the admissibility of qualified expert testimony, providing that an expert witness may testify if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. Rule 702's requirements have been examined in detail by the Supreme Court of the United States in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and have been said to embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *see also B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010).[3] As to this Motion, at issue is the reliability and "fit" of Ms. Kinsey's proposed expert testimony.

With regard to the requirement of reliability, Rule 702 mandates that the relevant expert testimony "must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590; *see also Schneider ex rel. Estate of Schneider v. Fried*, 320

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[3] In applying Rule 702 to a patent action, the Court will look to the law of the regional circuit. *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1371 (Fed. Cir. 2015).

F.3d 396, 404 (3d Cir. 2003). This reliability requirement applies not only to an expert providing "scientific" knowledge, but also to one providing "technical" or "other specialized" knowledge in a case (i.e., testimony that may not necessarily be categorized as "scientific"). *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 146-47 (1999). Such testimony should amount to "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. In examining whether the reliability factor has been met, a court's focus must be on "principles and methodology" rather than on the conclusions generated by the expert. *Id.* at 595; *see also Daddio v. Nemours Found.*, 399 F. App'x 711, 713 (3d Cir. 2010).

As to the "fit" requirement, it "goes primarily to relevance" as the testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue" and have "a valid . . . connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591-92 (internal quotation marks and citations omitted); *see also Schneider*, 320 F.3d at 404. The standard for fit, however, is not a high one; it is met "when there is a clear 'fit' connecting the issue in the case with the expert's opinion that will aid the jury in determining an issue in the case." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009) (citations omitted).

Overall, "Rule 702 embodies a 'liberal policy of admissibility.'" *B. Braun Melsungen AG*, 749 F. Supp. 2d at 222 (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008)). Nonetheless, the burden is placed on the party offering expert testimony to show that it meets each of the standards for admissibility. *Id.* (citing *Daubert*, 509 U.S. at 592 n.10).[4]

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[4] Although the Court held oral argument on the pending summary judgment and *Daubert* motions, (D.I. 296), neither party sought an evidentiary hearing as to this *Daubert* Motion or suggested that the factual record was insufficiently developed such that a hearing of

B. Analysis

1. Reliability

The Court will first address Plaintiffs' argument as to Rule 702's reliability requirement. The Supreme Court (in *Daubert* and its progeny) and the United States Court of Appeals for the Third Circuit have listed certain factors that can be helpful in assessing the reliability of expert testimony, including: "(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 n.8 (3d Cir. 1994). Here, Plaintiffs initially pointed to these eight *Daubert*-inspired reliability factors, and suggested that Ms. Kinsey's opinion should be rejected because it "fails most, if not all" of these factors. (D.I. 212 at 5)

However, the Third Circuit has explained that these factors will "often be of little use in evaluating non-scientific expert testimony" (i.e., in assessing "expert testimony based on

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that type was required. The United States Court of Appeals for the Third Circuit has held that a trial court need not conduct an evidentiary hearing on a *Daubert* challenge if the record is sufficient to allow the Court to make a determination on the issues in dispute. *See, e.g.*, *Oddi v. Ford Motor Co.*, 234 F.3d 136, 151-55 (3d Cir. 2000); *Maldonado v. Walmart Store No. 2141*, Civil Action No. 08-3458, 2011 WL 1790840, at *13 n.10 (E.D. Pa. May 10, 2011). Here, Ms. Kinsey's expert report was provided to the Court, as was certain of her deposition testimony regarding that report. The parties also ably addressed issues relating to Ms. Kinsey's report in their briefing. In light of this, the Court has determined that the record before it is sufficient to allow for a decision on the admissibility of Ms. Kinsey's testimony under *Daubert*. *See, e.g.*, *Furlan v. Schindler Elevator Corp.*, 516 F. App'x 201, 205-06 (3d Cir. 2013); *Oddi*, 234 F.3d at 151-55; *Maldonado*, 2011 WL 1790840, at *13 n.10.

'technical or other specialized knowledge[]'"). *United States v. Davis*, 397 F.3d 173, 178 (3d Cir. 2005) (quoting *Kumho Tire*, 526 U.S. at 141). When a court is reviewing that type of proposed testimony, and determining whether it "'rests on a reliable foundation[,]'" it should consider, *inter alia*, whether the depth and breadth of the witness's prior experience provides a suitable foundation on which to rest her opinion. *Id.* (citation omitted); *see also Kumho Tire*, 526 U.S. at 150 (noting that in some cases "the relevant reliability concerns may focus upon personal knowledge or experience"). "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached [and] why that experience is a sufficient basis for the opinion[.]" Fed. R. Evid. 702 advisory committee's note to 2000 amendment.

This is the case with Ms. Kinsey's testimony, which is "derived largely from [her] own practical experiences" gained throughout nearly two decades in the pharmaceutical and healthcare industries. *First Tenn. Bank Nat. Ass'n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001). And in assessing the reliability of that testimony, Defendants have sufficiently explained how Ms. Kinsey's past and present work experience provides a firm foundation for her opinions. (D.I. 252 at 3-5) After all, Ms. Kinsey is opining on the steps that pharmacists would and do take when presented with prescriptions for branded drugs for which there is an AB-rated generic substitute—and whether the generic would be substituted for a branded product if the generic was not FDA-approved for all of the branded drug's indications. And Ms. Kinsey has deep experience in this world. She oversaw generic drug substitution policy for over 5,000 Walmart pharmacies, where she worked for nearly two decades, and today, she serves as a pharmacist herself in two states and regularly works with independent pharmacists. (Kinsey Report at ¶¶ 2-

3); *cf. Davis*, 397 F.3d at 178-79 (concluding that the testimony of a police offer serving as an expert witness as to "methods of operation for drug traffickers in the South Philadelphia area" was sufficiently reliable under *Daubert*, and noting that the officer's "non-scientific expert testimony" was sufficiently grounded in his 14 years of experience as a veteran of the Philadelphia police force and 12 years of experience with narcotics trafficking cases); *Triad Capital Mgmt., LLC v. Private Equity Capital Corp.*, Case No. 07 C 3641, 2010 WL 10076450, at *6 (N.D. Ill. Nov. 22, 2010) (concluding that the testimony of an investment banker with 30 years of experience in the field as to merger and acquisition practice utilized a sufficiently reliable methodology for *Daubert* purposes, where the expert's opinions were "based on usual business practices in the industry 'as he has seen and experienced it'") (citation omitted).[5]

Much of Plaintiffs' objections are really focused on the fact that while Ms. Kinsey offers an opinion as to how pharmacists *generally* dispense prescription drugs (and how that general practice would apply to this case), she did not conduct any *COREG-specific*, or *Glenmark/Teva-specific* investigation as to how COREG or Defendants' generic carvedilol products were *actually dispensed* in the relevant time period. (D.I. 212 at 3-4) That is, Plaintiffs fault Ms. Kinsey for failing to: (1) investigate whether Glenmark or Teva told pharmacies that their generic drug was not approved for all of the same indications as COREG; (2) perform testing or research to determine whether the rate of substitution between generic carvedilol and COREG would have changed if Glenmark and Teva had done so; (3) conduct any surveys to discover how

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[5] The Court also has little doubt that the sometimes complicated subjects of pharmaceutical "industry practice, state substitution laws, and the real world impact of section viii carve-outs[,]" (D.I. 252 at 3), are suitable topics for expert testimony. This is because they are "not within the common knowledge of the average juror." *Davis*, 397 F.3d at 179.

dispensing practices may have been affected if pharmacies had been made aware that Glenmark and Teva's generic carvedilol was not approved for all of the same indications as COREG; or (4) speak with anyone from Glenmark and Teva, or to any pharmacists who actually dispensed the Defendants' drug products. (*Id.*)

In the Court's view, these criticisms of Ms. Kinsey's approach are more properly characterized as (1) disagreements with the central premises motivating her opinions, or (2) good points as to why a jury might give her opinion lesser weight, but not (3) indicators of the use of a legally unreliable "methodology."

For example, one of Ms. Kinsey's opinions is that even had Glenmark/Teva and pharmacies had communications during the relevant period as to the fact that Defendants' products were not approved for all of the same indications as COREG, this *would not have affected* prescription decisions. (*See, e.g.*, Kinsey Report at ¶ 49) This conclusion was drawn based on her years of experience in the field. And so, she did not deem it necessary to obtain information about such Glenmark/Teva-specific communications, since she has explained why, in her view, they would ultimately be irrelevant to prescribing decisions.

Additionally, with regard to the failure to obtain data as to pharmacies' actual prescribing habits for COREG or carvedilol, Ms. Kinsey's view is that prescription of COREG vs. generic carvedilol would have followed "normal pharmacy substitution practices"—practices that would not have been affected by the fact that Defendants' products were not FDA-approved for all of COREG's indications. (D.I. 252 at 6-7) These substitution practices, according to Ms. Kinsey, are driven not by whether there are differences in approved indications, nor even by what particular drug is at issue. Instead, she set out a list of other factors (such as whether a

substitutable AB-rated drug exists, the physician's prescribing instructions, available inventory and price) that would instead impact such decisions. (Kinsey Report at ¶¶ 33-50) The Court disagrees with Plaintiffs that such opinions amount to "nothing more than [Ms. Kinsey's] subjective belief[,]" that they "lack[] citation to any real-world example" or that they provide "nothing to explain how [Ms. Kinsey's] experience" leads to her conclusions "about a generic's indications and how that would be received or acted upon by the industry." (D.I. 270 at 2-3) To the contrary, Ms. Kinsey's report and her deposition, read in context, clearly indicate that her conclusions *are* driven by her experience. It is clear that she is basing those conclusions on what she has observed over the past two decades while overseeing pharmacies at Walmart and in her own practice as a pharmacist and a consultant. (*See, e.g.*, Kinsey Report at ¶¶ 45, 48 (Ms. Kinsey explaining that her opinion on this subject is impacted by her knowledge that, *inter alia*, "most pharmacy buyers have no medically-related education to understand diagnostic conditions" and that it "is extremely rare for a pharmacist to know the diagnostic details leading to the physician's care plan for a patient, which may include one or more prescriptions"); D.I. 213, ex. 1 at 65 (Ms. Kinsey explaining that her opinion is derived from her "experience and [her] regular interaction with pharmacists and executives within the industry"); *id.* at 155 (Ms. Kinsey pointing to her experience with Walmart's standard operating procedures and its pharmacies); Tr. at 158)

It could be that a factfinder will ultimately fault Ms. Kinsey for failing to obtain COREG-specific or Glenmark/Teva-specific data when formulating conclusions on generic substitution patterns. But if those are flaws in her testimony, then those flaws should be assessed by the jury, who can determine the appropriate weight that her opinion should receive. *See Veleron Holding,*

B.V. v. Morgan Stanley, 117 F. Supp. 3d 404, 443-45 (S.D.N.Y. 2015) (finding the testimony of an expert, who was opining on industry practices relevant to disclosure of confidential information in the securities and derivatives industry, to be sufficiently reliable, and concluding that "the fact [that the expert] did not conduct a 'survey' [to probe industry customs] before reaching his conclusion," "or did not obtain a copy of every other bank's internal policies [on the subject before doing so], is at best an avenue for cross-examination, rather than a disqualification from testifying"); *cf. Paoli*, 35 F.3d at 744-45 (noting that a court "frequently should find an expert's methodology helpful even when the judge thinks that the expert's technique has flaws sufficient to render the conclusions inaccurate" as "[he] or she will often still believe that hearing the expert's testimony and assessing its flaws was an important part of assessing what conclusion was correct" and that a jury "attempting to reach an accurate result should consider the evidence").

2. Fit

Nor does the Court agree with Plaintiffs' arguments as to "fit." As to this assessment, the Court would expect the witness to explain why her particular experience "is reliably applied to the facts" of the case. Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, Ms. Kinsey has done so.

It is not disputed that the practices of pharmacies filling prescriptions for generic carvedilol or COREG are relevant to issues in this case (such as the extent of any infringement, or the damages associated therewith). Ms. Kinsey is set to provide testimony, based on her experience working with and overseeing numerous pharmacies in the United States, regarding how such prescriptions are filled. There is a fair level of generality to her testimony, to be sure.

(D.I. 212 at 5 (Plaintiffs' faulting Ms. Kinsey for relying on "general information regarding pharmacy procedures" in order to discuss what would occur when pharmacists filled prescriptions for COREG)) But the Court disagrees with Plaintiffs that Ms. Kinsey's opinions are built on "speculation[.]" (*Id.*) Her report contains non-speculative information about standard pharmaceutical-industry practices regarding generic substitution. She describes how these practices inform whether an AB-rated generic product like Defendants' carvedilol would be dispensed in favor of a branded product like COREG. (Kinsey Report at ¶¶ 23, 43, 46, 50) That these general industry practices might also apply to other substitution decisions regarding drugs other than COREG/carvedilol does not make them irrelevant to the facts of this case.

Keeping in mind that the "standard for [this] factor is not high[,]" *Meadows*, 306 F. App'x at 790, the Court finds that Defendants have met the standard for fit.

III. CONCLUSION

For the reasons set out above, the Court hereby ORDERS that the Motion be DENIED.

This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a) and D. Del. LR 72.1. The parties may serve and file specific written objections by no later than **May 12, 2017**; responses are due by no later than **May 22, 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).

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 **May 9, 2017** for review by the Court, along with a 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.

Dated: May 2, 2017

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE