IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EURAND, INC., CEPHALON, INC., and ANESTA AG, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., MYLAN INC., BARR PHARMACEUTICALS INC., and BARR LABORATORIES, INC., Defendants.	:	C. A. No. 08-889-SLR

MEMORANDUM ORDER

Plaintiffs and defendants, Mylan Pharmaceuticals, Inc. and Mylan Inc. ("Mylan"), are locked in a discovery dispute that centers on the relevance of recent discovery requests by Mylan. The dispute relates to the '793 patent, which is directed to an extended-release formulation of cyclobenzaprine, and Mylan's demand for production of documents concerning drugs other than cyclobenzaprine, which is the subject of plaintiffs' NDA, Mylan's ANDA and the patent-in-suit. This memorandum order addresses the issues raised in that discovery dispute.

Background

The parties previously sought the court's assistance in another discovery dispute clearly related to the present matter. In that dispute, Mylan sought production of various documents and records concerning the "compositions of and testing relating to the two properties claimed in the '793 patent for two prior art Diffucaps®

products–methylphenidate and amitriptyline; and . . . with respect to other Diffucaps® formulations." Mylan's arguments in the prior discovery dispute were directed to invalidity (obviousness) and inequitable conduct (materiality).[1] Previously, in its second answer, defenses and counterclaims filed on September 30, 2009, Mylan added the affirmative defense and counterclaim of inequitable conduct, asserting: that the '215 patent discloses the same method of measuring the desired release profile as disclosed and claimed in the '793 patent; that the inventors of the '793 patent claimed a formulation[2] whereby they substituted one active ingredient for another using the same extended-release technology disclosed in the '215 patent, making that patent material in the prosecution of the '739 patent; and that the inventors and prosecuting counsel, with the intent to deceive, failed to disclose the '215 patent to the patent examiner during the prosecution of the '739 patent. Mylan argues that the '793 patent is, therefore, unenforceable due to such inequitable conduct. At present, these are the only allegations of inequitable conduct.

Plaintiffs opposed Mylan's discovery requests primarily based on relevance. The court ruled on December 9, 2009, denying and granting in part Mylan's various

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[1] The prior discovery was significantly more extensive that what is presently requested and focused on non-public documents (research and development documents regarding drugs other than cyclobenzaprine and the Diffucaps® platform) in relation to obviousness and materiality under inequitable conduct.

[2] The '215 patent deals with methylphenidate formulations based on the Diffucaps® technology, involving immediate release (IR) beads and extended release (ER) beads, which allows a therapeutic release of the medication over a 12 hour period. The '739 patent claims ER dosage forms or beads of cyclobenzaprine having a particular drug release profile, in which the core particle has an ER coating that slows the rate of cyclobenzaprine release, allowing the dosage form to be therapeutically effective over a period of 24 hours. Mylan had previously raised the '215 patent to support its claim of obviousness.

requests.[3]

Since then, Mylan claims that it has more narrowly focused its earlier discovery by limiting its document requests to those materials "evidencing the two inventors' awareness and understanding of" certain purported prior art that was not submitted to the PTO during "a defined period of time (*i.e.*, prior to and during the filing and prosecution of the '793 patent)." Mylan argues that during the prosecution of the '793 patent, both the inventors and their attorneys failed to disclose prior art which shows the same extended release technology claimed as novel in the '793 patent. It asserts that it has found additional prior art, specifically the Razaghi reference and an osmotic pump under the tradename OROS®, which was not disclosed.[4] Mylan is seeking the discovery of what the inventors knew and were saying about such prior art during the prosecution of the '793 patent. Not surprisingly, plaintiffs opposed Mylan's discovery requests maintaining that they are "an attempted 'end run' around" this court's prior Memorandum Order for documents to, from, or by the two inventors relating to amitriptyline and methylphenidate.

Parties' Positions[5]

The parties respective positions are briefly summarized above. In further detail,

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[3] *See* D.I. 116 for further background regarding the prior discovery dispute, which will not be repeated here.

[4] Although only limitedly discussed in its letter of March 1, 2010, Mylan apparently seeks extended release formulations for what it terms as a "very closely-related drug, amitriptyline, to . . . cyclobenzaprine." *See* Transcript March 3, 2010 at 9.

[5] The parties submitted written arguments on their respective positions: Mylan in its letter of March 1, 2010 (D.I. 141) and plaintiffs in their letter dated March 2, 2010 (D.I. 145). Further argument was presented during the teleconference of March 3, 2010. *See* Transcript March 3, 2010.

Mylan argues that the '215 patent discloses a formulation with methylphenidate using the Diffucaps® technology, involving the same ingredients and manufacturing process to obtain the same release profile as disclosed in the '793 patent. It maintains through its proposed requests that it is merely seeking fact discovery of the inventors' knowledge and understanding of undisclosed prior art. It points out that such documents are "uniquely in the possession of the inventors" and "will . . . provide direct evidence of knowledge and intent and rebut any claim that the withheld prior art was immaterial." It argues that any statements or comments made by the inventors about the '215 patent and other prior art methylphenidate extended release "formulations, their properties and their potential applicability for use with other active ingredients" evidences their intent and contradicts any denial of materiality based on the alleged unique properties of the different drugs involved in each patent. It similarly contends that comments by the inventors in relation to the osmotic pump technology disclosed in the Razaghi reference and prior art OROS® osmotic dosage forms for both methylphenidate and cyclobenzaprine reveal the inventors' states of mind, particularly in light of the comments by inventor Venkatesh in the '215 patent which suggest that the patent's formulation should be used in lieu of osmotic pump technology. Mylan maintains what it seeks about the prior art technology, which was used for both drugs, is "relevant to whether [the inventors] understood that methylphenidate and cyclobenzaprine could be delivered using similar technologies . . . ." It asserts that the proposed discovery requests are therefore reasonable and appropriate.[6]

[6] Mylan's present discovery seeks any document "referring to, discussing, or constituting prior art to the '793 patent . . . that discloses extended release products" for

Plaintiffs take a jaundiced view of Mylan's requests, maintaining that a "comprehensive search" of all relevant files, including those of the named inventors, has occurred regarding the patent-in-suit and cyclobenzaprine. They further note that no document was withheld merely because it discussed other drugs, including methylphenidate or amitriptyline, "or any piece of prior art, public or otherwise." Although their search targeted cyclobenzaprine, it included all of the cyclobenzaprine development files and product files without withholding documents related to methylphenidate, amitriptyline "or anything else." Plaintiffs contend that the court has previously ruled on this issue and that Mylan's present requests for information that refer to or discuss such a prior art reference encompass the same confidential information which the court previously determined as not discoverable. They note that Mylan's sole allegation of inequitable conduct based on the '215 patent does not meet the requirements of Fed. R. Civ. P. 9(b) to obtain the discovery that it demands. Moreover, as a matter of law, plaintiffs argue that the discovery requested does not address the materiality prong of inequitable conduct because that determination is objective and not subjective. In other words, plaintiffs maintain that Mylan's proposed discovery regarding prior art beyond the '215 patent will not provide any potentially relevant information on materiality. In essence, plaintiffs contend that Mylan's most recent discovery is a "back door" effort to obtain what it has been previously denied by the court.

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each prior art reference/technology as noted herein ("methlyphenidate amitriptyline specifically including the '215 patent;" "cyclobenzaprine, specifically including . . . Razaghi"; and "any OROS®, or other osmotic pump, formulation of methylphenidate or cyclobenzaprine.").

Discussion

The court experienced a sense of *deja vu* while reviewing the submissions by the parties. Despite an uneasy feeling that Mylan's present arguments may be an "end run" around this court's prior decision, and may circumvent the requirements of LR 7.1.5 or Fed. R. Civ. P. 72(a), its arguments will be addressed.

As previously noted herein, the status of Mylan's inequitable conduct claims as raised in its pleadings is the same as it was at the time of the December 9, 2009 Memorandum Order. The only prior art reference or technology alleged to be evidence of inequitable conduct is the '215 patent. No other prior art references or technology have been suggested.

Because the patent application process is *ex parte*, patent applicants and their counsel, or those involved in the preparation and prosecution of patent applications, owe a duty of candor, honesty and good faith to the PTO. The duty of candor, good faith and honesty includes the obligations to submit truthful information and to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application.[7] Information is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to issue the application as a patent.[8] Breach of the duty of candor may render a patent unenforceable for inequitable conduct.[9] To

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[7] *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999).

[8] *Elk Corp.*, 168 F.3d at 31.

[9] *M. Eagles Tool Warehouse, Inc. v. Fisher Tolling Co.*, 439 F.3d 1335, 1339 (Fed. Cir. 2006); 37 CFR § 1.56.

prove unenforceability by inequitable conduct, "the alleged infringer must provide clear and convincing evidence of (1) affirmative misrepresentations of a material fact, the failure to disclosure material information, or submission of false material information and (2) an intent to deceive."[10] When analyzing whether inequitable conduct occurred, the court balances the inverse relationship between materiality and intent.[11] Thus, it is unlikely that a patentee, who faces a high level of materiality can show subjective good faith sufficient to prevent the inference of intent to mislead. Mere denial of intent to mislead is inadequate.[12]

When inequitable conduct is alleged, the court balances the application of Rule 8 and the requirements of Rule 9(b). Since inequitable conduct is a claim sounding in fraud, Rule 9(b) applies. Under that rule, the elements of inequitable conduct must be pled with particularity. The purpose of the heightened pleadings requirements of Rule 9(b) is to "deter the filing of charges of fraud as a pretext for discovery of unknown wrongs."[13] Inequitable conduct allegations, however, "remain subject to the liberal pleading standard of Rule 8, which requires only a 'short and plain' statement of a claim or defense," the purpose of which is to place the opposition on notice of the misconduct charged.[14] Therefore, "'pleadings that disclose the name of [the allegedly withheld]

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[10] *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006). *See also*, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).

[11] *Star Scientific, Inc.*, 537 F.3d at 1366.

[12] *FMC Corp. v. Manitowac Company, Inc.*, 835 F.2d 1411, 1416 (Fed. Cir. 1987).

[13] *Stowe Woodward L.L.C. v. Sensor Products, Inc.*, 230 F.R.D. 463, 466 (W.D. Va. 2005).

[14] *McKesson Information Solutions LLC v. The Trizetto Group, Inc.*, 2005 WL 914776, at *3 (D. Del. Apr. 20, 2005); *TruePosition, Inc. v. Allen Telecom, Inc.*, 2003 WL

relevant prior art and disclose the acts of the alleged fraud fulfill the requirements of Rule 9(b).'"[15] Further, the particularity requirement does not mandate that a party plead the date, time, or place of the alleged fraud, if that party uses "an alternative means of injecting precision and some measure of substantiation into [its] allegations of fraud."[16] Thus, "courts still must apply Rule 9(b) with some flexibility so that a party is not required to plead issues which may have been concealed by an adverse party."[17]

To date, Mylan has failed to provide plaintiffs notice of the misconduct charged in relation to the Razaghi reference, the extended release formulation of amitriptyline, and the osmotic pump under the tradename OROS®. No allegations have been raised identifying those references or technology as relevant prior art, nor have any acts of alleged misconduct been disclosed in relation to that prior art. Nothing has been alleged by Mylan regarding the purported materiality of that prior art in support of inequitable conduct. To obtain the discovery that it seeks, Mylan argues that information regarding the inventors' awareness and knowledge of those references or technology and why they were not disclosed is relevant. Moreover, to meet the requirements of Rule 11, it maintains that it needs such discovery *before* making any allegations of inequitable conduct in relation to that prior art.

151227, at *5 (D. Del. Jan. 21, 2003).

[15] *France Telecom, S.A. v. Novell, Inc.*, 2002 WL 31355255, at *3 (D. Del. Oct. 17, 2002) (quoting *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996)).

[16] *Martek Biosciences Corp. v. Nutrinova Inc.*, 2004 WL 2297870, at *3 (D. Del. Oct. 8, 2004).

[17] *Mars Inc. v. JCM American Corp.*, 2006 WL 1704469, at *5 (D.N.J. June 14, 2006) (citing *Rolo City Investing Co. Liquidation Trust* , 155 F.3d 644, 658 (3d Cir. 1998)).

In support of that proposition, Mylan relies on *Enzo Life Sciences, Inc. v. Digene Corp.*[18] and *Ormco Corp v. Align Tech, Inc.*[19] The issues involved in *Enzo* and *Ormco* are distinguishable from the discovery issues under consideration. Both matters dealt with motions to amend an answer to assert inequitable conduct after the cut-off date in the scheduling order for such motions had expired. Both cases involved the analysis and operation of Rules 9(b), 15(a), and 16(b). They did not address issues related to discovery. The brief discussion in these cases regarding confirmation of factual allegations before adding an inequitable conduct defense on which Mylan heavily relies relates only to the good cause requirement for failure to timely amend. As noted in *Ormco*, when a motion to amend is filed after the cut-off date in the scheduling order, the Rule 16(b) requirement of good cause, rather than the permissive standard under Rule 15(a), operates.[20] Therefore, the comments in *Enzo* and *Ormco* regarding discovery before seeking to amend are directed to the good cause analysis of Rule 16(b) and reasonableness of the delay. *Enzo* and *Ormco* only conclude that it is reasonable for a defendant to conduct some discovery before seeking to amend to add a claim of inequitable conduct. Moreover, unlike the present matter, *Enzo* and *Ormco* and the cases referenced therein involved depositions of the inventors, during which their sworn statements to the PTO regarding the prior art at issue in the proposed motions to amend was explored.[21] None of the cases relied on by Mylan address the

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[18] 270 F. Supp. 2d 484, 487-90 (D. Del. 2003).

[19] No. SACV 03-16 CAS, 2008 WL 4501805, at *10 (C.D. Cal. Oct. 3, 2008).

[20] *Ormco*, 2008 WL 4501805 at *3.

[21] Plaintiffs' counsel agreed during the teleconference addressing the present dispute that Mylan would be allowed to explore with the inventors their awareness or knowledge concerning prior art references/technology other than the '215 patent in

extent or appropriateness of the discovery requested before the assertion of specific inequitable conduct.

Mylan is requesting substantial discovery under Rule 34 on subjective intent related to prior art not yet plead as a basis for inequitable conduct to figure out whether it has *any* basis for inequitable conduct in relation to that prior art. It is improper to use discovery in search of a factual predicate required to be pled in the first instance.[22]

The issue regarding intent (the inventors' knowledge and intent to deceive) in relation to the '215 patent differs from the other prior art. The failure to disclose the '215 patent during the prosecution of the '793 patent as inequitable conduct has been alleged. Mylan argues that plaintiffs' search of only the research and development files for AMRIX (the '793 patent) does not address the inventors thoughts and understanding or what they knew of the '215 patent (methylphenidate patent) in relation to the '793 patent. It claims that plaintiffs' failure to apply certain key word search terms to the emails of the two inventors of the '215 patent, who were the same inventors of the '793 patent, was inadequate.[23]

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relation to inequitable conduct. Tr. at 20-21.

[22] *See, e.g. Segan v. Dreyfus Corp.*, 513 F.2d 695, 696 (2d Cir. 1975); *Leonard v. Merrill, Lynch, Pierce, Fenner & Smith, Inc.*, 64 F.R.D. 432, 435 (S.D.N.Y. 1974). *See also,* Fed. R. Civ. P. 26(b)(1) and 2000 ADVISORY COMMITTEE NOTES in relation to Rule 26(b)(1) wherein it is noted that "[t]he rule change signals to the court that it has the authority to confine discovery to the claims and defenses asserted in the *pleadings*, and signals to the parties that they have *no entitlement* to discovery to develop new claims or defenses that are not already identified in the pleadings." (emphasis added).

[23] During the teleconference, Mylan suggested limited key word terms, such as the '215 patent, the methylphenidate patent, Razaghi, amitriptyline with extended release, OROS® and the like be used to search the relevant files, that is "anywhere the inventors believe would be a place where discussion of these references could be found," but specifically the emails of the inventors. Tr. at 28-29. Mylan further refined its request to the 2000-2008 time frame (about two years before the issuance of the

Plaintiffs respond that a search as proposed by Mylan of just the emails of the two inventors would involve review of a large number of potential emails and substantial expense ("tens of thousands of dollars for the initial search," not including attorney time) and contains terms that have nothing to do with the present inequitable conduct claim. Plaintiffs explained that their search of the broad development project would have included the prior art which Mylan currently wants searched. They represented that the "broad development project" involved a "number of people" and cyclobenzaprine. The files searched included "anything paper that related to that . . . development project regardless of whether it had AMRIX or cyclobenzaprine on the title of the folder; and also all of the relevant custodians that were involved in the project" including the inventors. Further, "[s]earches were done of their e-mail for anything related to cyclobenzaprine," so that "[a]nything connected with that project and the '793 patent would have been produced whether it referred to methylphenidate or amitriptyline or anything else."[24]

Mylan's arguments force the court into the mysteries of keyword search techniques, specifically the efficacy of various methods used to search electronically stored information, which often involve the interplay of computer technology, statistics and linguistics–complex issues on which counsel deign to "express as facts what are actually highly debatable propositions."[25] Neither lawyers nor judges are generally qualified to opine that certain search terms or files are more or less likely to produce

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'215 patent through the issue date of the '739 patent) and excluded the methylphenidate research and development projects. Tr. at 35-36.

[24] Tr. at 37-38.

[25] *Equity Analytics, LLC v. Lundin*, 248 F.R.D. 331, 333 (D.C.C 2008).

information than those keywords or data actually used or reviewed.[26]

As understood by the court, plaintiffs searched the inventors' e-mail files regarding cyclobenzaprine, as well as all of the cyclobenzaprine development and product files. Regardless of the contents, if they related to the product, the materials were searched. Except for privilege, responsive documents were produced even if they related to methylphenidate or amitriptyline "or anything else."[27] Further, to the extent that any reference to the '215 patent is contained in those materials, including the inventors' emails, relating to the cyclobenzaprine development project, the documents were produced.[28] Although plaintiffs did not use search terms such as "the '215 patent," "215,""the methylphenidate patent," or "methylphenidate", to the extent that those terms are referenced in the inventors' files, including their emails, or other Eurand files relating either to the broad development project or to any cyclobenzaprine-related materials, such documents would have been included in their search and produced, subject to privilege.

In evaluating whether search terms or search methods employed to carry out the search were appropriate, the court applies a "reasonableness test to determine the 'adequacy' of search methodology." An adequate search is one that "could . . . have been expected to produce the information requested."[29]

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[26] Magistrate Judge John M. Facciola succinctly, but eloquently described this as going "where angels fear to tread." *United States v. O'Keefe*, 537 F. Supp. 2d 14, 24 (D.C.C. 2008).

[27] Tr. at 18.

[28] Tr. at 19.

[29] *See Campbell v. U.S. Dep't. of Justice*, 164 F.3d 20, 27 (D.C.C. 1998); *Public Citizen, Inc. v. Dep't. of Education*, 292 F. Supp 2d 1, 6-7 (D.C.C. 2003). Although both cases deal with the adequacy of a FIOA search under FIOA regulations, the

The court understands, based upon the representations of plaintiffs, that their world of cyclobenzaprine and the '739 patent was searched and all responsive documents, except those subject to privilege, were produced. The inclusive dates of that search is unknown to the court. What is known is that the '739 patent was filed on November 14, 2003 and issued June 17, 2008, while the '215 patent was filed October 27, 2000 and issued February 5, 2002. Plaintiffs' search of all materials related to cyclobenzaprine did not include keywords on the inventors' knowledge or awareness of the materiality of the '215 patent to the '739 patent. Plaintiffs' prior search appears adequate on the materiality prong of inequitable conduct, but may not have included circumstantial evidence of subjective intent, such as the inventors' awareness of the relationship, or materiality of the '215 patent to the '793 patent.[30] Such knowledge, under the circumstances of the present matter and in light of the prior search and document production, would be most likely found in the emails of the inventors concerning the '215 patent.[31]

At the end of the teleconference, Mylan requested that all keywords used in

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reasonableness standard of FIOA is consistent with Fed. R. Civ. P. 26(1) and (2)(B) where reasonableness is the touchstone to determine the scope and appropriateness of the discovery requested and accessibility of electronically stored information.

[30] *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (recognizing that intent "can be inferred from indirect and circumstantial evidence"). *See also, FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (noting that a "'failure to disclose'" form of inequitable conduct includes clear and convincing proof of "knowledge chargeable to the applicant of that prior art or information and of its materiality").

[31] The court will not enter the wilderness of keyword search usage and is not directing the appropriate search terms for plaintiffs to employ. However, because the search involves the '215 patent, terms such as the "'793 patent" or "cyclobenzaprine patent" may be appropriate.

plaintiffs' prior search be produced to determine whether it was likely that those search terms encompassed what it is looking for in its present request. In response, plaintiff advised that the parties had agreed that their respective search terms would not be the subject of disclosure, discovery or second guessing. Mylan countered that this agreement was based on expediency and good faith. Because there is now an "issue between the parties," in the context of such dispute, Mylan is demanding those search terms. The court indicated in a "what is good for the goose, is good for the gander" approach, that if any door was opened in that regard, both sides would be subject to the same requirement. However, in light of the findings herein and the limited discovery that will be order, the court finds that such disclosure is not required. Therefore,

IT IS ORDERED that consistent with the findings and rulings herein, Mylan's requests for documents and other materials contained in its letter of March 1, 2010 and argued during the teleconference of March 3, 2010 is denied in part and granted in part.

IT IS FURTHER ORDERED that plaintiffs shall search the emails of the inventors related to the '215 patent and produce, subject to privilege, those emails that are relevant to the inventors' knowledge of materiality of the '215 patent to the '793 patent and failure to disclose the '215 patent during the prosecution of the '793 patent. The inclusive date range for the search is from the date of the filing of the '215 patent to the date of issuance of the '793 patent.[32]

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[32] To the extent that this ruling appears in conflict with the court's prior order of December 9, 2009, it is not. That order, as noted herein, dealt with different discovery requests and was primarily directed to obviousness, and only the first prong of the analysis of inequitable conduct based on failure to disclose, that is, "prior art or

Date: April 13, 2010

/s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE

information that is material." *FMC Corp.*, 835 F.2d at 1415.