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

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION	)	
Plaintiffs,	)	
v.	)	
	)	CASE NO. 08-CV-1083
PENTECH PHARMACEUTICALS, INC. and COBREK PHARMACEUTICALS, INC.	)	Judge Robert M. Dow, Jr.
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Before the Court are several *Daubert* motions brought by the parties in this patent litigation: Defendants' Motion to Preclude Trial Testimony of Dr. Lee-Jen Wei [345], Plaintiffs' Motion to Preclude the Testimony of Michael Sofocleous [406], and Plaintiffs' Motion to Preclude Defendants' Experts from Providing Speculative Testimony on the Issues of Intent for Inequitable Conduct and the Facts Supporting Date of Conception [424]. For the reasons and to the extent stated below, each of the motions [345, 406, 424] is granted in part and denied in part.

I. Legal Framework for Rule 702 Analysis

Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provide the legal framework for the admissibility of expert testimony. See *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009).[1] Rule 702 permits the admission of expert testimony if "scientific, technical, or other

[1] As the parties appear to recognize, although any appeal in this case would be taken in the Court of Appeals for the Federal Circuit, the law of the Seventh Circuit controls in regard to the Court's evidentiary rulings. See *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1276 (Fed. Cir. 1999)

specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Rule 702 requires that the district court act as a "'gatekeeper' who determines whether proffered expert testimony is reliable and relevant before accepting a witness as an expert." *Winters v. Fru-Con Inc.*, 498 F.3d 734, 741-42 (7th Cir. 2007) (quoting *Autotech Tech. Ltd. P'ship v. Automationdirect.com*, 471 F.3d 745, 749 (7th Cir. 2006)); see also *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-49 (1999); *Daubert*, 509 U.S. at 589.

In assessing a motion to exclude testimony under Rule 702, the Court must consider whether the proposed opinion witness (1) is qualified to offer opinion testimony under Rule 702, (2) has employed a reliable methodology, (3) proposes to offer opinions that follow rationally from the application of his "knowledge, skill, experience, training, or education," and (4) presents testimony on a matter that is relevant to the case at hand, and thus helpful to the trier of fact. See *Kumho Tire*, 526 U.S. at 151-53; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Daubert*, 509 U.S. at 589-93; see also *Walker v. Soo Line R. R. Co.*, 208 F.3d 581, 586 (7th Cir. 2000). "The proponent of the expert bears the burden of demonstrating that the expert's testimony would satisfy the *Daubert* standard." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). District judges possess considerable discretion in dealing with expert testimony. *Carroll v. Otis Elevator Co.*, 896 F.2d 210, 212 (7th Cir. 1990); see also *Gen. Elec. Co.*, 522 U.S. at 141-43 (holding that abuse of discretion standard applies in reviewing district court rulings on admissibility of proposed Rule 702 opinion testimony).

In regard to qualifications, Federal Rule of Evidence 702 allows parties to introduce expert opinions if the expert has the requisite "knowledge, skill, experience, training, or education." Anyone who has relevant expertise and can offer responsible opinion testimony that

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("Because these evidentiary rulings raise procedural issues not unique to patent law, this court applies the law of the regional circuit where appeals from the district court would normally lie").

is helpful to a judge or jury may qualify as an expert witness. See *Tuf Racing Prod., Inc. v. Am. Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000). In assessing an expert's qualifications, a court should consider the proposed expert's full range of education, experience, and training. *LG Elec. U.S.A., Inc. v. Whirlpool Corp.*, 661 F. Supp. 2d 940, 951 (N.D. Ill. 2009). In addition, given that "[m]odern science is highly specialized," a court must take care to confirm that a proposed expert is qualified to offer opinion testimony in the specific area of his or her proposed testimony. *Braun v. Lorrillard, Inc.*, 84 F.3d 230, 235 (7th Cir. 1996).

Daubert lists a number of relevant considerations in evaluating an expert's reasoning and methodology – including testing, peer review, error rates, and acceptability in the relevant scientific community. *Daubert* at 593-94. "[T]he test of reliability is flexible," however, "and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Kumho,* 526 U.S. at 141 (internal quotation omitted). "Rather the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id.* at 142 (emphasis omitted); see also *Pansier,* 576 F.3d at 737 (the Seventh Circuit "gives the [district] court great latitude in determining not only how to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable") (emphasis omitted) (citing *Jenkins v. Bartlett,* 487 f.3d 482, 489) (7th Cir. 2007); *Lewis,* 561 F.3d at 704-05 ("the law grants the district court great discretion regarding the manner in which it conducts that [*Daubert*] evaluation").

In assessing the admissibility of proposed expert testimony, the Court's "focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." *Daubert,* 509 U.S. at 595. However, as the Supreme Court has recognized, "conclusions and methodology are not entirely distinct from one another," and while "[t]rained experts commonly

extrapolate from existing data[,] * * * nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec.*, 522 U.S. at 146. In other words, "[a]n expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Wendler & Ezra, P.C. v. Am. Int'l Grp., Inc*., 521 F.3d 790, 791-92 (7th Cir. 2008) (quoting *Mid-State Fertilizer Co. v. Exch. Nat'l Bank*, 877 F.2d 1333, 1339 (7th Cir. 1989)). To ensure that the expert's conclusions follow reliably from his or her methods, the Seventh Circuit has stressed that "the district court is responsible for making sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Braun*, 84 F.3d at 234. In short, "[i]t is critical under Rule 702 that there be a link between the facts or data the expert has worked with and the conclusion the expert's testimony is intended to support." *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2003). Where that link is missing, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec.*, 522 U.S. at 146.

Finally, it is important to bear in mind the Seventh Circuit's teaching about the critical distinction between a jury trial and a bench trial with respect to the Rule 702 inquiry:

> Where the gatekeeper and the factfinder are one and the same – that is, the judge – the need to make such decisions prior to hearing the 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*, ___ F.3d ___, 2010 WL 3385961, at *7 (7th Cir. Aug. 30, 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 sensible approach, where there is no jury demand, and therefore 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.*, 2010 WL 3385961, at *7.

II. Analysis

A. Defendant's Motion to Preclude Trial Testimony of Dr. Wei

Defendants have filed a motion in limine [345] to preclude Plaintiffs from presenting evidence at trial that pertains to biostatistical expert Dr. Lee-Jen Wei's report comparing the results of two clinical studies that administered different vitamin D analogs to patients suffering hyperparathyroidism secondary to end-stage renal failure. Defendants contend that Dr. Wei's report is the product of unreliable methodology and will not be helpful to the trier of fact.

By way of background, Defendants seek to prove that claim 7 of the '116 patent is invalid on the ground of, *inter alia*, obviousness under 35 U.S.C. § 103. Section 103 states that an issued patent may be invalid if the "subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). A patentee may rebut a claim of obviousness of the

invention by putting forth evidence of so-called "secondary considerations" of non-obviousness. *Graham v. John Deere, Co.*, 383 U.S. 1, 17-18 (1966). One such secondary consideration may be that the invention produced such "unexpected results" that it could not have been obvious to a person of ordinary skill in the art at the time of the invention. *Sud-Chemie, Inc. v. Multisorb Tech., Inc.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009).

Claim 7 of the '116 patent teaches a method of lowering levels of parathyroid hormone ("PTH") in patients with hyperparathyroidism secondary to end-stage renal failure by administering an effective amount of the drug doxercalciferol, a vitamin D_2 analog. Defendants posit that prior art relating to use of the drug calcitriol, a vitamin D_3 analog, made the claim 7 invention obvious, since calcitriol was known to persons skilled in the art at the time to reduce PTH. Plaintiffs counter that the invention of administering doxercalciferol to secondary hyperparathyroidism patients yielded results so unexpected that it was non-obvious. The alleged unexpected result was that, unlike calcitriol, doxercalciferol did not cause the side effect of hypercalcemia (elevated levels of calcium in the bloodstream, potentially so high as to be poisonous). In other words, doxercalciferol allegedly proved unexpectedly less toxic than other methods of treatment that a person of ordinary skill in the art would have been aware of at the time.

In support of the "unexpected results" secondary consideration, Plaintiffs retained Dr. Wei, a statistician, to provide an expert comparison of two clinical studies: (1) the "Sprague" study,[2] describing hypercalcemia levels in secondary hyperparathyroidism patients treated with calcitriol, and (2) an internal Bone Care clinical study, known as "H-114", describing hypercalcemia levels in secondary hyperparathyroidism patients treated with doxercalciferol. As

[2] This study was reported in Sprague, S. et al., "*Paricalcitol versus calcitriol in the treatment of secondary hyperparathyroidism*," Kidney Int'l 63:1483-90 (2003).

Dr. Wei acknowledged, the scope of his assignment was quite narrow: he was simply to provide a statistical comparison of the incidence rates of hypercalcemia in patients treated with equipotent doses of calcitriol and doxercalciferol as shown by the Sprague and the H-114 studies, respectively. In carrying out that assignment, Dr. Wei undertook a comparative analysis of the two studies using "Poisson distribution," a method that counts the probability that a particular number of events will occur across a fixed period of time based on certain assumptions. In his expert report of October 30, 2009, Dr. Wei concluded that "treatment with doxercalciferol is significantly safer than treatment with calcitriol" due to the lower incidence of hypercalcemia with doxercalciferol treatment. (Dr. Lee-Jen Wei, Expert Report, at 6 (Oct. 30, 2009).)

After submitting the October 2009 report, Dr. Wei received electronic patient level data ("SAS" data) from Plaintiffs regarding the H-114 study that enabled him to confirm the results of his analysis. Also, subsequent to the submission of Dr. Wei's initial expert report, Dr. Langman, a nephrologist whom Plaintiffs had retained as an expert, accounted for clinically significant variables of the Sprague and H-114 studies, and thereby confirmed the results Dr. Wei had put forth in his October 2009 report. Dr. Wei acknowledged during his deposition that the confirmatory steps that the SAS data and Dr. Langman's review enabled were necessary to a reliable methodology. He further acknowledged that he had not taken either step as of the filing of his October 2009 report. Dr. Wei filed a second expert report after receiving the SAS data that, he contends, confirmed and provided further explanation of the results reported in his first report. The second report was stricken by Magistrate Judge Ashman as untimely on June 8, 2010. [372] Thus, Dr. Wei's October 2009 report is the only report that is properly before the Court for consideration in this trial.

Defendants ask the Court to preclude (1) Dr. Wei from testifying at trial as to the statistical analysis set forth in his expert report; and (2) Plaintiffs from offering any evidence, testimonial or otherwise, comparing the Sprague and H-114 studies unless Plaintiffs can lay a foundation that the methodologies are the same between the two studies.[3] Defendants submit that any evidence presented on the basis of Dr. Wei's comparison of the two studies is unreliable due to the allegedly flawed methodology that he employed in his analysis, and would not be helpful to the trier of fact.

1. Dr. Wei's Testimony

As a threshold matter, Defendants do not challenge Dr. Wei's credentials as an expert in statistics; Dr. Wei holds a Ph.D. in statistics and is a tenured professor of biostatistics at Harvard University. But Defendants argue that the methodology that Dr. Wei employed in the October 2009 report, based on the data and resources available to him at the time,[4] was so incomplete that the conclusions set forth in his report are unreliable and unhelpful to the Court (as the trier of fact). In short, Defendants submit that Dr. Wei's opinions are "unscientific speculation offered by a genuine scientist." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996).

More specifically, Defendants argue that Dr. Wei's testimony must be precluded for two reasons. First, Defendants contend that Dr. Wei failed to account for the differences in the way that the Sprague and H-114 studies calculated the incidence of hypercalcemia. For example, Sprague reported the number of hypercalcemic events while PTH was suppressed, whereas H-114 reported the total number of hypercalcemic events without suppressing PTH. Second,

[3] The second prong of Defendants' motion presumably would preclude Plaintiffs' expert Dr. Langman, from offering any testimony that draws on Dr. Wei's comparison of the Sprague and H-114 studies.

[4] As Defendants acknowledge, Dr. Wei eventually was able to obtain the patient level data and clinician input that were necessary to account for the differences between the Sprague and H-114 studies and to confirm the findings in his October 2009 report. However, he was able to do so only well after submission of his initial report and the deadline for submission of expert reports in this case.

Defendants state that Dr. Wei failed to account for clinically important variables prior to arriving at his conclusion. Although Dr. Wei himself testified that when comparing "two different groups of patients on two different studies" a biostatistician should (1) "get the patient level data," (2) "talk to the clinician," and (3) "do another analysis" – a "sensitivity analysis" that incorporates the feedback from the clinician to take into account "confounders in the comparisons," Dr. Wei acknowledged that he did not complete steps (1)-(3) prior to submitting his first report. See Wei Dep. at 76-89. As a result, Defendants argue, variables such as dosage, dosing method, endpoint target levels, treatment regimens, patient demographics, and duration of treatment confounded Dr. Wei's analysis.[5] Indeed, Defendants submit that the only way to show non-obviousness based on unexpected results would be through a study conducted under completely identical conditions – *i.e.*, with no distinct variables save for the novel feature of the claimed invention.

In response, Plaintiffs contend preliminarily that Defendants' motion goes to the merits of whether the method claimed in the '116 patent had unexpected results, and as such is not a proper *Daubert* motion. Plaintiffs misconstrue Defendants' argument. The basis of Defendants' motion is not that Dr. Wei's conclusions are wrong, but rather that his methodology was so incomplete as to render unreliable any opinions that rest on his analysis. That argument is properly presented in a *Daubert* motion.

Plaintiffs also make several arguments in defense of Dr. Wei's methodology. First, they state that the Sprague and H-114 studies themselves are reputable and support Dr. Wei's

[5] Specifically, Defendants argue that six variables were unaccounted for in Dr. Wei's report: (1) the studies identified different levels of PTH as their endpoint targets; (2) the patients in H-114 experienced suspensions in their treatments, while the patients in Sprague did not; (3) dosing for the H-114 patients began at high levels and was reduced over the course of the study, whereas dosing for the Sprague patients began at low levels and was increased over the course of the study; (4) the patient demographics were similar; (5) the studies do not indicate how much phosphate binder (which changes the risk factor of hyperphosphotemia—another side effect of vitamin D treatment that was tested in the studies) was given to patients during treatment; and (6) the Sprague study provided 12-32 weeks of treatment, whereas the H-113 study provided 12 weeks of treatment.

conclusion that the claimed method of administering doxercalciferol to treat secondary hyperparathyroidism is safer, insofar as it has a lower incidence of hypercalcemia, than the prior art methods of administering calcitriol. That argument misses the point. Defendants argue not that the *source material* of Dr. Wei's analysis is unreliable, but that the statistical method that he employed in analyzing the source material was incomplete and thus unreliable. Although the studies supply the raw materials from which Dr. Wei eventually fashioned his conclusions, they are themselves insufficient to validate his methodology. Moreover, any testimony concerning the reliability of the studies themselves must come from a person with the appropriate scientific background – Dr. Langman, perhaps – not from a statistician, no matter how reputable he may be.

Plaintiffs also assert that Dr. Wei's subsequent consideration of the SAS data confirmed that the conclusion in his October 2009 report was correct. This, too, misconstrues the *Daubert* argument. It is not Dr. Wei's *conclusion* that is at issue in this *Daubert* motion – Plaintiffs correctly point out that that issue goes to the merits of the obviousness question and is not appropriate to a *Daubert* analysis. Unfortunately for Plaintiffs, by Dr. Wei's own admissions, the "conclusion" of his first report might better be termed a hypothesis, tested and proven only later in light of the SAS data and Dr. Langman's assessment.

As noted above, Dr. Wei testified that when comparing "two different groups of patients on two different studies," a biostatistician should undertake additional steps before offering an opinion that compares the studies from a statistical perspective. Specifically, Dr. Wei referenced the following additional work that should be done before the analysis is complete: (1) "get the patient level data," (2) "talk to the clinician," and (3) "do another analysis" – a "sensitivity analysis" that incorporates the feedback from the clinician to take into account "confounders in

the comparisons." Wei Dep. at 79, 85, 89. As Dr. Wei acknowledged, he did not complete those additional steps prior to submitting his report. See *id*. at 76-89. Yet, Dr. Wei also admitted that if a student submitted a similar report, it would be "incomplete" and that the additional steps should be undertaken. *Id*. at 79.

The foregoing paragraph sets up a classic illustration of the Seventh Circuit's admonition to district courts to "mak[e] sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Braun*, 84 F.3d at 234. As of the time that Dr. Wei submitted his initial report, his analysis was (by his own admission) incomplete. The steps that he omitted are ones that, by his own reckoning, a statistician would take before offering a reasoned and developed opinion on the relative incidences of hypercalcemia in the two studies at issue. The patient information that Dr. Wei needed to continue with his analysis was not available to him at the time that his report was due, apparently through no fault of his. At the end of the day, however, the only Wei report that is properly before the Court at this time rests on a fatally incomplete application of the expert's own methodology. As such, any testimony based on the report must be stricken as unreliable.

Plaintiffs have tried to salvage Dr. Wei's October 2009 report and opinion by pointing to the work of Dr. Langman, a clinical nephrologist, as confirming that Dr. Wei's conclusions had clinical relevance. For example, Plaintiffs argue that Dr. Wei properly assumed population sameness in his October 2009 comparison of the two studies (even though Dr. Wei had not consulted with Dr. Langman at the time – a step that Dr. Wei acknowledged was important to his methodology) and that Dr. Langman's subsequent assessment as to population sameness confirmed and thus justified Dr. Wei's assumption. The Court is not persuaded that Dr. Langman's subsequent work can shore up the reliability of a methodology that Dr. Wei, by his

own admission, deemed unacceptable by the standards of his field. See, *e.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004) ("an expert may not reach his conclusion first and do the research later"). To the extent that Dr. Langman's work supports an opinion that Dr. Wei arrived at reliable conclusions despite employing an admittedly incomplete methodology may speak to Dr. Wei's skill as a scientist. But it does not make his testimony as to the October 2009 report reliable. As the Seventh Circuit has observed, "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen*, 78 F.3d at 319.

2. Other Comparisons of the Sprague and H-114 Studies

Although the Court agrees with Defendants that Dr. Wei's testimony is inadmissible, the Court is not persuaded that it should go further and also grant Defendants' request to preclude all testimony or evidence drawing on the Sprague and H-114 studies.[6] While the statistical analysis employed in forming the conclusions asserted in Dr. Wei's first report fell short in regard to compliance with the statistical methodology that Wei himself would require, it is too speculative to say at this stage that any comparison of the Sprague and H-114 studies by another expert would not assist the trier of fact. For example, Plaintiffs contend that the unexpected results of claim 7, as evidenced by the comparison of the Sprague and H-114 studies, may be tested at trial through the examination of Dr. Langman. In that regard, the Court notes that Defendants have not specifically mounted a *Daubert* challenge to Dr. Langman's proposed testimony on unexpected results and it is at least conceivable that Dr. Langman's qualifications render him an

[6] Defendants submit that Plaintiffs have conceded that other evidence comparing the Sprague and H-114 studies is excludable. This is not the case. Plaintiffs argue that Dr. Langman has the clinical expertise to testify as to the unexpected results of using doxercalciferol as evidenced by the population-same studies of Sprague and H-114.

appropriate person to discuss the two studies, subject to Defendants' right to raise appropriate objections and cross-examine at trial.[7]

In sum, for the foregoing reasons, Defendants' *Daubert* motion regarding testimony and evidence pertaining to Dr. Wei's October 2009 report [345] is granted in part and denied in part.

B. Plaintiffs' Second Motion *In Limine* to Exclude Expert Testimony Regarding the Intent to Deceive Element of the Inequitable Conduct Claim and the Date of Conception of the Invention and Related Business Goals and Strategies

Plaintiffs have filed a motion *in limine* [424] seeking to exclude (1) the testimony of Defendants' expert witnesses Dr. John F. Keana, Ph.D., and Dr. Charles H. Chesnut III, M.D., as it pertains to the "intent to deceive" element of Defendants' inequitable conduct counterclaims and affirmative defenses; and (2) the testimony of Dr. Keana as it pertains to the date of conception of the '116 patent's invention (*i.e.*, a method for using doxercalciferol to treat secondary hyperparathyroidism) and related business goals and strategies. Plaintiffs contend that at least some of the proposed testimony of Drs. Keana and Chesnut relating to these issues fails to meet the standards set forth in Rule 702 and the Supreme Court's decision in *Daubert*.

1. Timeliness of the Motion

As an initial matter, Defendants urge that this motion *in limine*, which Plaintiffs filed in June 23, 2010, should be denied as procedurally improper. The Court notified both parties at the April 28, 2010, status conference that *Daubert* motions were due on May 21, 6010, 60 days before the then-set trial date in July 2010. Defendants argue that Plaintiffs' filing of the instant motion more than one month beyond that deadline contributed to the Court's decision to postpone the trial until October 2010. They further argue that this delay prejudiced them and

[7] Defendants' motion also seeks to preclude on the ground of irrelevancy Dr. Wei's testimony that the claimed invention of the '116 patent is "treatment" with doxercalciferol, rather than the compound doxercalciferol itself. The exhaustive claim construction proceedings, including the Court's revised claim construction order – issued after the instant motion was fully briefed – resolve the issue of "treatment" versus "compound." The Court therefore concludes that Defendants' argument is moot.

violated the statutory mandate that parties must reasonably cooperate to expedite this type of pharmaceutical patent case. 21 U.S.C. § 355(j)(5)(B)(iii) (requiring reasonable cooperation of parties to a patent infringement or invalidity suit involving an Abbreviated New Drug Application to the Food and Drug Administration).

Although it is true that the instant motion *in limine* was filed after the deadline for *Daubert* motions, the trial was pushed back to October for a variety of reasons that went well beyond the filing of this motion *in limine*. And it is fair to say that the volume of paper filed by both parties contributed in roughly equal measure to the postponement of the trial date. In addition, and most significantly, the postponement provided ample opportunity for Defendants to fully and fairly respond to the additional *Daubert* motion. For all of these reasons, the Court finds good cause to extend the time allowed for this motion (Fed. R. Civ. P. 6(b)), and in the exercise of its discretion will proceed with a decision on the merits of the motion.

2. Testimony Pertaining to Intent to Deceive

Defendants have proffered as testimonial witnesses under Rule 702 Dr. John F. Keana, Ph.D., an expert in synthetic and medicinal chemistry with experience in prosecuting pharmaceutical patents and consulting for and managing pharmaceutical companies, and Dr. Charles H. Chesnut, III, M.D., an expert in metabolic bone diseases. Defendants propose to elicit testimony from both experts on the issue of whether Plaintiffs engaged in inequitable conduct during prosecution of the ‘488 application (which issued as the ‘116 patent) or its ancestor applications. Specifically, Defendants intend to call Dr. Keana and Dr. Chesnut to testify on the subject of whether Plaintiffs or their agents—specifically, inventor Dr. Charles Bishop and prosecuting attorneys Theresa Welch and Carl Gulbrandsen—intended to deceive the PTO during prosecution of the patent applications.

A finding of inequitable conduct rests on proof that a patentee or its agents (including inventors and attorneys) withheld material information from the patent examiner or submitted false material information with the intent to deceive or mislead the examiner into granting the patent. See *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000). Intent to deceive is a question of fact. *Id.* (quoting *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 19996)). There are thus two substantive elements of a claim of inequitable conduct: the first is the materiality of misrepresentations, misinformation, or withheld information; the second is intent to deceive. See *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).

a. Qualifications

Plaintiffs do not contest that Dr. Chesnut and Dr. Keana are trained and qualified in their respective fields of metabolic bone diseases and synthetic and medicinal chemistry. But Plaintiffs argue that whatever the experts' scientific and medical qualifications, they lack the qualifications necessary to testify as to whether Plaintiffs or their agents had the intent to deceive the PTO during prosecution of the '488 application and its ancestor applications.

Defendants respond that Dr. Keana and Dr. Chesnut are qualified to opine on the "materiality" element of inequitable conduct as well as to "facts showing what the applicants and their prosecuting attorneys knew * * * [which] is important to the knowledge/intent element." Plaintiffs have not sought preclusion of these experts' testimony as to the materiality element, but only as to the intent-to-deceive element of Defendants' inequitable conduct claim.

With respect to Dr. Keana, Defendants state that he will testify not only on the basis of his expertise in chemistry but also on the basis of his experience as an inventor or co-inventor of

more than 70 issued or pending patent applications as well as his consulting and executive experience in the pharmaceutical industry. Defendants argue that the latter areas of expertise qualify Dr. Keana to discuss alleged inconsistencies between the inventor's affidavits and his representations to the FDA regarding the views of a person of ordinary skill in the art, and to offer an opinion based on inferences from those inconsistencies that the inventor lacked candor in his representations. Defendants contend that Dr. Keana also is qualified to describe prior art references, their relevance to the '488 and related applications, the prosecuting attorneys' and inventors' knowledge of the prior art references based on their inclusion in ancestor applications, their omission of the prior art references in the '488 application, and how narrowing the claims of the '488 application avoided the prior art.

The Court agrees that, in light of Dr. Keana's background in the sciences coupled with his experience in pharmaceutical patent prosecution, he is qualified to testify to Dr. Bishop's allegedly inconsistent representations, the relevance and inclusion or omission of the prior art references during patent prosecution, and the significance of representations made to the PTO. Dr. Keana's education, training, and experience, however, do not qualify him with the expertise to plumb the inventor's and attorneys' minds and discern whether they "lacked candor" or had actual intent to deceive during prosecution of the '488 and related applications. See, *e.g.*, *Se-Kure Controls, Inc. v. Diam USA, Inc.*, 2009 WL 77463, at *2 (N.D. Ill. Jan. 9, 2009) (holding that a patent expert is "not a mind-reader. He may not testify that he knows [patentee's] intent to hide certain information nor may he testify that he knows [patentee] lied about certain information"). The Court finds that Dr. Keana is qualified to offer evidence regarding the history of the '488 application's prosecution that may be probative to the issue of intent, but is not qualified to offer conclusions as to the existence of that intent. The Court therefore denies

Plaintiffs' motion to preclude Dr. Keana from opining on the facts relevant to the intent to deceive inquiry, but cautions that Dr. Keana must refrain from speculating as to whether the inventor or attorneys actually had such intent.

With respect to Dr. Chesnut, Defendants argue that his knowledge, research, and clinical experience in treating metabolic bone disease and osteoporosis and in the utilization of vitamin D metabolites to manage those diseases qualify him to explain the prior art references (including the Potts prior art, DeLuca '716 patent, Baggiolini patent, and the Gallagher Abstracts) and their relevance to the '488 application and its ancestor applications. The Court has no doubt that this is so given the accomplishments described in Dr. Chesnut's *curriculum vitae*. Such testimony, however, goes to the materiality element of inequitable conduct, not the intent-to-deceive element, and Plaintiffs seek to preclude Dr. Chesnut's testimony only as to the latter.

With respect to the intent-to-deceive element, Defendants fail to show that Dr. Chesnut has any of the qualifications that, for example, imbue Dr. Keana's testimony with the requisite indicia of reliability – namely, expertise in patent prosecution practice and procedure. And without such expertise, there is no basis for permitting Defendants to elicit Dr. Chesnut's testimony as to facts that pertain to the procedural background of the '488 application and its ancestor applications. In particular, Defendants have not established that Dr. Chesnut is qualified to testify about (1) whether the inventor was aware of certain prior art because he was apprised of prosecution activity; (2) whether the prosecuting attorneys should have disclosed material references in the prosecution of the '488 application in light of claims in ancestor applications that were rejected on the basis of those references (although, as stated above, he may testify to the materiality of those references); (3) why the Gallagher abstracts should have been disclosed to the PTO examiner (although he may opine on the materiality of the Gallagher

abstracts); (4) whether the inventors were in fact aware of the Potts prior art reference as evidenced by claims of a related U.K. patent application that were rejected because of Potts; (5) why the inventor may have been interested in obtaining a license from the Wisconsin Alumni Research Foundation; and (6) why the prosecuting attorneys' use of the terms "surprising," "unexpected," and "previously known" with respect to an ancestor application's prophetic example constitute a breach of candor and good faith (although he may testify to what a prophetic example is, how it is developed, and why it is useful). The Court therefore grants Plaintiffs' motion *in limine* with respect to Dr. Chesnut's testimony on the intent to deceive the PTO. The Court reiterates that Dr. Chesnut is qualified to testify to the materiality element of inequitable conduct. The Court further notes that Defendants are left with two experts, Dr. Keana and Mr. Sofocleus (see *infra* at 22-26), who are qualified to present testimony on general practices and procedures of patent prosecution as well as to the specific procedural and substantive history of the '488 application and its ancestor applications – areas that may be probative of intent to deceive the PTO.

b. Reliability

One element of the reliability analysis requires a court to "rule out subjective belief or unsupported speculation." *Cummins*, 93 F.3d at 368 (quoting *Deimer v. Cincinnati Sub Zero Prods., Inc.*, 58 F.3d 341 (7th Cir. 1995) (other citations omitted)). Plaintiffs argue that Dr. Keana's and Dr. Chesnut's testimony in regard to whether Plaintiffs and their agents had the requisite intent to deceive the PTO is conclusory and based only on their subjective beliefs. For example, Plaintiffs state, the expert reports never draw upon the deposition testimony of the '116 patent's inventors or prosecuting attorneys to support their allegations as to intent to deceive.

Because Plaintiffs' motion *in limine* is granted with respect to Dr. Chesnut based on his lack of qualifications to discuss intent to deceive the PTO, the Court here considers only the question of whether Dr. Keana's conclusions are sufficiently substantiated. Defendants contend that Dr. Keana's conclusions are amply supported, "as evidenced by at least the fact that Dr. Keana's expert and rebuttal reports total approximately 235 pages * * *." They also submit that the opinions contained in Dr. Keana's reports are based on and soundly supported by documents provided by Plaintiffs, deposition testimony, and other discovery material. Dr. Keana's testimony regarding amendments that the prosecuting attorneys made to the '488 application's claims, PTO office actions during prosecution of the '488 and related applications, and the references included in or omitted from the relevant applications will of course be based on the documented prosecution history of the applications, which has been made available to Defendants and the Court. Similarly, Dr. Keana's analysis of alleged inconsistencies in the inventor's communications with the FDA is based on his review of documents provided by Plaintiffs and available to the Court. The Court therefore deems Dr. Keana's testimony on the patent prosecution history sufficiently well founded to be presented at trial.

c. Relevance – Helpfulness to the Trier of Fact

Rule 702 bars the admission of an expert's opinions unless such opinions will assist the trier of fact in understanding the evidence or determining a fact in issue. In order to satisfy this "helpfulness" requirement, expert testimony must satisfy two elements. First, the proffered testimony must relate to a fact in issue: "expert testimony which does not relate to an issue in the case is not relevant, and, ergo, non-helpful." *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607, 613 (7th Cir. 1993) (quoting *Daubert*, 509 U.S. at 591). Second, the proffered testimony must assist the fact finder in understanding what otherwise might be outside its grasp. See *S.E.C.*

v. Lipson, 46 F.Supp.2d 758, 763 (N.D. Ill. 1998); *Sommerfield v. City of Chicago*, 254 F.R.D. 317, 329 (N.D. Ill. 2008) (holding that "[e]xpert testimony is helpful to the [trier of fact] if it concerns a matter beyond the understanding of the average person").

Plaintiffs and Defendants do not address the helpfulness prong of the *Daubert* analysis with respect to Dr. Keana's testimony. The Court determines, however, that Dr. Keana's testimony regarding prosecution of the '488 application and its ancestor applications relates to issues relevant to the inequitable conduct claim and thus may be helpful to the Court in regard to the significance of the patent prosecution procedures as they relate to the historical development of the '116 patent. The Court therefore denies Plaintiffs' motion with respect to Dr. Keana's testimony on facts probative of intent to deceive – subject to the caveat that in a bench trial the Court's duty is to assign appropriate weight to the testimony or to disregard it altogether if in hindsight the testimony is either irrelevant or unreliable. See *Metavante Corp.*, 2010 WL 3385961, at *7; *In re Salem*, 465 F.3d at 777.

3. Testimony Pertaining to the Date of Conception

Plaintiffs also move to preclude Dr. Keana from testifying to the date of conception of using doxercalciferol to treat secondary hyperparathyroidism and "related business goals and strategies." Plaintiffs contend once again that Dr. Keana is unqualified to testify as to these matters given that his expertise is limited to synthetic and medicinal chemistry. The Court provisionally rejects this argument. Dr. Keana's experience as a consultant to and executive of pharmaceutical and drug development companies makes him qualified to opine on technical and/or specialized areas of knowledge pertaining to pharmaceutical patent strategy. To the extent that further development on cross-examination reveals gaps in Dr. Keana's experience and expertise, the Court may of course give less weight to his testimony or disregard it altogether.

Plaintiffs also contend that Dr. Keana's opinions as to the date of conception of the invention and related business strategies are "wholly speculative." Defendants respond that Dr. Keana's opinions are founded on documents produced during discovery, deposition testimony of the inventors and prosecuting attorneys, and his own independent analysis of the '116 patent and its related applications.

The Court is persuaded that Dr. Keana's opinions are well founded and will be helpful to the trier of fact, subject to certain limitations. Dr. Keana may testify regarding the evolution of the Bone Care patent applications' description of the invention as using doxercalciferol to treat bone disease to using doxercalciferol to treat secondary hyperparathyroidism. He may not, however, speculate in light of this evolution as to when the idea for the latter use actually was first conceived. Dr. Keana also may testify as to Bone Care's relationships with Lunar and WARF as well as SmithKline Beecham, Takeda Chemical, Miles Pharmaceuticals, IVAX Corporation, *et al.*, in relation to the history of the '488 application and its ancestor applications. Dr. Keana may not, however, speculate as to whether those relationships had any actual bearing on how doxercalciferol's use was indicated. Subject to these limitations, the Court denies Plaintiffs' motion to preclude Dr. Keana from testifying as to facts probative of the date of conception of the invention and related business strategies.

In sum, for the foregoing reasons, Plaintiffs' motion *in limine* [424] is granted with respect to Dr. Chesnut, and granted in part and denied in part with respect to Dr. Keana.

C. Plaintiffs' Motion to Preclude Trial Testimony of Mr. Sofocleous

Plaintiffs' seventh motion *in limine* [406] seeks to bar the testimony of Defendants' expert, Michael Sofocleous, on grounds that it is unreliable and excludable under Federal Rule of Evidence Rule 702 and *Daubert*, and irrelevant and inadmissible under Rules 401 and 402. Mr. Sofocleous is a patent lawyer with experience in private patent litigation and in the prosecution of patents within the PTO. He spent more than 30 years working as a PTO examiner, a patent interference examiner for the Board of Patent Interferences, and an administrative patent judge at the Board of Patent Appeals & Interferences. Mr. Sofocleous's proposed testimony includes a description of the various sections of a patent, operations and functions of the PTO, the patent application process, the nature of the examination performed by the PTO in determining patentability, alleged defects in the prosecution of the applications leading to the '116 patent, "and why certain information not disclosed to the examiner, or concealed, was material to the prosecution of the '116 patent." (Defs. Opp. to Pls.' 7th Mot. *in Limine* at 8.)

1. Qualifications

Mr. Sofocleous acknowledges that he is not a technical expert, a medical expert, or a person of ordinary skill in the art of the subject matter at issue in the '116 patent. Defendants state that they will not elicit testimony from Mr. Sofocleous as a person of ordinary skill in the relevant art. Plaintiffs nevertheless object to Mr. Sofocleous in part on the ground that he is not qualified to offer scientific or technical testimony. In view of those limitations, Plaintiffs contend that any testimony that Mr. Sofocleous offered as to whether certain scientific references would have been considered material to the patent applications in question, whether the '116 patent's ancestor applications would have reasonably conveyed to a person of ordinary skill in

the art that the inventors possessed the invention claimed in the patent, or when the inventors first conceived of the invention would be unreliable and thus excludable under *Daubert*.

The Court agrees that Mr. Sofocleous is not qualified to offer opinions on scientific or technical matters. Apart from his undergraduate degree in the "chemical arts," he has no education or training that bears on the endocrinological or nephrological implications of the '116 patent's invention. (Defs. Opp. to Pls. 7th Mot. *in Limine* at 3). The Court therefore grants in part Plaintiffs' motion *in limine*, and bars Mr. Sofocleous from opining on scientific or technological facts at issue, including the scientific significance and materiality of prior art references and the date of conception of the invention at issue. The Court finds that Mr. Sofocleous is qualified to offer specialized knowledge as to PTO practice and procedure, the reliability and helpfulness of which are discussed more fully below.

2. Reliability and Relevance

Plaintiffs also submit that Mr. Sofocleous should be barred from testifying regarding the area in which they concede Mr. Sofocleous has professional experience: patent law. Plaintiffs premise their objections on two grounds: first, that it would be improper for Mr. Sofocleous to testify on matters of law or offer legal conclusions on matters of fact; and second, that any testimony he may seek to offer regarding the PTO procedural history of the applications leading to the '116 patent would be irrelevant because that history is plain on the face of the application documents in the record.

The Court agrees that any testimony Mr. Sofocleous might seek to offer about his conclusions of law on issues in this case are excludable. *Sommerfield v. City of Chicago*, 254 F.R.D. 317, 330 (N.D. Ill. 2008) ("expert testimony that contains a legal conclusion that determines the outcome of a case is inadmissible"); *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL

1155954, at *8 (N.D. Ill. Apr. 25, 2006) (excluding expert testimony that consisted of "plainly inadmissible legal conclusions" that "would be completely unhelpful to the fact finder"); *Clintec Nutrition Co. v. Baxa Corp.*, 1998 WL 560284, at *9 (N.D. Ill. Aug. 26, 1998) ("Legal conclusions are not admissible because they are not helpful to the trier of fact").[8] The critical issue for the parties, the Court, and the witnesses themselves to bear in mind is what the Seventh Circuit has described as the "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. The Court also bars any testimony by Mr. Sofocleous that recites or explains patent law, including the requirements of patentability under the law. *Bausch & Lomb, Inc.*, 79 F. Supp. 2d at 258; see also *Amsted Indust., Inc. v. Nat'l Castings, Inc.* 1990 WL 106548, at *28 (N.D. Ill. Jul. 11, 1990) ("it would not be appropriate for [patent law expert] * * * to discuss the law governing patent validity). Plaintiffs' motion is thus granted to the extent that Mr. Sofocleous is barred from testifying to the substance, significance, or application of patent law.

However, the Court concludes that Mr. Sofocleous's proposed testimony relating to the patent application process, the operations and functions of the PTO, and the criteria to which examiners look in assessing patentability (including obviousness, priority, etc.) are based in Mr. Sofocleous's specialized knowledge and touch on the core issues of the case. Although Plaintiffs complain that such testimony is needless since the proceedings of the patent are clear and easily understood on the face of the PTO records, the Court believes that such testimony would likely

[8] "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)); see also *Se-Kure Controls, Inc. v. Diam USA, Inc.*, 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).

be helpful. See *Bausch & Lomb, Inc.*, 79 F. Supp. 2d at 256 ("PTO procedures are foreign to the average person, and it may be helpful to the [trier of fact] to hear someone experienced in those procedures explain how they operate in terms that a layperson can understand").[9]

The Court further finds that Mr. Sofocleous may opine on the priority filing date and other issues going to the validity of the '116 patent so long as he tethers his testimony to objective facts in the record. Thus, Mr. Sofocleous may provide factual context that goes to the underlying contentions of inequitable conduct, obviousness, priority, and other key legal issues, but he may not speculate or offer his subjective conclusions on those contentions. See *Se-Kure Controls, Inc.*, 2009 WL 77463, at *2. Similarly, Mr. Sofocleous may offer any extant facts regarding acts or omissions in the applications giving rise to the '116 patent, but may not speculate as to the intent of the inventors or attorneys. See *id.* (holding that a patent expert is "not a mind-reader. He may not testify that he knows [patentee's] intent to hide certain information nor may he testify that he knows [patentee] lied about certain information"). In a similar vein, while Mr. Sofocleous may present testimony to the extent that he has a basis for opining on actual defects in the patent applications relating to the '116 patent, he will not be permitted to offer generalized testimony about potential memory problems of examiners or other non-case specific testimony "insinuating that the PTO does not do its job properly." *Bausch & Lomb, Inc.*, 79 F. Supp. 2d at 255-56 (citing *Applied Materials, Inc. v. Advanced Semiconductors Materials America, Inc.*, 1995 WL 261407, at *3 (N.D. Cal. Apr. 25, 1995)). With those caveats in mind, the Court denies Plaintiffs' motion *in limine* to the extent that it seeks to preclude Mr.

[9] Plaintiffs' expressed concerns about bias may be addressed on cross-examination and/or through Rule 403 objections.

Sofocleus from testifying as to factual matters relating to general PTO practice and procedure and the prosecution history of applications relating to the '116 patent.[10]

In sum, as stated above, Plaintiffs' seventh motion *in limine* [406] seeking to bar the testimony of Defendants' expert, Michael Sofocleous, is granted in part and denied in part.

III. Conclusion

For the reasons and to the extent stated above, Defendants' Motion to Preclude Trial Testimony of Dr. Lee-Jen Wei [345] is granted in part and denied in part; Plaintiffs' Motion to Preclude the Testimony of Michael Sofocleous [406] is granted in part and denied in part; and Plaintiffs' Motion to Preclude Defendants' Experts from Providing Speculative Testimony on the Issues of Intent for Inequitable Conduct and the Facts Supporting Date of Conception [424] is granted in part and denied in part.[11]

Dated: October 1, 2010

Robert M. Dow, Jr.
United States District Judge

[10] At the risk of stating the obvious, neither Mr. Sofocleous nor any other witness may present testimony on issues that no longer are in the case – for example, any claims of inequitable conduct as to which a motion to dismiss or summary judgment has been granted.

[11] The Court anticipates issuing written rulings in advance of trial on the following pending matters: (1) Plaintiffs' Sixth Motion in Limine to Preclude Supplemental Opinion by Donald Sherrard [403], Defendants' Objections to Magistrate Judge Ashman's July 16 Memorandum and Order [465], and Defendants' Motions to Alter or Amend the Court's Order on Plaintiffs' Motion for Summary Judgment on Affirmative Defense "D" [505, 513].