IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 11-cv-1285
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

Plaintiff The Medicines Company's ("TMC") has moved to preclude certain opinions of Dr. David E. Auslander offered by Defendant Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively, "Mylan"), pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). For the reasons discussed below, the Court grants in part and denies in part TMC's motion.

BACKGROUND

This action arises out of a patent infringement case involving U.S. Patent No. 7,582,727 (R. 358-1, "the '727 Patent") The '727 patent "relates to a compounding process for preparing a pharmaceutical batch(es) of a drug product or a pharmaceutical formulation(s) comprising bivalirudin as an active ingredient." (*Id.*, '727 patent at col. 2 ll. 29-32) Bivalirudin is the active ingredient in TMC's Angiomax® drug product, an injectable anticoagulant used to prevent blood clotting during coronary procedures. TMC has sold Angiomax® since 2001. Before expiration

of the patent-in-suit, Mylan submitted Abbreviated New Drug Application ("ANDA") No. 202471 to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic equivalent to Angiomax®. TMC claimed that Mylan's ANDA No. 202471 infringes several claims of the patents-in-suit.

Mylan disclosed three separate expert reports of Dr. David E. Auslander in this case.[1] Mylan served Dr. Auslander's Opening Report on February 8, 2013, setting forth his opinions regarding the invalidity and unenforceability of TMC's '727 patent. (R. 340-1, Auslander Open Report) Dr. Auslander submitted a second expert report on March 8, 2013, setting forth his opinions related to non-infringement. On April 8, 2013, Dr. Auslander served his reply to the responsive report of TMC's technical expert, Dr. Alexander Klibanov[2], on issues of invalidity and inequitable conduct. (R. 340-2, Auslander Reply Rpt.)

Dr. Auslander reviewed certain disclosures withheld by TMC in its application to the Patent Office to determine whether such information would have been material to the Patent Examiner. (R. 340-2, Auslander Reply Rpt. ¶¶ 40-41.) Following his review, Dr. Auslander opined that information regarding the prior art would have been material to the examiner in determining the patentability of the claims. *Id.* In particular, Dr. Auslander noted that in Table 6 of the '727 Patent, TMC disclosed only that prior art batches of Angiomax had a mean Asp^9 value of 0.5% (with a standard deviation of 0.4% plus or minus), and a maximum Asp^9 result of 3.6%. (R. 358-1, "the '727 Patent" at col 22, ll. 9-20.) Dr. Auslander concluded that the information omitted by TMC in Table 6, relating to the high rate at which the prior art batches

[1] The Court is only addressing Dr. Auslander's opinions regarding the '727 patent.
[2] The Court, in a previous summary judgment opinion, struck Dr. Klibanov's opinions as untimely, including opinions on infringement under the doctrine of equivalents. (R. 309 at 22–23.)

actually met the 0.6% Asp[9] maximum of the '727 patent claims, would have been material and misleading to the Patent Examiner's determination. (R. 340-2, Auslander Reply Rpt. ¶ 40.)

LEGAL STANDARD FOR *DAUBERT* MOTIONS

"The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)." *Lewis v. Citgo Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). Rule 702 provides, in relevant part, that "[i]f scientific, technical or other specialized knowledge will assist the trier of fact[,] . . . a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion. . . ." *Id.* *See also Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 824 (7th Cir. 2010).

Under the expert-testimony framework, courts perform the gatekeeping function of determining whether the expert testimony is both relevant and reliable prior to its admission at trial. *See id.*; *Power Integrations, Inc. v. Fairchild Semiconductor Intern., Inc.*, 711 F.3d 1348, 1373 (Fed. Cir. 2013); *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) ("To determine reliability, the court should consider the proposed expert's full range of experience and training, as well as the methodology used to arrive [at] a particular conclusion."). In doing so, courts "make the following inquiries before admitting expert testimony: first, the expert must be qualified as an expert by knowledge, skill, experience, training, or education; second, the proposed expert must assist the trier of fact in determining a relevant fact at issue in the case; third, the expert's testimony must be based on sufficient facts or data and reliable principles and methods; and fourth, the expert must have reliably applied the principles and methods to the facts of the case." *Lees v. Carthage College*, 714 F.3d 516, 521-22 (7th Cir. 2013); *see also Stollings*

v. Ryobi Tech., Inc., 725 F.3d 753, 765 (7th Cir. 2013); *Power Integrations*, 711 F.3d at 1373; *Pansier*, 576 F.3d at 737.

It is clear that "genuine expertise may be based on experience or training." *United States v. Conn*, 297 F.3d 548, 556 (7th Cir. 2002) (quoting *Tyus v. Urban Search Mgmt.*, 102 F.3d 256, 263 (7th Cir. 1996)). "[W]hile extensive academic and practical expertise in an area is certainly sufficient to qualify a potential witness as an expert, Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience." *Trustees of Chicago Painters & Decorators Pension, Health & Welfare, & Deferred Sav. Plan Tr. Funds v. Royal Int'l Drywall & Decorating, Inc.*, 493 F.3d 782, 787-88 (7th Cir. 2007) (citations and quotations omitted). As such, courts "consider a proposed expert's full range of practical experience, as well as academic or technical training, when determining whether that expert is qualified to render an opinion in a given area." *Id.* (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000)).

The Seventh Circuit has also noted:

> Where the gatekeeper and the factfinder are one and the same – that is, the judge – the need to make such decisions prior to hearing testimony is lessened. *See United States v. Brown*, 415 F.3d 1257, 1268-69 (11th Cir. 2005). That is not to say that the scientific reliability requirement is lessened in such situations; the point is only that the court can hear the evidence and make its reliability determination during, rather than in advance of, trial. Thus, where the factfinder and the gatekeeper are the same, the court does not err in admitting the evidence subject to the ability later to exclude it or disregard it if it turns out not to meet the standard of reliability established by Rule 702.

In re Salem, 465 F.3d 767, 777 (7th Cir. 2006); *see also Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010) (observing that "the court in a bench trial need not make reliability determinations before evidence is presented" because "the usual concerns of the rule – keeping unreliable expert testimony from the jury – are not present in such a setting"); *Brown*,

415 F.3d at 1269 ("There is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself."). Where the judge will be the trier of fact at trial, the Court may choose to (1) allow the presentation of borderline testimony, (2) subject the testimony to the rigors of cross-examination, and (3) decide later whether the testimony is entitled to some consideration or whether it should be excluded as irrelevant, unreliable, or both. Nevertheless, at some point before disposition of the case, the court "must provide more than just conclusory statements of admissibility or inadmissibility to show that it adequately performed its gatekeeping function." *Metavante Corp.*, 619 F.3d at 760.

ANALYSIS

TMC seeks to exclude certain opinions of Dr. David Auslander. First, TMC asks the Court to preclude Dr. Auslander's testimony regarding what the Patent Office Examiner would have done or thought had the Examiner had different information during the prosecution of the patents-in-suit. Second, TMC seeks to preclude Dr. Auslander from testifying in reliance on statistics expert, Dr. Ian McKeague's, "unreliable" Table 6 statistical analysis. The Court will address each argument in turn.

I. Dr. Auslander

Dr. David Auslander operates Deatech Associates, a worldwide pharmaceutical development consulting company. Deatech Associates focuses on pharmaceutical product and process development strategies, including process improvements, scale up, commercialization, and validation efforts. Dr. Auslander obtained a Masters of Science in Pharmaceutics from Columbia University in 1965 and a Ph.D. in Pharmaceutical Sciences from Rutgers University in 1973. Dr. Auslander has over 35 years of experience in drug development, drug formulations, and the role of scale up and validation for successful implementation of pharmaceutical products

meeting both good manufacturing procedures and FDA regulatory requirements. He has worked extensively in the pharmaceutical industry on process development related to pharmaceutical drug products, including injectables. (R. 340-1, Auslander Opening Report ¶¶ 4-10.)

Based on his expertise in the pharmaceutical industry, Dr. Auslander opined in his first and third expert reports that the '727 patent is unenforceable due to TMC's failure to disclose material information to the Patent Office during prosecution of the patent. In particular, the '727 patent purports to claim pharmaceutical batches of bivalirudin drug product having certain maximum impurity levels. (R. 358-1, "the '727 Patent" at col. 25, l. 55 - col 28, l. 24.) For example, claim 1 recites pharmaceutical batches having a maximum Asp^9-bivalirudin impurity level of "about 0.6%." (*Id*. col 25, ll. 55-64.) TMC relied upon this maximum Asp^9 impurity level in distinguishing its prior art Angiomax® product and obtaining allowance of the '727 patent claims over that prior art. (R. 278-8, at MEDMYL0001284.)

II. Dr. Auslander May Rely on Dr. Ian McKeague's Analysis

TMC first argues that the Court should preclude Mylan expert Dr. David E. Auslander from testifying in reliance on statistics expert Dr. Ian McKeague's Table 6 statistical analysis and conclusions. As described in greater detail in the Court's Memorandum Opinion and Order regarding the *Daubert* motion to preclude testimony of Dr. McKeague, his expert statistical analysis of Table 6 in the '727 patent is reliable. (R. 408) An expert need not base his testimony on first-hand knowledge or research actually conducted by the expert. *See Daubert*, 509 U.S. at 592; *Walker v. Soo Line R.R.*, 208 F.3d 581, 588 (7th Cir. 2000) ("Indeed, courts frequently have pointed to an expert's reliance on the reports of others as an indication that their testimony is reliable."); *Kimberly-Clark Worldwide, Inc., v. First Quality Baby Prods., LLC*, No. 1:09-CV-1685, 2013 WL 6230484, at *2-3 (M.D. Penn. Dec. 2, 2013) (expert may render opinions in

reliance on other expert's opinions). Thus, Dr. Auslander can rely on testimony and reports from Dr. McKeague's analysis of Table 6 in formulating his own expert opinions.

In addition, Dr. Auslander independently opined on Table 6 based on his technical expertise. Dr. Auslander stated that "[b]ased upon [his] own independent review of that data and Table Six" that he agrees with Dr. McKeague's opinion that Table 6 of the '727 Patent provides misleading and incomplete information concerning TMC's prior art Angiomax® product. (R. 340-2, Auslander Reply Rpt. ¶ 40.) TMC's motion on this issue is therefore denied.

III. Dr. Auslander's Opinions Regarding the Significance of the Asp[9] Levels of Prior Art Batches are Admissible

TMC also moves to exclude statements by Dr. Auslander regarding his opinion of what the Patent Office Examiner would have done or thought had TMC given her different information:

- "The obviousness of TMC's solution ***would have been clear to the Patent Office Examiner*** had TMC fully and forthrightly described the details of the Angiomax® prior art formulation process in its patent application." (R. 340-1, Auslander Opening Report ¶ 129.) (emphasis added);

- "***In my opinion, the Patent Office would have found it material*** to learn that the difference between the prior art Angiomax® and the claimed invention was merely the incremental difference between a 90% success rate and a 100% success rate, in achieving Asp9 levels at or below about 0.6%. . . ." (R. 340-2, Auslander Reply Report ¶ 41.) (emphasis added);

- "Consequently, ***the Patent Office was led to believe*** that the differences between the 'old' and 'new' compounding processes were much greater than they actually were." (*Id*.) (emphasis added);

- "While Dr. Klibanov may balk that the prior art Angiomax® was disclosed to the Patent Office, the evidence shows that TMC concealed important aspects of its prior art compounding process, and the results achieved by that process, from the Patent Office. In my opinion, had those additional facts been disclosed, ***the Patent Office probably would not have allowed the asserted claims*** to

issue." (*Id*. ¶ 81.) (emphasis added); and

- "And, ***would the Patent Office have allowed*** the claims to issue had it been informed that this was the type of incremental difference as to which TMC was filing for patent protection? I think the answer to that question is no . . . ." (*Id*. ¶ 105.) (emphasis added).

To satisfy the materiality standard for an inequitable conduct claim, the accused infringer must show that "but-for" the nondisclosure of the withheld prior art, the Patent Office Examiner would not have allowed at least one claim of the patent to issue. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291-92 (Fed. Cir. 2011). Under *Therasense*, an accused infringer asserting inequitable conduct "must provide evidence that the applicant in question (1) misrepresented or omitted material information, and (2) did so with specific intent to deceive the PTO." *Id*. Although materiality can be inferred from indirect and circumstantial evidence, "it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011).

Certain statements of Dr. Auslander's go beyond permissible opinions and speculate as to what the Examiner would have done or thought had she been given different information. *See, e.g., Se-Kure Controls, Inc. v. Diam USA, Inc.*, No. 06 C 4857, 2009 WL 77463, at *2 (N.D. Ill. Jan. 9, 2009) (curtailing the expert's proposed testimony and explaining that experts are not "mind-reader[s]"); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, No. C 92-20643, 1995 WL 261407, at *2 (N.D. Cal. Apr. 25, 1995) ("The court grants Applied's motion precluding Nusbaum from testifying about what the examiner would have done if Nusbaum had been the examiner, or if the examiner had different information. The evidence would be irrelevant speculation . . . ."). Thus, the Court grants Plaintiff's motion to preclude Dr.

Auslander from opining on what the Patent Office Examiner would have done or thought had she been given different information.

Dr. Auslander, may, however, opine as to what he believes would have been material to the patent examiner based on the statistical data generated by Dr. McKeague. Experts are permitted to opine on materiality. *CBOE v. ISE*, No. 07 C 623, ECF No. 701 at 3-4 (N.D. Ill. March 7, 2013) (citing *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 n.5 (Fed. Cir. 2008)) (allowing relevant expert testimony from expert who did not have "ordinary skill in the field of computer programming," the relevant art); *Bone Care Int'l LLC v. Pentech Pharms. Inc.*, No. 08-CV-1083, 2010 WL 3928598, at *9 (N.D. Il.. Oct. 1, 2010) (holding technical expert may opine on materiality). Dr. Auslander is permitted to discuss and disclose facts, without opining on what the Patent Office Examiner would have done or thought. Specifically, given Dr. Auslander's uncontested and extensive expertise of pharmaceutical industry and FDA standards, his opinions relating to Dr. McKeague's statistical analysis and their potential materiality are admissible. (*See* R. 340-2, Auslander Reply Rpt. ¶¶ 40-41.) This aspect of the motion is therefore denied.

CONCLUSION

For the reasons discussed in detail above, the Court grants in part and denies in part TMC's motion to preclude certain testimony of Mylan's expert, Dr. David Auslander.

Dated: April 17, 2014

AMY J. ST. EVE
United States District Court Judge