NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC., Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-cv-3770 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motions *in limine* by Eli Lilly & Co. ("Plaintiff") and Defendants Actavis Elizabeth LLC, Apotex Inc., Aurobindo, Sun Pharmaceuticals, Sandoz Inc., and Mylan Pharmaceuticals Inc. ("Defendants"). Plaintiff has filed four motions *in limine*, and Defendants have filed six.[1] This case concerns the validity and alleged infringement of U.S. Patent No. 5,658,590 ("the '590 Patent"). A bench trial is scheduled to begin on May 18, 2010.

As the Court writes for the parties, it presumes familiarity with the factual and procedural

[1] Not all Defendants joined in each of the six motions, however, the Court will refer to Defendants collectively for the purpose of this Opinion.

history of this case as recited in Eli Lilly & Co. v. Actavis Elizabeth LLC, 676 F. Supp. 2d 352 (D.N.J. 2009). The Court references only the facts and law necessary to its consideration of the motions addresses herein.

The remaining issues for trial are: **(I)** whether the '590 Patent is invalid for lack of enablement/utility; **(II)** whether the '590 Patent is invalid for obviousness; and **(III)** whether the '590 Patent is unenforceable as a result of inequitable conduct before the United States Patent and Trademark Office ("PTO"). The parties' motions *in limine* are discussed below, and are arranged according to the legal issue to which each motion pertains.

I. MOTIONS *IN LIMINE* RELATED TO ENABLEMENT/UTILITY

Defendants assert that the '590 Patent is invalid for lack of enablement. To satisfy the enablement requirement for patentability, a patent applicant must describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same," 35 U.S.C. § 112, and "the specification [must] disclose as a matter of fact a practical utility for the invention." See In re Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999). Accordingly, § 112 requires that a patent disclose the claimed invention's utility, **and** disclose to one skilled in the relevant art how to make (or in the case of a process, how to carry out) the claimed invention without undue experimentation.

Defendants argue that the '590 Patent fails to meet the enablement requirement for two reasons: first, the patent specification did not establish that the claimed method of treating ADHD had utility; second, the specification did not enable a person of ordinary skill in the art to carry out the full scope of the patent.

The parties have filed five motions *in limine* related to the issue of enablement.

A. Defendants' motion to preclude any testimony by Dr. Pliszka regarding enablement

Defendants move to preclude any testimony by Plaintiff's expert Dr. Pliszka regarding enablement. This motion is **denied**.

In response to Defendants' enablement argument, Plaintiff seeks to introduce the expert testimony of Dr. Pliszka. In his expert reports, Dr. Pliszka expressed opinions on a wide variety of issues, including the state of the art, the differences between the invention and the prior art, and the level of skill and capabilities of a person of ordinary skill in the art. Defendants argue that this testimony is primarily relevant to obviousness and, therefore, Dr. Pliszka should not be permitted to testify with respect to enablement.

Although Dr. Pliszka's testimony is directly related to Defendants' obviousness defense, some parts are also relevant to the enablement inquiry. For example, Plaintiff seeks to demonstrate utility by showing that a person of ordinary skill in the art at the time of the patent's filing would have recognized the utility of the invention in view of the specification and the prior art. See e.g., Janssen, 583 F.3d at 1327 n.12; Eli Lilly, 676 F. Supp. 2d at 371-73. The Court's enablement/utility determination, then, is based on considerations that overlap significantly with the obviousness analysis.[2] Dr. Pliszka's opinions were presented in his expert reports, and he may properly testify on matters related to the enablement inquiry.

To the extent that Defendants are concerned that certain portions of Dr. Pliszka's testimony

[2] In fact, Defendants themselves relied on the testimony of Dr. Pliszka in making their lack of enablement argument at summary judgment stage.

will exceed the scope of his expert report, they are clearly entitled to raise objections at trial.

B. Plaintiff's motion to preclude Defendants from introducing the testimony of James R. Johnson, PhD

Plaintiff moves to preclude Defendants from introducing the testimony of James R. Johnson, PhD, who will testify with respect to Defendants' second enablement argument (regarding dosage formulation). This motion is **denied**.

To provide context for Plaintiff's motion, the Court will summarize the substantive issue before the Court. Defendants' second argument as to non-enablement is that the '590 Patent is not enabled because a person of skill in the art would not have been able to practice the full scope of the patent's claims in view of the specification.[3] In particular, Defendants argue that a skilled artisan (in 1995) would be unable to determine the various effective doses for the claimed method of treatment for formulations **other than immediate-release capsules and tablets** without undue experimentation. Therefore, they contend, the patent does not disclose how to make/use the claimed invention in its entirety, and is invalid for lack of enablement.

Plaintiff responds that the '590 Patent need not teach a person of ordinary skill in the art how to make/use each claimed dosage form because creation of such forms is common knowledge. See id. (arguing that the failure to disclose how to make/use conventional dosage forms does not render a patent non-enabled "in the absence of some novel problem to be solved or effect to be obtained.")

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[3] Claim 1 of the '590 patent claims "[a] method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine." Def. Br. 565, at 21. Accordingly, because the claim does not narrowly define the particular amount of atomoxetine that must be administered, or the method of administration, Claim 1 encompasses "encompasses all dosage forms comprising any form of atomoxetine, [and] any dosing frequency." Id. at 20.

(citing Alza Corp. v. Andrx Pharms., LLC, No. 2009-1350 (Fed. Cir. Apr. 26, 2010)). Plaintiff contends that the dosage formulations need not be specifically laid out in the patent because "the development of such conventional dosage forms is well known and routine." Pl. Br. 583, at 1.

To demonstrate that the '590 Patent specification did not adequately disclose how to make/use the full scope of the patent, Defendants intend to introduce the expert testimony of Dr. Johnson. Plaintiff moves *in limine* to preclude his testimony, asserting that Dr. Johnson (1) is not qualified to testify as an expert because he is not a clinical physician, and (2) his opinions are not reliable. See In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1994) (explaining that for expert testimony to be admissible under the Federal Rules: the witness must be qualified as an expert; the expert must testify about matters requiring scientific, technical, or specialized knowledge; and the expert's testimony must assist the trier of fact.).

1. Qualifications

Plaintiff asserts that Dr. Johnson is not qualified to provide expert testimony of dose formulation because he is not a clinician. Plaintiff notes that "he is not a medical doctor, has never treated a patient with ADHD, and has never developed a dosage form for ADHD." Pl. Br. 583, at 4. Accordingly, Plaintiff argues, Dr. Johnson does not have "knowledge, skill, experience, training, or education" relevant to the evidence or facts at issue. Fed. R. Evid. 702. The Court does not agree.

The fact that Dr. Johnson is not a clinician is inapposite. Plaintiff cites no case that stands for the proposition that an expert must be a clinical physician to provide an expert opinion on dose formulation. Indeed, Plaintiff's expert is also a dosage formulation expert who does not practice clinically. See also, e.g., Alza Corp. v. Andrx Pharms., LLC, 607 F. Supp. 2d 614, 640 (D. Del. 2009), aff'd, 2010 U.S. App. LEXIS 8553 (Fed. Cir. Apr. 26, 2010) (noting the distinction between

clinicians and formulators in discussing expert testimony on dosage formulation).

Dr. Johnson's testimony, in conjunction with the expert report of Dr. Shukla (the contents of which have been adopted by Dr. Johnson), is admissible under Fed. R. Evid. 702.

2. Reliability of his Opinions

Plaintiff next asserts that Dr. Johnson's opinions are unreliable because he "did no research (in the laboratory or the library) to determine if atomoxetine had any characteristics that would create formulation problems." The Court, again, does not agree.

First, Plaintiff's characterization of Dr. Johnson's testimony as being based on "no research" is incorrect. In rendering his opinion, Dr. Johnson was informed by the characteristics of the compound in question (atomoxetine), the prior art, and—in a limited fashion[4]— by Lilly's own development efforts. See Def. Br. 604, at 14-15. Accordingly, his opinions on dose formulation, and the amount of experimentation that would be required to develop new dosages, are not mere speculation.

Next, the fact that Dr. Johnson did not conduct his own formulation experiments on atomoxetine does not render his opinion unreliable and inadmissible. Dr. Johnson in not required to conduct tests in order to properly provide expert testimony. See, e.g., Promega Corp. v. Novagen, Inc., 6 F. Supp. 2d 1004, 1030 (W.D. Wis. 1997) ("The fact that defendant's experts conducted experiments on the prior art may make their testimony more credible than plaintiffs' experts who did not recreate the prior art and rely solely on the text of the prior art and their own knowledge, but that is not necessarily so[;] Plaintiff's experts are not bound to conduct their own experiments before

[4] Defendants asserts that Plaintiff did not fully disclose evidence related to Lilly's own formulation development research. See Section I.C, infra.

giving expert testimony surrounding the significance of the prior art."); Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592 (1993) ("Unlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on first hand knowledge."). In conducting an enablement analysis, a court properly considers expert testimony as to the dose formulation process in general as well as testimony directed to the formation process for the compound covered by the patent in issue. See Alza Corp., 607 F. Supp. 2d at 656.

The Court will permit Dr. Johnson to provide expert testimony as to dose formulation in general, as well as testimony on the particular challenges faced by Lilly in developing its atomoxetine ADHD formulations.

C. Defendants' motion to preclude Plaintiff "from introducing evidence regarding Lilly's own formulation efforts to prepare any dosage forms of atomoxetine other than the immediate release atomoxetine capsules"

Defendants move to preclude Plaintiff from introducing evidence regarding Lilly's own formulation efforts to prepare any dosage forms of atomoxetine other than the immediate release atomoxetine capsules. Defendants' motion will be **granted in part**.

As noted above, see Section I.B, supra, Defendants argue that although the '590 Patent adequately discloses how to administer atomoxetine to treat ADHD using the immediate release ("IR") capsules, it fails to disclose how to use the other forms that are within the scope of the patent's claims (i.e., "injectable solutions, depot injections, suppositories and the like" and potentially "transdermal formulations, injectables, sustained-release tablets, modified-release tablets, sustained-release capsules, dispersible tablets, fast-dissolve tablets, chewable tablets, sublingual

tablets, elixirs, emulsions, aerosols, lozenges, ointments and creams."). See Def. Br. 565, at 22.[5]

Defendants argue that during document production and depositions Plaintiff did not fully disclose evidence regarding its own efforts to prepare dosage formulations for atomoxetine—specifically, evidence regarding forms other than the IR atomoxetine capsules. Such information may potentially have been relevant to Defendants' enablement defense. For instance, Defendants could show that Plaintiff's own efforts to develop various forms of atomoxetine demonstrate that "undue experimentation" is required to develop non-IR dose formulations. In so doing, Defendants would be able to show that the full scope of the '590 Patent's claimed method is not enabled.

Plaintiff responds that it disclosed a large number of documents related to "clinical trial synopses and reports, annual reports, and clinical investigation brochures, which described the bioavailability and bioequivalence studies Lilly conducted with atomoxetine capsules, tablets, oral solutions, and intravenous solutions." Pl. Br. 690, at 1. Plaintiff also asserts that it did not limit the scope of any depositions, and that Defendant was able to question a number of witnesses regarding formulations.

The Court agrees with Defendants. On a number of occasions, Plaintiff appears to have limited its document production to information regarding the IR-form of atomoxetine. See Def. Br. 573, Ex. 1, Ex. 10. Plaintiff also limited the scope of the deposition testimony provided. For instance, although Defendants requested "a witness who could testify about the research and development of all formulations of tomoxetine for ADHD," Plaintiff responded that Defendants'

[5] There is no disagreement that the '590 Patent discloses to a person of skill in the art how to carry out "a conventional immediate-release solid oral dosage tablet or capsule comprising atomoxetine hydrochloride because of certain disclosures in the prior art." Def. Tr. Br. at 21.

request was overly broad, and suggested that it would "provide **general testimony** concerning the development of formulations of atomoxetine listed in the '590 patent . . ." See Pl. Br. 609, at 5 (emphasis added).

The most critical 30(b)(6) witness that was called upon to testify with respect to formulation-related research and development was Dr. Hynes. The parties disagree as to whether Dr. Hynes was improperly prevented from presenting testimony on dosage formulation. Plaintiff asserts that at his deposition, Dr. Hynes "answered almost all formulation questions posed by defendants' counsel." The deposition transcripts, however, indicate that Dr. Hynes only provided general testimony as to the types of formulations that Plaintiff explored. When directly questioned regarding any difficulties Plaintiff had while developing such formulations—information that could be critical to Defendants' "undue experimentation" theory for lack of enablement—Dr. Hynes was largely unable to provide specifics. See Def. Br. 573 at 4, Ex. 7.

Plaintiff responds that Dr. Hynes' deposition was adequate, and observes that Defendants were able to question other witnesses with respect to formulation research. These witnesses, however, for the most part gave only general information on formulation. See Doc. No. 609, Ex. 29-31. In any case, it was Dr. Hynes who was designated to testify in response to Defendants' request that they depose an individual who had knowledge regarding "general research and development of Strattera . . . including the research and development of all formulations of tomoxetine for ADHD described in the specification and within the scope of the claims of the '590 patent." See Def. Br. 573, Ex. 5, at 2. Plaintiff responded that deposing Dr. Hynes regarding "all formulations of tomoxetine for ADHD" would be "impermissibly broad[]." See id., Ex. 6, at 2. Plaintiff asserted that Defendants request was "overbroad, unduly burdensome and not reasonably calculated to lead

to the discovery of admissible evidence . . . [and stated that, Plaintiff will only] provide general testimony concerning the development of formulations of atomoxetine listed in the '590 patent."

Plaintiff will be precluded from introducing any evidence that was not produced. The Court will not impose a blanket restriction, however, on evidence that is **within the scope** of the evidence elicited through deposition testimony and contained in documents that were produced.[6] With respect to such evidence, its admissibility will be determined on a case-to-case basis, as the Court recognizes that Defendant could potentially be prejudiced by incomplete disclosure.

D. Defendants' motion to preclude Plaintiff from introducing post-filing date test data to demonstrate utility

Defendants move to preclude Plaintiff from introducing post-filing date test data to demonstrate utility. This motion is **granted**.

This Court has already determined that Plaintiff's test data showing that the method of treatment claimed in the '590 Patent is useful are irrelevant under the circumstances of this case. See Eli Lilly, 676 F. Supp. 2d at 366-74; Eli Lilly, 2010 U.S. Dist. LEXIS 16156, at *8-12.[7] Whether the claimed method of treatment is in fact useful is not the issue before this Court—the issue here is whether such utility was properly disclosed in the patent specification to a person of

[6] The Court finds it is significant that "[D]efendants have not alleged in their motion [to exclude evidence related to formulation development] that they complained about Lilly's atomoxetine formulation document production." Pl. Br. 690, at 3. Similarly, Defendants "did not complain about the adequacy of Dr. Hynes' preparation at the deposition or afterwards." Id. at 6. As Defendants did not previously raise these issues with the Court, Plaintiff will not be entirely prevented from introducing evidence regarding Lilly's own formulation efforts to prepare any dosage forms of atomoxetine other than the immediate release atomoxetine capsules.

[7] In some cases, where a credible assertion of utility is made, pre/post filing date test data may be relied upon to bolster a patent specification's initial assertion of utility. Here, however, the '590 Patent specification made essentially no initial disclosure of utility.

skill in the art at the time of filing.

To the extent that Plaintiff seeks to introduce particular test data for the purpose of demonstrating nonobviousness (e.g., to demonstrate unexpected results, etc.), it is entitled to do so.

E. Defendants' motion to preclude Plaintiff from introducing evidence concerning IND 46,806

Defendants ask that the Court exclude all evidence regarding Investigational New Drug Application ("IND") 46,806 other than the portions of the deposition testimony of Dr. Spencer that Plaintiff designated in the Final Pretrial Order, and further, to preclude Plaintiff from offering into evidence the certified version of IND 46,086.

Defendants argue that Plaintiff violated Rule 30(b)(6) by failing to designate and prepare a corporate representative to testify as to the filing of IND 46,806, a study of the effect of atomoxetine on adults with ADHD. See Ierardi v. Lorillard, Inc., 1991 U.S. Dist. LEXIS 11887, at *3 (E.D. Pa. Aug. 13, 1991) ("Under Rule 30(b)(6), [the organization] has an obligation to prepare its designee to be able to give binding answers on behalf of [the organization]. If the designee testifies that [the organization] does not know the answer to [deposing attorney]'s questions, [the organization] will not be allowed to effectively change its answer by introducing evidence during trial. The very purpose of discovery is to avoid trial by ambush."). Defendants' Deposition Topic 18 requested testimony on, broadly, "the preparation and filing of IND 46,806." Plaintiff stated that it had no responsive information concerning the IND, and that it "objects to this Topic as overbroad and not reasonably calculated to lead to the discovery of admissible evidence." Plaintiff explained that "it is aware of the deposition testimony of Dr. Thomas Spencer concerning the preparation and filing of the IND 46,806 and beyond that, does not have any responsive information within its possession,

custody, or control **concerning the preparation and filing** of IND 46,806." Def. Br. 582, Ex. at 14. Defendants assert that, based upon this response, Plaintiff's should be preclude from introducing evidence related to (i.e., "**concerning**") the preparation and filing of the IND.

Plaintiff argues that its response to Deposition Topic 18 was more narrow than Defendants contend. Plaintiff asserts that it did not prepare or file the IND, and did not have possession of the relevant documents pertaining to the IND; accordingly, it was not required to designate a corporate witness for deposition as to the IND filing process. Moreover, Plaintiff contends that Defendants' exclusion request is overbroad, as Defendants' seek to preclude Plaintiff "from relying on evidence concerning two completely separate topics: the significance of the FDA's and MGH Institutional Review Board's ("IRB's") approvals of the Phase II study of tomoxetine for ADHD conducted at MGH." Pl. Br. 606, at 2. Plaintiff characterizes these topics as beyond the scope of Deposition Topic 18, which pertains exclusively to the filing and preparation of the IND—not the .

Based on Plaintiff's response to the 30(b)(6) request, it appears that Plaintiff should be precluded from entering into evidence testimony or documents that were "known or reasonably available" to Plaintiff. Reichhold, Inc. v. United States Metals Ref. Co., 2007 U.S. Dist. LEXIS 34284, at *3 (D.N.J. 2007). Under Rule 30(b)(6) a deponent must "make a conscientious good-faith endeavor to designate the persons having knowledge of the matters sought … and to prepare those persons in order that they can answer fully, completely, unevasively, the questions posed … as to the relevant subject matters." Harris v. New Jersey, 2007 U.S. Dist. LEXIS 61457, at *10 (D.N.J. 2007) ("The duty of preparation goes beyond matters personally known to the designee or to matters in which the designee was personally involved, and if necessary the deponent must use documents, past employees or other resources to obtain responsive information.")

On the other hand, the Court is hesitant to exclude public documents that would likely be judicially noticeable. For instance, Plaintiff seeks to introduce a number of medical ethics codes, as well as a certified version of the FDA's records concerning IND 46,806, that it refers to in support of its enablement/utility argument.[8]

With the above considerations in mind, the Court will **reserve judgment** on the admissibility of evidence related to IND 46,806.

II. MOTIONS *IN LIMINE* RELATED TO OBVIOUSNESS

A. Defendants' motion to preclude Plaintiff from introducing into evidence the "Spencer Document"

Defendants move to preclude Plaintiff from introducing into evidence the Spencer Document. This motion is **granted**.

Dr. Thomas Spencer, a physician at Massachusetts General Hospital, conducted clinical trials of atomoxetine for the treatment of ADHD. The Spencer Document is an affidavit that Dr. Spencer submitted to the Brazilian Patent Office during prosecution of the Brazilian counterpart to the '590 Patent. In relevant part, the document states that "in my opinion, the use of tomoxetine to treat attention deficit hyperactivity disorder is a pioneering advance over previous state of the art." Plaintiff seeks to introduce the affidavit to demonstrate nonobviousness by showing that the claimed treatment received scientific acclaim (an objective indication of nonobviousness).

Defendants assert that the document is inadmissible for a number of reasons, arguing that it is: opinion testimony from a fact witness, hearsay, and unauthenticated; further, they argue that it

[8] Such documents are still subject to Defendants' objections on other grounds, e.g., relevance, at trial

cannot properly be relied upon by Plaintiff's expert, Dr. Plizska.

1. *Opinion Testimony*

The Spencer Document was an affidavit filed with the Brazilian Patent Office in 2004. The letter reads, in pertinent part:

> In my opinion, the use of tomoxetine to treat attention deficit hyperactivity disorder would not have been obvious to medical practitioners from the disclosure in [a piece of prior art describing] the use of tomoxetine . . .
>
> [. . .]
>
> [I]n my opinion, the use of tomoxetine to treat attention deficit hyperactivity disorder is a pioneering advance over previous state of the art medicines used for this purpose since it is a non-stimulant, selective norepinephrine reuptake inhibitor. . . . None of the foregoing drugs, or any other drugs previously used to treat attention deficit hyperactivity disorder, is a selective norepinephrine reuptake inhibitor.

Doc. No 598, Ex. 1. This statement is made after Dr. Spencer details his credentials and describes his experience as a clinician and academic.

Defendants assert that the excepts above constitute impermissible opinion testimony, as the testimony is "based on scientific, technical, or other specialized knowledge." FED. R. EVID. 701. "[T]he Third Circuit and other courts have noted the global preclusion of any kind of lay opinion on specialized or technical subjects." See McCrary v. N.J. Transit Rail Operations, Inc., 2008 U.S. Dist. LEXIS 56719, at *10 (D.N.J. July 23, 2008)

Plaintiff responds that the document constitutes fact testimony. That is, Plaintiff argues that the letter is merely evidence of peer recognition and acclaim from a person of ordinary skill in the art, and therefore, serves as an objective indication of nonobviousness of the method claimed in the '590 Patent.

The Court agrees with Defendants. Dr. Spencer does not assert, for instance, that it is widely

held throughout the field that practitioners believe that atomoxetine is a pioneering treatment for ADHD—he states that in his summary opinion, he believes it to be pioneering because it holds a number of medical advantages over other ADHD treatments. Moreover, in a previous paragraph in the letter he opines on the legal "obviousness" of using a particular compound for a medical treatment. These opinions constitute expert testimony. Dr. Spencer has not been designated as an expert, and accordingly, has not been deposed as such.[9]

2. *Hearsay*

Defendants also asserts that the Spencer Document constitutes inadmissible hearsay. The Court agrees.

In the document, Dr. Spencer states that: "in my opinion, the use of tomoxetine to treat attention deficit hyperactivity disorder is a pioneering advance over previous state of the art." Doc. No 598, Ex. 1. Plaintiff asserts that it plans to introduce the document not to demonstrate that atomoxetine is actually a pioneering advance in treating ADHD, but rather, "to show the state of mind of a person working in the relevant field, i.e., as evidence of the belief of Dr. Spencer." The Court finds this distinction to be without merit under the circumstances here. To the extent that Plaintiff only seeks to demonstrate Dr. Spencer state of mind (to show scientific acclaim), this affidavit does not suffice. The Spencer Document is a summary opinion; indeed, Plaintiff's own expert appeared to agree that the affidavit does not constitute scientific acclaim. Accordingly, the minimal value that the affidavit has with respect to scientific acclaim is outweighed by the fact that

[9] The Court notes that Dr. Spencer was subpoenaed by Defendants, however, Plaintiff disclosed the Spencer Document.

the document essentially contains an expert opinion.[10]

3. *Reliance By Dr. Pliszka*

Plaintiff's also argue that even if the letter is inadmissible as an exhibit, it may still be relied upon by Dr. Pliszka in his expert testimony, as he relied on the document in his expert report. The Court finds, however, that the Spencer Document must still be inadmissible.

Dr. Pliszka asserted in his report that atomoxetine was the subject of scientific acclaim, and that the invention was not obvious. To demonstrate such recognition, he referenced the affidavit of Dr. Spencer. For the reasons stated above, see Section II.A.2, the Court cannot find that the document constitutes evidence of scientific acclaim. Accordingly, the only remaining use of the document (i.e., to demonstrate the truth of the matter asserted) is barred by the hearsay rule.

For an expert to properly rely on hearsay, such hearsay must be reasonably relied upon by experts in the field. See In re TMI Litig., 193 F.3d at 697. Notwithstanding Dr. Spencer's credentials, his affidavit to the Brazilian Patent Office was summary in nature, and the Court cannot find that his net opinion constitutes the type of data typically relied upon by individuals in the field. TK-7 Corp. v. Estate of Barbouti, 993 F.2d 722, 733 (10th Cir. Okla. 1993) (declining to permit an expert to rely on a hearsay statement because "the expert failed to demonstrate any basis for concluding that another individual's opinion on a subjective financial prediction **was reliable**, other than the fact that it was the opinion of someone he believed to be an expert.") (emphasis added); see also United States v. Smith, 869 F.2d 348, 355 (7th Cir. 1989) ("An expert witness may not simply

[10] The Court need not consider Defendants' argument regarding authentication, as it finds the document inadmissible on other grounds.

summarize the out-of-court statements of others as his testimony."); Total Containment, Inc. v. Dayco Prods., Inc., 2001 U.S. Dist. LEXIS 15838, at *6-7 (E.D. Pa. Sept. 6, 2001) (excluding expert opinions where the expert failed to conduct any independent research to determine the reliability of his assumptions). Moreover, through introduction of the Spencer Document, Plaintiff would be improperly introducing Dr. Spencer's expert testimony despite the fact that he was not designated or deposed as an expert in this case.

B. Defendants' motion to prevent Plaintiff from proffering any evidence of commercial success

Defendants move to prevent Plaintiff from proffering any evidence of commercial success to demonstrate that the '590 Patent is nonobvious. This motion is **denied**.

Defendants assert that "commercial success has no relevance to any issue properly before the Court because everyone except Lilly was legally barred from marketing any atomoxetine product, including an atomoxetine product to treat attention deficit/hyperactive disorder." Defendants argue that Plaintiff's sales of Strattera are, therefore, not truly indicative of commercial success. Although this argument may have some weight with respect to the sales during the period of patent exclusivity (i.e., through 1999), it does not apply to the post-1999 sales of Strattera because the period of exclusivity over atomoxetine had expired.

Under the facts here the Court finds that Defendants' arguments are more related to the weight of the commercial success evidence than its admissibility (i.e., relevance). See P&G v. Teva Pharms. USA, Inc., 566 F.3d 989, 999 (Fed. Cir. 2009) (permitting a party to introduce evidence of commercial success, even where such evidence was properly afforded **less weight** under the circumstances) (emphasis added); Ortho McNeil Pharm., Inc. v. Barr Labs., Inc., 2009 U.S. Dist.

LEXIS 62721 (D.N.J. July 21, 2009) (determining that the patent-holder "blocked competitors from entering the marketplace, and that, therefore, any inference of nonobviousness based on TCL's commercial success is weak [. . .and given] **little weight** in the obviousness inquiry.").

Accordingly, Plaintiff should not be prevented from introducing evidence of commercial success. (The Court notes that it is not clear at this time whether Plaintiff intends to set forth its argument regarding commercial success. See Section II.C, infra).

C. Plaintiff's motion to preclude Defendant from introducing the testimony of Mr. Boghigian, parts of Dr. Staller's testimony, and any related exhibits having to do with commercial success

As noted above, Plaintiff may choose not to present arguments regarding commercial success as a secondary consideration of nonobviousness in responding to Defendants' case-in-chief. In the event that it does not, it asks that the Court preclude the testimony of Mr. Boghigian, parts of Dr. Staller's testimony, and any related exhibits having to do with commercial success as irrelevant under FED. R. EVID. 401 and 402. This request is premature at this stage, and the Court will **reserve judgment** on this motion.

Plaintiff moves to exclude materials related to advertising, budgets, sales forecasts, doctors' statements concerning prescribing Strattera, discussion notes to physicians, FDA documents relating to Lilly's marketing of Strattera, and other marketing documents such as promotional materials related to Strattera. Plaintiff argues that this evidence, if relevant, is specifically relevant with respect to lack of commercial success. Plaintiff claims, then, that because it will no longer assert commercial success as part of its nonobviousness argument, Defendants' evidence pertaining to a purported lack of commercial success must be excluded as irrelevant. The Court cannot agree with Plaintiff's argument in its entirety.

Although Plaintiff contends that it will not rely on a commercial success argument, they will rely on other objective indicia of nonobviousness, such as "long felt unmet need" for the invention. Some of Defendants' evidence related to commercial success may also be relevant in rebutting that issue. Defendants, then, must be permitted to introduce any evidence necessary to rebut Plaintiff's "long felt unmet need" argument—as well as any evidence pertaining to whichever objective indica that Plaintiff relies on in support of its nonobvious argument. In short, if Plaintiff attempts to establish "commercial success" or "long felt unmet need," then Defendants may respond with appropriate evidence.

For the reasons stated, the Court cannot presently determine the relevance of the testimony of Mr. Boghigian, Dr. Staller and any related documents. Accordingly, the Court cannot determine their admissibility. As such time as Defendant seeks to introduce such evidence, Plaintiff may make appropriate objections.[11]

III. MOTION *IN LIMINE* RELATED TO INEQUITABLE CONDUCT

Defendants' final defense to infringement of the '590 Patent is that the patent is unenforceable for inequitable conduct before the PTO.

In short, inequitable conduct occurs when a patent applicant breaches his or her "duty of

[11] It is foreseeable that much of the evidence that Defendants hope to rely on to demonstrate a lack of commercial success will not be relevant to "long felt but unmet, need" argument. The Court, however, will not make an assessment as to the admissibility of all materials related to advertising, budgets, sales forecasts, doctors' statements concerning prescribing Strattera, discussion notes to physicians, FDA documents relating to Lilly's marketing of Strattera, and other marketing documents such as promotional materials related to Strattera until such time as it can determine what secondary consideration of nonobviousness Plaintiff has put in issue.

candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." McKesson Info. Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 913 (Fed. Cir. 2007). A breach of this duty constitutes inequitable conduct, which renders any resulting patent unenforceable. To establish inequitable conduct, a party must show that the patent applicant, "with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submit[ted] material false information to the PTO during prosecution." Id. Inequitable conduct, therefore, has two elements: materiality and intent.

A. Plaintiff's motion to exclude the testimony of John T. Goolkasian

Plaintiff moves to exclude the testimony of John T. Goolkasian, Defendants' expert on PTO policy and procedure. This motion is **denied**.

Plaintiff asserts that Mr. Goolkasian should not be permitted to testify. Plaintiff argues that: (1) "testimony on the legal conclusions of obviousness and inequitable conduct are not proper subjects of expert testimony"; (2) "testimony regarding the intent of . . . prosecuting attorneys . . . is improper"; (3) "Mr. Goolkasian is not competent to testify regarding issues of materiality"; (4) "testimony suggesting deficiencies or inadequacies in the patent examination process is improper"; and, (5) "[Mr. Goolkasian's] expected testimony regarding general patent prosecution procedures is unnecessary." Each argument is addressed in turn.

First, Mr. Goolkasian will not testify with respect to conclusions of law. Def. Br. 601, at 4 (stating that Mr. Goolkasian will not "testify as to any legal conclusion, only to underlying facts related to the inequitable conduct inquiry."). To the extent that his testimony contains impermissible conclusions of law, the Court will disregard such information. Plaintiff's concerns with respect to

the scope of Mr. Goolkasian's testimony are mitigated by the fact that this is a bench trial.

Second, Defendants have represented that Mr. Goolkasian will not testify as to the mental state of the attorneys who prosecuted the '590 Patent. His testimony will "relate only to facts underlying the prosecution of the patent in suit, evidence of factual inconsistencies, and a factual explanation regarding what is required to comply with the duty of candor." Id. at 4.

Third, this Court has already determined that Mr. Goolkasian is competent to testify on inequitable conduct. See Eli Lilly, 676 F. Supp. 2d at 359-61 (D.N.J. 2009); see also Nisus Corp. v. Perma-Chink Sys., 2005 U.S. Dist. LEXIS 41068, at *16 (E.D. Tenn. May 27, 2005) (noting that the "test for materiality involves whether a reasonable examiner would consider the withheld information material," and therefore, a former patent examiner may appropriately offer an opinion on the issue of materiality); Oasis Industries, Inc. v. G.K.L. Corp., 1996 U.S. Dist. LEXIS 1057, at *33 (N.D. Ill. Feb. 2, 1996) (finding three former PTO examiners with experience in examining design patents were qualified to testify regarding a reasonable examiner's opinion on materiality); Ring Plus, Inc. v. Cingular Wireless LLC, 637 F. Supp. 2d 423, 430 (E.D. Tex. 2009). The Court noted that Mr. Goolkasian "has extensive experience working at the PTO as an examiner, and in prosecuting pharmaceutical patents. Further, he has relevant academic training at the undergraduate and graduate levels." Eli Lilly, 676 F. Supp. 2d at 359-61. Mr. Goolkasian is sufficiently qualified to offer his opinion as to materiality for the purposes of the Court's inequitable conduct analysis.

As to Plaintiff's fourth and fifth arguments, while the Court agrees with Plaintiff that testimony merely as to "deficiencies or inadequacies in the patent examination process is improper," see Neutrino Dev. Corp. v. Sonosite, Inc., 410 F. Supp. 2d 529, 544 (S.D. Tex. 2006); Bausch & Lomb, Inc. v. Alcon Labs., Inc., 79 F. Supp. 2d 252, 255 (W.D.N.Y. 2000), it is inappropriate to

altogether prevent Mr. Goolkasian from providing testimony regarding PTO prosecution procedures. If expert testimony becomes cumulative or unhelpful, the Court will address that at trial. Again, due to the fact that this case will be heard without the benefit of a jury, this Court as trier of fact will have latitude as to what to consider or reject.

IV. MOTION *IN LIMINE* RELATED TO TRIAL STRUCTURE

A. Plaintiff's request that it be permitted to do a 2-hour tutorial on ADHD and provide background material.

Plaintiff asks this Court to permit its expert Dr. Pliszka to present a 2-hour tutorial on ADHD, and related background material, prior to Defendants' case-in-chief. This motion is **denied**.

The Court finds presentation of a tutorial to be unnecessary. Dr. Pliszka, one of Plaintiff's experts, will have ample opportunity to present background material as necessary when offering his expert testimony. At such time, he will be subject to cross-examination, and there will be no prejudice to Defendants.

CONCLUSION

For the reasons stated above: Defendants' motion to preclude any testimony by Dr. Pliszka regarding enablement is **denied** [Doc. Entry No. # 569]; Plaintiff's motion to preclude Defendants from introducing the testimony of James R. Johnson, PhD is **denied** [# 583]; Defendants' motion to preclude Plaintiff "from introducing evidence regarding Lilly's own formulation efforts to prepare any dosage forms of atomoxetine other than the immediate release atomoxetine capsules" is **granted in part** [# 572]; Defendants' motion to preclude Plaintiff from introducing post-filing date data to

demonstrate utility is **granted** [# 580]; the Court's judgment on Defendants' motion to preclude Plaintiff from introducing evidence concerning IND 46,806 is **reserved** [# 582]; Defendants' motion to preclude Plaintiff from introducing into evidence the Spencer Document is **granted** [# 570]; Defendants' motion to preclude Plaintiff from proffering any evidence of commercial success is **denied** [# 571]; the Court's judgment on Plaintiff's motion to preclude Defendant from introducing the testimony of Mr. Boghigian, parts of Dr. Staller's testimony, and exhibits related to commercial success is **reserved** [# 586]; Plaintiff's motion to exclude the testimony of John T. Goolkasian is **denied** [# 579]; Plaintiff's request that it be permitted to do a 2-hour tutorial on ADHD and provide background material is **denied** [# 581].

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: May 13, 2010
Original: Clerk's Office
cc: All Counsel of Record
The Honorable Mark Falk, U.S.M.J.
File