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** **AMENDED OPINION** Civil Action No. 07-cv-3770 (DMC)

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

This matter comes before the Court upon motions for summary judgment by Eli Lilly & Co. ("Plaintiff"), and by Defendants Actavis Elizabeth LLC, Apotex Inc., Aurobindo, Sun Pharmaceuticals, Teva Pharmaceuticals, Sandoz Inc., and Mylan Pharmaceuticals Inc. ("Defendants"). This case concerns the validity and alleged infringement of U.S. Patent No. 5,658,590 ("the '590 Patent").

BACKGROUND

Strattera® is the commercial name for the drug tomoxetine, which is now known as atomoxetine. The '590 Patent is a method-of-use patent which claims methods of treating Attention Deficit/Hyperactivity Disorder ("ADHD") with atomoxetine. Claim 1 of the patent covers: A

method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine. Claims 2-16 cover specific treatment plans for subtypes of ADHD, and for certain groups of patients.

Plaintiff alleges that Defendants infringed the '590 Patent when they filed Abbreviated New Drug Applications ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiff's Strattera® drug products. Defendants notified Plaintiff in separate notice letters that they intended to sell generic atomoxetine capsules. In these letters, Defendants alleged that the '590 Patent was invalid, unenforceable or would not be infringed by the sale of generic atomoxetine capsules.

Plaintiff brings this action for infringement of the '590 Patent against all Defendants. Defendants respond that Plaintiff's patent is unenforceable and/or invalid based upon: inequitable conduct before the United States Patent and Trademark Office ("PTO"); anticipation; lack of enablement/utility; obviousness. Alternatively, Defendants assert that, if the '590 Patent is enforceable, they have not infringed upon the patent's claims.

STANDARD OF REVIEW

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). The moving party bears the burden of showing either (1) there is no genuine issue of fact and it must prevail as a matter of law; or (2) that the non-moving party has not shown facts relating to an essential element of the issue for which he bears the burden. Celotex, 477 U.S. at 331. If either showing is made then the burden shifts to the non-moving party,

who must demonstrate facts that support each element for which he bears the burden and must establish the existence of genuine issues of material fact. Id. The non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, FED. R. CIV. P. 56(e), but must produce sufficient evidence to support a jury verdict in his favor. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574 (1986). The Court will consider all facts and their reasonable inferences in the light most favorable to the non-moving party. See Penn. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995).

DISCUSSION

The parties move for summary judgment on a number of grounds. Plaintiff moves for summary judgment asking this Court to find that there was no inequitable conduct before the PTO (Section I), and that the '590 Patent is not invalid based on anticipation (Sec. II). Defendants move for summary judgment asking that the '590 Patent be deemed invalid based upon lack of enablement/utility (Sec. III), and for obviousness (Sec. IV). Plaintiff and Defendants both move for summary judgment on the issue of infringement, and the Court will consider the parties' motions together (Sec. V).[1]

I. PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AS TO NO INEQUITABLE CONDUCT

Defendants assert that the '590 Patent is unenforceable because Plaintiff (i.e., patent applicants) committed inequitable conduct during the prosecution of the patent. Plaintiff denies inequitable conduct, and moves for summary judgment on this issue. For the reasons stated below, Plaintiff's motion is granted in part and denied in part.

[1] Plaintiff moves for summary judgment on infringement. Defendants move for summary judgment of no infringement. Although Defendants do not move collectively, the Court will consider the parties' arguments together.

A. Applicable Law

It is well settled that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of 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 subjects any resulting patent to nullification. 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[ed] material false information to the PTO during prosecution." Id. Inequitable conduct, therefore, has two elements–materiality and intent.

Information is material "when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1297 (Fed. Cir. 2008). However, "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000). An otherwise material reference is not material if it is merely cumulative to, or less relevant than, information already considered by the examiner. See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1577 (Fed. Cir. 1996); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).

To determine whether there is intent to deceive the examiner, courts look at all the facts surrounding an applicant's overall conduct to infer culpability because "[i]ntent rarely can be, and need not be, proven by direct evidence." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007). More than an omission of material information is necessary, "clear and convincing

evidence of conduct sufficient to support an inference of culpable intent is required." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990).

Materiality and intent are separate elements of inequitable conduct, and must each be proven by clear and convincing evidence for a patent to be rendered unenforceable. Id. Nonetheless, the showing of intent can be proportionally less when balanced against high materiality. N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987). Similarly, the showing of intent must be proportionally greater when balanced against low materiality. Id.

B. Analysis

Defendants' claim of inequitable conduct is premised upon Plaintiff's failure to disclose certain documents and information during prosecution of the '590 Patent, as well as allegedly making a misrepresentation to the PTO. Specifically, Defendants allege that Plaintiff improperly failed to disclose (1) a prior art reference concerning the compound tandamine, (2) a Patent Office Board of Appeals opinion, (3) a prior art paper titled "Effects of Antidepressants on Uptake and Receptor Systems in the Brain," and (4) contradictory statements Plaintiff made to the FDA in seeking approval to market atomoxetine; Defendants also contend that (5) Plaintiff intentionally mislead the PTO by deceptively drafting the '590 Patent's specification.[2]

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[2] In Defendants' Response to Plaintiff's Motion for Summary Judgment of No Inequitable Conduct, they contend that the patent applicants' non-disclosure of the following four references constitutes inequitable conduct: BOLDIN-WATSON AND RICHELSON, *Blockade by Newly-Developed Antidepressants of Biogenic Amine Uptake into the Rat Brain Synaptosomes*, LIFE SCIENCES, 1993, Vol. 52, pp. 1023-1059; ZAMETKIN AND RAPOPORT, *Neurobiology of Attention Deficit Disorder with Hyperactivity: Where Have We Come in 50 Years?*, J. AMER. ACAD. CHILD ADOL. PSYCHIAT., 1987, Vol. 26, 5:676-686; BALDESSARINI, *Antidepressant Agents*, CHEMOTHERAPY IN PSYCHIATRY: PRINCIPLES AND PRACTICE, 1985 Chapter 4, pp. 130-234; U.S. Patent No. 4,314,081. Defendants assert that these four references taught that there were substantial similarities between atomoxetine and tricyclic compounds (i.e., they have similar effects as to norepinephrine uptake inhibition). As discussed in Section I.B.3, infra, this

This Court will discuss the materiality and intent elements of inequitable conduct with respect to each alleged act of inequitable conduct.

1. *The Tandamine Reference*

Defendants assert that Plaintiff improperly failed to disclose material prior art. The first reference allegedly withheld was a paper reporting the results of a depression study in 1977 concerning the drug tandamine, a tricyclic antidepressant ("the Tandamine Reference").

Defendants argue that the Tandamine Reference was material because it teaches that tandamine was a tricyclic "norepinephrine reuptake inhibitor [like atomoxetine] with practically no serotonin potentiation, MAO inhibition and anticholinergic activity." Thus, Defendants argue, the study reveals that tandamine shared the characteristic of selectivity with atomoxetine, the compound utilized in the '590 Patent. Defendants argue that the reference refutes Plaintiff's statements during prosecution that "[a]tomoxetine is a highly selective and specific norepinephrine inhibitor, which is not suggested by the numerous activities of the prior art tricyclics."

Plaintiff disputes the materiality of the reference. Plaintiff argues that the reference is irrelevant because tandamine was used to treat depression, not ADHD. As such, Plaintiff asserts that the reference was not related to the patentability of the claimed method. Plaintiff also argues that,

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teaching was contained in a number of references before the patent examiner. These four references are thus cumulative, and cannot form the basis for a claim of inequitable conduct.

Additionally, Defendants assert that U.S. Patent Nos. 4,018,895, 4,194,009, and 4,626,549 were not properly disclosed. Defendants appear to dispense with arguments as to these references in their entirely, as they omitted any discussion pertaining to the patents in their Memorandum in Opposition to Eli Lilly's Motion for Summary Judgment. In any case, for the same reasons as discussed with respect to the four references above, the relevant teachings of these patents provide information that was already before the examiner.

The Court will consider the remaining five references that form the primary basis for Defendants' inequitable conduct claim.

even if relevant, the study is "less relevant" than other references, and is therefore cumulative and not material. Specifically, Plaintiff suggests that the reference "would have been far less relevant to the '590 patent Examiner than information regarding other [tricyclic compounds] that had actually been used to treat ADHA, such as desipramine."

Regarding the requisite intent to deceive the examiner, Defendants assert that Plaintiff knew of the Tandamine Reference, as it appeared in a search report conducted by the European Patent Office during the prosecution of another Eli Lilly patent application. Defendants also note that the reference was disclosed in other patent applications, including the '590 Patent's corresponding Canadian application. Defendants assert, then, that Plaintiff had a policy of disclosure that was deviated from in the prosecution of '590 Patent. Under these circumstances, Defendants argue that intent to deceive can be inferred.

Plaintiff, in response, argues that disclosure of the reference to the Canadian Patent Office does not show an intent to deceive the U.S. examiner. Plaintiff asserts that it only disclosed the document because the Canadian office specifically requested it (and, absent such a request, it would not have found disclosure necessary). Further, when submitting the Tandamine Reference to the European Patent Office, Plaintiff explained that it did not believe that the study was material. Plaintiff contends that this fact establishes its lack of deceptive intent in failing to disclose the reference.

The Court does not find summary judgment to be appropriate here. First, the fact that the Tandamine Reference might not have rendered the patent obvious does not necessarily mean that the reference is irrelevant. A reference does not have to be potentially dispositive as to the patentability of a patent claim in order to be material for the purposes of inequitable conduct. Larson Mfg. Co.

of S.D. v. Aluminart Prods., 559 F.3d 1317, 1327 (Fed. Cir. 2009) (citing Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000)). Even if the Tandamine Reference would not invalidate the patent for obviousness, it may have been relevant to a reasonable examiner, as it appears to have information potentially contradictory to Plaintiff's representations to the PTO.

Furthermore, at this stage this Court cannot find the reference to be cumulative. Simply because other materials provided to the examiner might have been more specific to the condition being treated by the claimed method (ADHD), it does not necessarily follow that references relating to depression are immaterial. See Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1575 (Fed. Cir. 1997) ("What is relevant is whether [the withheld material] discloses subject matter relevant to the examination of the . . . patent application that is not taught by the [material already before the PTO]."). The Tandamine Reference's teachings, therefore, such as those related to the selectivity of tandamine (a tricyclic antidepressant), may provide information that was not already before the examiner.[3]

A material question of fact similarly remains regarding Plaintiff's intent to deceive the examiner. Plaintiff's proffered explanation for its non-disclosure of the Tandamine Reference is partial at best. Plaintiff explains why it disclosed the reference to the Canadian Patent Office. It does not, however, explain why it disclosed the reference to the USPTO during other prosecutions, while not disclosing the study to the '590 Patent examiner. Viewing the facts in the light most favorable to the Defendants, a finder of fact could infer an intent to deceive the PTO by failing to disclose the

[3] The Court notes that the testimony of two of Defendants' own experts–doubting the materiality of the Tandamine Reference–is a relevant consideration in ultimately determining materiality and Plaintiff's intent. At this point, however, there is conflicting testimony, and the Court cannot resolve this question on summary judgment.

Tandamine Reference. The Court will not resolve the issue of intent on summary judgment. See KangaROOS U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1577 (Fed. Cir. 1985) (concluding that "intent to deceive or mislead is a genuine issue of material fact"; noting that "state of mind inquiries are rarely appropriate" at the summary judgment stage).

There are questions of fact as to the materiality of Tandamine Reference, and Plaintiff's intentions in failing to disclose the reference. Plaintiff's motion for summary judgment of no inequitable conduct as to the Tandamine Reference is denied.

2. *The Board of Patent Appeals and Interferences Opinion*

Defendants assert that Plaintiff committed inequitable conduct by failing to disclose a relevant Board of Patent Appeals and Interferences ("BPAI") decision that was issued during the prosecution of another patent ("the '985 Patent").

The '985 Patent pertains to a method of treating incontinence with tomoxetine. During the '985 prosecution, the examiner initially rejected the claims, reasoning that "tomoxetine was known in the prior art to inhibit norepinephrine uptake" and "the inhibition of norepinephrine uptake (by tricyclic antidepressants) was known in the prior art to control incontinence." Similarly, here, in the prosecution of the '590 Patent, the examiner initially rejected Plaintiff's claims because "tomoxetine was known in the prior art to inhibit norepinephrine uptake" and "the inhibition of norepinephrine uptake (by tricyclic antidepressants) was known in the prior art to treat ADHD." Defendants assert that the two patents' claims were substantially similar, and therefore a rejection by the '985 examiner would be material to the '590 examiner. Defendants' expert, Dr. John T. Goolkasian, asserted that

the examiner would have considered the adverse BPAI decision to be material.[4]

Plaintiff denies that the BPAI decision was material, and relies on the testimony of Dr. Craig W. Berridge and Dr. Floyd R. Sallee–Defendants' experts. Plaintiff asserts that, in light of the experts' testimony, the reference would not have been considered prior art for the purposes of determining the patentability of the claimed method. Further, Plaintiff argues that Dr. Goolkasian is not qualified to render an opinion on materiality, as he is not a person of ordinary skill in the art. Accordingly, Plaintiff argues, there is no conflict in testimony, and no genuine issue of material fact.

The Court cannot grant Plaintiff's motion for summary judgment of no inequitable conduct as to the non-disclosure of the '985 Patent's adverse BPAI decision. The testimony of Dr. Goolkasian regarding the materiality of the BPAI decision creates a material issue of fact. See 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).[5] Dr. Goolkasian has extensive experience working at the PTO as an examiner, and in prosecuting

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[4] Defendants also assert that Plaintiff's expert Dr. Steven R. Pliszka implied that the decision would be relevant. The Court does not agree that the testimony cited by Defendants stands for such a proposition.

[5] These cases are distinguishable from cases wherein a party's patent law expert does not have significant background in the relevant art. See, e.g., Pharmacia Corp. v. Par Pharm., Inc., 2004 U.S. Dist. LEXIS 30988 (D.N.J. Feb. 18, 2004) (determining that a patent law expert, who had no technical expertise in the relevant art, was not qualified to opine as to materiality).

pharmaceutical patents. Further, he has relevant academic training at the undergraduate and graduate levels. Dr. Goolkasian is sufficiently qualified to offer his opinion as to the materiality of the BPAI decision for the purposes of the Court's inequitable conduct analysis.[6]

As there is conflicting expert testimony as to the materiality of the BPAI opinion, summary judgment is inappropriate. See Metro. Life Ins. Co. v. Bancorp Servs., L.L.C., 527 F.3d 1330, 1338-39 (Fed. Cir. 2008) (holding the "conflict in [expert] declarations created a genuine issue of material fact that made summary judgment inappropriate"); In re Gabapentin Patent Litig., 2005 U.S. Dist. LEXIS 37654, at *13 (D.N.J. Aug. 25, 2005).

Plaintiff's motion for summary judgment of no inequitable conduct is denied as to its non-disclosure of the BPAI opinion.

3. *The Fuller and Wong Paper*

Defendants assert that a paper titled *Effects of Antidepressants on Uptake and Receptor Systems in the Brain* by Fuller and Wong ("FULLER AND WONG") contradicts statements Plaintiff made to the examiner in obtaining the '590 Patent. Accordingly, Defendants argue that nondisclosure of the article constitutes inequitable conduct.

The FULLER AND WONG article contains a number of statements regarding the pharmacological effect of desipramine and other tricyclic antidepressants. Based on these statements, Defendants assert that the effects of desipramine are substantially similar to atomoxetine,

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[6] Admittedly, Dr. Goolkasian is not a person of ordinary skill in the art. Moreover, Defendants' two technical experts do not appear to be in complete agreement with Dr. Goolkasian–in fact Dr. Berridge squarely disagrees. These facts are highly relevant to the weight to be given to Dr. Goolkasian's opinion; however, they do not altogether prevent him from opining as to the materiality of the reference. See Nisus, 2005 U.S. Dist. LEXIS 41068, at *14-20.

and Plaintiff's attempt to distinguish the two compounds (to prevent the patent application from being denied as obvious) was disingenuous. Defendants, then, contend that the article was not disclosed in an effort to deceive the patent examiner. Defendants cite to two statements, in particular, that they believe contradict Plaintiff's arguments before the examiner. The statements are: "Compounds that inhibit norepinephrine reuptake but not dopamine or serotonin uptake include desipramine, protriptyline, maprotiline, nisoxetine and tomoxetine"; and, "There seems to remain a reasonable basis for expecting that monoamine uptake inhibition is a primary action of some antidepressant drugs that is relevant to their therapeutic use." Defendants assert that these statements evidence the similarities between desipramine and tomoxetine–similarities that Plaintiff tried to downplay in order to obtain its patent. Moreover, Defendants argue that even if teachings similar to those contained in FULLER AND WONG were disclosed in references before the examiner, they are presented in a more straightforward manner in this reference.

Plaintiff responds that the information contained in FULLER AND WONG is cumulative of material already before the examiner, and is thus not material. See Elk Corp. v. GAF Bldg. Materials Corp., 168 F.3d 28, 31 (Fed. Cir. 1999). Plaintiff argues that it provided statements to the examiner that were substantially similar to the statements Defendants cite, for instance: "Tomoxetine and the tricyclic antidepressants share the ability to inhibit the reuptake of the neurotransmitter norepinephrine"; "[T]omoxetine, imipramine, and desipramine selectively inhibited the depletion of norepinephrine"; "[Desipramine] has relatively high selectivity against neuronal uptake of norepinephrine"; and, "Duloxetine resembles . . . tomoxetine, desipramine . . . in antagonizing the depletion of cortical norepinephrine but not the depletion of striatal dopamine." Plaintiff argues that these teachings are akin to those of FULLER AND WONG, and therefore render the reference

cumulative.

The Court agrees with Plaintiff. The above-excerpted quotations illustrate that teachings substantially similar to those in FULLER AND WONG were before the examiner. Defendant Sun's expert, Dr. Sallee, confirms this conclusion. In his report, he opined that "[b]oth desipramine and tomoxetine are characterized in the literature as selective inhibitors of norepinephrine uptake." To support this opinion, Dr. Sallee cited BOLDEN WATSON 1993, WONG ET AL. 1982, and FULLER AND WONG 1985, among other sources. This indicates that he read the three cited references to stand for the same proposition. Defendants cannot now claim that the absence of one of these articles was a non-cumulative, material reference.

To the extent that Defendants suggest that the teachings were presented in a more straightforward way in FULLER AND WONG, that is inapposite. See Regents of the Univ. of Cal., 119 F.3d as 1575. To determine whether a reference is material to an examiner, "[w]hat is relevant is whether [a reference] discloses subject matter relevant to the examination of the . . . patent application that is not taught by the [references before the examiner]."[7] Here, the relevant teachings were presented to the examiner, and thus any article containing the same information is cumulative.

The sources disclosed to the examiner provided the relevant information contained in FULLER AND WONG. The reference is cumulative, and therefore not material.

Plaintiff is entitled to summary judgment on Defendants' claim of inequitable conduct for failing to disclose FULLER AND WONG.

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[7] Defendants argue that by not disclosing FULLER AND WONG, in effect, Plaintiff made it more difficult for the examiner to make a determination on patentability. However, this argument does not have any bearing on whether the material contained in FULLER AND WONG is non-cumulative and thus material.

4. *Plaintiff's Statements to the FDA*

Defendants next assert that Plaintiff improperly failed to disclose statements that it made to the FDA to the patent examiner.

Defendants argue that Plaintiff's statements to the FDA were material because they conflicted with statements Plaintiff made to the PTO in support of the '590 Patent application. Specifically, Defendants claim that Plaintiff emphasized the similarities between tomoxetine and desipramine to get FDA approval to conduct clinical studies, as desipramine was known to be effective in treating ADHD. Defendants argue that Plaintiff, in contrast, emphasized differences between the two compounds to the PTO to obtain its patent (i.e., to distinguish tomoxetine from the prior art). Defendants also assert that Plaintiff's contradictory representations to the FDA and the PTO permit an inference of Plaintiff's intent to deceive. This Court disagrees, and finds that Plaintiff did not engage in inequitable conduct by failing to disclose its statements to the FDA.

In 1995, Plaintiff represented to the PTO that although tomoxetine shared similarities with prior tricyclic compounds such as desipramine, the way that desipramine worked to treat ADHD was unknown. Plaintiff averred that the two compounds both operated to treat ADHD, and that desipramine appeared to be less selective than tomoxetine. Subsequently, in its 1997 Rational Statements to the FDA, Plaintiff noted that the two compounds may be similar in their effect, and that they both operate by blocking norepinephrine reuptake. The FDA statement can not be a material omission, because, as noted above, Plaintiff provided the examiner with a number of references that discussed the similarities between tomoxetine and desipramine. Notably, the references indicated that both compounds are similar with respect to norepinephine reuptake inhibition. See Section I.B.3. Additionally, as Dr. Sallee's report confirms, the examiner had

multiple references indicating that this norepinephrine inhibition function was relevant to ADHD treatment. See Expert Report of Dr. Floyd R. Sallee, ¶ 50. Plaintiff's statements to the FDA are not material in light of substantially similar information already before the PTO.[8]

Moreover, the Court notes that Plaintiff had additional information when it made its Rationale Statements to the FDA in 2007–namely, the results of an atomoxetine clinical study which Defendants' own expert, Dr. Berridge, characterized as "compelling" and "further support[ing] the idea that selective norepinephrine reuptake activity is the key to desipramines's action." Plaintiff, therefore, had further reason to believe that there were substantial similarities between the operation of tomoxemtine and desipramine based upon studies conducted **after** it made its disclosures to the patent office.

In short, Plaintiff acknowledged similarities between atomoxetine and desipramine, while at the same time emphasizing certain distinctions and/or uncertainties which would favor patentability. This is proper. See Young v. Lumenis, Inc., 492 F.3d 1336, 1349 (Fed. Cir. 2007) ("When an examiner has the references to refer to during a patent examination, he is free to reach his own conclusion in the face of attorney argument, attempting to distinguish the claims from the prior art."); Bayer Schering Pharma AG v. Barr Labs., Inc., 2008 U.S. Dist. LEXIS 15917, at *151 (D.N.J. Mar. 3, 2008), aff'd, 575 F.3d 1341 (Fed. Cir. 2009) ("An applicant's arguments supporting its patent application do not constitute inequitable conduct when the examiner has the prior art

[8] Defendants assert that Plaintiff impermissibly failed to disclose material information to the patent examiner. They, again, argue that "multiple references with consistent teachings [are] not cumulative [for the purposes of determining materiality] if to disprove a reference with contradictory teachings." Defendants' Brief in Opposition to Plaintiff's Motion for Summary Judgment of No Inequitable Conduct, at 23-24. Defendants provide no support for this assertion, and the Court will not depart from its materiality analysis above. See note 7, supra, and accompanying text.

before him throughout the prosecution and, despite the applicant's attempt to distinguish that prior art, [t]he examiner was free to reach his own conclusion regarding [the prior art].") (internal citations omitted). Here, there was no material (i.e., non-cumulative) information withheld from the examiner.

For the reasons stated, Plaintiff's motion for summary judgment of no inequitable conduct for not disclosing the Rationale Statements it made to the FDA to the patent examiner is granted.

5. *Plaintiff's Drafting of the '590 Patent's Specification*

Defendants' final basis for its inequitable conduct claim is Plaintiff's use of prophetic language in the specification of the '590 Patent.

The '590 Patent does not include any experimental data or examples demonstrating the claimed benefits of using atomoxetine to treat ADHD. Nonetheless, Plaintiff used present tense language in the patent specification to describe the "superiority" and "efficacy" of the compound. Defendants assert that this constitutes inequitable conduct, as it would lead a patent examiner to believe that testing had already taken place. This Court disagrees.

Prophetic language in a patent is permissible. See Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1376 n.1 (Fed. Cir. 2003) ("Prophetic examples are set forth in the present tense to indicate that they were not carried out.") (internal citation omitted); Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1364-68 (Fed. Cir. 2003) (distinguishing between examples set out in the past tense and prophetic examples permissibly set forth in the present tense). Here, Plaintiff properly used the present tense in drafting the patent specification.

Although Defendants argue that a patent examiner would have been mislead by the patent's

language, the testimony of their own expert does not confirm this assertion.[9] Plaintiff did not commit inequitable conduct by using present tense language in the '590 Patent specification

Plaintiff's motion for summary judgment as to no inequitable conduct is granted as to its drafting of the '590 Patent specification.

II. PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON ANTICIPATION

Defendants initially asserted that the '590 Patent was invalid as anticipated by a piece of prior art, the Chouinard reference ("CHOUINARD"). Plaintiff moves for summary judgment, asking the Court to find no anticipation. Plaintiff also contends that the Court should rule on the issue of anticipation in this case more generally. For the reasons stated below, Plaintiff's motion is granted.

A. Applicable Law

A patent may be invalidated as anticipated if the claims of the patent are disclosed in a prior art reference. Anticipation is governed by 35 U.S.C. § 102 which states:

> A person shall be entitled to a patent unless . . .
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

35 U.S.C. § 102.

Anticipation requires that a single prior art reference discloses "each and every feature of the claimed invention, either explicitly or inherently." Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1375 (Fed. Cir. 2006), cert. denied, 128 S. Ct. 146 (2007); see also Telemac Cellular

[9] Dr. Goolkasian indicated that patent applicants often submit test data at the time of application, if such data is available. Goolkasian Dep. Tr. at p. 201-02. Accordingly, it does not follow that a patent examiner would assume that Plaintiff had data from clinical tests, as Defendants contend.

Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327 (Fed. Cir. 2001). Here, Defendants do not allege that any reference explicitly anticipated the '590 Patent, so the Court will only discuss inherent anticipation.

"Under the principles of inherency, if [a piece of] prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (unpublished). That is, the prior art reference **must** encompass the claims of the anticipated invention. It is not sufficient that the invention **could** fall within the scope of the anticipatory reference–probabilities and possibilities cannot establish inherency. Id. The anticipatory reference must also sufficiently describe the claimed invention such that a person of ordinary skill in the field could combine the description of the invention in said reference, with that person's own knowledge, to make the claimed invention. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1055 (Fed. Cir. 2003).

"Anticipation is a question of fact. However, without genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law." SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005).

B. Analysis

Defendants initially asserted that the '590 Patent was invalid as inherently anticipated by the CHOUINARD publication. The publication describes a clinical study wherein atomoxetine (the active ingredient in Plaintiff's patent) was administered to patients to treat depression. Defendants now concede that the publication does not anticipate Plaintiff's patent.[10] A dispute remains, however, as

[10] Defendants do not dispute Plaintiff's motion for summary judgment as to no anticipation by the CHOUINARD publication. The Court will not detail the parties' arguments on this point.

to whether summary judgment should be granted on the anticipation defense in this case more generally.

Defendants contend that although CHOUINARD does not anticipate the '590 Patent, there may be other Eli Lilly studies that can support an anticipation defense. Defendants argue, in their Opposition to Plaintiff's Motion for Summary Judgment, that "[i]f [the disclosed studies] indicate that each and every element of at least one of the claims of the '590 patent were met, this **could** serve as a reliable basis for an inherent anticipation defense." Defendants' Brief at 5 (emphasis added). They go on to assert that "[i]t is **likely** that at least one patient in one of [the disclosed studies] suffered from ADHD" and this fact, therefore, may support an anticipation defense. Id. (emphasis added).[11] Defendants' prediction as to the likelihood of ADHD in one of the patients treated in the depression studies in inapposite. It is well-settled that invalidity based on anticipation requires more than a showing of possible, or even probable, anticipation. See MEHL/Biophile Int'l Corp., 192 F.3d at 1365. Accordingly, Defendants' predictions in their Opposition Brief are insufficient to withstand summary judgment. See Celotex Corp. v. Catrett, 477 U.S. at 322 (party opposing the motion for summary judgment bears the burden of responding after the moving party has met its burden). The Court finds that Defendants' arguments regarding anticipation are insufficient to withstand summary judgment.

The Court must also decide whether Defendants should be permitted to introduce new arguments regarding an anticipation defense if new facts pertaining to such arguments are discovered. Defendant's urge that more time is needed before making a final determination, as

[11] Defendants, then, essentially urge that Plaintiff's summary judgment motion should be limited in scope. For the reasons stated below, the Court disagrees.

support for their anticipation defense may arise after further document review. The Court disagrees. The documents concerning these other studies have already been provided to Defendants. In fact, the documents were made available in November/December of 2008, and electronic versions were subsequently provided to Defendants in January and February 2009. On June 15, 2009, Plaintiff moved for summary judgment on anticipation. Defendants filed their response on July 8, 2009. Plaintiff's summary judgment motion was filed more than seven months after Defendants had access to and/or possession of the documents related to their anticipation defense. If, as Defendants assert, they were still reviewing the discovered documents when Plaintiff's motion was filed, Defendants' proper course of action would have been to file an affidavit pursuant to Rule 56(f). Such an affidavit requires that a party identify "with specificity what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained." Bradley v. United States, 299 F.3d 197, 206 (3d Cir. 2002); St. Surin v. Virgin Islands Daily News, Inc., 21 F.3d 1309, 1314 (3d Cir. 1994); Haddonbrook Assocs. v. GE, 2009 U.S. Dist. LEXIS 20783, at *16-17 (D.N.J. Mar. 13, 2009) (rejecting plaintiff's argument that a summary judgment motion was premature where plaintiff's "counsel [argued that it had] not yet had the opportunity to review the entirety of the documents Defendant produced in response to Plaintiff's discovery requests" where Plaintiff failed to file a 56(f) affidavit). "[I]n all but the most exceptional cases, failure to comply with Rule 56(f) is fatal to a claim of insufficient discovery." Bradley, 299 F.3d at 207. Defendants have had ample time to file a Rule 56(f) affidavit, and have not done so. Defendants may not present new arguments on anticipation.

For the reasons stated, Plaintiff's motion for summary judgment as to no anticipation is granted.

III. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON ENABLEMENT

Defendants assert that the '590 Patent has failed to meet the enablement requirement of 35 U.S.C. § 112, and is thus invalid. More specifically, Defendants argue that Plaintiff did not properly establish that the claimed method of treating ADHD has utility. As lack of utility renders a patent not enabled, Defendants ask this Court to grant summary judgment as to the invalidity of the patent.

By way of background, the Court notes that before filing the '590 Patent application on January 11, 1995, Plaintiff began to work with Dr. Joseph Biederman and Massachusetts General Hospital ("MGH") to conduct a double-blind, placebo-controlled clinical trial on the use of atomoxetine to treat ADHD (the "Lilly/MGH study"). Preparations for the first clinical trial to test atomoxetine for the treatment of ADHD began before the filing date of the '590 Patent application, although the first patient to take atomoxetine in connection with the trial did so shortly after the '590 Patent application was filed. Plaintiff had gathered the results by May 1995, when MGH sent Dr. Heiligenstein (the patent's co-inventor) a report of the study. Plaintiff later performed phase II and III clinical trials, successfully using atomoxetine to treat ADHD patients, and resulting in FDA approval. It is undisputed that the '590 Patent did not disclose any test data indicating that atomoxetine is useful in treating ADHD. Plaintiff and Dr. Heiligenstein, however, had human clinical data supporting and confirming the asserted utility of the patent in May 1995, approximately five months after the '590 Patent application was filed in January 1995.

Defendants ask the Court to find that the '590 Patent specification did not establish utility, and that the patent is, therefore, invalid for lack of enablement. Defendants contend that the specification fails to establish utility because: (1) Plaintiff did not submit test results showing that atomoxetine could be used to treat ADHD; and (2) a person of ordinary skill in the art at the time

of filing would not have recognized the claimed method's utility by reading the specification of the '590 Patent. Plaintiff responds that post-filing date evidence confirms the utility of the invention, and a person of ordinary skill in the art would have recognized the utility of the '590 Patent in view of the specification.

A. Applicable Law

To satisfy the enablement requirement for patentability, a patent applicant must describe the manner of making and using 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." Id. The enablement requirement of § 112, "incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." See In re Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999); In re Schoenwald, 964 F.2d 1122, 1124 (Fed. Cir. 1992). The Federal Circuit has explained:

> The enablement requirement of 35 U.S.C. § 112, requires that the specification adequately discloses 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. The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement.

Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed. Cir. 1999). Therefore, if an applicant presents no evidence "to demonstrate that the claimed products [or methods] have . . . [the stated] effects, an applicant has failed to demonstrate utility and therefore cannot establish enablement." Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1322 (Fed. Cir 2005).

The utility requirement prevents parties from patenting a mere research proposal or an invention that is simply an object of research. Janssen Pharmaceutica N.V. v. Teva Pharms. USA,

Inc., 583 F.3d 1317, 1324 (Fed. Cir. 2009). A process or product "which either has no known use or is useful only in the sense that it may be an object of scientific research" is not patentable. Brenner v. Manson, 383 U.S. 519, 535 (1966); In re Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005).

Enablement is determined as of the effective filing date of the patent application. Janssen, 583 F.3d at 1323 (quoting Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339 (Fed. Cir. 2003)); see also In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995); In re Glass, 492 F.2d 1228, 1232 (CCPA 1974) (noting that enablement, or utility, is determined as of the application filing date).

The utility requirement for patentability in the context of medical treatments has been developed in Federal Circuit case law. "Typically, patent applications claiming new methods of treatment are supported by test results." Janssen, 583 F.3d at 1324. However, "human trials are not required for a therapeutic invention to be patentable, [as] results from animal tests or in vitro experiments may be sufficient to satisfy the utility requirement." Id. For example "in vitro test results for a claimed pharmaceutical compound, combined with animal test results for a structurally similar compound, [may] show[] a reasonable correlation between the disclosed in vitro utility and an in vivo activity." Id. Therefore, "a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence." Id.

There is little guidance in the case law regarding whether utility can be established absent test data. The Federal Circuit decision in Janssen Pharmaceutica N.V. v. Teva Pharms. USA, Inc. (In re '318 Patent Infringement Litig.), 583 F.3d 1317, 1324 (Fed. Cir. 2009), however, is instructive. The Court assessed whether a patent applicant can demonstrate utility for a method-of-use patent covering a medical treatment without providing in vitro or animal tests with its patent application.

As the Janssen Court confronted a scenario legally and factually similar to this case, this Court will discuss the decision at length.

The Janssen case concerned U.S. Patent No. 4,663,318 ("the '318 Patent"), which was owned by Janssen Pharmaceutica. Teva Pharmaceuticals challenged the '318 Patent's validity on several grounds, including obviousness and enablement. The patent claimed a method for treating Alzheimer's disease with galantamine.[12] The '318 Patent application was filed on January 15, 1986. Id. at 1320. At the time of the application's filing, researchers had observed a correlation between Alzheimer's disease symptoms and a reduced level of the neurotransmitter acetylcholine in the brain. Id. It was also known that the compound galantamine inhibited acetylcholinesterase, an enzyme that breaks down acetylcholine. Id. at 1320. Therefore, acetylcholinesterase inhibitors like galantamine increase the amount of acetylcholine available for binding to muscarinic or nicotinic receptors. Id. at 1320-21. The patent applicants argued that reducing the level of acetylcholinesterase with galantamine, then, could potentially be useful in treating Alzheimer's disease by increasing levels of acetylcholine in the brain.

The '318 Patent specification disclosed six papers that reported various effects of administering galantamine. Id. at 1321. Four of the papers discussed the compound's effect in animal studies relating to memory, and two suggested that galantamine was also able to have certain effects on the human brain. Id. Based on this prior art, Janssen reasoned that galantamine could be used to treat memory loss in humans with Alzheimer's disease. Id. at 1326. Although specific tests

[12] Claim 1 is representative. The claim covers "[a] method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galantamine or a pharmaceutically-acceptable acid addition salt thereof."

were not carried out to show galantamine's effect in treating Alzheimer's disease, the specification cited a seventh paper which set forth a model through which researchers could test acetylcholine's impact on memory and Alzheimer's-related cognitive functions. The test would hypothetically track the effect increased levels of acetylcholine (through the administration of galantamine) could have on Alzheimer's symptoms. Id. at 1321-22. As the Federal Circuit noted, however, "the specification did not refer to any **then-existing** animal test results involving the administration of galantamine in connection with this animal model of Alzheimer's disease." Id. at 1322 (emphasis added).

The '318 Patent issued on May 5, 1987. Id. Although, during prosecution, there was an initial rejection based on indefiniteness and obviousness, the examiner never rejected the application for lack of enablement. Id. In response to the initial rejection, though, the applicant stated that "experiments [are] underway using animal models which are expected to show that treatment with galantamine does result in an improvement in the condition of those suffering from Alzheimer's disease," and that it was "expected that data from this experimental work will be available in two to three months and will be submitted to the Examiner promptly thereafter." Id. The applicant did not receive "the results of the animal testing experiments–which suggested that galantamine could be a promising Alzheimer's disease treatment–until July 1987, after the '318 Patent had issued." Id.

In February 2005, Janssen sued several manufacturers for infringing the '318 Patent. Id. at 1323. A bench trial was held in May 2007 on the issues of anticipation, obviousness and enablement. Id. The District Court concluded that the '318 Patent was invalid for lack of enablement for two reasons. Id. The Court found that the specification did not demonstrate utility because (1) relevant animal testing experiments were "not finished . . . by the time the '318 patent was allowed" and (2) the specification provided only "minimal disclosure" of utility. Id. The

Federal Circuit affirmed. Id. at 1327.

Regarding the Janssen court's first basis for its holding (i.e., the lack of completed test experiments), the Federal Circuit observed that

> [t]ypically, patent applications claiming new methods of treatment are supported by test results. But it is clear that testing need not be conducted by the inventor. In addition, human trials are not required for a therapeutic invention to be patentable.
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> . . .
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> We have held that results from animal tests or in vitro experiments may be sufficient to satisfy the utility requirement.
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> . . .
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> In this case, however, neither in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions were provided. The results from the '318 patent's proposed animal tests of galantamine for treating symptoms of Alzheimer's disease were not available at the time of the application, and the district court properly held that they could not be used to establish enablement.

Id. at 1324. The Court did not find Janssen's post-filing date testing to be sufficient to satisfy the enablement requirement, despite the fact that the test results became available prior to the issuance of the patent. Id. at 1325. The Court was not persuaded by the fact that the PTO was made aware of ongoing tests during prosecution of the patent–and noted that, in any case, the results were never submitted to the PTO. Id. at 1325 & n.7.

As Janssen did not have timely test results to establish utility, Janssen also argued that through analytical reasoning based on the patent specification, utility could be established. Id. at 1326. Janssen's rationale was as follows: (1) galantamine has positive memory-related effects on animals, (2) galantamine was shown to produce activity in the human brain, (3) galantamine would, therefore, produce memory-related effects in the human brain, and (4) galantamine would be efficacious in treating Alzheimer's. See id. The Court rejected this argument. Id. at 1327.

The Federal Circuit observed that it was not aware of a single case where utility was

established solely by analytical reasoning. Nonetheless, the Court did not outright reject the possibility that under the appropriate circumstances analytical reasoning could suffice. Id. at 1326.[13] The Janssen Court assessed whether a person of skill in the art would have a reasonable expectation that galantamine would be effective in treating Alzheimer's Disease in light of the '318 Patent's specification. Id. at 1322.

To determine whether utility could be inferred from the specification, the Janssen Court considered the testimony of the parties' expert witnesses. Plaintiff's own witnesses indicated that a person of skill in the art would not have a reasonable expectation that galantamine would be effective in treating Alzheimer Disease. Id. Specifically, the Court noted a statement of the patent's inventor, Dr. Bonnie Davis, in response to the obviousness rejection before the PTO. Id. With regard to the prior art studies cited in the specification showing galantamine's ability to reverse amnesia in normal rats, Dr. Davis opined that "[n]othing in this teaching leads to an expectation of utility against Alzheimer's disease." Id. Janssen's other expert, Dr. Raskind, testified that studying a compound's effects on amnesia "ignores the whole other [nicotinic] part that's damaged in Alzheimer's disease" and thus "doesn't mimic Alzheimer's disease." Id. Both witnesses, then, asserted that it was unforeseeable that galantamine could be used to treat Alzheimer's Disease. The Court relied on this testimony to determine that utility could not be established by patent's

[13] The Manual of Patent Examining Procedure ("MPEP"), states that establishing "a reasonable correlation between" a compound's activity and its asserted therapeutic use may involve "statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof." Id. at 1326 n.10 (quoting MPEP § 2107.03). The Janssen Court noted that although "[t]he MPEP and [PTO Utility] Guidelines are not binding on this court, [it] may be given judicial notice to the extent they do not conflict with the statute." Id. (citation omitted).

specification. See id. The Court found that the conclusion that galantamine would be beneficial in treating Alzheimer's was "nowhere described in the specification[; n]or was there evidence that someone skilled in the art would infer galantamine's utility from the specification." Id. at 1326.

In light of the similarities between Janssen and the case here, this Court has referred to the Janssen case extensively in the following Analysis section.

B. Analysis

1. *Clinical Test Results Establishing the Utility of the Claimed Invention*

Defendants first argue that the '590 Patent's specification fails to establish utility because Plaintiff did not submit test results showing that atomoxetine could be used to treat ADHD. Plaintiff responds that the results of successful clinical test studies were available prior to the issuance date of the patent, and these results indicate that the drug had utility. Further, Plaintiff asserts that doctors approved clinical test studies prior to the patent application date, thus indicating that the claimed method had utility. This Court finds neither of Plaintiff's arguments compelling.

Plaintiff first asserts that it received test results from its human clinical trials shortly after the application filing date. Human test trials can, of course, provide the most clear indication of a method-of-treatment's utility. The test results, here, however cannot establish utility because they were not available at the time of the patent application's filing date. As the Janssen Court held, "[t]he results from the . . . patent's proposed animal tests . . . were not available at the time of the application, and the district court properly held that they could not be used to establish enablement." Id. at 1325; Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1345 (Fed. Cir. 2000), cert denied, 532 U.S. 1019 (2001); see Brana, 51 F.3d at 1567; Alcon, Inc. v. Teva Pharms. USA, Inc., 2009 U.S. Dist. LEXIS 97757, at *70 (D. Del. Oct. 19, 2009) ("Enablement is determined as

of the filing date of the patent application.").

Moreover, even if the results were available prior to the application date as required, they still would not be sufficient to establish utility as they were not provided to the examiner. Id. at 1325 ("In this case, however, neither in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions **were provided** [to the PTO]."); see also Brana, 51 F.3d at 1567 (noting that the test results were submitted to the PTO during prosecution); In re Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999) (noting that the patent's written description must "illuminate a credible utility" to meet the enablement requirement); In re Ziegler, 992 F.2d 1197, 1201 (Fed. Cir. 1993) ("The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 **that the specification disclose** as a matter of fact a practical utility for the invention." (emphases added)); In re Schoenwald, 964 F.2d 1122, 1124 (Fed. Cir. 1992) (stating that utility must be **disclosed** to satisfy the section 112 enablement requirement). Here, Plaintiff did not provide the results of the clinical tests to the patent office. Such results, then, cannot be relied upon to establish utility.

Plaintiff also asserts that "doctors did find that utility [of the '590 Patent was] credible, even before the patent was filed [as] the FDA granted permission to begin human testing of atomoxetine for ADHD, and [MGH] physicians Drs. Biederman and Spencer agreed to conduct the trial." Plaintiff's Supplemental Brief Regarding In Re '318 Patent Infringement Litigation ("Plaintiff's Supp. Br."), at 1. Plaintiff argues that clinical trials of atomoxetine in humans would not have been approved if the method of treatment was not expected to be useful in treating ADHD. Id. at 5. Plaintiff also notes that the Manual for Patent Examination and Procedure provides that where "experts at the FDA have assessed the rationale for the drug or research upon which an asserted

utility is based and found it satisfactory," the PTO should be hesitant to challenge utility. See MPEP § 2107.02(f). These arguments, however, suffer from the same defects as noted above with respect to the clinical test data–Plaintiff's information regarding utility was never submitted to the PTO.[14]

Plaintiff's arguments regarding its clinical test data do not compel a result different from that in Janssen. A patent's written description must evidence the utility of the invention. Janssen, 583 F.3d at 1328 ("The relevant question here is whether, at the time [the inventor] filed her application, the **patent's written description would have credibly revealed** to an ordinarily skilled artisan galantamine's utility for [Alzheimer's Disease] treatment.") (J. Gajarsa, dissenting).

Plaintiff cannot satisfy the utility/enablement requirement by relying on non-disclosed materials, even if the materials show that the claimed method is useful.

2. *The Claimed Method's Utility as Presented in the Specification of the '590 Patent, as Understood by a Person of Ordinary Skill in the Art*

Plaintiff claims, alternatively, that even if its clinical testing can not be relied upon to provide evidence of utility, a person of ordinary skill in the art in 1995 (the time of filing) would have recognized the utility of the invention based upon the specification of the '590 Patent. See, e.g., Janssen, 583 F.3d at 1327 n.12 (considering "whether a person skilled in the art could infer [a medical treatment's] utility from the selected prior art described in the . . . patent's specification.").

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[14] Plaintiff emphasizes that "the MPEP provides that where . . . experts at the FDA have assessed the rationale for the drug or research study upon which an asserted utility is based and found it satisfactory, the Office should be particularly hesitant to challenge utility." Plaintiff's Supp. Br. at 6. The utility in-fact of the claimed method is not disputed. The utility requirement for patentabililty, however, requires that utility properly be disclosed in the patent. Regardless of whether doctors at MGH and experts at the FDA recognized the invention's utility, without providing the PTO with evidence of such recognition, Plaintiff cannot show that the patent credibly discloses utility.

Plaintiff explains that there were a number of successful ADHD drugs on the market at the time of the invention. See '590 Patent, 1:11-40. Many of which were disclosed by the '590 Patent. For instance, the specification discloses methylphenidate, which "has norepinephrine and dopaminergic activities." Id. at 1:19-28. It also disclosed tri-cyclic anti-depressants for use in treating ADHD. Id. at 1:29-31. Based on these disclosures, Plaintiff argues that a person of ordinary skill in the art would have been able to infer atomoxetine's utility in treating ADHD. Essentially, Plaintiff asserts that a person of skill in the art would know that: (1) the compounds disclosed in the specification were effective in treating ADHD because they inhibited norepinephrine; (2) atomoxetine was, similarly, an active norepinephrine inhibitor; and (3) atomoxetine would therefore be successful in treating ADHD.

The Court in Janssen addressed a similar argument. The Janssen Court assessed whether a person of skill in the art at the time of the application's filing would have inferred the invention's utility. Id.[15] Accordingly, this Court must determine whether the '590 Patent specification would

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[15] There, the plaintiff/patent applicant, argued that

> the prior art tests summarized in the specification would lead one skilled in the art to infer that galantamine affected the ability of acetylcholine to bind to both nicotinic and muscarinic receptors in the brain . . . [and] the animal tests proposed in the specification as a model for Alzheimer's disease would further lead one skilled in the art to infer that the model's method of impairing brain acetylcholine availability would allow both muscarinic and nicotinic effects to be observed. . . . [and thus,] because nicotinic receptors in the brain are involved with the ability to learn, the specification suggested that galantamine could have beneficial effects on learning (unlike prior art treatments, which had primarily affected muscarinic receptors).

Janssen, 583 F.3d at 1326. The Court found that such analytical reasoning was insufficient to establish utility. It explained, as "[t]hese insights . . . are nowhere described in the specification[; n]or was there evidence that someone skilled in the art would infer galantamine's utility from the specification, even if such inferences could substitute for an explicit description of utility." Id. This statement appears to indicate that the Federal Circuit was hesitant to accept evidence that a

establish utility/enablement to a person of ordinary skill in the art in 1995. Defendants assert that Plaintiff's own witnesses indicate that utility could not be inferred. First, they argue that Dr. Heiligenstein, the patent's inventor, admitted that treating ADHD with atomoxetine was merely hypothetical. See Defendants' Certification in Support of its Supplemental Memorandum in Support of Defendant's Motion for Summary Judgment of Invalidity, at Ex. BB: 89:13-23, 127:4-128:24, 147:20, 148:5, Ex. CC: 509:20-24. Next, Plaintiff's expert Dr. Pliszka testified that if in 1995 he heard the hypothesis that atomoxetine would be effective in treating ADHD, he would have responded: "[y]ou're wrong, it's not a good model." Dr. Pliszka also explained that a person of ordinary skill in the art "would not predict atomoxetine would be effective" as "we were moving away from single neurotransmitter drugs." Defendants urge that–like in Janssen–the testimony of Plaintiff's witnesses indicates that a person of skill in the art would not infer utility by reading the patent's specification.

Although the Court appreciates the substantial similarities between this case and Janssen, there is one critical difference–in addition to the testimony of Plaintiff's witnesses, there is the conflicting testimony of Defendants' experts.[16] Defendants' expert Dr. Jud A. Staller opined that

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person of skill in the art would infer utility–in lieu of requiring a explicit statement of utility in the specification. Nonetheless, the Court did, in fact, consider the specification's disclosure in light of the knowledge of one skilled in the art at the time the application was filed. See id. at 1321, 1326, 1327 n.12. In so doing, the Court relied on testimony regarding the state of the art at the time of the application. See id. at 1326-27 ("[T]he specification, **even read in the light of the knowledge of those skilled in the art**, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis."). In short, the Janssen Court discussed the specification, as viewed by a person of skill in the art, to determine whether the patent disclosed utility, and was thus enabled.

[16] There initially was conflicting expert testimony in the Janssen case. However, after full trial, the Janssen Court chose not to credit Defendant's proffered expert testimony. Accordingly, when the Court determined the utility/enablement issue, there was no conflict in the

"it would not have been unexpected, based on what was known as of the filing of the '590 patent, for atomoxetine to treat ADHD." See Certification of John F. Brenner in Support of Lilly's Brief Regarding the In Re '319 Patent Infringement Litigation, at Ex. 6. He explained, "desipramine and atomoxetine are both SNRIs [Serotonin-norepinephrine reuptake inhibitors] . . . [a]nd at the time the '590 patent was filed, a number of SNRIs, including desipramine, were readily available and successfully being used to treat ADHD." Id. Defendants' expert Dr. Floyd R. Sallee expressed a similar opinion in his expert report, where he observed, "[i]t has long been known that tricyclic antidepressants . . . inhibit monoamine (dopamine, norepinephrine, or serotonin)" and "a person of skill in the art would understand tomoxetine to be similar to desipramine in mechanism of action. . . [as t]here is no meaningful difference between the application of desipramine and tomoxetine for the treatment of ADHD." Id. at Ex. 8. Finally, Defendants' expert Dr. Craig W. Berridge stated in his expert report that certain prior art references "teach that desipramine and atomoxetine are similar in their ability to inhibit the reuptake of norepinephrine." Id. at Ex. 6. Unlike the Janssen case, here, there is evidence of record that could support a finding that a person skilled in the art could infer atomoxetine's utility from the selected prior art described in the '590 Patent's specification.[17]

As material issues of fact are in dispute, the Court must deny Defendants' motion for summary judgment for lack of enablement. See Metro. Life Ins. Co. v. Bancorp Servs., L.L.C., 527 F.3d 1330, 1338-39 (Fed. Cir. 2008) (holding the "conflict in [expert] declarations created a genuine issue of material fact that made summary judgment inappropriate"); In re Gabapentin Patent Litig.,

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expert testimony. Here, in contrast, there is direct conflict between the parties' expert testimony, which should not be resolved on summary judgment.

[17] See note 16, supra.

2005 U.S. Dist. LEXIS 37654, at *13 (D.N.J. Aug. 25, 2005).

IV. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON OBVIOUSNESS

Defendants assert that the patent is obvious under 35 U.S.C. § 103, and ask this Court to grant summary judgment as to the invalidity of the patent.

A. Applicable Law

A party seeking to invalidate a patent pursuant to 35 § U.S.C. 103(a) must demonstrate obviousness by clear and convincing evidence. Typeright Keyboard Corp. v. Microsoft Corp., 374 F.3d 1151, 1157 (Fed. Cir. 2004).[18]

The Supreme Court has enumerated four factors to be considered by courts to assess whether an invention is obvious. Takeda v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (citing Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966)). The four factors are: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations, or "objective indicia of non-obviousness." Id.; see also KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 405 (2007). A court must make findings of fact and conclusions of law as to each of the four Graham factors.

In the context of chemical compounds, a Defendant challenging the validity of a patent must

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[18] Even where a party relies in court on prior art that was not considered by the patent examiner, as is the case here, the presumption of patent validity and the clear and convincing evidence standard have not been disturbed. Defendants state that the appropriate burden of proof on invalidity is the preponderance of evidence standard, as the PTO did not consider the prior art on which Defendants' obviousness argument relies. This is incorrect. The clear and convincing standard is proper even in cases where the Court considers prior art that was not before the patent examiner. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007); Z4 Techs., Inc. v. Microsoft Corp., 507 F.3d 1340, 1354-55 (Fed. Cir. 2007); Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050 (Fed.Cir.1988) ("The burden of proof is not reduced when prior art is presented to the court which was not considered by the PTO.").

initially make a prima facie showing of obviousness. Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1345 (Fed. Cir. 2000); Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 974-75 (Fed. Cir. 1986). Such a showing is made under the first three Graham factors, as the challenging party must (1) identify the prior art compound that a person of ordinary skill in the art would have chosen as the "lead compound" to select for further research, and (2) show that there is adequate support in the art for making the modifications necessary to arrive at the claimed compounds. Proctor & Gamble Co. v. Teva Pharmaceuticals, 566 F.3d 989, 994-97 (Fed. Cir. 2009); Takeda, 492 F.3d at 1356-57 (Fed. Cir. 2007) (explaining, after the Supreme Court's decision in KSR, that, "a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound in the prior art," and then the challenging party must identify "a reason that would have prompted a person of ordinary skill in the relevant field to combine [or modify] the elements in the way the claimed new invention does" to prove obviousness.).

If a party challenging a patent establishes a prima facie case of obviousness, then the patent-holder can rebut this showing by presenting objective evidence of non-obviousness. Yamanouchi, 231 F.3d 1339, 1345 (Fed. Cir. 2000). The "objective indicia" of non-obviousness, the fourth Graham factor, instructs courts to consider the circumstances surrounding the invention process including, but not limited to: (1) meeting a long-felt need, (2) the inventors' success despite the failure of others, (3) commercial success, (4) copying, (5) praise and recognition for the invention, (6) unexpected results, and (7) significant effort and serendipity. See Ruiz v. A.B. Chance Co., 234 F.3d 654, 660-62 (Fed. Cir. 2000); see also Proctor & Gamble, 566 F.3d at 994 (Fed. Cir. 2009); Ortho-McNeil, 520 F.3d. 1358, 1364 (Fed. Cir. 2002).

B. Analysis

Defendants argue that the claims of the '590 Patent are obvious. To show obviousness, Defendants must identify the prior art compound that a person of ordinary skill in the art would have chosen as the "lead compound" to select for further research, and then show that there is adequate support in the art for making the modifications necessary to arrive at the claimed compound. The Court will discuss the parties' arguments as to each step in turn.

Defendants assert that desipramine was a known treatment for ADHD, and thus would be a likely lead compound. Defendants next argue that desipramine was known to inhibit norepinephrine uptake–and that it was this inhibition function that was responsible for desipramine's effectiveness in treating ADHD. Atomoxetine, similarly, was a known norepinephrine reuptake inhibitor. Accordingly, then, Defendants argue that desipramine was a likely lead compound, and replacing desipramine with atomoxetine in an ADHD treatment was obvious.

Plaintiff responds that desipramine was not a likely lead compound, because by 1995 the compound's use in the treatment of ADHD was waning. Further, Plaintiff argues that even if desipramine was a likely lead compound, it was not known that norepinephrine reuptake inhibition was the compound's key mechanism of action for treating ADHD. Specifically, Plaintiff argues that desipramine was not an entirely selective drug, and therefore its mechanism of action could not easily be determined. Therefore, Plaintiff responds, it would not have been obvious to substitute atomoxetine for desipramine in an ADHD treatment.

Defendants' motion for summary judgment on the issue of obviousness is denied, as there are questions of material fact that cannot be resolved at this stage.

First, the Court must determine whether, as Defendants assert, desipramine was a likely lead compound. Defendants assert that it was a "well-established practice" to treat ADHD with desipramine. Plaintiff, in contrast, argues that it was not an established practice, and other treatments were more prevalent. Moreover, Plaintiff contends, desipramine's reputation as a strong ADHD treatment was diminishing because of certain negative properties associated with the drug. There is conflicting evidence as to whether a person of ordinary skill in the art would select desipramine as a lead compound for further ADHD research. The Court cannot resolve this material question of fact on summary judgment.

Second, even if the Court determined that desipramine was a likely lead compound (or among a number of potential likely lead compounds), there remains a question of fact as to whether there was adequate support in the art for making the substitution of atomoxetine for desimpramine in the treatment of ADHD. Defendants assert that the two compounds have the same mechanism of action (i.e., operated in the same way). Plaintiff responds that a person of ordinary skill in the art would not have known that the compounds had the same mechanism of action. More specifically, Plaintiff asserts that atomoxetine is more selective than desipramine, and therefore the two compounds did not have the same pharmacologies. As such, the difference in neurochemical activity caused by the two compounds could very well result in different effects when used to treat ADHD. The Court finds that a material question of facts exists as to whether a person of ordinary skill in the art would expect atomoxetine to operate in the same way as desipramine in treating ADHD.

Defendants' motion for summary judgment as to obviousness is denied.[19]

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[19] The Court notes that Plaintiff emphasizes the differences between atomoxetine and the prior art for the purposes of refuting Defendants' obviousness argument, while at the same time asserting that the prior art and atomoxetine are in some ways similar in order to demonstrate

V. THE PARTIES' MOTIONS FOR SUMMARY JUDGMENT ON INFRINGEMENT

Plaintiff moves for summary judgment asking this Court to find that Defendants have infringed of the '590 Patent, by inducing another party to infringe Plaintiff's patent. Defendants' oppose this motion and move for summary judgment of no infringement.[20]

The '590 Patent is a method-of-use patent that covers "[a] method of treating attention-deficit/hyperactivity disorder [ADHD] comprising administering to a patient in need of such treatment an effective amount of tomoxetine." The Patent's claimed use of atomoxetine–use in treating ADHD–is the only use that is permitted by the FDA. Defendants have applied to the FDA seeking permission to sell atomoxetine. As the only use of atomextine that has been approved by

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enablement/utility. Defendants argue, then, that the Court must find the patent invalid as either obvious or not enabled. For example, if the Court determines that a person of ordinary skill in the art would be able to infer utility based upon the patent's specification, Defendants' enablement argument might fail, but its obviousness argument would presumably be bolstered. In essence, Defendants argue that whichever set of experts is credited, Plaintiff's patent will be invalidated. The Court, however, at this stage, cannot resolve factual disputes as to either enablement or obviousness.

[20] This Court previously determined that Defendants have not directly infringed the '590 Patent. Lilly failed to establish that Defendants will infringe each asserted claim of the '590 Patent (i.e., by "administering to a patient in need of ADHD treatment an effective amount of tomoxetine."), as Defendants do not diagnose patients or administer drugs. Nor do they employ others to diagnose or administer the drug. Accordingly, the Court found there to be no direct infringement as a matter of law. The Court will consider the parties' various motions for summary judgment as to indirect infringement together.

The Court also notes that one of the Defendants–Sun Pharmaceuticals–asks this Court to construe the claims of the patent as part of the infringement analysis. In short, Sun asks the Court to limit the definition of "ADHD" in the '590 Patent to mean ADHD as described in the Diagnostic and Statistical Manual of Mental disorders. Plaintiff and the other Defendants argue that any such construction is unnecessary, and the Court agrees. Sun's proposed limitation takes an example from the Patent specification and imparts an unwarranted limitation on the term ADHD. See MBO Labs, Inc. v. Becton, Dickinson & Co., 474 F3d 1323, 1333 (Fed. Cir. 2007); Kara Technologies Inc. v. Stamps.com Inc., 2009 U.S. App. LEXIS 21120 at *13 (2009).

the FDA is administration to patients for treating ADHD, Defendants are required to include a label that instructs proper application of the drug for treatment of ADHD. This label must be included regardless of whether the atomextine sold by Defendants is ultimately used in the treatment of ADHD.

Plaintiff argues that Defendants application to the FDA evidences their intent to infringe upon the patent. Defendants respond that they do not intend to infringe upon the patent, and simply intend to sell atomoxetine without any intent or concern as to its ultimate use.

1. Applicable Law

In order to prove infringement, a plaintiff must show that the accused product or method includes every limitation of an asserted claim of a patent. Baxter Healthcare Corp. V. Spectramed, Inc., 49 F.3d 1575, 1582 (Fed. Cir. 1995). A party need not commit the full act of infringement itself. As 35 U.S.C. § 271(b) provides, "whoever actively induces infringement of a patent shall be liable as an infringer." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003).

To succeed on a claim of inducement, a patentee must show, that there has been (i) direct infringement, and that (ii) the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement. See Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1292 (Fed. Cir. 2008) (quoting MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005)). In the context of ANDA filings the direct infringing acts are hypothetical–since the generic manufacturers have not yet distributed the product–so a court need only consider the second element. Id.[21] The proper inquiry here, then, is

[21] Defendants urge that they cannot be liable for inducement to infringe because the acts of infringement cannot be attributed to one person. Essentially, they argue, that both doctors and

whether specific intent exists.

The specific intent necessary to induce infringement "requires more than just intent to cause the acts that produce direct infringement. . . . [T]he inducer must have an affirmative intent to cause direct infringement." Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1292 (Fed. Cir. 2008) (quoting DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006)). The Federal Circuit has held that, "a method of use patent holder may sue an ANDA applicant for induced infringement of its patent, if the applicant is seeking FDA approval for the use claimed in the patent." Warner-Lambert, 316 F.3d at 1354-55. Intent may be inferred based on marketing literature or product instructions. See, e.g., Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc., 145 F. 3d 1303,1312 (Fed. Cir. 1998) (advertisements encouraging use during the time of the claimed process); AstraZeneca LP v. Apotex, Inc., 623 F. Supp. 2d 579, 603 (D.N.J. 2009) (finding that "the language of [a manufacturer's] label is relevant to the issue of intent" to induce infringement under § 271); VLT Corp. v. Unitrode Corp., 130 F. Supp. 2d 178, 200 (D. Mass. 2001) ("[I]t is a textbook violation of § 271(b) where . . . a defendant selling products capable of either innocent or infringing use provides through labels, advertising or other sales methods instructions and directions as to the infringing use") (internal citations omitted).

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patients are needed to perform the "treating" and "administering" steps covered by the patent. They argue, then, that because no single party directly infringes upon the patent, there will be no direct infringement, and therefore Defendants cannot be liable for inducement to infringe. This Court disagrees. A number of courts have conflated the actions of patients and doctors in determining whether the combined actions (i.e., treating/administering) infringe upon a patent. AstraZeneca LP v. Apotex, Inc., 623 F. Supp. 2d 579, 598-600 (D.N.J. 2009); Alza Corp. v. Andrx Pharms., LLC, 607 F. Supp. 2d 614, 623 (D. Del. 2009). The actions of the doctors and patients will be treated together, and will be considered a directly infringing act.

2. Analysis

Whether Defendants will induce infringement of Plaintiff's patent depends on whether they have the requisite intent to cause direct infringement.[22]

Defendants' primary argument in support of their contention that they cannot be liable for inducing infringement is that they lack the necessary intent. They argue that they market the product as a commodity, and do not encourage any particular use of the drug. As such, they assert that they have no intent to infringe the patent (i.e., to induce others to violate the patent by using atomextine in the patented manner). In support of this argument, they note that doctors prescribe the drug for a number of non-infringing uses as well. Defendants, essentially, conclude that there is no evidence of their intent to induce infringement of the patent.

Plaintiff asserts that Defendants are aware of Plaintiff's patent, and they supply a product to customers with instructions on how to use the product in a manner that encourages acts of infringement. Plaintiff suggests that this evidences Defendants' intent to induce. See Minn. Mining and Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1305 (Fed. Cir. 2002); Abraxis Bioscience, Inc. v. Navinta, LLC, 2009 U.S. Dist. LEXIS 66958 (D.N.J. Aug. 3, 2009).

Defendants respond that the labels, which instruct consumers to use the drug in an infringing manner, cannot be evidence of their intent because they are required by the FDA to include the label. Indeed, the only use of atomoxetine approved by the FDA is the infringing one. Therefore, Defendants **must** include the label encouraging infringement if they are to sell the drug. The

[22] As noted above, the Court has determined that direct infringement will occur based upon the acts of doctors and patients who prescribe and administer the drug. See note 21, supra.

question for this Court, then, is whether Defendants intent to induce infringement of the patent can be established notwithstanding the fact that the label instructing the infringing use of the product is required by the FDA.

The only other Court to address this precise issue was Alcon Labs., Inc. v. Bausch & Lomb, Inc., 52 U.S.P.Q.2d 1927, 1933-34 (N.D. Tex. 1999). There, an alleged infringer argued that it did not have intent to induce infringement because its package inserts, which instructed the infringing use, were required by the FDA. The alleged infringer, there, as here, asserted that doctors will prescribe the drug for non-infringing uses. The Court nonetheless determined that there was no "authority, however, indicating that the FDA's requirements regarding the package insert absolve [the alleged infringer] of liability for inducing infringement when the suggested uses in its package insert come within the method claimed in the . . . patent." Id. The Court went on to explain that it "finds unpersuasive the fact that doctors may not always use the product in the manner specified on the package insert's indications[; t]he sole question is whether B&L actively encourages the use of its generic in a manner that infringes the patent." Id. Accordingly, the Court found that the labeling could be sufficient to establish intent.

In Aventis Pharms., Inc. v. Barr Labs., Inc., 411 F. Supp. 2d 490, 518 (D.N.J. 2006), aff'd, 208 Fed. Appx. 843 (Fed. Cir. 2006), the Court explained that intent is determined "from an objective viewpoint, not by undertaking an analysis of whether the accused inducer subjectively experienced a purpose or an intent that the steps affirm." Here, the accused infringers will be labeling the product in a manner which encourages direct infringement by others. See id.; AstraZeneca LP, 623 F. Supp. 2d at 598-607 (determining that a generic manufacturer intended to induce infringement of plaintiff's patent by including a label instructing an infringing use,

notwithstanding the fact that defendant took several affirmative steps to work around the potential infringement; noting that defendant's demonstrated intentions were overcome by its decision to move ahead with an infringing label). This objective evidence is critical in determining whether intent to cause infringement exists, and such evidence is sufficient to establish Defendants' intent.

Plaintiff's motion for summary judgment as to Defendants' infringement is granted.

CONCLUSION

For the reasons stated above, Plaintiff's motion for summary judgment of no inequitable conduct before the PTO is **granted in part** and **denied in part**; Plaintiff's motion for summary judgment of no invalidity based on anticipation is **granted**; Defendants' motion for summary judgment of invalidity based upon lack of enablement/utility is **denied**; Defendants' motion for summary judgment of invalidity based upon obviousness is **denied**; Plaintiff's motion for summary judgment of infringement is **granted**; and, Defendants' motion for summary judgment of no infringement is **denied**.

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

Date: December 31, 2009
Original: Clerk's Office
cc: All Counsel of Record
The Honorable Mark Falk, U.S.M.J.
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