

**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 the testimony and opinions of Dr. Nancy J. Linck, 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 patents-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. The Court granted in part and denied in part Defendants’ motion for summary judgment of non-infringement, invalidity, and willful infringement.¹ In defense of the remaining infringement claims, Mylan has asserted that TMC committed inequitable conduct during the prosecution of the ‘727 patent.

On February 8, 2013, Mylan served TMC with the expert report of Dr. Nancy J. Linck. Mylan seeks to offer Dr. Linck’s testimony to support its claims that the co-inventors of the ‘727 patent, Drs. Gary Musso and Gopal Krishna, committed inequitable conduct during the prosecution of the ‘727 patent. Dr. Linck is a patent attorney who also holds a Ph.D. in inorganic chemistry, and has more than twenty years of experience in patent law and with the United States Patent and Trademark Office’s (“Patent Office”) practices and procedures. Dr. Linck was formerly the Solicitor of Patents and Trademarks at the Patent Office. She also was an Administrative Patent Judge, where she evaluated the decisions of Patent Office examiners. Dr. Linck opined on Mylan’s theory of inequitable conduct based on her knowledge and expertise in the field, the ‘727 file history, and the record of the case.

Specifically, Dr. Linck opined that certain material information was known to Drs. Musso and Gopal Krishna during the prosecution of the ‘727 patent, and that the material information was either withheld from the Patent Office or misrepresented to the patent examiner.

¹ The Court granted Defendants’ motion for summary judgment of non-infringement of the other patent-in-suit (U.S. Patent No. 7,598,343), and also granted Defendants’ motion for summary judgment on Plaintiffs’ claim for willful infringement. (R. 309, Mem, Op, & Order.)

Linck concluded that an examiner would not have issued the claims of the '727 patent had the information been disclosed or had misrepresentations not been made. (R. 324-1 ¶¶ 114-34.) Dr. Linck also identified certain record evidence from which the Court could draw an inference of intent to deceive the Patent Office. (*Id.* ¶¶ 135-49.)

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 Pharms., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993).” *See also Apple Inc. v. Motorola, Inc.*, __ F.3d __, 2014 WL 1646435 at *18 (Fed. Cir. Apr. 25, 2014); *Lewis v. Citgo Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). Rule 702 provides, in the 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. In evaluating these issues, “[a] judge must be cautious not to overstep its gatekeeping role and weigh facts, evaluate the correctness of conclusions, impose its own preferred methodology, or judge credibility, including the credibility of one expert over another. These tasks are solely reserved for the fact finder.” *Apple*, 2014 WL 1646435 at * 19.

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)).

In addition, as the Seventh Circuit teaches:

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.”). Under this approach, where the judge will serve as 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 the entire testimony of Dr. Nancy J. Linck, or in the alternative, limit several of Dr. Linck’s opinions on certain issues relating to the prosecution of the ‘727 patent. TMC asks the Court to preclude Dr. Linck’s testimony alleging that she is not a qualified expert to testify on Mylan’s inequitable conduct theories, and that Dr. Linck’s testimony will not aid the trier of fact. Alternatively, TMC argues that the Court should preclude Dr. Linck from offering several legal and technical opinions, particularly in the area of inequitable conduct. Specifically, TMC argues that the Court should strike Dr. Linck’s opinions and testimony regarding: (1) the intent or state of mind of the inventors; (2) the interpretation of patent law and court decisions; (3) conclusions of law; (4) the intent or state of mind of the Patent Office

Examiner; (5) mistakes made by the Patent Office; and (6) technical matters outside Dr. Linck's expertise. The Court will address each argument in turn.

I. Dr. Nancy J. Linck

Mylan expert Dr. Nancy Linck is an attorney who has more than twenty years of experience in patent law and Patent Office practices and procedures. Dr. Linck is the former Solicitor of Patents and Trademarks, serving as general counsel and the highest-ranking lawyer at the Patent Office. She also is a former Administrative Patent Judge who was responsible for reviewing determinations of Patent Office examiners, including denials of patent applications. Additionally, she has testified before Congress, the Federal Trade Commission, and the Department of Justice regarding improvements to the U.S. patent system.

Dr. Linck received a Juris Doctor degree in 1984 from Johns Hopkins University, has been a partner at two law firms, and in-house counsel at a chemical company and a pharmaceutical company. Dr. Linck is an Adjunct Professor of Law at Georgetown University Law Center, a position she has held since 1998, and was previously an Adjunct Professor at George Washington School of Law. Dr. Linck holds a B.S. in chemistry from the University of California, Berkeley, and an M.S. and Ph.D. in inorganic chemistry from University of California, San Diego. Based on her significant legal and technical qualifications, Mylan offered Dr. Linck's opinions in support of its claim that TMC's inventors committed inequitable conduct during the prosecution of the '727 patent.

II. Dr. Linck is Qualified to Testify as an Expert in This Case

TMC first moves the Court to preclude Dr. Linck's testimony in its entirety because she is not qualified to opine on the examination of the '727 patent conducted by the Patent Office, or to provide opinions supporting Mylan's position that the co-inventors committed inequitable

conduct. TMC asserts that Dr. Linck is not a qualified expert capable of testifying about inequitable conduct because she has “never been a patent examiner.” (R. 320 at 4.)

The Court finds TMC’s argument regarding the qualifications of Dr. Linck unavailing. Dr. Linck has more than twenty years of patent law experience including serving as the Solicitor of Patents and Trademarks, the highest-ranking attorney in the Patent Office. Further, Dr. Linck served as an Administrative Patent Judge responsible for reviewing the determinations of Patent Office examiners. While Dr. Linck has never been a Patent Office examiner, she actually reviewed the decisions of Patent Office examiners, making her well-qualified to opine on issues arising in the patent prosecution process. Additionally, Dr. Linck is well-regarded in the patent field, having testified before Congress, the Federal Trade Commission, and the Department of Justice regarding improvements to the U.S. patent system. She is an adjunct law professor, and a patent attorney, giving even more weight to her expertise in the field of patent law. One court explicitly found Dr. Linck “undoubtedly qualified to testify as an expert on patent application issues relating to inequitable conduct” solely based on her work at the Patent Office. *See Wyeth v. Apotex Inc.*, No. 08-22308-CIV, 2009 WL 8626786, at *2-4 (S.D. Fla. Oct. 6, 2009). The Court finds Dr. Linck’s extensive, impressive qualifications more than sufficient to allow her to opine on Mylan’s theories of inequitable conduct and other prosecution issues relating to the ‘727 patent.

TMC also asks the Court to preclude Dr. Linck’s testimony in its entirety because it would “fail to assist the trier of fact.” (R. 320 at 4.) To support its position TMC cites District of Delaware cases where the courts precluded legal experts from testifying at trial. *See Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, Civ. No. 07-457 (D. Del. Mar. 4, 2009) (striking any legal expert from testifying at trial including Dr. Linck’s inequitable-conduct opinions); *Brigham*

& Women's Hosp. Inc. v. Teva Pharms. USA, Inc., Civ. A. No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (barring parties from explaining patent prosecution histories through expert testimony). These cases are not binding on the Court.

TMC also relies on *National Diamond*, where the Court excluded a patent expert's testimony regarding inequitable conduct. *Nat'l Diamond v. Flanders Diamond*, 00 C 6402, 2003 WL 24890292, at *1 (N.D. Ill. Apr. 30, 2003). *National Diamond*, however, involved a jury trial rather than a bench trial where the expert sought to "simplify" the issues in the area of inequitable conduct for purposes of the jurors' understanding. *Id.* As the Court noted in *National Diamond*, the parties did not need to present such issues to the jury since it was not a jury issue. Here, preclusion of Dr. Linck's testimony is unnecessary because the Court is the trier of fact, with the capability of curtailing her opinions if necessary at trial. *See, e.g., Bone Care Int'l LLC v. Pentech Pharm., Inc.*, No. 08 C 1083, 2010 WL 3928598, at *2-3 (N.D. Ill. Oct. 1, 2010).

Additionally, courts within this District and others routinely allow qualified patent experts to testify on inequitable conduct. *Id.* at *9 (patent law experts may testify on "the history of the '488 application's prosecution that may be probative to the issue of intent [to deceive]" and on the "materiality element of inequitable conduct"); *Se-Kure Controls, Inc. v. Vanguard Prods. Grp., Inc.*, No. 02 C 3767, 2008 WL 169054, at *3-4 (N.D. Ill. Jan. 17, 2008) (patent law expert may testify about general patent procedures, operations and functions of the PTO, materiality of relevant prior art, and factual context for why plaintiff's behavior may have been inequitable). *See also Worldwide Home Products, Inc. v. Time Inc.*, 11 CIV. 3633 LTS MHD, 2013 WL 5477480, at *5 (S.D.N.Y. Sept. 30, 2013).

Because Dr. Linck is qualified by her experience and expertise to testify as a patent law

expert regarding the application and issuance of the '727 patent relating to Mylan's inequitable conduct claims, the Court denies TMC's request to exclude her opinions and testimony in their entirety. TMC can challenge Dr. Linck's opinions regarding inequitable conduct allegedly committed by the inventors of the '727 patent through its own witnesses and through rigorous cross-examination during trial.

III. Inequitable Conduct

An accused infringer asserting a claim for inequitable conduct "must show by clear and convincing evidence that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive the PTO." *Network Signatures, Inc. v. State Farm Mut. Auto. Ins. Co.*, 731 F.3d 1239, 1242 (Fed. Cir. 2013) (quoting *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012)). "Materiality and intent must be separately established." *Id.* The intent to deceive element of an inequitable conduct claim is a question of fact. *Bone Care*, 2010 WL 3928598, at *9 (citing *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000)). Thus, there are two elements of a claim of inequitable conduct: first, the materiality of misrepresentations, misinformation, or withheld information; and second, the intent to deceive. *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007); *see also Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

IV. Dr. Linck's Opinions Regarding Patent Law and Inequitable Conduct

A. Dr. Linck May Testify on Facts Relating to the Intent to Deceive Element of the Inequitable Conduct Claim

TMC argues the Court should preclude Dr. Linck's opinions regarding the state of mind of each of the inventors, and her opinions on their intent to deceive the Patent Office regarding the application and examination of the '727 patent. (R. 320 at 7.) Specifically, TMC asserts that

Dr. Linck is not qualified to testify on the co-inventors' intent to deceive because she does not possess any special qualifications that would allow her to discern the co-inventors' thoughts.

(*Id.*)

Patent experts may not testify that they know the patentee's intent to hide or lie about certain information during the patent prosecution process "because they are not mind-readers." *Bone Care*, 2010 WL 3928598, at *9. Additionally, patent experts may not "plumb the inventor's and attorney's minds and discern whether they 'lacked candor' or had actual intent to deceive during the patent prosecution process." *Id.* (citing *Se-Kure Controls*, 2008 WL 169054, at *2). Mylan concedes that Dr. Linck cannot testify as to whether the inventors actually had a specific intent to deceive the Patent Office, but asserts that Dr. Linck may identify certain facts from the file history and record to support an inference that the applicants acted with intent to deceive. (R. 377 at 6.) *See Bone Care*, 2010 WL 3928598, at *9 (Attorney expert's Patent Office experience "qualified [him] to offer evidence regarding the history of the '488 application's prosecution [as it] may be probative to the issue of intent [to deceive the Patent Office]."). The Court agrees. This aspect of TMC's motion is granted only to preclude Dr. Linck's opinions regarding the inventors' intent to deceive.

B. The Legal Standards Upon Which Dr. Linck Bases Her Opinions

Next, TMC asks the Court to preclude several of Dr. Linck's opinions "explaining or interpreting patent law and court decisions." (R. 320 at 2.) TMC asserts that such opinions will not assist the Court in interpreting the issue of inequitable conduct in the application and issuance of the '727 patent. Dr. Linck's opinions include certain Patent Office procedures and practices such as: the grounds which an examiner can reject a patent application (R. 324-1 ¶¶ 31-38.); the grounds under which a reference would be prior art (R. 324-3 ¶¶ 16.); the duty of

candor an applicant has during prosecution (R. 324-1 ¶¶ 41-60.); and the standard that examiners apply in determining whether a reference is material. (*Id.*)

Dr. Linck may offer opinions regarding the Patent Office's practices and procedures based on her prior experience in the Patent Office and her extensive experience in patent law and procedure. *See Bone Care*, 2010 WL 3928598, at *14 (holding that patent expert's proposed testimony admissible relating to patent application process, operations and functions of the PTO, and the criteria which examiners evaluate in assessing patentability). Indeed, courts allow patent law experts to testify on "general procedures involved in the patent application process." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008). She may also opine on whether a certain criteria is material to a Patent Office examiner. *See Bone Care*, 2010 WL 3928598, at *14 (admitting discussion of "criteria to which examiners look in assessing patentability (including obviousness, priority, etc.)"); *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 01 C 6934, 2004 WL 2260626, at *7 (N.D. Ill. Oct. 1, 2004) (finding admissible patent law expert discussion of materiality); *Worldwide Home Products*, 2013 WL 5477480, at *5.

TMC also challenges Dr. Linck's statements regarding the legal standards upon which she relies to formulate her opinions as improper legal opinions. Dr. Linck may testify regarding the legal standards upon which she relies for her opinions. *See, e.g., A.E. ex rel. Evans v. Indep. Sch. Dist. No. 25, of Adair Cnty., Okl.*, 936 F.2d 472, 476 (10th Cir. 1991) ("An expert may [] refer to the law in expressing his or her opinion.") Citing to statutes, legal definitions, and cases is acceptable when a legal expert is explaining the bases of how she arrived at her opinions. CHECK *See Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 6:09-CV-1968-ORL-19, 2011 WL 87306, at *4 (M.D. Fla. Jan. 11, 2011) (district court refused to strike an expert's

opinion when he properly cited to statute and standards for evaluating obviousness announced in case law, and applied the principles to his obviousness analysis). She may not, however, give general testimony interpreting patent law.

Finally, the trial in this case is a bench trial. The Court is fully aware of the law of inequitable conduct in the context of patent applications and examinations. The Court, as the trier of fact in this case, is free to disregard or curtail the testimony provided by Dr. Linck. *See, e.g., Bone Care*, 2010 WL 3928598, at *2-3; *Armament Sys.*, 2007 WL 1267877, *1.

C. Some of Dr. Linck's Opinions Are Improper Legal Conclusions

TMC next asks the Court to preclude certain legal conclusions found in Dr. Linck's expert report. (R. 320 at 9-11.) Specifically, TMC points out three examples in Dr. Linck's opening report as legal conclusions concerning conception², inventorship³, and inequitable conduct⁴. (*Id.*) TMC claims each of these opinions contains legal conclusions, which the Court may address at the end of the trial. In the Seventh Circuit, "expert testimony that contains a legal conclusion that determines the outcome of a case is inadmissible." *Sommerfield v. City of Chicago*, 254 F.R.D. 317, 330 (N.D. Ill. 2008) (citing *RLJCS Enterprises, Inc. v. Prof'l Ben. Trust Multiple Emp'r Welfare Ben. Plan & Trust*, 487 F.3d 494, 498 (7th Cir. 2007)). "Rule 704 was not intended to allow experts to offer opinions embodying legal conclusions." *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F.Supp.2d 252, 255 (W.D.N.Y. 2000) (quoting *United States v. Scop*, 846 F.2d 135, 139 (2d Cir.1988)); *Se-Kure Controls, Inc. v. Diam USA, Inc.*, 06 C 4857,

² "In my opinion, the single most reasonable conclusion to be drawn from this evidence is that the inventors and possibly others acted with a deliberate intent to deceive the USPTO and obtain allowance of patent claims to which they are not entitled." (R. 324-1 ¶ 146.)

³ "In any case, the relevant point is that Ben Venue ("BVL") staff who are not named as inventors undeniably contributed to the alleged 'conceptions' of the claimed invention." (R. 324-3 ¶ 15.)

⁴ "Had this information been disclosed to Examiner Ha, in my opinion she would have rejected the application claims as invalid under 35 U.S.C. § 102(f)." (R. 324-1 ¶ 130.)

2009 WL 77463, at *2 (N.D. Ill. Jan. 9, 2009) (concluding that proposed testimony of a patent expert on whether the patent at issue is enforceable, whether the patentee committed inequitable conduct, or the level of intent behind any alleged failures to disclose prior art was all inadmissible).

In opposition, Mylan asserts that Dr. Linck's opinions are admissible on two grounds. First, Mylan argues that expert testimony on legal conclusions is properly precluded in jury trials for fear it will usurp the court's role, but such testimony is acceptable in bench trials as long as the court remains the trier of fact and draws its own legal conclusions. *See Bone Care*, 2010 WL 3928598, at *3; *Se-Kure Controls*, 2009 WL 77463, at *2; *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1325 (Fed. Cir. 1987). Second, Mylan contends that Dr. Linck's testimony does not contain legal conclusions or speculation, stating that there is a "difference between stating a legal conclusion and providing concrete information against which to measure abstract legal concepts." *United States v. Blount*, 502 F.3d 674, 680 (7th Cir. 2007). "The former is prohibited; the latter is not." *Bone Care*, 2010 WL 3928598, at *14. Mylan argues that Dr. Linck's challenged opinions are tying an abstract legal concept to the objective facts on the record. (R. 377 at 10.) *Id.* (citing *Se-Kure Controls*, 2009 WL 77463, *2) (allowing "factual context" for why prosecution behavior was inequitable, including "materiality of the relevant prior art"); *Worldwide Home Products*, 2013 WL 5477480, at *5 ("He has based his opinions on the factual record . . . , His opinions are relevant to the adequacy of Plaintiff's disclosures to . . . , which is a question of mixed law and fact.").

The opinions identified by TMC and cited above go beyond proper opinion testimony. Instead, they are improper legal conclusions and speculation. TMC's motion on this issue is therefore granted. denied.

D. Dr. Linck May Provide Opinions Regarding What Facts Would Have Been Material to the Patent Office Examiner

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

- “Moreover, *Examiner Ha would not have allowed* the patents to issue had she known that the allegedly ‘new’ process used to make bivalirudin resembled the ‘old’ process more closely than admitted by TMC in its patent application.” (R. 324-1 ¶ 128.) (emphasis added);
- “*It is my opinion that Examiner Ha would not have allowed* the claims of the patents-in-suit had she know that multiple techniques described as ‘efficient mixing’ in the patents were already in the prior art, or had been suggested by persons not named as inventors in the applications. (*Id.*) (emphasis added);
- “*It is my opinion that instead [Examiner Ha] would have rejected* the claims as obvious over the prior art compounding process.” (*Id.*) (emphasis added)
- “Finally, *Examiner Ha would not have allowed* the patents to issue had she known that the true inventors had not been named.” (*Id.* ¶ 129.) (emphasis added);
- “In my opinion, had the USPTO been informed that the claimed invention was in fact derived from concepts provided to the named inventors by a third party under no common duty of assignment, *the USPTO would not have allowed* the claims to issue.” (R. 324-3 ¶ 19.) (emphasis added)

These statements by Dr. Linck do more than merely reference the Patent Office examiner; they speculate as to what she would have done or thought had she been given different information. *See, e.g., Se-Kure Controls*, 2009 WL77463, at *2 (curtailing the expert’s proposed testimony and explaining that experts are not “mind-reader[s]”); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, C 92-20643 RMW, 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 TMC’s motion to preclude Dr. Linck from opining on what the Patent Office Examiner would have done or thought had she been given different information.

Additionally, the parties agree that courts permit experts to opine on facts that may be relevant to an inequitable conduct defense.⁵ While Dr. Linck is precluded from opining on what the patent examiner would have done or thought had she been presented other information, Dr. Linck may opine as to what she believes would have been material to the patent examiner, based on her expertise in patent law. Experts are permitted to opine on materiality and make relevant testimony. *CBOE v. ISE*, No. 07 C 623, ECF No. 701 at 3-4 (N.D. Ill. March 7, 2013) (citing *Sundance*, 550 F.3d at 1363 n.5) (allowing relevant expert testimony from expert who did not have “ordinary skill in the field of computer programming,” the relevant art). Thus, the Court denies this aspect of Plaintiff’s motion to preclude Dr. Linck’s testimony, and she may opine on the materiality to the Patent Examiner of the undisclosed prior art’s potential effect on the ‘727 patent application process.

E. The Presumption of Validity

Next, TMC argues that the testimony Dr. Linck intends to provide regarding “the general likelihood of the Patent Office to make mistakes . . . would undermine the statutory presumption of validity of issued patents under 35 U.S.C. § 282.” (R. 320 at 11.) Specifically, TMC references Paragraph 20 of Dr. Linck’s opening expert report:

From time to time, patents are granted that do not meet one or more of the statutory requirements for patentability. In other words,

⁵ See *Bone Care*, 2010 WL 3928598, at *14 (“Mr. Sofocleous may provide factual context that goes to the underlying contentions of inequitable conduct . . . , but he may not speculate or offer his subjective conclusions on those contentions. Similarly, Mr. Sofocleous may offer any extant facts regarding acts or omissions in the applications giving rise to the [patent in suit], but he may not speculate as to the intent of the inventors or attorneys.”) (citations omitted).

the USPTO makes mistakes. The courts may declare such patents invalid. Also, under some circumstances, ordinarily involving misconduct by the patentee(s) before the USPTO, the courts may declare patents unenforceable based on inequitable conduct.

(R. 324-1 ¶ 20.) Courts have precluded patent experts from offering “generalized testimony about potential memory problems of examiners or other non-case specific testimony ‘insinuating that the PTO does not do its job properly.’” *Bone Care*, 2010 WL 3928598, at *15 (citations omitted).

Mylan argues that the Court is capable of filtering between passing references to “mistakes” in the Patent Office made by Dr. Linck and the presumption of validity of a patent, and that the Court still may nonetheless find a patent invalid or unenforceable. This argument fails to address TMC’s assertion that generalized testimony about “other non-case specific testimony ‘insinuating that the PTO does not do its job properly’” is not permitted. *See Bausch & Lomb*, 79 F. Supp. 2d at 255-56 (citing *Applied Materials*, 1995 WL 261407, at *3). The Court agrees with TMC. Dr. Linck may present testimony to the extent that she has a basis for opining on actual defects in the patent application process or inequitable conduct relating to the '727 patent. The Court will not, however, permit Dr. Linck to offer generalized, non-case specific testimony insinuating that the Patent Office makes mistakes or does not do its job properly.

F. Dr. Linck Does Not Opine on “Technical” Matters Outside of Her Expertise

Finally, TMC argues that the Court should preclude Dr. Linck from opining on “technical opinions” outside of her field of expertise. (R. 320 at 12.) Specifically, TMC alleges that Dr. Linck improperly analyzes and compares the original and improved Angiomax® drug product, improperly opines on the materiality of technical information, and improperly interprets the patent in suit. (*Id.*) TMC further alleges that Dr. Linck, as an attorney, lacks the required

technical qualifications to opine on such technical issues. (*Id.*)

1. Dr. Linck Is Qualified to Provide Technical Opinions Related to Her Experience and Expertise in the Pharmaceutical Industry

TMC first argues that Dr. Linck is not qualified to provide technical opinions, “including opinions regarding: (i) scientific matters; (ii) the materiality of technical information; and (iii) the interpretation of the patent in suit.” (R. 320 at 13.) TMC claims that Dr. Linck is not a person of ordinary skill in the art (“POSITA”) under Mylan’s definition⁶ because “[Dr. Linck] lacks experience in formulating peptide drugs.” (*Id.*) Using Mylan’s definition, TMC asks the Court to preclude Dr. Linck from providing technical opinions and from offering testimony as to whether scientific and technical information would have been material during prosecution of the patents in suit, because she is not a POSITA or an expert on technical aspects of the ‘727 patent. *Bone Care*, 2010 WL 3928598, at *13 (precluding the expert from testifying on the “the scientific significance and materiality of prior art references . . .” because the expert lacked qualifications to opine on “scientific or technological facts . . .”). TMC also asks the Court to preclude Dr. Linck from interpreting the patents in suit. “Unless a patent lawyer is also a qualified technical expert, his testimony on these kinds of technical issues is improper and thus inadmissible.” *Sundance*, 550 F.3d at 1362 (holding that the district court abused its discretion in allowing defendant’s patent-law expert to testify on how the disclosed invention operates because he lacked relevant expertise in the pertinent art). The Court rejects TMC’s arguments.

Dr. Linck has a sufficient technical background to offer these opinions. She has several years of work experience in both the chemical and pharmaceutical industries, both technically-related and legally-related. Indeed, based on Dr. Linck’s combination of legal experience and

⁶ According to Mylan, a POSITA would “understand the use of active pharmaceutical ingredients and excipients to formulate a drug product, including use of peptides as API” (R. 324-7 ¶ 106.)

years of experience working with drug formulations, one court permitted her to opine on both the legal and technical aspects of a pharmaceutical patent. *See Wyeth*, 2009 WL 8626786, at *3-4 (“Dr. Linck is not being offered simply as a patent lawyer opining as one who was actually skilled in the art, but instead that Dr. Linck could be considered a person skilled in the art given her legal expertise coupled with her practical work experience in the pharmaceutical industry.”) Furthermore, Dr. Linck meets TMC’s definition of a POSITA – someone who possesses a B.S. in chemistry and a “few years” of pharmaceutical work experience. (R. 361-2 ¶ 27.)

Given her experience, Dr. Linck is qualified to rely on her own independent review of the ‘727 patent, and opine on (i) scientific matters; (ii) the materiality of technical information; and (iii) the interpretation of the ‘727 patent. TMC is free to vigorously cross examine Dr. Linck regarding her qualifications to testify on both technical and non-technical.

2. Dr. Linck May Rely on the Opinions of Other Experts Combined

TMC further argues that Dr. Linck is unqualified to combine her own technical opinions with opinions of Mylan’s technical experts. TMC challenges her reliance on the opinions of other Mylan experts. TMC’s challenge fails.

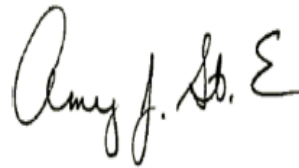
Dr. Linck has relied on the technical analyses of several other Mylan experts in rendering her opinions, including Dr. Ian McKeague, Dr. David Auslander, and Dr. Fred Regnier. (R. 324-3 ¶¶ 8, 11, 13-14, 18, 30, 32, 33, 36, 38, 39.) Mylan contends that Dr. Linck formed her patent prosecution opinions relying on the opinions of these several experts. As the Federal Circuit recently noted, “[e]xperts routinely rely upon other experts hired by the party they represent for expertise outside of their field.” *Apple Inc. v. Motorola, Inc.*, ___ F.3d ___, 2014 WL 1646435, 25 (Fed. Cir. Apr. 25, 2014). Indeed, experts need not base their opinions on first-hand knowledge or research actually conducted by the expert herself. *See Daubert*, 509 U.S. at 592; *Walker v.*

Soo Line R.R., 208 F.3d 581, 588 (7th Cir. 2000) (“courts frequently have pointed to an expert's reliance on the reports of others as an indication that their testimony is reliable”). Dr. Linck properly relied on these other expert opinions. TMC’s motion to exclude Dr. Linck’s opinions formed in reliance on other experts and her own technical expertise is 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. Nancy J. Linck.

Dated: May 2, 2014

A handwritten signature in black ink, reading "Amy J. St. Eve". The signature is written in a cursive, flowing style.

AMY J. ST. EVE
United States District Court Judge